Subject to Completion. Dated March 14, 2018

3,333,333 Shares

PolyPid Ltd.

Ordinary Shares

This is an initial public offering of the ordinary shares of PolyPid Ltd. All of the 3,333,333 ordinary shares in this offering are being sold by the company.

Prior to this offering, there has been no public market for our ordinary shares. It is currently estimated that the initial public offering price per share will be between $21.00 and $24.00. Application has been made to list the ordinary shares on The Nasdaq Global Market under the symbol ''POLY.''

We are an ''emerging growth company'' as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our ordinary shares involves a high degree of risk. *See ''Risk Factors'' on page 11 to read about factors you should consider before buying our ordinary shares.*

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions[1]	$	$
Proceeds to PolyPid Ltd., before expenses	$	$

[1] See ''Underwriting'' beginning on page 169 for additional information regarding underwriting compensation.

Certain of our existing shareholders have indicated an interest in purchasing up to an aggregate of $19.5 million in ordinary shares in this offering at the initial public offering price per share. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these shareholders, or any of these shareholders may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these shareholders as they will on any other shares sold to the public in this offering.

The underwriters have the option to purchase up to an additional 500,000 ordinary shares from us at the initial price to the public less the underwriting discounts and commissions, within 30 days from the date of this prospectus.

The underwriters expect to deliver the ordinary shares against payment in New York, New York on or about , 2018.

Goldman Sachs & Co. LLC **Cowen**

Cantor

Raymond James **Oppenheimer & Co.**

Prospectus dated , 2018

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Neither we nor the underwriters have authorized anyone to provide you with information that is different from that contained in this prospectus, any amendment or supplement to this prospectus, or in any free writing prospectus we may authorize to be delivered or made available to you. Neither we nor the underwriters take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell ordinary shares and seeking offers to purchase ordinary shares only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front of this prospectus, regardless of the time of delivery of this prospectus or any sale of ordinary shares. Our business, financial condition, results of operations and prospects may have changed since the date on the front cover of this prospectus.

Neither we nor any of the underwriters have taken any action to permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PolyPid and BonyPid are trademarks of ours that we use in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus appear without the ® or ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to our trademark and tradenames.

MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. Life Science Intelligence, Inc., the primary source for our market opportunity data included in this prospectus, was commissioned by us to compile this information.

In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in ''Risk Factors.'' These and other factors could cause our future performance to differ materially from our assumptions and estimates. See ''Special Note Regarding Forward-Looking Statements.''

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our ordinary shares, you should read this entire prospectus carefully, including the sections of this prospectus entitled ''Risk Factors'' and ''Management's Discussion and Analysis of Financial Condition and Results of Operations'' and our consolidated financial statements and the related notes included elsewhere in this prospectus. Unless the context otherwise requires, references in this prospectus to the ''company,'' ''PolyPid,'' ''we,'' ''us,'' ''our'' and other similar designations refer to PolyPid Ltd. and its subsidiary, PolyPid Inc. The terms ''shekel,'' ''Israeli shekel'' and ''NIS'' refer to New Israeli Shekels, the lawful currency of the State of Israel, and the terms ''dollar,'' ''U.S. dollar'' or ''$'' refer to United States dollars, the lawful currency of the United States of America. All references to ''shares'' in this prospectus refer to ordinary shares of PolyPid Ltd., par value NIS 0.80 per share.

Overview

We are a clinical-stage pharmaceutical company focused on developing and commercializing novel, locally administered therapies using our transformational PLEX (Polymer-Lipid Encapsulation matriX) technology. Our product candidates are designed to address unmet medical needs by pairing PLEX with active pharmaceutical ingredients, or APIs, which are delivered locally at customized, predetermined release rates and durations over periods ranging from days to several months. We believe that our PLEX technology represents a paradigm shift in the treatment of a wide variety of localized medical conditions, including infection, pain, inflammation and cancer. Our initial family of product candidates pairs PLEX with the widely-used, versatile antibiotic doxycycline, which we refer to as the D-PLEX family. Based on results from our clinical trials to date, none of the 101 patients treated in our clinical trials of our D-PLEX product candidates developed an infection at the treatment site after treatment.

We are initially focused on the development of our lead product candidate, D-PLEX$_{100}$, for the prevention of surgical site infections, or SSIs, in bone and soft tissue. We recently reported interim results from our fully-enrolled Phase 1b/2 clinical trial of D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery. During the three-month period after treatment, we observed no sternal wound infections in any of the patients treated with D-PLEX$_{100}$ in combination with the standard of care. In contrast, we observed a 4.5% infection rate in the control group of patients who received the standard of care alone. According to recent literature, the expected infection rate for patients receiving the standard of care alone is 5% to 8%. We plan to submit an Investigational New Drug, or IND, application for D-PLEX$_{100}$ to the U.S. Food and Drug Administration, or FDA, and a clinical trial application, or CTA, to the European national competent authorities early in the fourth quarter of 2018, and to commence a Phase 3 clinical trial in this indication shortly thereafter. Early in the fourth quarter of 2018, we also plan to commence a Phase 2 clinical trial of D-PLEX$_{100}$ for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery. Assuming a successful outcome in our Phase 2 clinical trial and subject to FDA feedback, we plan to initiate a Phase 3 clinical trial in the same indication. Although we have not yet discussed our plans with FDA to develop D-PLEX$_{100}$ for the prevention of SSIs in patients undergoing abdominal surgery, we believe that if the results of this Phase 3 trial, together with the results from our planned Phase 3 trial for the prevention of sternal SSIs, are favorable, these two Phase 3 studies could support a New Drug Application, or NDA, for the prevention of SSIs in bone and soft tissue. We intend to seek approval for our product candidates under the Section 505(b)(2) pathway for marketing approval by the FDA, in the United States, and the hybrid application pathway in the European Union. We may ultimately pursue a broad label for D-PLEX$_{100}$ for the management of SSIs depending on the results of our clinical trials and further discussions with the FDA regarding this

strategy. We received a designation of Qualified Infectious Disease Product, or QIDP, from the FDA for D-PLEX$_{100}$ for the prevention of sternal infection after cardiac surgery.

Systemic administration of drugs is currently used for the treatment of a wide variety of medical conditions. However, we believe there can be significant disadvantages to systemic administration of drugs for localized conditions, such as the need to use a higher amount of drugs in treatment, prolonged exposure to drugs that may cause side effects (including damage to non-targeted organs), limited efficacy due to poor penetration or access from the bloodstream into the target tissue and challenges related to solubility or sensitivity to blood factors. Localized delivery systems that have been developed to address the problems of systemic administration also have disadvantages, including short release periods and poor control of drug release rates. We believe our PLEX technology has the potential to improve patient outcomes and lower the overall cost of treatment by enabling local, customizable, predetermined and controlled delivery of drugs, thereby addressing many of the shortcomings of systemic administration and existing localized delivery systems.

Our PLEX technology consists of a proprietary matrix of layers of chemically-inert and biodegradable polymers and lipids that physically entrap an API in a protected reservoir, enabling localized, bioavailable drug delivery at customizable, predetermined release rates and durations over periods ranging from days to several months. We believe that these characteristics may enable our PLEX product candidates to be therapeutically effective using only a small fraction of the APIs required in systemic administration of currently marketed therapies. Because PLEX is agnostic to the nature and size of the underlying drug, it has the potential to be paired with a wide variety of currently marketed drugs or product candidates in development, including small molecules, peptides, antibodies, as well as nucleic acid-based APIs, to create novel therapies in a broad range of indications.

We are initially developing product candidates using our PLEX technology for the prevention of SSIs. Infection resulting from surgery and trauma can be fatal and creates a significant public health burden despite the extensive use of systemically administered antibiotics both pre- and post-surgery. SSIs occur in approximately 2% to 5% of patients undergoing inpatient surgery worldwide. The WHO reports that SSIs account for an estimated $10 billion of incremental hospital costs per year in the United States and €11 billion per year in the European Union. We expect the costs associated with SSIs to continue to grow in the face of the increasing resistance of bacteria to antibiotics, as safety concerns often preclude the increase of systemic dosages and/or treatment duration to address resistance.

We believe that, by combining doxycycline with our proprietary PLEX technology, D-PLEX$_{100}$ has the potential to overcome the limitations of other available treatments and deliver significant advantages in the management of SSIs, including:

- localized delivery of an antibiotic at therapeutically effective concentrations for up to four weeks;
- applicability to a wide range of bacteria in a variety of settings, including methicillin-resistant *Staphylococcus aureus*, or MRSA, and community-associated MRSA;
- increased penetration and access to the infection site;
- reduced risk of overall toxicity and adverse side effects due to minimization of systemic exposure and significant decrease of total drug volume delivered;
- simplicity of administration during surgery;
- biodegradability; and

• reduction of patient compliance concerns.

Our lead product candidate from this family, D-PLEX$_{100}$, which is being developed to prevent bone and soft tissue SSIs, received QIDP designation from the FDA in February 2017 for the prevention of sternal infection after cardiac surgery. We recently announced the results of the primary efficacy endpoint from our fully-enrolled Phase 1b/2 clinical trial of D-PLEX$_{100}$ in 81 patients in this indication, observed at the three month follow-up study period. During the three-month period after treatment, we observed no sternal wound infections in any of the 58 patients treated with D-PLEX$_{100}$ in combination with the standard of care. In contrast, we observed a 4.5% infection rate in the control group of patients who received the standard of care alone. According to recent literature, the expected infection rate for patients receiving the standard of care alone is 5% to 8%. We held an end of Phase 2 meeting with the FDA in the first quarter of 2018 to obtain alignment on our Phase 3 clinical trial design for the prevention of sternal infection after cardiac surgery. We plan to submit an IND for D-PLEX$_{100}$ to the FDA and a CTA to the European national competent authorities early in the fourth quarter of 2018, and to commence our Phase 3 clinical trial in sternal SSIs after cardiac surgery shortly thereafter. We also plan to commence a Phase 2 trial of D-PLEX$_{100}$ for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery early in the fourth quarter of 2018. Assuming a successful outcome in our Phase 2 clinical trial and subject to FDA feedback, we plan to initiate a Phase 3 clinical trial in the same indication. Although we have not yet discussed our plans with FDA to develop D-PLEX$_{100}$ for the prevention of abdominal SSIs, we believe the results of this Phase 3 trial, together with the results from our planned Phase 3 trial for the prevention of sternal SSIs, could support an NDA. We plan to seek approval of D-PLEX$_{100}$ in the United States under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the FFDCA, which is administered by the FDA, and the comparable hybrid application pathway in the European Union.

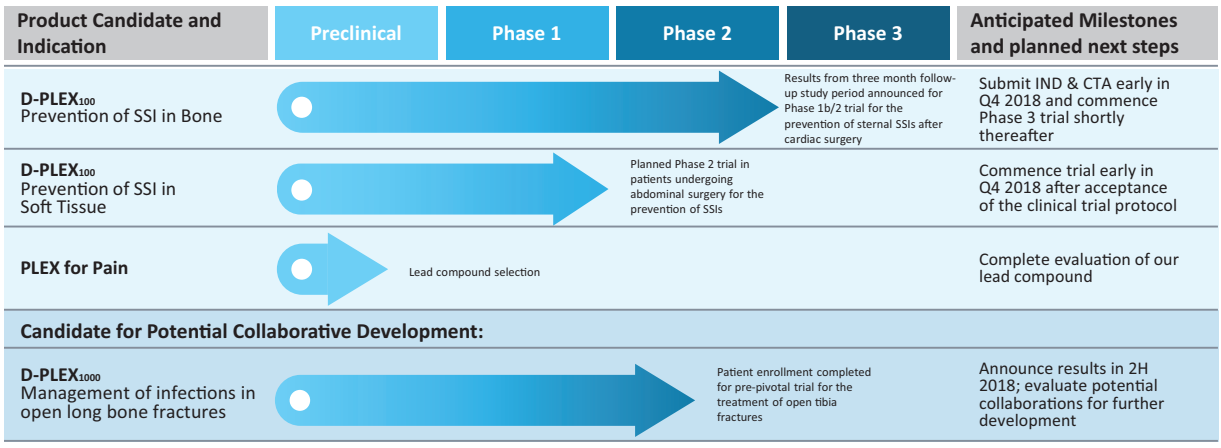
We have developed D-PLEX$_{1000}$, which was formerly known as BonyPid-1000 and is another product candidate from the D-PLEX family, for use in connection with orthopedic surgeries for the management of SSIs and support of bone recovery. Often, bone will not heal in the presence of infection. Based on results from our clinical trials of D-PLEX$_{1000}$ to date, none of the 43 patients treated with D-PLEX$_{1000}$ developed infections in the target fracture. In a retrospective analysis of the medical records of 49 patients treated for similar open long bone fractures with the standard of care at the same clinical trial sites where we conducted our D-PLEX$_{1000}$ clinical trials, we found a target fracture infection rate of up to 25%. We have completed enrollment of a pre-pivotal trial in 51 patients evaluating the safety and effectiveness of D-PLEX$_{1000}$ for the treatment of open tibia fractures. Patients were assessed on a monthly basis. In interim results from the six-month follow-up period of our pre-pivotal trial, we observed that 92% of the 12 evaluable patients treated with D-PLEX$_{1000}$ in addition to the standard of care reached the primary performance endpoint, the presence of solid radiographic markers for bone healing, as assessed by the establishment of a callus in three out of four cortices, as compared to 62% of the 13 evaluable patients treated with the standard of care alone. Sixty percent of the patients treated with D-PLEX$_{1000}$ in combination with the standard of care had reached the primary performance endpoint by three months post-operation, as compared to 17% of patients treated with the standard of care alone. Only 36% of patients receiving the standard of care alone showed these markers at four months. It was only at the five-month evaluation that patients in the standard of care arm showed a comparable percentage of patients with these markers as that observed in the group treated with D-PLEX$_{1000}$ in combination with the standard of care at three months post-operation. We do not currently plan to pursue further independent development of D-PLEX$_{1000}$, as we believe the orthopedic SSI market can be adequately addressed by D-PLEX$_{100}$.

Our PLEX platform technology may have broad applications for localized medical conditions other than the prevention of SSIs. We are pursuing research and development programs for our

PLEX platform in a variety of potential indications, including for the treatment of SSIs, pain, inflammation and cancer. We are in discussions with global biopharmaceutical companies to license our PLEX platform for use with various biologics and small molecules.

Product Candidate Pipeline

Our PLEX product candidate pipeline is set forth below:



Growth Strategy

- Complete clinical development of and seek approval for D-PLEX$_{100}$ for the prevention of bone and soft tissue SSIs in the United States and the European Union.
- Pursue expedited and fast track regulatory pathways for the approval and commercialization of our product candidates.
- Leverage our PLEX technology to expand our product pipeline for other indications.
- Evaluate and selectively pursue collaborations with leading biopharmaceutical companies.
- Retain commercial rights in the United States and selectively partner outside of the United States.
- Establish our cGMP manufacturing facility.
- Expand our intellectual property position.

Risks Associated With Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the ‘‘Risk Factors’’ section of this prospectus immediately following this prospectus summary. These risks include, among others, the following:

- We have a limited operating history and have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.
- We have never generated any revenue from product sales and may never be profitable.

- We are heavily dependent on the success of our product candidates, including obtaining regulatory approval to market our product candidates in the United States and in the European Union.
- Our product candidates are based on a novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.
- Our product candidates and the administration of our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.
- We rely on third parties to conduct certain elements of our preclinical studies and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates.
- Although we intend to establish our own cGMP compliant manufacturing facility, we expect to utilize a third party to conduct our product manufacturing, in whole or in part, at least through 2019. Therefore, we are subject to the risk that this third party may not perform satisfactorily.
- We currently have no marketing and sales organization. If we are unable to establish sales and marketing capabilities, or enter into agreements with third parties to market and sell our product candidates, if approved, we may be unable to generate any product revenue.
- We may be classified as a passive foreign investment company for the current taxable year and in the foreseeable future, which could cause our U.S. shareholders to suffer adverse tax consequences.

Corporate Information

We are an Israeli corporation based in Israel near Tel Aviv, and were incorporated in 2008. Our principal executive offices are located at 18 Hasivim Street, P.O. Box 7126, Petach Tikva 4959376 Israel. Our telephone number is +972 (74) 719-5700. Our website address is *www.polypid.com*. The information contained on our website and available through our website is not incorporated by reference into and should not be considered a part of this prospectus, and the reference to our website in this prospectus is an inactive textual reference only.

Implications of Being an ''Emerging Growth Company'' and a Foreign Private Issuer

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an ''emerging growth company'' as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- a requirement to include only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure in our initial registration statement;
- reduced executive compensation disclosure; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earlier to occur of: (1) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (2) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (3) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or the SEC. We may choose to take advantage of some but not all of these reduced burdens, and therefore the information that we provide holders of our ordinary shares may be different than the information you might receive from other public companies in which you hold equity. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies. We have irrevocably elected to opt out of such extended transition period.

Upon consummation of this offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we continue to qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations with respect to a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial statements and other specified information, and current reports on Form 8-K upon the occurrence of specified significant events.

Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

THE OFFERING

Ordinary shares offered by us	3,333,333 ordinary shares
Ordinary shares to be outstanding immediately after this offering	13,112,219 ordinary shares (or 13,612,219 ordinary shares if the underwriters exercise their option to purchase an additional ordinary shares in full)
Option to purchase additional ordinary shares	We have granted the underwriters an option for a period of 30 days after the date of this prospectus to purchase up to additional 500,000 ordinary shares.
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $67.8 million, or approximately $78.2 million if the underwriters exercise their option to purchase 500,000 additional ordinary shares in full, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, based on an assumed initial public offering price of $22.50 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus. We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term deposits: (i) to fund the clinical development of D-PLEX$_{100}$, primarily for our planned Phase 3 clinical trial for the prevention of sternal SSIs after cardiac surgery, as well as our planned Phase 2 clinical trial for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery, and, assuming a successful outcome in our Phase 2 clinical trial, our planned Phase 3 clinical trial in the same indication, and clinical supporting activities, (ii) to continue construction of our pilot manufacturing facility and initiate preparations for our larger commercial-scale cGMP compliant manufacturing facility and (iii) for other research and development activities and general corporate purposes and working capital. See ''Use of Proceeds'' for more information about the intended use of proceeds from this offering.
Passive foreign investment company considerations	Based upon the expected value of our assets, including any goodwill, and the expected nature and composition of our income and assets, we may be classified as a passive foreign investment company, or a PFIC, for the taxable year ending December 31, 2018 and in future taxable years. In particular, so long as we do not generate revenue from operations for any taxable year and do not receive any research and development grants, or if such grants that we receive do not constitute gross income for purposes of the PFIC test, we likely will be classified as a PFIC for such taxable year.

Proposed Nasdaq Global Market symbol	Application has been made to have our ordinary shares listed on The Nasdaq Global Market under the symbol ''POLY.''

Unless otherwise stated, the number of ordinary shares to be outstanding after this offering is based on 9,778,886 ordinary shares outstanding as of December 31, 2017, and excludes the following:

- 2,019,001 ordinary shares reserved for issuance upon the exercise of outstanding options as of December 31, 2017, at a weighted average exercise price of $4.84 per share;
- 898,473 ordinary shares reserved for issuance under our Amended and Restated 2012 Share Option Plan, as of the date of this prospectus, as well as any automatic increases in the number of ordinary shares reserved for issuance under the Amended and Restated 2012 Share Option Plan; and
- 2,882,215 ordinary shares issuable upon the exercise of outstanding warrants to purchase Series D-2 preferred shares, at a weighted average exercise price of $8.83 per share, which warrants will automatically convert into warrants to purchase ordinary shares upon the closing of this offering and are expected to remain outstanding at the consummation of this offering.

Unless otherwise indicated, all information in this prospectus assumes or gives effect to:

- an initial public offering price of $22.50 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus;
- no exercise of the underwriters' option to purchase up to an additional ordinary shares;
- the automatic conversion of all outstanding preferred shares into 9,138,485 ordinary shares, which will occur upon the closing of this offering;
- the exercise of warrants to purchase 56,250 Series A preferred shares, and the automatic conversion thereof into 56,250 ordinary shares, which will occur upon the closing of this offering;
- a 1-for-8 reverse share split, and par value adjustment from NIS 0.10 per share to NIS 0.80 per share, effected on February 21, 2018; and
- the adoption of our amended and restated articles of association prior to the closing of this offering, which will replace our amended and restated articles of association as currently in effect.

Certain of our existing shareholders have indicated an interest in purchasing up to an aggregate of $19.5 million in ordinary shares in this offering at the initial public offering price per share. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these shareholders, or any of these shareholders may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these shareholders as they will on any other shares sold to the public in this offering.

SUMMARY FINANCIAL DATA

The following table summarizes our financial data. We have derived the following statements of operations data for the years ended December 31, 2016 and 2017 and the balance sheet data as of December 31, 2017 from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future, and our results for any interim period are not necessarily indicative of results that may be expected for any full year. The following summary financial data should be read in conjunction with ''Selected Financial Data,'' ''Management's Discussion and Analysis of Financial Condition and Results of Operations'' and our consolidated financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2016	2017
	(in thousands, except share and per share amounts)	
Research and development, net	$ 7,708	$ 9,736
General and administrative	2,551	4,064
Operating loss	10,259	13,800
Financial expenses, net	1,133	40,688
Net loss	$ 11,392	$ 54,488
Deemed dividend	$ —	$ 1,255
Net loss attributable to ordinary shares	11,392	55,743
Basic and diluted net loss per ordinary share	$ (24.64)	$ (102.00)
Weighted average number of ordinary shares, basic and diluted	568,078	584,176
Pro forma basic and diluted net loss per ordinary share[1]		$ (6.32)
Pro forma weighted average number of ordinary shares, basic and diluted		8,822,520

(1) See Note 13 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma basic and diluted net loss per ordinary share.

	As of December 31, 2017		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2]
		(unaudited) (in thousands)	
Balance Sheet Data:			
Cash, cash equivalents and short-term deposits	$ 17,938	$17,951	86,117
Working capital[3]	15,366	15,379	84,217
Total assets	22,984	21,909	90,075
Convertible preferred shares	59,983	—	—
Convertible preferred shares warrant liability	47,399	—	—
Total shareholders' equity (deficiency)	(88,646)	17,661	86,498

(1) Pro forma balance sheet data give effect to: (i) the automatic conversion of all outstanding preferred shares into 9,138,485 ordinary shares upon the closing of this offering and (ii) the exercise of warrants to purchase 56,250 Series A preferred shares, and the automatic conversion thereof into 56,250 ordinary shares, which will occur upon the closing of this offering.

(2) Pro forma as adjusted balance sheet data give additional effect to the sale of 3,333,333 ordinary shares in this offering at the assumed initial public offering price of $22.50 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Working capital is defined as total current assets minus total current liabilities

The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing. Each $1.00 increase (decrease) in the assumed initial public offering price of $22.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and short-term deposits, total assets and shareholders' equity (deficiency) by $3.1 million, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of ordinary shares offered by us at the assumed initial public offering price would increase (decrease) each of cash, cash equivalents and short-term deposits, total assets and shareholders' equity (deficiency) by $20.9 million.

RISK FACTORS

Investing in our ordinary shares involves a high degree of risk. You should carefully consider the risks and uncertainties described below, in addition to the other information set forth in this prospectus, including the consolidated financial statements and the related notes included elsewhere in this prospectus, before purchasing our ordinary shares. If any of the following risks actually occurs, our business, financial condition, cash flows and results of operations could be negatively impacted. In that case, the trading price of our ordinary shares would likely decline and you might lose all or part of your investment.

Risks Related to Our Financial Condition and Capital Requirements

We have a limited operating history and have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.

We are a clinical stage pharmaceutical company with a limited operating history. We have incurred net losses each year since our inception, including net losses of $11.4 million and $54.5 million for the years ended December 31, 2016 and 2017, respectively, and net losses attributable to ordinary shares of $11.4 million and $55.7 million for the years ended December 31, 2016 and 2017, respectively. As of December 31, 2017, we had an accumulated deficit of $92.3 million.

We have devoted substantially all of our financial resources to designing and developing our product candidates, including conducting preclinical studies and clinical trials and providing general and administrative support for these operations. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our ability to ultimately achieve recurring revenues and profitability is dependent upon our ability to successfully complete the development of our product candidates, obtain necessary regulatory approvals for and successfully manufacture, market and commercialize our products. We anticipate that our expenses will increase substantially based on a number of factors, including to the extent that we:

- continue our clinical development of D-PLEX$_{100}$ for the prevention of sternal surgical site infections, or SSIs, after cardiac surgery and SSIs in patients undergoing abdominal surgery, and other potential indications;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- identify, assess, acquire, license and/or develop other product candidates;
- establish and validate one or more commercial-scale current good manufacturing practices, or cGMP, manufacturing facilities;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- hire personnel and invest in additional infrastructure to support our operations as a public company and expand our product development;
- enter into agreements to license intellectual property from third parties;
- develop, maintain, protect and expand our intellectual property portfolio; and
- experience any delays or encounter issues with respect to any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges

that require longer follow-up of existing studies, additional major studies or additional supportive studies in order to pursue marketing approval.

To date, we have financed our operations primarily through the sale of equity securities, convertible loans made by certain of our shareholders, royalty-bearing and non-royalty bearing grants that we received from the Israeli Innovation Authority, or the IIA, formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry, and non-royalty bearing grants under the European Commission's Seventh Framework Programme for Research, or FP7. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or grants. Even if we obtain regulatory approval to market one or more product candidates, our future revenue will depend upon the size of any markets in which such product candidates receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors for such product candidates. Further, the net losses that we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Other unanticipated costs may also arise.

We have never generated any revenue from product sales and may never be profitable.

We have no products approved for marketing in any jurisdiction and we have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of our product candidates. We do not anticipate generating revenue from product sales for at least the next several years. Our ability to generate future revenue from product sales will depend heavily on our ability to:

- complete research and preclinical and clinical development of our product candidates in a timely and successful manner;
- obtain regulatory and marketing approval for those of our product candidates for which we complete clinical studies;
- develop and obtain regulatory approval for a sustainable and scalable in-house and/or third-party manufacturing process that meets all applicable regulatory standards for our approved product candidates;
- establish and maintain supply and, if applicable, manufacturing relationships with third parties that can provide adequate, in both amount and quality, products to support clinical development and the market demand for our product candidates, if and when approved;
- launch and commercialize our product candidates for which we obtain regulatory and marketing approval, either directly by establishing a sales force, marketing and distribution infrastructure, and/or with collaborators or distributors;
- expose, educate and train physicians and other medical professionals to use our products;
- obtain market acceptance, if and when approved, of our product candidates from the medical community and third-party payors;
- ensure our product candidates are approved for reimbursement from governmental agencies, health care providers and insurers in jurisdictions where they have been approved for marketing;

- address any competing technological and market developments that impact our product candidates or their prospective usage by medical professionals;
- identify, assess, acquire and/or develop new product candidates;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter and perform our obligations under such collaborations;
- maintain, protect and expand our portfolio of intellectual property rights, including patents, patent applications, trade secrets and know-how;
- avoid and defend against third-party interference or infringement claims;
- attract, hire and retain qualified personnel; and
- locate and lease or acquire suitable facilities to support our clinical development, manufacturing facilities and commercial expansion.

Even if one or more of our product candidates is approved for marketing and sale, we anticipate incurring significant incremental costs associated with commercializing such product candidates. Our expenses could increase beyond expectations if we are required by the United States Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other regulatory agencies, domestic or foreign, or ethical committees in medical centers, to change our manufacturing processes or assays or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate. Even if we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue earned from such product candidates will be dependent in part upon the size of the markets in the territories for which we gain regulatory approval for such products, the accepted price for such products, our ability to obtain reimbursement for such products at any price, whether we own the commercial rights for that territory in which such products have been approved and the expenses associated with manufacturing and marketing such products for such markets. Therefore, we may not generate significant revenue from the sale of such products, even if approved. Further, if we are not able to generate significant revenue from the sale of our approved products, we may be forced to curtail or cease our operations. Due to the numerous risks and uncertainties involved in product development, it is difficult to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability.

Even if this offering is successful, we will need to raise substantial additional funding, which may not be available on acceptable terms, or at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations.

We are currently advancing our product candidates through preclinical and clinical development in an effort to obtain regulatory approval. We recently announced interim results from our Phase 1b/2 clinical trial of our lead product candidate, D-PLEX$_{100}$, for the prevention of sternal SSIs after cardiac surgery. We plan to submit an Investigational New Drug, or IND, application for D-PLEX$_{100}$ to the FDA, and a clinical trial application, or CTA, to the European national competent authorities, early in the fourth quarter of 2018, and to commence a Phase 3 clinical trial in this indication shortly thereafter. Early in the fourth quarter of 2018, we also plan to commence a Phase 2 clinical trial in patients undergoing abdominal surgery for the prevention of SSIs.

Developing our product candidates is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates through clinical studies and regulatory approval.

Furthermore, upon the closing of this offering, we expect to incur additional ongoing costs associated with operating as a public company.

As of December 31, 2017, we had cash, cash equivalents and short-term deposits of $17.9 million. We will require significant additional financing in the future to fund our operations. Our future funding requirements will depend on many factors, including but not limited to:

- the progress, results and costs of our current and planned clinical trials of D-PLEX$_{100}$ and our other future product candidates;
- the cost, timing and outcomes of regulatory review of D-PLEX$_{100}$ and our other future product candidates;
- the costs of establishing and maintaining one or more of our own commercial-scale cGMP manufacturing facilities and/or engaging third-party manufacturers therefor;
- the scope, progress, results and costs of product development, laboratory testing, manufacturing, preclinical development and clinical trials for any other product candidates that we may develop or otherwise obtain in the future;
- the cost of our future activities, including establishing sales, marketing and distribution capabilities for any product candidates in any particular geography where we receive marketing approval for such product candidates;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the level of revenue, if any, received from commercial sales of any product candidates for which we receive marketing approval.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if and when approved, may not achieve commercial success. Our product revenues, if any, will be derived from or based on sales of product candidates that may not be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all, and the terms of any financing may adversely affect the interests or rights of our shareholders. Even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. The issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline.

We may seek additional capital through a combination of equity offerings, debt financings and collaborations and strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. If we raise additional funds through collaboration

and licensing arrangements with third parties, it may be necessary to relinquish certain rights to our technologies or our product candidates, or to grant licenses on terms that are not favorable to us.

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

Risks Related to the Discovery, Development and Clinical Testing of Our Product Candidates

We are heavily dependent on the success of our product candidates, including obtaining regulatory approval to market our product candidates in the United States and the European Union.

To date, we have invested all of our efforts and financial resources to: (i) research and develop our PLEX technology, our lead product candidate, D-PLEX$_{100}$, and our other product candidates, including conducting preclinical and clinical studies and providing general and administrative support for these operations; and (ii) develop and secure our intellectual property portfolio for our product candidates. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our current and future product candidates. Our product candidates' marketability is subject to significant risks associated with successfully completing current and future clinical trials, including:

- the FDA's timely acceptance of our IND, and the European national competent authorities' timely acceptance of our CTA, which we intend to submit early in the fourth quarter of 2018, for our planned Phase 3 clinical trial of D-PLEX$_{100}$ for prevention of sternal SSIs after cardiac surgery, and pursuant to which we also plan to conduct a Phase 2 clinical trial in patients undergoing abdominal surgery for the prevention of SSIs, and for any other product candidates for which we may file an IND or a CTA, as applicable, without which we would be unable to commence such clinical trials in the United States or the European Union, respectively;
- acceptance by the FDA, EMA or other regulatory agencies of our parameters for regulatory approval relating to D-PLEX$_{100}$ and our other product candidates, including our proposed indications, primary and secondary endpoint assessments and measurements, safety evaluations and regulatory pathways;
- the acceptance by the FDA, EMA or other regulatory agencies of the number, design, size, conduct and implementation of our clinical trials, our trial protocols and the interpretation of data from preclinical studies or clinical trials;
- our ability to successfully complete the clinical trials of our product candidates, including timely patient enrollment and acceptable safety and efficacy data and our ability to demonstrate the safety and efficacy of the product candidates undergoing such clinical trials;
- our ability to commence a Phase 3 clinical trial of D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery in the United States following an IND submission, if accepted, and our ability to complete such trial in a timely fashion, and that such Phase 3 clinical trial, along with our planned Phase 3 clinical trial of D-PLEX$_{100}$ for the prevention of SSIs in patients undergoing abdominal surgery, even if both such trials are successfully completed, will be sufficient to support approval of a New Drug Application, or NDA, or that the FDA will allow us to use our planned Phase 3 clinical trial of D-PLEX$_{100}$ for the prevention of SSIs in patients undergoing abdominal surgery as the second Phase 3 clinical trial required to support such NDA;

- the FDA's acceptance of the sufficiency of the data we collected from our preclinical studies and our Phase 1b/2 clinical trial of D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery, and that we expect to collect from toxicological studies that we may conduct to support the submission of an IND without requiring additional preclinical studies or clinical trials;
- the willingness of the FDA, EMA or other regulatory agencies to schedule an advisory committee meeting in a timely manner to evaluate and decide on the approval of our regulatory filings, if such advisory committee meetings are required;
- the recommendation of the FDA's advisory committee to approve our applications to market D-PLEX$_{100}$ and our other product candidates in the United States, and the EMA in the European Union, if such advisory committee reviews are scheduled, without limiting the approved labeling, specifications, distribution or use of the products, or imposing other restrictions;
- the satisfaction of the FDA, EMA or other regulatory agencies with the safety and efficacy of our product candidates;
- the prevalence and severity of adverse events associated with our product candidates;
- the timely and satisfactory performance by third-party contractors, trial sites and principal investigators of their obligations in relation to our clinical trials;
- our success in educating medical professionals and patients about the benefits, administration and use of our product candidates, if approved;
- the availability, perceived advantages, relative cost, safety and efficacy of alternative and competing treatments for the indications addressed by our product candidates;
- the effectiveness of our marketing, sales and distribution strategy, and operations, as well as that of any current and future licensees;
- our ability to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP;
- our ability to obtain, protect and enforce our intellectual property rights with respect to our product candidates; and
- changes to regulatory guidelines.

Many of these clinical, regulatory and commercial risks are beyond our control. Accordingly, we cannot assure you that we will be able to advance any of our product candidates through clinical development, or to obtain regulatory approval of or commercialize any of our product candidates. If we fail to achieve these objectives or overcome the challenges presented above, we could experience significant delays or an inability to successfully commercialize our product candidates. Accordingly, we may not be able to generate sufficient revenues through the sale of our product candidates to enable us to continue our business.

We may be unable to obtain regulatory approval for our product candidates.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, recordkeeping, marketing, distribution, post-approval monitoring and reporting and export and import of drug products are subject to extensive regulation by the FDA, the EMA and by foreign regulatory authorities in other countries. These regulations differ from country to country. To gain approval to market our product candidates, we must provide data from well-controlled clinical trials that adequately demonstrate the safety and efficacy of the product for the intended indication to the satisfaction of the FDA, EMA or other regulatory authority. We have not yet obtained regulatory approval to market any of our product candidates in the United States

or any other country. The FDA, EMA or other regulatory agencies can delay, limit or deny approval of our product candidates for many reasons, including:

- regulatory requests for additional analyses, reports, data, non-clinical and preclinical studies and clinical trials;
- our inability to demonstrate that the product candidates are safe and effective for the target indication to the satisfaction of the FDA, EMA or other regulatory agencies;
- the FDA's, EMA's, or other regulatory agencies' disagreement with our trial protocol, the interpretation of data from preclinical studies or clinical trials, or adequacy of the conduct and control of clinical trials;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- the population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the patient population for which we seek approval;
- unfavorable or inconclusive results of clinical trials and supportive non-clinical studies, including unfavorable results regarding safety or efficacy of our product candidates observed in clinical trials;
- our inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- any determination that a clinical trial presents unacceptable health risks to subjects;
- our inability to obtain approval from institutional review boards, or IRBs, to conduct clinical trials at their respective sites;
- the FDA's determination that the 505(b)(2) regulatory pathway is not available for our product candidates;
- the non-approval of the formulation, labeling or the specifications of our product candidates;
- the failure to accept the manufacturing processes or facilities at our manufacturing facility or those of third-party manufacturers with which we contract;
- the potential for approval policies or regulations of the FDA, EMA or other regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval; or
- resistance to approval from the advisory committees of the FDA, EMA or other regulatory agencies for any reason including safety or efficacy concerns.

In the United States, we will be required to submit an NDA to obtain FDA approval before marketing any of our product candidates. An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and efficacy for each desired indication. In the case of an NDA covered by Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the FFDCA, we may rely in part on data not developed by us and for which we have not obtained a right of reference or use, including published scientific literature or the FDA's findings of safety and/or effectiveness for a previously approved drug. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. The FDA may further inspect our manufacturing facilities to ensure that the facilities can manufacture our product candidates and our products, if and when approved, in compliance with the applicable regulatory requirements, as well as inspect our clinical trial sites to ensure that our studies are properly conducted. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. Upon submission of an NDA, the FDA must

make an initial determination that the application is sufficiently complete to accept the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA, or ultimately be approved. If the application is not accepted for review or approval, the FDA may require that we conduct additional clinical or preclinical trials, or take other actions before it will reconsider our application. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. For example, in connection with our end of phase 2 meeting with the FDA related to our proposed indication for the prevention of SSIs after cardiac surgery, the FDA indicated that two Phase 3 studies would be required to support an NDA for D-PLEX$_{100}$. We have not yet discussed with the FDA our plan to conduct our second Phase 3 study in abdominal surgery patients rather than in subjects having undergone cardiac surgery to prevent sternal infections. The FDA could determine that a Phase 3 study in abdominal surgery patients does not satisfy the FDA's requirement for a second Phase 3 study to support an NDA for D-PLEX$_{100}$. Moreover, even if the FDA agrees that a Phase 3 study evaluating D-PLEX$_{100}$ for the prevention of post-cardiac surgery sternal infections and a second Phase 3 study for the prevention of SSIs following abdominal surgery is sufficient to support an NDA, the FDA may determine that the data from these studies support a more narrow indication than we may propose, if the FDA were to approve the NDA at all. In addition, the FDA may not consider any additional information to be complete or sufficient to support approval.

Regulatory authorities outside of the United States, such as in the European Union, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction could have a negative impact on our ability to obtain approval in a different jurisdiction. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time consuming. Foreign regulatory approval may include all of the risks associated with obtaining FDA approval. For all of these reasons, if we seek foreign regulatory approval for any of our other product candidates, we may not obtain such approvals on a timely basis, if at all.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of costly and potentially time-consuming additional post-approval clinical trials or subject to contraindications, black box warnings, restrictive surveillance or Risk Evaluation and Mitigation Strategies, or REMS. Further, the FDA, EMA or other foreign regulatory authorities may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and these regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Following any approval for commercial sale of our product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, as well as new safety information, will be subject to additional FDA notification, or review and approval. Also, regulatory approval for any of our product candidates may be withdrawn. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would thus negatively impact our business, results of operations and prospects.

Clinical drug development is difficult to design and implement and involves a lengthy and expensive process with uncertain outcomes.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. We do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including failure to:

- generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtain regulatory approval, or feedback on trial design, in order to commence a trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among CROs and clinical trial sites, and have such CROs and sites effect the proper and timely conduct of our clinical trials;
- obtain and maintain IRB approval at each clinical trial site;
- identify, recruit and enroll suitable patients to participate in a trial;
- have a sufficient number of patients complete a trial or return for post-treatment follow-up;
- ensure clinical investigators and clinical trial sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites;
- manufacture sufficient quantities at the required quality of product candidate for use in clinical trials; or
- raise sufficient capital to fund a trial.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or amend a trial protocol;

- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and CROs;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- there may be changes in government regulations or administrative actions;
- our product candidates may have undesirable adverse effects or other unexpected characteristics;
- we may not be able to demonstrate that a produce candidate's clinical and other benefits outweigh its safety risks;
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care of future competitive therapies in development;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

We may also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the trial's data safety monitoring board, by the FDA, EMA or other regulatory agencies. Such authorities may suspend or terminate one or more of our clinical trials due to a number of factors, including our failure to conduct the clinical trial in accordance with relevant regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory agencies resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we plan to do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

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

The results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates.

Results from preclinical studies or early stage clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. For example, we observed preliminary evidence of efficacy in our preclinical studies of D-PLEX$_{100}$ for sternal SSIs after cardiac surgery, but we have not yet conducted a clinical trial of D-PLEX$_{100}$ in this indication that included efficacy as a final endpoint. We intend to assess efficacy in our upcoming Phase 3 clinical trial of D-PLEX$_{100}$ in this indication. However, later stage clinical trials may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical and early clinical studies. This failure would cause us to abandon further development of D-PLEX$_{100}$ in this indication, which is currently our most advanced product candidate.

There is a high failure rate for drug candidates proceeding through clinical trials. Many companies in the pharmaceutical industry have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of our product candidate development. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials.

Interim, ''top-line'' and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, ''top-line'' or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or ''top-line'' data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse changes between preliminary or interim data and final data could significantly harm our business prospects.

If the FDA does not conclude that D-PLEX$_{100}$ satisfies the requirements under Section 505(b)(2) of the FFDCA, or Section 505(b)(2), or if we are unable to utilize the hybrid application pathway in the European Union, or if the requirements are not as we expect, the approval pathway for D-PLEX$_{100}$ will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We intend to utilize the FDA's Section 505(b)(2) regulatory pathway, and the hybrid application pathway in the European Union, which is analogous to the Section 505(b)(2) pathway, to seek NDA approval for D-PLEX$_{100}$. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FFDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference or use from the person by or for whom the investigations were

conducted, which we believe could expedite the development program for D-PLEX$_{100}$ by potentially decreasing the amount of preclinical and clinical data that we would need to generate in order to obtain FDA approval. However, while we believe that D-PLEX$_{100}$ is a reformulation of an already-approved drug and, therefore, will be eligible for submission of an NDA under Section 505(b)(2), the FDA may disagree and determine that D-PLEX$_{100}$ is not eligible for review under such regulatory pathway.

If we are unable to pursue these regulatory pathways as anticipated, we may need to conduct additional preclinical experiments and clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for D-PLEX$_{100}$, and complications and risks associated with D-PLEX$_{100}$, would likely increase significantly. Moreover, inability to pursue the Section 505(b)(2) or similar regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely harm our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) or similar regulatory pathway, D-PLEX$_{100}$ may not receive the requisite approvals for commercialization, and there is no guarantee the 505(b)(2) or similar pathway would ultimately lead to faster product development or earlier approval.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our potential future NDAs for up to 30 months depending on the outcome of any litigation. It is also not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

Moreover, even if these product candidates are approved under the Section 505(b)(2) pathway, as the case may be, the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

PLEX is a novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval of our product candidates.

We have concentrated our efforts and product research on our PLEX drug delivery technology, and our future success depends on the successful development of this technology and products based on it. To our knowledge, no regulatory authority has granted approval to any person or entity, including us, to market and commercialize therapeutics using our novel delivery system. We may never receive approval to market and commercialize any product candidate that utilizes PLEX.

As an organization, we have never conducted pivotal clinical trials, and we may be unable to do so for any product candidates we may develop, including D-PLEX$_{100}$.

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, EMA or other regulatory agencies to market D-PLEX$_{100}$ or any of our other product candidates. Carrying out later-stage clinical trials and the submission of a successful NDA is a complicated process. As an organization, we have not previously conducted any later stage or pivotal clinical trials and have limited experience in preparing, submitting and prosecuting regulatory filings. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission and approval of D-PLEX$_{100}$. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing D-PLEX$_{100}$. See ''— Risks Related to our Reliance on Third Parties — We rely on third parties to conduct certain elements of our preclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates.''

We may find it difficult to enroll patients in our clinical studies, which could delay or prevent us from proceeding with clinical trials.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any drugs that may be approved for the indications we are investigating, the eligibility criteria for the study, our ability to obtain and maintain patient consents and the risk that patients enrolled in clinical trials will drop out of the trials before completion.

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

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

Undesirable side effects, including toxicology, caused by our product candidates, or the drugs encapsulated by our product candidates, could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or other regulatory agencies. Results of our studies could reveal a high

and unacceptable severity and prevalence of these or other side effects. In such an event, our clinical studies could be suspended or terminated, and the FDA, EMA or other regulatory agencies could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. Moreover, during the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions.

Drug-related, drug-product related, formulation-related and administration-related side effects could affect patient recruitment, the ability of enrolled patients to complete the clinical study or result in potential product liability claims, which could exceed our clinical trial insurance coverage. We do not currently have product liability insurance and do not anticipate obtaining product liability insurance until such time as we have received FDA, EMA or other comparable foreign authority marketing approval for one of our product candidates and such product is being provided to patients outside of clinical trials.

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

- regulatory authorities may suspend or withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label, such as a ''black box'' warning or contraindication;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be required to create a REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we may be required to recall a product, change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

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

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize any of our product candidates, and the approval may be for a more narrow indication than we seek or be subject to other limitations or restrictions that limit its commercial profile.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our current or future product candidates meet safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of warnings or a REMS. These regulatory authorities may require precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any of our product candidates. For example, the FDA may disagree that a Phase 3 study evaluating D-PLEX$_{100}$ for the prevention of post-cardiac surgery sternal infections and a second Phase 3 study for the prevention of SSIs following abdominal surgery are sufficient to support an NDA for the prevention of SSIs in bone and soft tissue. Even if the FDA were to agree that these studies were sufficient to support an NDA, the FDA may determine that the data from these studies support a more narrow indication than we may propose, if the FDA were to approve the NDA at all. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially and adversely affect our business, financial condition, results of operations and prospects.

Although D-PLEX$_{100}$ has been granted Qualified Infectious Disease Product designation by the FDA for the prevention of sternal infection after cardiac surgery, this designation does not guarantee a shorter FDA review process, or that D-PLEX$_{100}$ will ultimately be approved by the FDA.

Under the Generating Antibiotic Incentives Now Act, or GAIN Act, the FDA may designate a product as a ''qualified infectious disease product,'' or QIDP. In order to receive this designation, a drug must qualify as an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens, or (2) a so-called ''qualifying pathogen'' found on a list of potentially dangerous, drug-resistant organisms established and maintained by the FDA under the GAIN Act. A sponsor must request such designation before submitting a marketing application. We requested and received QIDP designation for D-PLEX$_{100}$ for the prevention of sternal infection after cardiac surgery. We anticipate that the QIDP designation will provide, among other benefits, an overall increased level of communication with the FDA during the development process. The benefits of QIDP designation also include eligibility for priority review and an extension by an additional five years of any non-patent market exclusivity period awarded, such as a five-year exclusivity period awarded for a new molecular entity or a three-year market exclusivity period awarded to an applicant whose application relies on new clinical investigations essential to the approval. This extension is in addition to any pediatric exclusivity extension that may be awarded. However, there is limited precedent for understanding the way in which the GAIN Act will be implemented. Receipt of QIDP designation in practice may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures, and does not assure ultimate approval by the FDA or related exclusivity benefits.

Even if we obtain regulatory approval for a product candidate, our products and business will remain subject to ongoing regulatory obligations and review.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and comparable requirements outside of the United States. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. We will also be required to report certain adverse reactions and production problems, if any, to the FDA, EMA or other regulatory agencies and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have FDA, EMA or other regulatory agency approval. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our product candidates in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a clinical study could result in the withdrawal of marketing approval. Furthermore, any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. Foreign regulatory authorities impose similar requirements. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us or our strategic partners;
- restrict the marketing or manufacturing of our products;
- seize or detain products, or require a product recall;
- refuse to permit the import or export of our product candidates; or
- refuse to allow us to enter into government contracts.

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and

spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these Executive Orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

If one or more of our product candidates is approved for marketing in the United States, we may be subject, directly or indirectly, to U.S. federal and state healthcare fraud and abuse laws, false claims laws, physician payment transparency laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly or indirectly through our relationships with physicians, patients, third-party payors and customers, subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business or financial arrangements and relationships through which we research, market, sell and distribute our products. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- The U.S. Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other U.S. federal healthcare programs. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution.
- The U.S. federal false claims and civil monetary penalties laws, including the False Claims Act, or FCA, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the U.S. federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the U.S. federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes ''any request or demand'' for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed

to ''cause'' the submission of false or fraudulent claims. The FCA also permits a private individual acting as a ''whistleblower'' to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for ''off-label'' uses; and submitting inflated best price information to the Medicaid Rebate Program.

- The U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.
- The Physician Payments Sunshine Act, enacted as part of the PPACA, imposes, among other things, annual reporting requirements for covered manufacturers for certain payments and ''transfers of value'' provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Many states have analogous state laws and regulations, such as state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. In addition, certain states require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, file reports relating to pricing information or marketing expenditures and have laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices, including arrangements we may have with physicians and other healthcare providers, some of whom may receive stock options as compensation for services provided, do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from government funded healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates and to produce, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- change in protocol design;
- additional treatment arm (control);
- recall, replacement, or discontinuance of one or more of our products; and
- additional recordkeeping.

In addition, in the United States, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. The pharmaceutical industry in the United States, as an example, has been affected by the passage of the Patient Protection and Affordable Care Act and the Health Care and Education

Reconciliation Act of 2010, collectively PPACA, which, among other things, imposed new fees on entities that manufacture or import certain branded prescription drugs and expanded pharmaceutical manufacturer obligations to provide discounts and rebates to certain government programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been enacted. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the ''individual mandate''. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called ''Cadillac'' tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. We continue to evaluate the effect that the PPACA and its possible repeal and replacement has on our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

Further, there has been particular and increasing legislative and enforcement interest in the United States with respect to drug pricing practices in recent years, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. There have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and in some cases, designed to encourage importation from other countries and bulk purchasing. In the future, there will likely continue to be proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of drug products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Our results of operations could be adversely affected by the PPACA and by other health care reforms that may be enacted or adopted in the future.

We face intense competition in an environment of rapid technological change and the possibility that our competitors may develop products and drug delivery systems that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our product candidates.

The pharmaceutical industry in which we operate is intensely competitive and subject to rapid and significant technological change. We are currently aware of various existing therapies in the market and in development that may in the future compete with our product candidates, including other therapies that address the management of SSIs, as well as other drugs delivery mechanisms that utilize polymer and/or lipid technology to deliver APIs at the local level. Other approaches may also emerge for the prevention or treatment of any of the indications on which we focus, and new technologies may emerge in localized drug delivery.

We have competitors both in the United States and internationally, including major multinational pharmaceutical companies and specialty pharmaceutical companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis products that are more

effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors. See ''Business — Competition.''

Even if we obtain and maintain approval for D-PLEX$_{100}$ or our other product candidates from the FDA, we may never obtain approval outside of the United States, which would limit our market opportunities and adversely affect our business.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, the failure to obtain approval from the FDA or other regulatory authorities may negatively impact our ability to obtain approval in other foreign countries. Sales of D-PLEX$_{100}$ or our other product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our product candidates, if approved, is also subject to approval.

We intend to submit a marketing authorization application to the EMA for approval of D-PLEX$_{100}$ in the European Union, but obtaining such approval from the European Commission following the opinion of the EMA is a lengthy and expensive process. Even if a product candidate is approved, the applicable regulatory agency may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the European Union also have requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for a product candidate may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of D-PLEX$_{100}$ or our other product candidates will be harmed and our business, financial condition, results of operations and prospects will be adversely affected.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

If the FDA does not agree that our data support the prevention of SSIs in bone and soft tissue, we intend to seek marketing approval for D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery and the prevention of SSIs in patients undergoing abdominal surgery. We will train our marketing and sales personnel to not promote our products, if approved, for any other uses

outside of any FDA-approved indications for use, known as ''off-label uses.'' We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. For example, if we obtain approval of D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery and the prevention of SSIs in patients undergoing abdominal surgery, physicians may nevertheless decide to use D-PLEX$_{100}$ in an attempt to prevent infections in connection with other types of surgeries, and there may be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved. Furthermore, the use of our products for indications other than those approved by the FDA or any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA, EMA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

Risks Related to our Reliance on Third Parties

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

We have relied upon, and plan to continue to rely upon, third-party vendors, including CROs, to monitor and manage data for our ongoing preclinical and clinical studies. We rely on these parties for execution of our preclinical and clinical studies, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the vendors and CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with good clinical practice, or GCP, cGMP, the Helsinki Declaration, the International Conference on Harmonization Guideline for Good Clinical Practice, applicable European Commission Directives on Clinical Trials, laws and regulations applicable to clinical trials conducted in other territories, and good laboratory practices, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, including GCP and cGMP regulations, the clinical data generated in our clinical studies may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. Our failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs or vendors terminate, we may not be able to enter into arrangements with alternative CROs or vendors or do so on commercially reasonable terms. In addition, our CROs are not our employees, and, except for remedies available

to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical studies may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated, which could adversely affect our results of operations and the commercial prospects for our product candidates, increase our costs and delay our ability to generate revenue.

Replacing or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, we may encounter similar challenges or delays in the future, which could have a material adverse impact on our business, financial condition and prospects.

Independent clinical investigators and CROs that we engage to conduct our clinical trials may not devote sufficient time or attention to our clinical trials or be able to repeat their past success.

We expect to continue to depend on third parties, including independent clinical investigators and CROs, to conduct our clinical trials. CROs may also assist us in the collection and analysis of data. There is a limited number of third-party service providers and vendors that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs.

These investigators and CROs will not be our employees and we will not be able to control, other than through contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop.

Investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a financial relationship between us and an investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval or rejection of our marketing applications by the FDA or other regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Further, the FDA and other regulatory authorities require that we comply with standards, commonly referred to as GCP, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. Failure of clinical investigators or CROs to meet their obligations to us or comply with GCP procedures could adversely affect the clinical development of our product candidates and harm our business.

We rely on third parties to manufacture the raw materials, including the active pharmaceutical ingredients, that we use to create our product candidates. Our business could be harmed if existing and prospective third parties fail to provide us with sufficient quantities of these materials and products or fail to do so at acceptable quality levels or prices.

We currently rely on third party suppliers for certain raw materials necessary to manufacture our product candidates for our preclinical studies and clinical trials. Some of these raw materials are difficult to source. Because there are a limited number of suppliers for these raw materials, we may need to engage alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. In several cases, we rely on a sole provider, and there may be a need to identify additional providers in the future. We do not have any control over the availability of raw materials. If we or our manufacturers are unable to purchase these raw materials on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the development and commercialization of our product candidates or any future product candidates, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of any approved products.

Even following our establishment of our own cGMP-compliant manufacturing capabilities, we intend to continue to rely on third party suppliers for these ingredients, which will expose us to risks including:

- reduced control for certain aspects of manufacturing activities;
- termination or nonrenewal of manufacturing and service agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider.

Certain of our raw material suppliers will be required to become cGMP-compliant and establish a drug master file for the applicable ingredient before we can submit our NDA for D-PLEX$_{100}$. If these suppliers do not successfully carry out their contractual duties or manufacture our raw materials in accordance with regulatory requirements, we will not be able to submit our NDA as planned or complete, or may be delayed in completing, the clinical trials required for approval of D-PLEX$_{100}$. In such instances, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay or increased expense prior to the approval of D-PLEX$_{100}$ and would thereby have a material adverse effect on our business, financial condition, results of operations and prospects.

Additionally, we have not yet entered into binding agreements with certain third-party manufacturers to produce the raw materials and products that we use to manufacture our product candidates. Although we intend to rely on third-party manufacturers for the raw materials and

products to support the manufacturing of our product candidates for commercialization, we have not yet entered into agreements with certain manufacturers. We may be unable to negotiate binding agreements with the manufacturers to support our commercialization activities at commercially reasonable terms.

Although we intend to establish our own cGMP compliant manufacturing facility, we expect to utilize a third party to conduct our product manufacturing, in whole or in part, at least through 2019. Therefore, we are subject to the risk that this third party may not perform satisfactorily.

Until such time as we establish our manufacturing facility that has been properly validated to comply with FDA cGMP requirements, we will not be able to independently manufacture material for our planned preclinical and clinical programs. We currently rely on a third party manufacturer for the production of D-PLEX$_{100}$ for our ongoing clinical trial materials. In the event that the establishment of our own manufacturing facility is delayed and if this third-party manufacturer does not successfully carry out its contractual duties, meet expected deadlines or manufacture D-PLEX$_{100}$ in accordance with regulatory requirements or if there are disagreements between us and this third-party manufacturer, we will not be able to complete, or may be delayed in completing, the clinical trials required for approval of D-PLEX$_{100}$. In such instances, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay or increased expense prior to the approval of D-PLEX$_{100}$ and would thereby have a material adverse effect on our business, financial condition, results of operations and prospects.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and our contract manufacturers must comply with cGMP requirements. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and contamination controls. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

We also rely on our third party manufacturer to conduct quality control reviews of and sterilization services for our product candidates. We cannot assure you that any stability, sterility or other issues relating to the manufacture of any of our product candidates will not occur in the future.

Additionally, our third-party manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the initiation or completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our

supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our product candidates and could have a material adverse effect on our business, prospects, financial condition and results of operations.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize D-PLEX$_{100}$. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of product manufacture.

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

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

Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets by third parties. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and product candidates.

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

As of December 31, 2017, our portfolio of owned patents and patent applications consists of seven families that protect our technology, including 55 issued patents and 49 pending patent applications in jurisdictions including the United States, the European Patent Organization, Canada, Australia, China, Japan and Israel. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

Further, the patent position of pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. This renders the patent prosecution process particularly expensive and time-consuming. There is no assurance that all potentially relevant prior art relating to our patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patent applications and any future patents may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

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

We may not have sufficient patent terms to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its priority date. Although various extensions may be available, including pursuant to the QIDP status we received for D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery, the life of a patent, and the protection it affords, is limited. Even if any of our patent applications mature into issued patents, if we do not have sufficient patent terms or regulatory exclusivity to protect our products, our business and results of operations will be adversely affected.

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

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of any patents that may issue from our patent applications, or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we or our licensors were the first to make the invention claimed in our owned and licensed patent or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, for United States patent applications filed prior to March 15, 2013, the first to conceive a claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the AIA, enacted on September 16, 2011, the United States has moved to a first to file system. The AIA also includes a number of significant changes that

affect the way patent applications are prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the United States Patent and Trademark Office, or the USPTO, must still implement various regulations, the courts have yet to address many of these provisions and the applicability of the AIA and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could have a material adverse effect on our business and financial condition.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks throughout the world.

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

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

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets and intellectual property could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets and intellectual property are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

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

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

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

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

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any materials formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidates unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable.

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

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

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license, or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, we may have to abandon development of that program and our business and financial condition could suffer.

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

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

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

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

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

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we

may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in or right to compensation with respect to our current patent and patent applications, future patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or claiming the right to compensation. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. To the extent that our employees have not effectively waived the right to compensation with respect to inventions that they helped create, they may be able to assert claims for compensation with respect to our future revenue. As a result, we may receive less revenue from future products if such claims are successful which in turn could impact our future profitability.

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

Our success is heavily dependent on intellectual property. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing these patents is costly, time consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain patents or to enforce patents that we might obtain in the future.

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly

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

Risks Related to Our Business Operations

Our future success depends in part on our ability to retain our senior management team and to attract, retain and motivate other qualified personnel.

We are highly dependent on the members of our senior management team. The loss of their services without a proper replacement may adversely impact the achievement of our objectives. Our employees may leave our employment at any time. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled personnel in our industry, which is likely to continue for the foreseeable future. As a result, competition for skilled personnel is intense, and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in preclinical or clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel, or the loss of the services of any members of our senior management team without proper replacement, may impede the progress of our research, development and commercialization objectives.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

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

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential candidates. These decisions may prove to have been wrong and may adversely affect our revenues.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular product candidates may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the pharmaceutical industry, in particular for our lead product candidate, our business, financial condition and results of operations could be materially adversely affected.

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

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of D-PLEX$_{100}$, the success of our business also depends upon our ability to identify, discover or license additional product candidates. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development for a number of reasons, including but not limited to the following:

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

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

Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our drug candidates could be delayed.

We will incur significant increased costs as a result of operating as a public company in the United States, and our management will be required to devote substantial time to new compliance initiatives.

As a public company whose ordinary shares are listed in the United States, we will be subject to an extensive regulatory regime, requiring us, among other things, to maintain various internal controls and facilities and to prepare and file periodic and current reports and statements, including reports on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002. Complying with these requirements will be costly and time consuming. We will need to retain additional employees to supplement our current finance staff, and we may not be able to do so in a timely manner, or at all. In the event that we are unable to demonstrate compliance with our obligations as a public company in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or The Nasdaq Global Market, and investors may lose confidence in our operating results and the price of our ordinary shares could decline.

Our independent registered public accounting firm was not engaged to perform an audit of our internal control over financial reporting, and as long as we remain an emerging growth company, as such term is defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we will be exempt from the requirement to have an independent registered public accounting firm perform such audit. Accordingly, no such opinion was expressed or will be expressed any during any such period. Once we cease to qualify as an emerging growth company our independent registered public accounting firm will be required to attest to our management's annual assessment of the effectiveness of our internal controls over financial reporting, which will entail additional costs and expenses.

Furthermore, we are only in the early stages of determining formally whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls. These controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

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

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

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits, and licenses;
- failure by us to obtain regulatory approvals for the use of our product candidates in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors, prince controls or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act its books and records provisions, or its anti-bribery provisions.

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

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

Our research, development and manufacturing activities and our third party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could

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

Our employees and independent contractors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees and independent contractors. Misconduct by these parties could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of information obtained in the course of clinical trials, including individually identifiable information, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Under 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.

We generally enter into non-competition agreements with our employees and certain key consultants. These agreements prohibit our employees and certain key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us.

For example, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such interests will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our ability to remain competitive may be diminished.

Risks Related to Commercialization of Our Product Candidates

We do not have experience producing our product candidates at commercial levels or establishing a cGMP manufacturing facility and may not obtain the necessary regulatory approvals or produce our product candidates at the quality, quantities, locations and timing needed to support commercialization.

We do not currently have the experience or ability to manufacture our product candidates at commercial levels. We may encounter technical or scientific issues related to manufacturing or development that we may be unable to resolve in a timely manner or with available funds. We also have not completed all of the characterization and validation activities necessary for commercialization and regulatory approvals. If we do not conduct all such necessary activities, our commercialization efforts will be delayed or halted.

We also may encounter problems hiring and retaining the experienced specialist scientific, quality control and manufacturing personnel needed to operate our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements. Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies, which could limit our access to additional attractive development programs. Problems in our manufacturing process or facilities also could restrict our ability to meet market demand for our product candidates.

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

Our projections of the number of people who have the potential to benefit from treatment with our product candidates are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics or market research, and may prove to be incorrect. Our target patient population may be lower than expected, may not be otherwise amenable to treatment with our product candidate or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. In addition, medical advances may reduce our target markets. For example, new processes and advances in oral antibiotic medications or new operative procedures may limit the need for localized delivery systems like our product candidates. Further, advances in treatments in the fields in which we are conducting research programs that reduce side effects and have better deliverability to target organs may limit the market for our future product candidates.

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

We have no experience selling and marketing our product candidates, and we currently have no marketing or sales organization. To successfully commercialize any product candidates that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If our product candidates receive regulatory approval, we intend to establish a sales and marketing organization independently or by utilizing experienced third parties with technical expertise and supporting distribution capabilities to commercialize our product candidates in major markets, all of which will be expensive, difficult and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact our ability to commercialize our product candidates.

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

Our efforts to educate the medical community, including physicians, hospital pharmacists and infectious disease specialists, and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. If any of our product candidates are approved but fail to achieve market acceptance among physicians, patients or third-party payors, we will not be able to generate significant revenues from such product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Delays in establishing and obtaining regulatory approval of our manufacturing process and facility or disruptions in our manufacturing process may delay or disrupt our product development and commercialization efforts.

We intend to establish our own cGMP compliant manufacturing facility. Building our own manufacturing facility will require additional investment, will be time-consuming and may be subject to delays, including because of shortage of labor or compliance with regulatory requirements. In addition, building a manufacturing facility may cost more than we currently anticipate. Delays or problems in the build out of our manufacturing facility may adversely impact our ability to provide supply for the development and commercialization of D-PLEX$_{100}$ as well as our financial condition.

Before we can begin to commercially manufacture D-PLEX$_{100}$ or any product candidate, whether in a third-party facility or in our own facility, once established, we must obtain regulatory approval from FDA for our manufacturing process and facility. A manufacturing authorization must also be obtained from the appropriate regulatory authorities in the European Union, Israel and

worldwide. In addition, we must pass a pre-approval inspection of our manufacturing facility by the FDA before D-PLEX$_{100}$ or any product candidate can obtain marketing approval. In order to obtain approval, we will need to ensure that all of our processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. For example, a recent cGMP audit by the Israeli Ministry of Health, or MOH, of the manufacturing process in the facility of our contract manufacturer for D-PLEX$_{100}$ resulted in certain critical observations, which we have been working with our contract manufacturer to address. There can be no guarantee, however, that future inspections by regulatory authorities of our manufacturing facilities or those of our contract manufacturers will result in MOH's agreement that these critical observations have been resolved or that similar inspectional observations will not be identified. If we do not demonstrate to the satisfaction of the applicable regulator that our manufacturing facilities, or those of our contract manufacturers, are in compliance with applicable requirements, we may be materially delayed in the development of our product candidates, which would materially harm our business. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any product candidate that we may develop.

If we receive marketing approval for our product candidates, sales will be limited unless the product achieves broad market acceptance by physicians, patients, third-party payors, hospital pharmacists, infectious disease specialists and others in the medical community.

The commercial success of our product candidates will depend upon the acceptance of the product by the medical community, including physicians, patients, healthcare payors, hospital pharmacists and infectious disease specialists. The degree of market acceptance of any approved product will depend on a number of factors, including:

- the demonstration of clinical safety and efficacy of our product candidates in clinical trials;
- the efficacy, potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment relative to alternative treatments;
- the prevalence and severity of any adverse side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- distribution and use restrictions imposed by the FDA or agreed to by us as part of a mandatory or voluntary risk management plan;
- our ability to obtain third-party coverage and adequate reimbursement;
- the willingness of patients to pay for drugs out of pocket in the absence of third-party coverage;
- the demonstration of the effectiveness of our product candidates in reducing the cost of treatment;
- the strength of marketing and distribution support;

- the timing of market introduction of competitive products;
- the availability of products and their ability to meet market demand; and
- publicity concerning our product candidates or competing products and treatments.

If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, patients, healthcare payors, hospital pharmacists and infectious disease specialists, we may not generate sufficient revenue from the product, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

It may be difficult for us to profitably sell our product candidates if coverage and reimbursement for these products is limited by government authorities and/or third-party payor policies.

In addition to any healthcare reform measures which may affect reimbursement, market acceptance and sales of our product candidates, if approved, will depend on, in part, the extent to which the procedures utilizing our product candidates, performed by health care providers, will be covered by third party payors, such as government health care programs, commercial insurance and managed care organizations. Our product candidates will be purchased or provided by health care providers for utilization in certain surgical procedures. In the event health care providers and patients accept our product candidates as medically useful, cost effective and safe, there is uncertainty regarding whether our product candidates will be directly reimbursed, reimbursed through a bundled payment or if the product candidates will be included in another type of value-based reimbursement program. Third party payors determine the extent to which new products will be covered as a benefit under their plans and the level of reimbursement for any covered product or procedure which may utilize a covered product. It is difficult to predict at this time what third party payors will decide with respect to the coverage and reimbursement for our product candidates.

A primary trend in the U.S. healthcare industry and elsewhere has been cost containment, including price controls, restrictions on coverage and reimbursement and requirements for substitution of less expensive products and procedures. Third party payors decide which products and procedures they will pay for and establish reimbursement and co-payment levels. Government and other third-party payors are increasingly challenging the prices charged for health care products and procedures, examining the cost effectiveness of procedures, and the products used in such procedures, in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement. We cannot be sure that coverage will be available for our product candidates, if approved, or, if coverage is available, the level of direct or indirect reimbursement.

We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product is:

- a covered benefit or part of a covered benefit under its health plan;

- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement are typically made by The Centers for Medicare and Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent products, and the procedures that utilize such products, will be covered and reimbursed under Medicare. Private payors may follow CMS, but have their own methods and approval processes for determining reimbursement for new products, and the procedures that utilize such products. It is difficult to predict what CMS as well as other payors will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. Further, no uniform policy requirement for coverage and reimbursement exists among third-party payors in the United States. Similarly, health care providers enter into participation agreements with third-party payors wherein reimbursement rates are negotiated. Therefore, coverage and reimbursement can differ significantly from payor to payor and health care provider to health care provider. As a result, we cannot be sure that coverage or adequate reimbursement will be available for our product candidates, if approved. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only to limited levels, we may not be able to commercialize our product candidates, or achieve profitably at all, even if approved.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material effect on our business, financial condition, results of operations or prospects.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. We do not currently have product liability insurance and do not anticipate obtaining product liability insurance until such time as we have received FDA or other comparable foreign authority approval for a product and there is a product that is being provided to patients outside of clinical trials. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material adverse effect on our business.

Risks Related to this Offering and Ownership of Our Ordinary Shares

Our executive officers, directors and principal shareholders will maintain the ability to exert significant control over matters submitted to our shareholders for approval.

Assuming the sale by us of 3,333,333 ordinary shares in this offering, our executive officers, directors and principal shareholders who owned more than 5% of our outstanding ordinary shares before this offering will, in the aggregate, beneficially own shares representing approximately 51.3% of our capital stock. Assuming an initial public offering price of $22.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, if certain of our existing shareholders purchase all the shares they have indicated an interest in purchasing in this offering, the number of our executive officers, directors and principal shareholders who owned more than 5% of our outstanding ordinary shares before this offering will, in the aggregate, beneficially own shares representing approximately 42.6% of our capital stock. As a result, if these shareholders were to act together, they would be able to control all matters submitted to our shareholders for approval, as well as our management and affairs. For example, these persons, if they act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in management of our company that our public shareholders disagree with.

If you purchase our ordinary shares in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The initial public offering price of our ordinary shares will be substantially higher than the net tangible book value per share of our ordinary shares. Therefore, if you purchase ordinary shares in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent outstanding options and warrants are exercised, you will incur further dilution. Based on an assumed initial public offering price of $22.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of $16.70 per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering at the assumed initial public offering price. In addition, purchasers of ordinary shares in this offering will have contributed approximately 54% of the aggregate price paid by all purchasers of our stock but will own only approximately 25% of our ordinary shares outstanding after this offering. See ‘‘Dilution.’’

An active trading market for our ordinary shares may not develop.

Prior to this offering, there has been no public market for our ordinary shares. The initial public offering price for our ordinary shares will be determined through negotiations with the underwriters. Although we have applied to have our ordinary shares listed on The Nasdaq Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our ordinary shares does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares, or at all. In addition, because certain of our existing shareholders have indicated an interest in purchasing up to an aggregate of approximately $19.5 million in ordinary shares in this offering at the initial public offering price per share, the overall trading market for our shares may not be as active as it otherwise would have been had these shares been purchased by other investors.

The market price of our ordinary shares may be highly volatile, which could result in substantial losses for purchasers of our ordinary shares in this offering.

The trading price of our ordinary shares is likely to be volatile. The stock market in general, and the market for pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your ordinary shares at or above the initial public offering price. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our ordinary shares:

- inability to obtain the approvals necessary to commence further clinical trials;
- unsatisfactory results of clinical trials;
- announcements of regulatory approvals or the failure to obtain them, or specific label indications or patient populations for their use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations or new products by us or our competitors;
- 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 or regulations applicable to any candidate product in any of our platforms;
- any adverse changes to our relationship with manufacturers or suppliers, especially manufacturers of candidate products;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability or our failure to meet expectations;
- our commencement of, or involvement in, litigation;
- any major changes in our Board of Directors or management; and
- legislation in the United States or any other territory relating to the sale or pricing of pharmaceuticals.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our ordinary shares could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

Sales of a substantial number of shares of our ordinary shares in the public market by our existing shareholders could cause our share price to fall.

Sales of a substantial number of shares of our ordinary shares in the public market, or the perception that these sales might occur, could depress the market price of our ordinary shares and

could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our ordinary shares. Substantially all of the shares owned by our existing shareholders and option and warrant holders are subject to lock-up agreements with the underwriters of this offering that restrict the shareholders' ability to transfer our ordinary shares for at least six months from the date of this prospectus. Substantially all of our outstanding shares will become eligible for unrestricted sale upon expiration of the lockup period, as described in the sections of this prospectus entitled ''Shares Eligible for Future Sale'' and ''Underwriting.'' In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of shares by these shareholders could have a material adverse effect on the trading price of our ordinary shares. Moreover, after this offering, holders of an aggregate of approximately 12,076,950 ordinary shares will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. We intend to register all ordinary shares that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the ''Underwriting'' section of this prospectus. Certain of our existing shareholders have indicated an interest in purchasing up to an aggregate of $19.5 million in ordinary shares in this offering at the initial public offering price per share. Any such shares purchased by these shareholders who are considered to be our affiliates could not be resold in the public market immediately following this offering as a result of restrictions under securities laws, but would be able to be sold following the expiration of these restrictions as described in the ''Shares Eligible for Future Sale'' section of this prospectus. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these shareholders, or any of these shareholders may determine to purchase more, less or no shares in this offering.

Our management will have broad discretion in the use of the net proceeds from this offering and may allocate the net proceeds from this offering in ways that you and other shareholders may not approve.

Our management will have broad discretion in the use of the net proceeds, including for any of the purposes described in the section entitled ''Use of Proceeds,'' and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure of our management to use these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities and depositary institutions. These investments may not yield a favorable return to our shareholders.

There is a substantial risk that we are or will become classified as a passive foreign investment company. If we are or become classified as a passive foreign investment company, our U.S. shareholders may suffer adverse tax consequences as a result.

Generally, for any taxable year, if at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income (including amounts derived by reason of the temporary investment of funds raised in

offerings of our shares) and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and gains from the sales of our shares.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets (which, assuming we are not a ''controlled foreign corporation,'' or a CFC, under Section 957(a) of the Internal Revenue Code of 1986, as amended, or the Code, for the year being tested, may be determined based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our common shares, which may be volatile). Our status may also depend, in part, on how quickly we utilize the cash proceeds from this offering in our business. Based upon the expected value of our assets, including any goodwill, and the expected nature and composition of our income and assets, we may be classified as a PFIC for the taxable year ending December 31, 2018 and in future taxable years. In particular, so long as we do not generate revenue from operations for any taxable year and do not receive any research and development grants, or even if we receive a research and development grant, if such grant does not constitute gross income for U.S. federal income tax purposes, we likely will be classified as a PFIC for such taxable year. Because the determination of whether we are a PFIC for any taxable year is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC in any taxable year.

The tax consequences that would apply if we are classified as a PFIC would also be different from those described above if a U.S. shareholder were able to make a valid qualified electing fund, or QEF, election. At this time, we do not expect to provide U.S. shareholders with the information necessary for a U.S. shareholder to make a QEF election. Prospective investors should assume that a QEF election will not be available.

If a United States person is treated as owning at least 10% of our shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a United States person is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our shares, such person may be treated as a ''United States shareholder'' with respect to each ''controlled foreign corporation'' in our group (if any). If our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations (regardless of whether we are or are not treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of ''Subpart F income'', ''global intangible low-taxed income'' and investments in U.S. property by controlled foreign corporations, whether or not we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. A failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries are treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations or furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting

and tax paying obligations. A United States investor should consult their own advisors regarding the potential application of these rules to its investment in the shares.

We have never paid cash dividends on our share capital, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid cash dividends on our ordinary shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, of our ordinary shares will be investors' sole source of gain for the foreseeable future. In addition, Israeli law limits our ability to declare and pay dividends, and may subject our dividends to Israeli withholding taxes.

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 decline.

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 cause our share price or trading volume to decline.

As a foreign private issuer, we are permitted, and intend, to follow certain home country corporate governance practices instead of otherwise applicable Nasdaq requirements, and we will not be subject to certain U.S. securities laws including, but not limited to, U.S. proxy rules and the filing of certain Exchange Act reports.

As a foreign private issuer, we will be permitted, and intend, to follow certain home country corporate governance practices instead of those otherwise required by the Nasdaq Stock Market for domestic U.S. issuers. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on The Nasdaq Global Market may provide less protection to you than what is accorded to investors under the listing rules of Nasdaq applicable to domestic U.S. issuers. See the section titled ''Management — Corporate Governance Practices.''

As a foreign private issuer, we will be exempt from the rules and regulations under the Securities Exchange Act of 1934, or the Exchange Act, related to the furnishing and content of proxy statements, including the applicable compensation disclosure requirements. Nevertheless, pursuant to regulations promulgated under the Israeli Companies Law, 5759-1999, or the Israeli Companies Law, we are required to disclose the annual compensation of our five most highly compensated office holders on an individual basis. Such disclosure will not be as extensive as that required of a U.S. domestic issuer. Our officers, directors and principal shareholders will also be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act and we will be exempt from filing quarterly reports with the SEC under the Exchange Act. Moreover, we will not be required to comply with

Regulation FD, which restricts the selective disclosure of material information, although we intend to voluntarily adopt a corporate disclosure policy substantially similar to Regulation FD. These exemptions and leniencies will reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U.S. domestic issuer.

We would lose our foreign private issuer status if a majority of our shares are owned by U.S. residents and a majority of our directors or executive officers are U.S. citizens or residents or we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. We may also be required to modify certain of our policies to comply with accepted governance practices associated with U.S. domestic issuers. Such conversion and modifications will involve additional costs. In addition, we would lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers.

We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and we may take advantage of certain exemptions from various requirements that are applicable to other public companies that are not emerging growth companies.

For as long as we remain an emerging growth company we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not ''emerging growth companies.'' These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited condensed consolidated interim financial statements, with correspondingly reduced ''Management's discussion and analysis of financial condition and results of operations'' disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We will remain an emerging growth company until the earliest of: (i) the last day of our fiscal year during which we have total annual gross revenues of at least $1.07 billion; (ii) the last day of our fiscal year following the fifth anniversary of the closing of this offering; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (iv) the date on which we are deemed to be a ''large accelerated filer'' under the Exchange Act. We have opted out of the extended transition period made available to emerging growth companies to comply with newly adopted public company accounting requirements.

When we are no longer deemed to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above. We cannot predict if investors will find our ordinary shares less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

Risks Related to Israeli Law and Our Operations in Israel

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

Our executive offices are located in Petach Tikva, Israel. In addition, the majority of our key employees, officers and directors are residents of Israel. If these or any future facilities in Israel were to be damaged, destroyed or otherwise unable to operate, whether due to war, acts of hostility, earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if performance of our research and development is disrupted for any other reason, such an event could delay our clinical trials or, if our product candidates are approved and we choose to manufacture all or any part of them internally, jeopardize our ability to manufacture our products as promptly as our prospective customers will likely expect, or possibly at all. If we experience delays in achieving our development objectives, or if we are unable to manufacture an approved product within a timeframe that meets our prospective customers' expectations, our business, prospects, financial results and reputation could be harmed.

Political, economic and military conditions in Israel may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries, Hamas (an Islamist militia and political group that has historically controlled the Gaza Strip) and Hezbollah (an Islamist militia and political group based in Lebanon). In addition, several countries, principally in the Middle East, restrict doing business with Israel, and additional countries may impose restrictions on doing business with Israel and Israeli companies whether as a result of hostilities in the region or otherwise. Any hostilities involving Israel, terrorist activities, political instability or violence in the region or the interruption or curtailment of trade or transport between Israel and its trading partners could adversely affect our operations and results of operations and the market price of our ordinary shares.

Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government is currently committed to covering 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, if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business, financial condition and results of operations.

Further, our operations could be disrupted by the obligations of our employees to perform military service. As of December 31, 2017, we had 55 employees based in Israel. Of these employees, some may be military reservists, and may be called upon to perform military reserve duty of up to 36 days per year (and in some cases more) until they reach the age of 40 (and in some cases, up to the age of 45 or older). Additionally, they may be called to active duty at any time under emergency circumstances. In response to increased tension and hostilities in the region, there have been, at times, call-ups of military reservists, and it is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of these employees due to military service. Such disruption could harm our business and operating results.

Our operations are subject to currency and interest rate fluctuations.

Although our functional currency is the U.S. dollar, and our financial records are maintained in U.S. dollars, we also incur expenses in Euros and New Israeli Shekels. In the future, we expect that a substantial portion of our revenues will be generated in U.S. dollars, Euros and other foreign currencies, although we currently incur a significant portion of our expenses in currencies other than U.S. dollars, mainly New Israeli Shekels. As a result, we are affected by foreign currency exchange fluctuations through both translation risk and transaction risk, and our financial results may be affected by fluctuations in the exchange rates of currencies in the countries in which our prospective product candidates may be sold. We do not currently hedge our foreign currency exchange rate risk.

We received Israeli government grants for certain of our research and development activities, the terms of which may require us to pay royalties and to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. If we fail to satisfy these conditions, we may be required to pay penalties and refund grants previously received.

Our research and development efforts have been financed in part through royalty-bearing and non-royalty-bearing grants in an aggregate amount of approximately $5.0 million that we received from the IIA as of December 31, 2017. The current IIA-approved research and development grants end on December 31, 2017. With respect to the royalty-bearing grants we are committed to pay royalties at a rate of 3.0% on sales proceeds from our products that were developed under IIA programs up to the total amount of grants received, linked to the U.S. dollar and bearing interest at an annual rate of LIBOR applicable to U.S. dollar deposits. We are further required to comply with the requirements of the Israeli Encouragement of Industrial Research, Development and Technological Innovation Law, 5744-1984, as amended, and related regulations, or the Research Law, with respect to those past grants. When a company develops know-how, technology or products using IIA grants, the terms of these grants and the Research Law restrict the transfer or license of such know-how, and the transfer of manufacturing or manufacturing rights of such products, technologies or know-how outside of Israel, without the prior approval of the IIA. Therefore, the discretionary approval of an IIA committee would be required for any transfer or license to third parties inside or outside of Israel of know how or for the transfer outside of Israel of manufacturing or manufacturing rights related to those aspects of such technologies. We may not receive those approvals. Furthermore, the IIA may impose certain conditions on any arrangement under which it permits us to transfer technology or development.

The transfer or license of IIA-supported technology or know-how outside of Israel may involve the payment of significant amounts, depending upon the value of the transferred or licensed technology or know-how, our research and development expenses, the amount of IIA support, the time of completion of the IIA-supported research project and other factors. These restrictions and requirements for payment may impair our ability to sell, license or otherwise transfer our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of Israel of technology or know-how developed with IIA funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the IIA.

Provisions of Israeli law and our amended and restated articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of, us, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date on which a merger proposal is filed by each merging company with the Israel Registrar of Companies and at least 30 days have passed from the date on which the shareholders of both merging companies have approved the merger. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, a tender offer for all of a company's issued and outstanding shares can only be completed if the acquirer receives positive responses from the holders of at least 95% of the issued share capital. Completion of the tender offer also requires approval of a majority of the offerees that do not have a personal interest in the tender offer, unless, following consummation of the tender offer, the acquirer would hold at least 98% of the Company's outstanding shares. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, claim that the consideration for the acquisition of the shares does not reflect their fair market value, and petition an Israeli court to alter the consideration for the acquisition accordingly, unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek such appraisal rights, and the acquirer or the company published all required information with respect to the tender offer prior to the tender offer's response date.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred. These provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders.

It may be difficult to enforce a judgment of a U.S. court against us and our executive officers and directors and the Israeli experts named in this prospectus in Israel or the United States, to assert U.S. securities laws claims in Israel or to serve process on our executive officers and directors and these experts.

We were incorporated in Israel. Substantially all of our executive officers and directors reside outside of the United States, and all of our assets and most of the assets of these persons are located outside of the United States. Therefore, a judgment obtained against us, or any of these persons, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It also may be difficult for you to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Additionally, it may be difficult for an investor, or any other person or entity, to initiate an action with respect to U.S. securities laws in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities

laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not 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 proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a U.S. or foreign court. See ''Enforceability of Civil Liabilities'' for additional information on your ability to enforce a civil claim against us and our executive officers or directors named in this prospectus.

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

The rights and responsibilities of the holders of our ordinary shares are governed by our amended and restated articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in U.S. companies. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the Company and other shareholders, and to refrain from abusing its power in the Company, including, among other things, in voting at a general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval, as well as a general duty to refrain from discriminating against other shareholders. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a vote at a meeting of the shareholders or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. See ''Management — Shareholder Duties'' for additional information. There is limited case law available to assist us in understanding the nature of these duties or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. companies.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as ''aim,'' ''anticipate,'' ''assume,'' ''believe,'' ''contemplate,'' ''continue,'' ''could,'' ''due,'' ''estimate,'' ''expect,'' ''goal,'' ''intend,'' ''may,'' ''objective,'' ''plan,'' ''predict,'' ''potential,'' ''positioned,'' ''seek,'' ''should,'' ''target,'' ''will,'' ''would,'' and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the timing and conduct of our clinical trials of D-PLEX$_{100}$ and our other product candidates, including statements regarding the timing, progress and results of current and future preclinical studies and clinical trials, and our research and development programs;
- the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of D-PLEX$_{100}$ and our other product candidates;
- our plans regarding utilization of regulatory pathways that would allow for accelerated marketing approval in the United States, the European Union and other jurisdictions;
- our expectations regarding timing for application for and receipt of regulatory approval for any of our product candidates;
- our ongoing and planned discovery and development of product candidates;
- our expectations regarding future growth, including our ability to develop, and obtain regulatory approval for, new product candidates;
- our expectations regarding when certain patents may be issued and the protection and enforcement of our intellectual property rights;
- our plans to develop and commercialize our product candidates;
- our estimates regarding the market opportunity for our product candidates;
- our ability to maintain relationships with certain third parties;
- our estimates regarding anticipated capital requirements and our needs for additional financing;
- our planned level of capital expenditures;
- our expectations regarding licensing, acquisitions and strategic partnering;
- our expectations regarding the maintenance of our foreign private issuer status;
- the impact of government laws and regulations; and
- our expectations regarding the use of proceeds from this offering.

Forward-looking statements are based on our management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our management's beliefs and assumptions, and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. Important factors that may cause actual results to differ materially from current expectations include, among other things, those listed under ''Risk Factors''

and elsewhere in this prospectus. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements.

The forward-looking statements included in this prospectus speak only as of the date of this prospectus. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that future results, levels of activity, performance and events and circumstances reflected in the forward-looking statements will be achieved or will occur. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See ''Where You Can Find More Information.''

USE OF PROCEEDS

We estimate that the net proceeds from the sale of ordinary shares in this offering will be approximately $67.8 million, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, based on an assumed initial public offering price of $22.50 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus. If the underwriters exercise their option to purchase up to an 500,000 additional ordinary shares in full, we estimate that the net proceeds to us from this offering will be approximately $78.2 million, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed initial public offering price of $22.50 per ordinary share would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by $3.1 million, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of ordinary shares we are offering. An increase (decrease) of 1.0 million in the number of ordinary shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by $20.9 million, assuming the assumed initial public offering price stays the same.

We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term deposits, as follows:

- approximately $55.0 million to $60.0 million to fund the clinical development of D-PLEX$_{100}$, primarily for our planned Phase 3 clinical trial for the prevention of sternal SSIs after cardiac surgery, as well as our planned Phase 2 clinical trial for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery, and, assuming a successful outcome in our Phase 2 clinical trial, our planned Phase 3 clinical trial in the same indication, and clinical supporting activities;
- approximately $5.0 million to $10.0 million to fund our manufacturing facility construction, including the construction of our pilot manufacturing facility and the initiation of preparations for our larger commercial-scale cGMP-compliant manufacturing facility; and
- the balance to fund other research and development activities and for other general corporate purposes, including general and administrative expenses and working capital.

We may also use a portion of the net proceeds from this offering to acquire or invest in complementary products, technologies or businesses, although we have no present agreements or commitments to do so.

Although we currently anticipate that we will use the net proceeds from this offering as described above, there may be circumstances where a reallocation of funds is necessary. Due to the uncertainties inherent in the clinical development and regulatory approval process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for any of the above purposes on a stand-alone basis. Amounts and timing of our actual expenditures will depend upon a number of factors, including our sales, marketing and commercialization efforts, regulatory approval and demand for our product candidates, operating costs and other factors described under ‘‘Risk Factors’’ in this prospectus. Accordingly, our management will have flexibility in applying the net proceeds from this offering. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

Based on our current plans, we believe that our existing cash resources will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least the next

12 months. We anticipate that these funds, together with the net proceeds of this offering, will be sufficient for the initiation and near-completion of our planned Phase 3 clinical trial of D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery, the completion of our planned Phase 2 clinical trial of D-PLEX$_{100}$ for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery, and, assuming a successful outcome in our Phase 2 clinical trial, the initiation of our planned Phase 3 clinical trial of D-PLEX$_{100}$ in the same indication. We anticipate that we will need to raise additional capital in order to complete our Phase 3 clinical trials and any potential future trials that may be required by regulatory authorities. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

Pending our application of the net proceeds from this offering, we plan to invest such proceeds in in short-term, investment-grade, interest-bearing securities and depositary institutions.

DIVIDEND POLICY

We have never declared or paid any cash dividends to our shareholders of our ordinary shares, and we do not anticipate or intend to pay cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors in compliance with applicable legal requirements and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, our strategic goals and plans to expand our business, applicable law and other factors that our board of directors may deem relevant.

The Israeli Companies Law imposes further restrictions on our ability to declare and pay dividends. See ''Description of Share Capital — Dividend and Liquidation Rights'' for additional information.

Payment of dividends may be subject to Israeli withholding taxes. See ''Taxation — Material Israeli Tax Considerations'' for additional information.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term deposits and capitalization as of December 31, 2017, on:

- an actual basis;
- a pro forma basis to give effect to (i) the automatic conversion of all outstanding preferred shares into 9,138,485 ordinary shares upon the closing of this offering and (ii) the exercise of warrants to purchase 56,250 Series A preferred shares, and the automatic conversion thereof into 56,250 ordinary shares, which will occur upon the closing of this offering; and
- a pro forma as adjusted basis to give further effect to the sale of 3,333,333 ordinary shares in this offering at the assumed initial public offering price of $22.50 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted data included in the table below are also unaudited. You should read this information together with our condensed consolidated financial statements appearing elsewhere in this prospectus and the information set forth under the headings ''Selected Financial Data,'' ''Use of Proceeds'' and ''Management's Discussion and Analysis of Financial Condition and Results of Operations.''

	As of December 31, 2017		
	Actual	Pro Forma	Pro Forma As Adjusted
		(unaudited) (in thousands)	
Cash, cash equivalents and short-term deposits[1]	$ 17,938	$ 17,951	$ 86,117
Convertible preferred shares warrant liability	47,399	—	—
Preferred A, A-1, B, B-1, C-1, C-2, D-1, D-2, D-3 and E shares of NIS 0.80 par value: 12,741,017 shares authorized, actual; no shares authorized, pro forma and pro forma as adjusted; 9,138,485 shares issued and outstanding, actual; no shares issued and outstanding, pro forma and pro forma as adjusted	59,983	—	—
Shareholders' (deficiency) equity:			
Ordinary shares of NIS 0.80 par value: 15,687,500 shares authorized, actual; 28,428,517 shares authorized pro forma; 43,750,000 shares authorized pro forma as adjusted; 584,151 issued and outstanding, actual; 9,778,886 shares issued and outstanding, pro forma; 13,112,219 shares issued and outstanding, pro forma as adjusted	129	2,251	1,050
Additional paid-in capital	3,540	107,725	177,763
Accumulated deficit	(92,315)	(92,315)	(92,315)
Total shareholders' (deficiency) equity[1]	(88,646)	17,661	86,498
Total capitalization[1]	$ 18,736	$ 17,661	$ 86,498

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $22.50 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, respectively, the amount of cash, cash equivalents and short-term deposits, total shareholders' (deficiency) equity and total capitalization by $3.1 million, assuming the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and

estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares we are offering. An increase or decrease of 1.0 million in the number of ordinary shares we are offering would increase or decrease, respectively, the amount of cash, cash equivalents and short-term deposits, total shareholders' (deficiency) equity and total capitalization by $20.9 million, assuming the assumed initial public offering price per ordinary share, as set forth on the cover page of this prospectus, remains the same. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

The number of ordinary shares issued and outstanding, actual, pro forma and pro forma as adjusted shown in the foregoing table and calculations excludes:

- 2,219,443 ordinary shares reserved for issuance under our Amended and Restated 2012 Share Option Plan, including 2,019,001 ordinary shares reserved for issuance upon the exercise of outstanding options at a weighted average exercise price of $4.84 per share; and
- 2,882,215 ordinary shares issuable upon the exercise of outstanding warrants to purchase Series D-2 preferred shares, at a weighted average exercise price of $8.83 per share, which warrants will automatically convert into warrants to purchase ordinary shares upon the closing of this offering and are expected to remain outstanding at the consummation of this offering.

DILUTION

If you invest in our ordinary shares in this offering, your interest will be immediately diluted to the extent of the difference between the initial public offering price per ordinary share in this offering and the pro forma as adjusted net tangible book value per ordinary share after this offering. Dilution results from the fact that the initial public offering price per ordinary share is substantially in excess of the net tangible book value per ordinary share. As of December 31, 2017, we had a historical net tangible book value of $18.7 million, or $32.08 per ordinary share. Our net tangible book value per share represents total tangible assets less total liabilities, divided by the number of ordinary shares outstanding on December 31, 2017.

Our pro forma net tangible book value as of December 31, 2017 was $17.7 million, or $1.81 per ordinary share. Pro forma net tangible book value per share represents total tangible assets less total liabilities, divided by the number of ordinary shares outstanding as of December 31, 2017, after giving effect to the automatic conversion of all outstanding preferred shares into ordinary shares and the exercise of warrants to purchase 56,250 Series A preferred shares, and the automatic conversion thereof into 56,250 ordinary shares, which will occur upon the closing of this offering.

After giving effect to the sale of ordinary shares in this offering at an assumed initial public offering price of $22.50 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses, and after taking into account the automatic conversion of all of our outstanding preferred shares into ordinary shares and the exercise of warrants to purchase 56,250 Series A preferred shares, and the automatic conversion thereof into 56,250 ordinary shares, which will occur upon the closing of this offering, our pro forma as adjusted net tangible book value at December 31, 2017 would have been $5.80 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $3.99 per share to existing shareholders and immediate dilution of $16.70 per ordinary share to new investors. The following table illustrates this dilution per ordinary share:

Assumed initial public offering price per ordinary share		$22.50
Historical net tangible book value per ordinary share as of December 31, 2017	$ 32.08	
Decrease in net tangible book value per ordinary share due to conversion of preferred shares and exercise of warrants to purchase shares of Series A preferred shares	$(30.27)	
Pro forma net tangible book value per ordinary share as of December 31, 2017	$ 1.81	
Increase in pro forma net tangible book value per ordinary share attributable to new investors	$ 3.99	
Pro forma as adjusted net tangible book value per ordinary share after this offering		$ 5.80
Dilution per ordinary share to new investors participating in this offering		$16.70

A $1.00 increase (decrease) in the assumed initial public offering price of $22.50 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value as of December 31, 2017 after this offering by approximately $0.24 per ordinary share, and would increase (decrease) dilution to investors in this offering by $0.24 per ordinary share, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares we are

offering. An increase (decrease) of 1.0 million in the number of ordinary shares we are offering would increase (decrease) our pro forma as adjusted net tangible book value as of December 31, 2017 after this offering by approximately $1.07 per ordinary share, and would decrease (increase) dilution to investors in this offering by approximately $1.07 per ordinary share, assuming the assumed initial public offering price per ordinary share remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise in full their option to purchase additional ordinary shares, the pro forma as adjusted net tangible book value will increase to $6.35 per ordinary share, representing an immediate increase in pro forma as adjusted net tangible book value to existing shareholders of $0.56 per ordinary share and an immediate dilution of $0.56 per ordinary share to new investors participating in this offering.

We may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our equity holders.

The following table shows, as of December 31, 2017, on a pro forma as adjusted basis, the number of ordinary shares purchased from us, the total consideration paid to us and the average price paid per share during the last five years by existing shareholders and by new investors purchasing ordinary shares in this offering at an assumed initial public offering price of $22.50 per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us:

(in thousands, except share and per share amounts and percentages)	Shares Subscribed for/ Purchased		Total Consideration		Average Price per Share
	Number	Percent	Amount	Percent	
Existing shareholders	7,818,165	70%	$ 61,526,000	45%	$ 7.87
Investors participating in this offering	3,333,333	30	75,000,000	55	22.50
Total	11,151,498	100%	$136,526,000	100%	

A $1.00 increase (decrease) in the assumed initial public offering price of $22.50 per ordinary share (the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) the total consideration paid by investors participating in this offering, total consideration paid by all shareholders and the average price per share paid by all shareholders by approximately $3.3 million, $3.3 million and $12.54, respectively, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Similarly, a 1.0 million share increase (decrease) in the number of ordinary shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) the total consideration paid by investors participating in this offering, total consideration paid by all shareholders and the average price per share paid by all shareholders by approximately $22.5 million, $22.5 million and $13.09, respectively, assuming the assumed initial public offering price of $22.50 per ordinary share (the midpoint of the price range set forth on the cover page of this prospectus) remains the same,

and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The tables and discussion above shown are based on 9,778,886 ordinary shares outstanding as of December 31, 2017, after giving effect to the automatic conversion of all outstanding preferred shares into ordinary shares and the exercise of warrants to purchase 56,250 Series A preferred shares, and the automatic conversion thereof into 56,250 ordinary shares, each of which will occur upon the closing of this offering, and excludes:

- 2,019,001 ordinary shares reserved for issuance upon the exercise of outstanding options as of December 31, 2017, at a weighted average exercise price of $4.84 per share;
- 898,473 ordinary shares reserved for issuance under our Amended and Restated 2012 Share Option Plan, as of the date of this prospectus, as well as any automatic increases in the number of ordinary shares reserved for issuance under the Amended and Restated 2012 Share Option Plan; and
- 2,882,215 ordinary shares issuable upon the exercise of outstanding warrants to purchase Series D-2 preferred shares as of December 31, 2017, at a weighted average exercise price of $8.83 per share, which warrants will automatically convert into warrants to purchase ordinary shares upon the closing of this offering and are expected to remain outstanding at the consummation of this offering.

Certain of our existing shareholders have indicated an interest in purchasing up to an aggregate of $19.5 million in ordinary shares in this offering at the initial public offering price per share. Based on an assumed initial public offering price of $22.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, these shareholders would purchase up to an aggregate of 866,667 of the 3,333,333 ordinary shares in this offering based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, these shareholders may determine to purchase more, less or no ordinary shares in this offering. It is also possible that these shareholders could indicate an interest in purchasing more ordinary shares. In addition, the underwriters could determine to sell fewer ordinary shares to any of these shareholders than the shareholders indicate an interest in purchasing or not to sell any ordinary shares to these shareholders. The foregoing discussion and tables do not reflect any potential purchases by these shareholders.

SELECTED FINANCIAL DATA

The following table summarizes our financial data. We have derived the following statements of operations data for the years ended December 31, 2016 and 2017 and the balance sheet data as of December 31, 2016 and 2017 from our audited consolidated financial statements included elsewhere in this prospectus, which have been prepared in accordance with U.S. GAAP. Our historical results are not necessarily indicative of the results that may be expected in the future, and our results for any interim period are not necessarily indicative of results that may be expected for any full year. The following selected financial data should be read in conjunction with ''Management's Discussion and Analysis of Financial Condition and Results of Operations'' and our consolidated financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2016	2017
	(in thousands, except share and per share amounts)	
Research and development, net	$ 7,708	$ 9,736
General and administrative	2,551	4,064
Operating loss	10,259	13,800
Financial expenses, net	1,133	40,688
Net loss	$ 11,392	$ 54,488
Deemed dividend	$ —	$ 1,255
Net loss attributable to ordinary shares	11,392	55,743
Basic and diluted net loss per ordinary share	$ (24.64)	$ (102.00)
Weighted average number of ordinary shares, basic and diluted	568,078	584,176

	As of December 31,	
	2016	2017
	(in thousands)	
Balance Sheet Data:		
Cash, cash equivalents and short-term deposits	$ 17,751	$ 17,938
Working capital[(1)]	16,556	15,366
Total assets	19,237	22,984
Convertible preferred shares	44,026	59,983
Convertible preferred shares warrant liability	6,616	47,399
Total shareholders' deficiency	(33,959)	(88,646)

(1) Working capital is defined as total current assets minus total current liabilities

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion in conjunction with our audited consolidated financial statements, including the related notes thereto, beginning on page F-1. In addition to historical information, this discussion contains forward-looking statements that involve risks and uncertainties. You should read the sections of this prospectus titled ''Risk Factors'' and ''Special Note Regarding Forward-Looking Statements'' for a discussion of the factors that could cause our actual results to differ materially from our expectations.

Overview

We are a clinical-stage pharmaceutical company focused on developing and commercializing novel, locally administered therapies using our transformational PLEX (Polymer-Lipid Encapsulation matriX) technology. Our product candidates are designed to address unmet medical needs by delivering active pharmaceutical ingredients, or APIs, locally at customizable, predetermined release rates and durations over extended periods ranging from days to several months. We believe that our PLEX technology represents a paradigm shift in the treatment of a wide variety of localized medical conditions, including infection, pain, inflammation and cancer. We are initially focused on the development of our lead product candidate, D-PLEX$_{100}$, which incorporates an antibiotic, for the prevention of SSIs in bone and soft tissue.

Since our inception in 2008, we have incurred significant operating losses. Our net losses of $11.4 million and $54.5 million for the years ended December 31, 2016 and 2017, respectively, and net losses attributable to ordinary shares were $11.4 million and $55.7 million for the years ended December 31, 2016 and 2017, respectively. As of December 31, 2017, we had an accumulated deficit of $92.3 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future, and our losses may fluctuate significantly from year to year. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- file an IND and a CTA and shortly thereafter initiate our Phase 3 clinical trial of D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery and our Phase 2 clinical trial of D-PLEX$_{100}$ in patients undergoing abdominal surgery for the prevention of SSIs and, assuming a successful outcome in our Phase 2 clinical trial, a Phase 3 clinical trial in the same indication;
- file an NDA seeking regulatory approval for D-PLEX$_{100}$ pursuant to the FDA's Section 505(b)(2) regulatory pathway in the United States and the hybrid application pathway in the European Union;
- continue to invest in the preclinical research and development of our future product candidates;
- build our pilot manufacturing facility and our larger-scale cGMP manufacturing facility;
- establish a commercial infrastructure to support the marketing, sale and distribution of D-PLEX$_{100}$ if it receives regulatory approval;
- hire additional research and development and general and administrative personnel to support our operations;
- maintain, expand and protect our intellectual property portfolio; and
- incur additional costs associated with operating as a public company following the completion of this offering.

We do not have any product candidates approved for sale and have not generated any revenue from product sales. To date, we have financed our operations primarily through private placements of equity securities and convertible debt, as well as grants from the IIA, and the

European Commission's Seventh Framework Programme for Research, or the FP7. From our inception through December 31, 2017, we have raised an aggregate of $63.7 million from private placements of equity securities and convertible debt. In February 2016, we received an aggregate of $21.9 million in gross proceeds from the sale of shares of our Series D-1 preferred shares and warrants to purchase Series D-2 shares. In August 2016, we received an aggregate of $5.3 million in gross proceeds from the sale of our Series D-3 preferred shares. In the third and fourth quarters of 2017, we received an aggregate of $15.0 million in gross proceeds from the sale of our Series E preferred shares, or the Series E Private Placement, $1.6 million of which we received in a deferred closing in November and December 2017. See ''—Results of Operations—Comparison of the Years ended December 31, 2016 and 2017—Net Loss Attributable to Ordinary Shares.''

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the next several years.

Research and Development Expenses, Net

Research and development expenses, net consist primarily of costs incurred in connection with our research and development activities. This includes conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for product candidates. Our research and development expenses primarily consist of:

- salaries and personnel-related costs, including benefits and share-based compensation expense, for our scientific personnel performing research and development activities;
- costs related to executing preclinical studies and clinical trials;
- costs related to acquiring, developing and manufacturing materials for our preclinical studies and clinical trials;
- costs of third party suppliers;
- fees paid to consultants and other third parties who support our product candidate development;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies;
- other costs incurred in seeking regulatory approval of our product candidates; and
- allocated facility-related costs and overhead.

Research and development expenses are expensed as incurred. We record accrued expenses for research and development activities conducted, on our behalf, by third-party service providers, which include the conduct of pre-clinical studies and clinical trials and contract manufacturing activities. We record these accrued expenses based upon research and development activities performed by such third-party service providers and reported to us, and we include these costs in accrued liabilities in the balance sheets and within research and development expense in the statement of operations.

We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or preclinical program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or preclinical programs.

From inception though December 31, 2017, we have incurred approximately $33.3 million in research and development expenses to advance the development of our product candidates and preclinical research and development programs. As of December 31, 2017, we have received

grants of $5.0 million in the aggregate from the IIA. Pursuant to the terms of the grants, we are required to pay royalties of 3.0% to the IIA on revenues from sales of products for which the research and development was funded, in whole or in part, by the IIA, up to a limit of 100% of the amount of the grant received, plus annual interest calculated at a rate based on 12-month LIBOR. In addition, we must abide by other restrictions associated with the receipt of such grants under the R&D Law that continue to apply following repayment to IIA. These restrictions may impair our ability to outsource manufacturing, engage in change of control transactions or otherwise transfer our knowledge outside of Israel and may require us to obtain IIA approval for certain actions and transactions and pay additional amounts to IIA. In addition, any change of control and any change of ownership of our ordinary shares that would make a non-Israel citizen or resident an ''interested party'' as defined in the R&D Law requires prior written notice from IIA. As of December 31, 2017, we have also received non-royalty bearing grants of $0.3 million in the aggregate from the IIA and $0.7 million in the aggregate from the FP7.

Substantially all of our research and development expenses for the years ended December 31, 2016 and 2017 were related to the development of the D-PLEX family.

We expect our research and development expenses will increase for the foreseeable future as we seek to advance our clinical-stage product candidates and preclinical research and development programs. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates. This is due to the numerous risks and uncertainties associated with developing such product candidates, including the uncertainty of:

- successful enrollment in and completion of clinical trials;
- establishing an appropriate safety profile;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- commercializing the product candidates, if and when approved, whether alone or in collaboration with others;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- continued acceptable safety profiles of products following approval; and
- retention of key research and development personnel.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and personnel-related expenses, including benefits and share-based compensation expense, for employees performing functions other than research and development. This includes personnel in executive, finance and administrative support functions. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expense, professional fees for auditing, tax and legal services and other consulting fees.

We expect our general and administrative expenses will increase in the future to support continued research and development activities. We also anticipate that we will incur increased

accounting, audit, legal, regulatory, compliance and director and officer insurance costs, as well as investor, public relations and compliance expenses, associated with operating as a public company. We also anticipate increased expenses if any of our product candidates receives regulatory approval and we determine to build a commercial infrastructure to support sales and marketing of our products.

Financial Income (Expense), Net

Financial income (expense), net consists of reevaluation of our preferred share warrant liability, as well as interest income on our cash, cash equivalents and short-term deposits and our foreign exchange gains and losses.

Results of Operations

Comparison of the Years Ended December 31, 2016 and 2017

The following table summarizes our results of operations for the years ended December 31, 2016 and 2017:

	Year Ended December 31,	
	2016	2017
	(in thousands)	
Research and development expenses, net	$ 7,708	$ 9,736
General and administrative expenses	2,551	4,064
Operating loss	10,259	13,800
Financial expenses, net	1,133	40,688
Net loss	$11,392	$54,488
Deemed dividend	—	1,255
Net loss attributable to ordinary shares	$11,392	$55,743

Research and Development Expenses, Net

Research and development expenses, net increased by $2.0 million during the year ended December 31, 2017 compared to the year ended December 31, 2016. The increase in research and development expenses resulted primarily from increases in expenses related to the research and clinical development of D-PLEX$_{100}$. More specifically, this amount included increases in third-party clinical and manufacturing research and development expenses and preclinical and clinical trial costs for our D-PLEX family product candidates, costs associated with the maintenance and prosecution of our intellectual property portfolio and salaries and personnel-related expenses, including benefits, and share-based compensation to research and development employees, driven by increased headcount across all research and development functions from 31 employees as of December 31, 2016 to 41 employees as of December 31, 2017. These increases were partially offset by decreases in third-party consultant costs and regulatory expenses. These increases were further offset by an increase in IIA grants.

General and Administrative Expenses

General and administrative expenses increased by $1.5 million during the year ended December 31, 2017 compared to the year ended December 31, 2016. The increase in general and administrative expenses resulted primarily from increases in salaries, personnel-related expenses, including benefits, and share-based compensation driven by increased headcount across all general and administrative functions from 12 employees as of December 31, 2016 to 14 employees

as of December 31, 2017, increases in legal and professional costs and facility and maintenance costs and compensation expenses of $387,000 with respect to an investment by an affiliate of a director in the deferred closing of the Series E Private Placement.

Financial Expenses, Net

Financial expenses, net increased by $39.6 million during the year ended December 31, 2017 compared to the year ended December 31, 2016. The increase in financial expenses, net relate primarily to the reevaluation of our preferred share warrant liability relating to the receipt of the results from our primary efficacy endpoint from our Phase 1b/2 clinical trial of D-PLEX$_{100}$, partially offset by increases related to financial income and exchange rate differences.

Net Loss Attributable to Ordinary Shares

Net loss attributable to ordinary shares increased by $44.3 million during the year ended December 31, 2017 compared to the year ended December 31, 2016. The increase in net loss attributable to ordinary shares includes a deemed dividend of $1.2 million related to shares issued in the deferred closing of the sale of our Series E preferred shares in November and December 2017. As the deferred closing occurred after we received the results of the primary efficacy endpoint from our Phase 1b/2 clinical trial of D-PLEX$_{100}$, we determined that the fair market value of the Series E preferred shares sold in the deferred closing was higher than at the initial closing.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue and have incurred net losses and negative cash flows from our operations. We have funded our operations primarily through the sale of equity securities and convertible debt. From our inception through December 31, 2017, we raised an aggregate of $63.7 million from private placements of equity securities and convertible debt. In the third and fourth quarters of 2017, we received an aggregate of $15.0 million in gross proceeds from the sale of our Series E preferred shares. As of December 31, 2017, we had $17.9 million in cash, cash equivalents and short-term deposits.

We currently have no ongoing material financing commitments, such as lines of credit or guarantees that are expected to affect our liquidity over the next five years, other than our lease obligations.

Cash Flows

The following table provides information regarding our cash flows for the periods indicated:

	Year Ended December 31,	
	2016	2017
	(in thousands)	
Net cash used in operating activities	$ (9,733)	$(12,312)
Net cash used in investing activities	(8,069)	(8,385)
Net cash provided by financing activities	26,344	14,383
Net increase (decrease) in cash and cash equivalents	$ 8,542	$ (6,314)

Operating Activities

Net cash used in operating activities related primarily to our net losses adjusted for non-cash charges and measurements and changes in components of working capital. Adjustments to net

loss for non-cash items mainly include depreciation, reevaluation of preferred share warrants and share-based compensation.

Net cash used in operating activities was $12.3 million for the year ended December 31, 2017, as compared to $9.7 million for the year ended December 31, 2016. The increase in net cash used in operating activities was attributable primarily to increased research and development costs, and associated general and administrative expenses, as we conducted research and development and regulatory work related to the D-PLEX family.

Investing Activities

Net cash used in investing activities related primarily to the acquisition of short-term deposits and the purchase of laboratory equipment, office equipment and furniture and leasehold improvements.

Net cash used in investing activities was $8.4 million for the year ended December 31, 2017, as compared to $8.1 million for the year ended December 31, 2016. The increase in net cash used in investing activities in 2017 primarily related to the acquisition of short-term deposits, the construction of our pilot manufacturing facility and for the purchase of equipment.

Financing Activities

Net cash provided by financing activities related primarily to funds raised by the issuance of convertible debt and preferred shares.

Net cash provided by financing activities was $14.4 million for the year ended December 31, 2017, related to the issuance of shares of our Series E preferred shares, as compared to $26.3 million for the year ended December 31, 2015, related to the issuance of shares of our Series D-1 and D-3 preferred shares.

Funding Requirements

To date, we have not generated any revenues from the commercial sale of our product candidates, and we do not expect to generate revenue for at least the next few years. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate large, late-stage clinical trials of, and seek marketing approval for, D-PLEX$_{100}$ and our future product candidates. In addition, if we obtain marketing approval for D-PLEX$_{100}$ or any of our future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of potential collaborators. Furthermore, following the completion of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect that our existing cash, cash equivalents and short-term deposits will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We anticipate that these funds, together with the net proceeds of this offering, will be sufficient for the initiation and near-completion of our planned Phase 3 clinical trial of D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery, the completion of our planned Phase 2 clinical trial of D-PLEX$_{100}$ for the prevention of SSIs in patients undergoing abdominal surgery, and, assuming a successful outcome in our Phase 2 clinical trial, the initiation of our Phase 3 clinical trial of D-PLEX$_{100}$ in the same indication. We anticipate that we will need to raise additional capital in order

to complete our Phase 3 clinical trials and any potential future trials that may be required by regulatory authorities. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our ongoing and planned nonclinical studies and clinical trials of D-PLEX$_{100}$;
- the number and development requirements of other future product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of D-PLEX$_{100}$ and our future product candidates;
- the costs and timing of establishing and validating manufacturing processes and facilities for development and commercialization of D-PLEX$_{100}$ and our future product candidates, if approved, including our pilot and larger-scale manufacturing facilities;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval, which may be affected by market conditions, including obtaining coverage and adequate reimbursement of our product candidates from third-party payors, including government programs and managed care organizations, and competition;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our commitments to settle contractual obligations at December 31, 2017:

	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years	Total
		(in thousands)			
Operating lease obligations[1]	$1,068	$3,103	$1,957	$1,965	$8,093

(1) Operating lease obligation consist of payments pursuant to lease agreements for our Israeli and U.S. facilities and motor vehicle leases.

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding. The table does not include obligations under agreements that we can cancel without a significant penalty.

We enter into contracts in the normal course of business for preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Off-Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts.

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with accepted accounting principles generally accepted in the United States. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates. Our most critical accounting policies are summarized below. See note 2 to our consolidated financial statements beginning on page F-1 of this prospectus for a description of our other significant accounting policies.

Share-Based Compensation

We account for share-based compensation granted to employees, non-employee directors and service providers in accordance with FASB ASC Topic 718, Compensation — Stock Compensation, or ASC 718, and FASB ASC Topic 505-50, Equity-Based Payments to Non-Employees, which requires companies to estimate the fair value of equity-based payment awards on the date of grant using the option-pricing model, or OPM. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in our statements of operations.

We recognize compensation costs net of a forfeiture rate only for those shares expected to vest using the straight line method over the requisite service period of the award, which is generally the option vesting term of three years. Upon adoption of ASU 2016-09, we elected to change our accounting policy to account for forfeitures as they occur.

Option Valuations

We selected the Black-Scholes-Merton model as the most appropriate fair value method for our option awards. The Black-Scholes-Merton model requires a number of assumptions, of which the most significant are the expected share price, volatility and the expected option term.

The fair value of ordinary shares underlying the options has historically been determined by management and the board of directors with the assistance of an independent financial and economic consultant. As there has been no public market for our ordinary shares, our board of directors has determined fair value of an ordinary share at the time of grant of the option by calculating the present value of expected future investment returns and considering a number of objective and subjective factors including our business model projections, historical operating and financial performance, data from other comparable companies, sales of convertible preferred shares to unrelated third parties, the lack of liquidity of share capital and general and industry specific economic outlook, among other factors. The fair value of the underlying ordinary shares will be determined by the board of directors until such time as our ordinary shares are listed on an established share exchange or national market system. Our board of directors determined the fair value of ordinary shares based on the valuation performed using the hybrid method, which takes into account the initial public offering and the non-initial public offering scenario method as of December 31, 2017.

Key Assumptions

The Black-Scholes-Merton option-pricing model requires the input of highly subjective assumptions, including the fair value of the underlying ordinary shares, the expected volatility of the price of our ordinary shares, the expected term of the option, risk-free interest rates and the expected dividend yield of our ordinary shares. These estimates involve inherent uncertainties and the application of the management's judgment. If such inputs change and different assumptions are used, our share-based compensation expenses could be materially different in the future. These assumptions are estimated as follows:

- *Fair value of our ordinary shares*. Since our shares were not publicly traded prior to our initial public offering, we estimated the fair value of our ordinary shares. Upon the completion of our initial public offering, our ordinary shares will be valued by reference to the publicly-traded price of our ordinary shares.
- *Volatility*. The expected share price volatility was based on the historical volatility of the ordinary shares of comparable companies that are publicly traded.
- *Expected term*. The expected term represents the period that our share-based awards are expected to be outstanding. As to the share-option awards granted to employees, the expected term is calculated using the average between the vesting period and the contractual term to the expected term of the options in effect at the time of grant. For option awards granted to non-employees, the expected term is equal to the remaining contractual life of the option, which is generally 10 years from the grant date.
- *Risk-free rate*. The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected term of the options in each option group.
- *Expected dividend yield*. We have never declared or paid cash dividends and we do not have plans to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

If any of the assumptions used in the Black-Scholes-Merton model change significantly, the share-based compensation expenses in future awards may differ materially as compared with the current awards granted.

The following table presents the assumptions used to estimate the fair value of options granted to employees, non-employee directors and service providers during the periods presented:

	Year Ended December 31,	
	2016	2017
Expected term (in years)	7 - 10	7 - 10
Expected volatility	75.0% - 89.0%	75.0% - 94.0%
Risk-free rate	2.2% - 2.7%	2.2% - 3.03%
Dividend yield	0.0%	0.0%

We incurred non-cash share-based compensation expense of $0.6 million and $1.4 million during the years ended December 31, 2016 and 2017, respectively. We expect to continue to grant share option awards in the future, and to the extent that we do, our actual share-based compensation expenses recognized are likely to increase.

Determination of the Fair Value of Stock-Based Compensation Grants

The following table summarizes by grant date the number of ordinary shares subject to share option awards granted between January 1, 2016 and the date of this prospectus, as well as the associated per-ordinary share exercise price of the award, the estimated fair value per ordinary share on the grant date and the aggregate grant date fair value:

Option Grant Date	Number of Ordinary Shares Underlying Options Granted	Estimated Fair Value Per Ordinary Share at Grant Date	Exercise Price Per Ordinary Share	Aggregate Grant Date Fair Value[1]
April 5, 2016	33,000	$ 2.96	$ 2.96	$ 81,890
August 24, 2016	15,106	$ 2.96	$ 2.96	$ 43,927
December 21, 2016	80,000	$ 3.76	$ 3.76	$ 232,202
March 8, 2017	23,875	$ 3.92	$ 3.92	$ 65,629
May 25, 2017	58,750	$ 4.00	$ 4.00	$ 168,990
June 1, 2017	206,823	$ 3.92	$ 3.92	$ 215,030
August 5, 2017	5,875	$ 4.16	$ 8.88	$ 20,900
November 2, 2017	565,937	$ 9.52	$ 7.36	$5,365,816
January 30, 2018	16,563	[2]	$18.32	[2]
February 8, 2018	37,500	[2]	$27.12	[2]

[1] Aggregate grant date fair value was determined using the Black-Scholes-Merton option pricing model.

[2] We have not obtained a valuation of our ordinary shares as of such dates but intend to obtain valuation for purposes of properly accounting for the grant of these options.

Based upon the assumed initial public offering price of $22.50 per share, the midpoint of the range set forth on the cover page of this prospectus, the intrinsic value of the awards outstanding as of December 31, 2017 was $35.5 million, of which $20.3 million related to vested options and $15.2 million related to unvested options.

Valuation of Our Ordinary Shares

The fair value of the ordinary shares underlying our option awards was determined by our board of directors, with input from management. We believe that our board of directors has the

relevant experience and expertise to determine the fair value of our ordinary share as of each respective grant date. The valuations of our ordinary shares were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or the AICPA Practice Aid. The assumptions used in the valuation model are based on future expectations combined with management judgment. Our board of directors, with input from management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our ordinary shares as of the date of each option grant, including the following factors:

- independent valuations performed at periodic intervals by independent third-party valuation specialist;
- our current business projections;
- our stage of development;
- the prices, rights, preferences and privileges of our convertible preferred shares;
- current business conditions;
- the likelihood of a liquidity event for the ordinary shares underlying these options, such as an initial public offering or sale of our company, given prevailing market conditions;
- any adjustments necessary due to the lack of marketability of our ordinary shares;
- the purchase of our preferred shares by third party investors in arms-length transactions; and
- the market performance of comparable publicly traded companies.

In the event of a qualified initial public offering, our preferred shares would convert into ordinary shares on a one-to-one basis, and accordingly would receive the same amount of proceeds per share as ordinary shares. In the case of a sale or liquidation of the Company, the preferred shares would receive their liquidation preferences and thereafter a fraction in the remaining proceeds with the ordinary shares on a pro-rata basis. Accordingly, we determined the fair value of our ordinary shares under two scenarios and then applied a weighted average of these values based on their relative probabilities in order to calculate the final per share value.

- First, we determined value in an exit scenario due to a liquidity event, such as an initial public offering using the market approach and based on discussions with investment banks. In this scenario, all preferred shares, warrants to purchase Series A preferred shares and options to purchase our ordinary shares convert into, or are deemed to be exercised for, ordinary shares. The firm value is divided by the resulting number of shares to determine a per share value.
- Second, we determined value using the Probability Weighted Excepted Return Method, or PWERM. The PWERM is a scenario-based methodology that estimates the fair value of our ordinary shares based upon an analysis of future values for our company, assuming various outcomes. The ordinary share value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available, as well as the rights of each class of our outstanding capital stock. The weighted average enterprise value is then calculated by applying the unleveraged discounted cash flow approach. We believe that this is the most appropriate valuation method as it theoretically captures various future possible outcomes, including an initial public offering.

We then allocated the value between all elements of our securities (preferred shares, ordinary shares, warrants for preferred shares and options for ordinary shares) using the OPM, on the assumption that our preferred shares will benefit from their liquidation preference, as follows:

- Under the OPM, preferred and ordinary shares are treated as a series of call options, with the preferred shares having an exercise price based on the liquidation preference of the respective preferred share. The OPM operates through a series of Black — Scholes — Merton option pricing models, with the strike prices of the options representing the upper and lower bounds of the proceed ranges that a security holder would receive upon a liquidity event. The strike prices occur at break points where the allocation of firm value changes among the various security holders. The ordinary shares are presumed to have value only if funds available for distribution to shareholders exceed the value of the respective liquidation preferences at the time of a liquidity event. The OPM requires an enterprise level input of firm value or a transaction level input of specific security value (typically, a recently issued convertible preferred security) to anchor the allocation of firm value among the various classes of securities.

In making the final determination, we also applied a discount for lack of marketability right, as applicable, to our ordinary shares.

In order to estimate the fair value of our ordinary shares for the option grants made on November 2, 2017, we relied primarily on the $12.72 price per share paid in the third and fourth quarters of 2017 for our Series E preferred shares, given the arm's length nature and due diligence associated with this transaction. In addition, we considered the outlook for an initial public offering in the near-term and our current business projections, as well as the results from the primary efficacy endpoint from our Phase 1b/2 clinical trial of D-PLEX$_{100}$, which we received on November 21, 2017 and considered a significant value-generating event. We then calculated the increase in fair value of our ordinary shares on a linear basis over the fourth quarter of 2017 and applied a discount for lack of marketability of our ordinary shares. Based on this analysis, we derived the fair value of our ordinary shares to be $9.52 per share for these option grants.

In order to determine the exercise price for the option grants made on January 30, 2018, we relied primarily on the December 31, 2017 valuation, which was the most recent valuation on the date of the grants. The December 31, 2017 valuation was influenced, in part, by the following considerations, in addition to the results from the primary efficacy endpoint from our Phase 1b/2 clinical trial of D-PLEX$_{100}$: (i) the completion of our sale of shares of Series E preferred shares at a price of $12.72 per share and (ii) the increased probability of an initial public offering.

In order to determine the exercise price for the option grants made on February 2, 2018, we relied primarily on the December 31, 2017 valuation, which was the most recent valuation on the date of the grants. However, we issued this grant with a higher exercise price to reflect the increased probability of an initial public offering and the end of Phase 2 meeting for D-PLEX$_{100}$ with the FDA held on February 6, 2018.

Future option awards

Following the completion of our initial public offering and the listing of our shares on The Nasdaq Global Market, the determination of the fair market value of our ordinary shares for purposes of setting the exercise price of future option awards or other share-based compensation to employees and other grantees will be based on the market price of our shares and will no longer require good faith estimates by our board of directors based on various comparisons or benchmarks.

Accounting Treatment of the Convertible Preferred Shares

We classify convertible preferred shares that are redeemable at the option of the holder as mezzanine equity on the balance sheet. They are not included as a component of shareholders' equity (deficiency). The carrying value of the preferred shares is equal to cost. We did not adjust the carrying value to redemption value since it is not probable that the preferred shares will be redeemed.

Warrants to Purchase Convertible Preferred Shares

Warrants to purchase our convertible preferred shares are classified as a liability on the balance sheet, and measured at fair value, as the underlying shares are contingently redeemable (upon a deemed liquidation event) and, therefore, may obligate us to transfer assets at some point in the future. The warrants are subject to re-measurement to fair value at each balance sheet date and any change in fair value is recognized as a component of financial expenses, net, in the statement of operations.

The fair value of the warrants on the issuance date and on subsequent reporting dates was determined using the OPM. The fair value of the underlying preferred share price was determined by the board of directors considering, among other things, a third party valuation. The Company's enterprise value was determined based on financing transactions with third parties, price indications from bankers and the discounted cash flow model. The OPM method was then employed to allocate the enterprise value among the various equity classes, deriving a fully marketable value per share for the preferred shares.

Grants and Participation

Royalty-bearing grants from the IIA for funding approved research and development projects are recognized at the time we are entitled to such grants, on the basis of the costs incurred, and are presented as a deduction from research and development expenses. Since the payment of royalties is not probable when the grants are received, we do not record a liability for amounts received from the IIA until the related revenues are recognized. Non-royalty-bearing grants from the IIA MAGNET program and from FP7 for funding approved research and development projects are recognized at the time we are entitled to such grants, on the basis of the costs incurred, and are presented as a deduction from research and development expenses. In the event of failure of a project that was partly financed by the IIA, we would not be obligated to pay any royalties or repay the amounts received.

As of December 31, 2017, we have received royalty-bearing grants totaling $4.7 million. Pursuant to the terms of the grants, we are required to pay royalties to IIA of 3.0% on revenues from sales of products developed financed in whole or in part by IIA, up to a limit of 100% of the grants received, plus annual interest calculated on the 12-month LIBOR rate as published on the first business day of each calendar year.

In addition, we must abide by other restrictions associated with the receipt of such grants under the R&D Law that continue to apply following repayment to IIA. These restrictions may impair our ability to outsource manufacturing or otherwise transfer our knowledge outside of Israel, or engage in change of control transactions, and may require us to obtain IIA approval for certain actions and transactions and pay additional amounts to IIA. In addition, any change of control and any change of ownership of our ordinary shares that would make a non-Israel citizen or resident an ''interested party'' as defined in the R&D Law requires prior written notice from IIA.

Recent Accounting Pronouncements

See note 2 to our consolidated financial statements beginning on page F-1 of this prospectus for a description of recent accounting pronouncements applicable to our consolidated financial statements.

Qualitative and Quantitative Disclosures about Market Risk

Foreign Currency Exchange Risk

We operate primarily in Israel, and approximately 75% of our expenses are denominated in New Israeli Shekels, or NIS. We are therefore exposed to market risk, which represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. We are subject to fluctuations in foreign currency rates in connection with these arrangements. Changes of 5% and 10% in the U.S. dollar/NIS exchange rate would have increased/decreased operating expenses by approximately 4% and 8%, respectively, during the fiscal year ended on December 31, 2017.

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

Interest Rate Risk

We do not anticipate undertaking any significant long-term borrowings. At present, our investments consist primarily of cash and cash equivalents. 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. Our investments may be exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments, if any.

Inflation-Related Risks

Inflation generally affects us by increasing our NIS-denominated expenses, including labor and rental costs and payment to local suppliers. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2016 and 2017.

JOBS Act Transition Period

Section 107 of the JOBS Act provides that an ‘‘emerging growth company’’ can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation, (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be

adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenues of at least $1.07 billion or (c) in which we are deemed to be a ''large accelerated filer'' under the rules of the U.S. Securities and Exchange Commission, which means the market value of our ordinary shares that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

BUSINESS

We are a clinical-stage pharmaceutical company focused on developing and commercializing novel, locally administered therapies using our transformational PLEX (Polymer-Lipid Encapsulation matriX) technology. Our product candidates are designed to address unmet medical needs by pairing PLEX with active pharmaceutical ingredients, or APIs, which are delivered locally at predetermined release rates and durations over periods ranging from days to several months. We believe that our PLEX technology represents a paradigm shift in the treatment of a wide variety of localized medical conditions, including infection, pain, inflammation and cancer. Our initial family of product candidates pairs PLEX with the widely-used, versatile antibiotic doxycycline, which we refer to as the D-PLEX family. Based on results from our clinical trials to date, none of the 101 patients treated in our clinical trials of our D-PLEX product candidates developed an infection at the treatment site after treatment.

We are initially focused on the development of our lead product candidate, D-PLEX$_{100}$, for the prevention of surgical site infections, or SSIs, in bone and soft tissue. We recently reported interim results from our fully-enrolled Phase 1b/2 clinical trial of D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery. During the three-month period after treatment, we observed no sternal wound infections in any of the patients treated with D-PLEX$_{100}$ in combination with the standard of care. In contrast, we observed a 4.5% infection rate in the control group of patients who received the standard of care alone. According to recent literature, the expected infection rate for patients receiving the standard of care alone is 5% to 8%. We plan to submit an Investigational New Drug, or IND, application for D-PLEX$_{100}$ to the U.S. Food and Drug Administration, or FDA, and a clinical trial application, or CTA, to the European national competent authorities early in the fourth quarter of 2018, and to commence a Phase 3 clinical trial in this indication shortly thereafter. Early in the fourth quarter of 2018, we also plan to commence a Phase 2 clinical trial of D-PLEX$_{100}$ for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery. Assuming a successful outcome in our Phase 2 clinical trial and subject to FDA feedback, we plan to initiate a Phase 3 clinical trial in the same indication. Although we have not yet discussed our plans with FDA to develop D-PLEX$_{100}$ for the prevention of SSIs in patients undergoing abdominal surgery, we believe that if the results of this Phase 3 trial, together with the results from our planned Phase 3 trial for the prevention of sternal SSIs, are favorable, these two Phase 3 studies could support a New Drug Application, or NDA. We intend to seek approval for our product candidates under the Section 505(b)(2) pathway for marketing approval by the FDA in the United States, and the hybrid application pathway in the European Union. We may ultimately pursue a broad label for D-PLEX$_{100}$ for the management of SSIs depending on the results of our clinical trials and further discussions with the FDA regarding this strategy. We received a designation of Qualified Infectious Disease Product, or QIDP, from the FDA for D-PLEX$_{100}$ for the prevention of sternal infection after cardiac surgery.

Systemic administration of drugs is currently used for the treatment of a wide variety of medical conditions. However, we believe there can be significant disadvantages to systemic administration of drugs for localized conditions, such as the need to use a higher amount of drugs in treatment, prolonged exposure to drugs that may cause side effects (including damage to non-targeted organs), limited efficacy due to poor penetration or access from the bloodstream into the target tissue and challenges related to solubility or sensitivity to blood factors. Localized delivery systems that have been developed to address the problems of systemic administration also have disadvantages, including short release periods and poor control of drug release rates. We believe our PLEX technology has the potential to improve patient outcomes and lower the overall cost of treatment by enabling local, customizable, predetermined and controlled delivery of drugs, thereby addressing many of the shortcomings of systemic administration and existing localized delivery systems.

Our PLEX technology consists of a proprietary matrix of layers of chemically-inert and biodegradable polymers and lipids that physically entrap an API in a protected reservoir, enabling localized, bioavailable drug delivery at customizable, predetermined release rates and durations over periods ranging from days to several months. We believe that these characteristics may enable our PLEX product candidates to be therapeutically effective using only a small fraction of the APIs required in systemic administration of currently marketed therapies. Because PLEX is agnostic to the nature and size of the underlying drug, it has the potential to be paired with a wide variety of currently marketed drugs or product candidates in development, including small molecules, peptides, antibodies and other proteins, as well as nucleic acid-based APIs, to create novel therapies in a broad range of indications.

We are initially developing product candidates using our PLEX technology for the prevention of SSIs. Infection resulting from surgery and trauma can be fatal and creates a significant public health burden despite the extensive use of systemically administered antibiotics both pre- and post-surgery. SSIs occur in approximately 2% to 5% of patients undergoing inpatient surgery worldwide. The World Health Organization, or the WHO, reports that SSIs account for an estimated $10 billion of incremental hospital costs per year in the United States and €11 billion per year in the European Union. We expect the costs associated with SSIs to continue to grow in the face of the increasing resistance of bacteria to antibiotics, as safety concerns often preclude the increase of systemic dosages and/or treatment duration to address resistance.

Our lead product candidate from this family, D-PLEX$_{100}$, which is being developed to prevent bone and soft tissue SSIs, received QIDP designation from the FDA in February 2017 for the prevention of sternal infection after cardiac surgery. We recently announced the results of the primary efficacy endpoint from our fully-enrolled Phase 1b/2 clinical trial of D-PLEX$_{100}$ in 81 patients in this indication, observed at the three month follow-up study period. During the three-month period after treatment, we observed no sternal wound infections in any of the 58 patients treated with D-PLEX$_{100}$ in combination with the standard of care. In contrast, we observed a 4.5% infection rate in the control group of patients who received the standard of care alone. According to recent literature, the expected infection rate for patients receiving the standard of care alone is 5% to 8%. We held an end of Phase 2 meeting with the FDA in the first quarter of 2018, in which we discussed the development of D-PLEX$_{100}$ for the prevention of post cardiac surgery sternal infection, to obtain alignment on our Phase 3 clinical trial design for the prevention of post-cardiac surgery sternal infections. We plan to submit an IND for D-PLEX$_{100}$ to the FDA and a CTA to the European national competent authorities early in the fourth quarter of 2018, and to commence our Phase 3 clinical trial in sternal SSIs after cardiac surgery shortly thereafter. We also plan to commence a Phase 2 trial of D-PLEX$_{100}$ for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery for the prevention of SSIs early in the fourth quarter of 2018. Assuming a successful outcome in our Phase 2 clinical trial and subject to FDA feedback, we plan to initiate a Phase 3 clinical trial in the same indication. Although we have not yet discussed our plans with FDA to develop D-PLEX$_{100}$ for the prevention of SSIs in patients undergoing abdominal surgery, we believe that if the results of this Phase 3 trial, together with the results from our planned Phase 3 trial for the prevention of sternal SSIs, are favorable, these two Phase 3 studies could support an NDA for the prevention of SSIs in bone and soft tissue. We plan to seek approval of D-PLEX$_{100}$ under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the FFDCA, which is administered by the FDA, in the United States, and the comparable hybrid application pathway in the European Union.

We have developed D-PLEX$_{1000}$, which was formerly known as BonyPid-1000 and is another product candidate from the D-PLEX family, for use in connection with orthopedic surgeries for the management of SSIs and support of bone recovery. Often, bone will not heal in the presence of infection. Based on results from our pre-pivotal and pilot clinical trials of D-PLEX$_{1000}$ to date, none of

the 43 patients treated with D-PLEX$_{1000}$ developed infections in the target fracture. In a retrospective analysis of the medical records of 49 patients treated for similar open long bone fractures with the standard of care at the same clinical trial sites where we conducted our D-PLEX$_{1000}$ clinical trials, we found a target fracture infection rate of up to 25%. We have completed enrollment of a pre-pivotal trial in 51 patients evaluating the safety and effectiveness of D-PLEX$_{1000}$ for the treatment of open tibia fractures. Patients were assessed on a monthly basis. In interim results from the six-month follow-up period of our pre-pivotal trial, we observed that 92% of the patients treated with D-PLEX$_{1000}$ in addition to the standard of care reached the primary performance endpoint, the presence of solid radiographic markers for bone healing, as assessed by the establishment of a callus in three out of four cortices, as compared to 62% of the 13 evaluable patients treated with the standard of care alone. Sixty percent of the patients treated with D-PLEX$_{1000}$ in combination with the standard of care had reached the primary performance endpoint by three months post-operation, as compared to 17% of patients treated with the standard of care alone. Only 36% of patients receiving the standard of care alone showed these markers at four months. It was only at the five-month evaluation that patients in the standard of care arm showed a comparable percentage of patients with these markers as that observed in the group treated with D-PLEX$_{1000}$ in combination with the standard of care at three months post-operation. We do not currently plan to pursue further independent development of D-PLEX$_{1000}$, as we believe the orthopedic SSI market can be adequately addressed by D-PLEX$_{100}$.

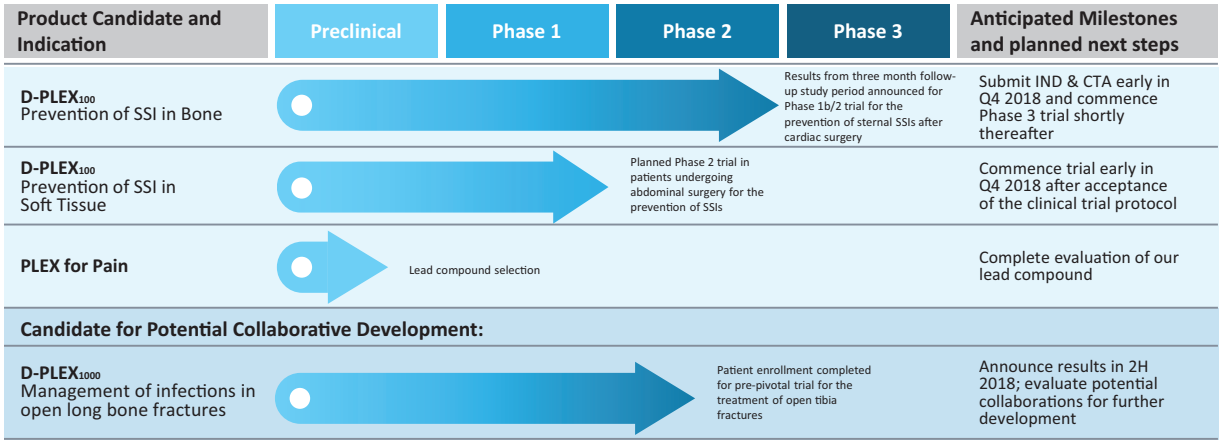
Our PLEX platform technology may have broad applications for localized medical conditions other than the prevention of SSIs. We are pursuing research and development programs for our PLEX platform in a variety of potential indications, including for the treatment of SSIs, pain, inflammation and cancer. We are in discussions with global biopharmaceutical companies to license our PLEX platform for use with various biologics and small molecules.

We are constructing our pilot manufacturing facility, which is intended to comply with the FDA's current good manufacturing practice, or cGMP, regulations, and European Medicines Agency, or EMA, regulations, in Israel to enhance supply chain control, increase supply capacity and meet clinical demand for our planned clinical trials and initial commercial demand in the event that D-PLEX$_{100}$ receives marketing approval. We also intend to build a larger-scale cGMP manufacturing facility in Israel in the future.

We have an experienced management team with an average of 14 years of experience in life sciences companies. Members of our board of directors also have extensive experience in the life sciences industry. We believe that our leadership team is well positioned to lead us through clinical development, regulatory approval and commercialization of our product candidates.

Product Candidate Pipeline

Our PLEX product candidate pipeline is set forth below:



Growth Strategy

Our goal is to leverage our PLEX technology to develop and commercialize a pipeline of transformative therapies for the local delivery of drugs to address unmet medical needs. The key elements of our strategy are as follows:

- ***Complete clinical development of and seek approval for D-PLEX$_{100}$ for the prevention of bone and soft tissue SSIs in the United States and the European Union.*** We recently announced the results of the primary efficacy endpoint from our Phase 1b/2 clinical trial of D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery. We plan to submit an IND for D-PLEX$_{100}$ to the FDA and a CTA to the European national competent authorities early in the fourth quarter of 2018, and to commence a Phase 3 clinical trial in this indication shortly thereafter. We also plan to commence early in the fourth quarter of 2018 a Phase 2 clinical trial in patients undergoing abdominal surgery for the prevention of SSIs. Assuming a successful outcome in our Phase 2 clinical trial and subject to FDA feedback, we plan to initiate a Phase 3 clinical trial in the same indication. Although we have not yet discussed our plans with FDA to develop D-PLEX$_{100}$ for the prevention of SSIs in patients undergoing abdominal surgery, we believe that if the results of this Phase 3 trial, together with the results from our planned Phase 3 trial for the prevention of sternal SSIs, are favorable, these two Phase 3 studies could support an NDA. We may ultimately pursue a broad label for D-PLEX$_{100}$ for the management of SSIs depending on the results of these trials and further discussions with the FDA regarding this strategy. We may also seek regulatory approval of our product candidates outside of the United States and the European Union.
- ***Pursue expedited and fast track regulatory pathways for the approval and commercialization of our product candidates in the United States and the European Union.*** We intend to pursue expedited pathways to approval for our portfolio of product candidates. PLEX is paired with an unmodified drug with established clinical safety, efficacy and tolerability, and the polymers and lipids that we use in PLEX have been used in other medical products that have been approved by the FDA and/or the EMA. Accordingly, we believe that we can pursue expedited clinical development and make regulatory submissions that allow us to rely in part on previous findings of safety and efficacy for the active ingredient, including the Section 505(b)(2) approval pathway in the United States and the comparable regulatory pathway in the European Union, as compared to the

development of traditional new molecular entities. Further, D-PLEX$_{100}$ has received QIDP designation from the FDA for the prevention of sternal infections after cardiac surgery, which we anticipate will provide an overall increased level of communication with the FDA during the development process as it may be eligible for fast track designation upon request and priority review once we submit an NDA.

- ***Leverage our PLEX technology to expand our product pipeline for the treatment of SSIs and the management of pain and for additional indications.*** In addition to the development of D-PLEX$_{100}$ for the prevention of SSIs, we intend to evaluate PLEX for the treatment of SSIs. We are also currently developing PLEX for the management of chronic or post-surgical pain. PLEX may have broad applications for other localized problems, including the treatment of inflammation and cancer. We intend to maximize the commercial potential of PLEX by exploring these additional indications, either independently or through collaborations with other biopharmaceutical companies.
- ***Evaluate and selectively pursue collaborations around our PLEX technology with leading biopharmaceutical companies.*** Many leading biopharmaceutical companies have currently marketed drugs or product candidates in development that are not viable for systemic administration due to instability, toxicity and cost. We believe that our PLEX technology can be paired with a wide variety of drugs or drug candidates, including small molecules, peptides, antibodies and nucleic acids, to address these limitations and potentially extend the drug's life cycle before and after patent expiration for the underlying drug.
- ***Independently commercialize in the United States and seek partners to commercialize outside of the United States.*** We intend to commercialize our product candidates independently in the United States using a targeted and capital efficient sales force. Outside of the United States, we intend to utilize partners for the commercialization of our product candidates.
- ***Establish our fully-integrated, cGMP-compliant manufacturing facility.*** We are in the process of establishing our pilot cGMP-compliant manufacturing facility in Israel to maintain supply chain control, increase supply capacity and meet clinical demand for our planned clinical trials. In the event that D-PLEX$_{100}$ receives marketing approval, we believe that the pilot facility will meet initial commercial demand. We also intend to build a larger commercial-scale cGMP-compliant manufacturing facility in Israel in the future.
- ***Expand our intellectual property position.*** We own numerous issued composition of matter and utility patents and pending patent applications that relate to our technology. As of December 31, 2017, we owned 55 issued patents, and we had 49 pending patent applications in the United States, the European Patent Office, Canada, Australia, China, Japan, Israel, Brazil, the Eurasian Patent Organization, India, Mexico, New Zealand, the Philippines, Singapore, South Africa, South Korea and Thailand. Our issued patents expire between 2029 and 2033. We intend to continue to expand our intellectual property portfolio as we develop PLEX for other indications.

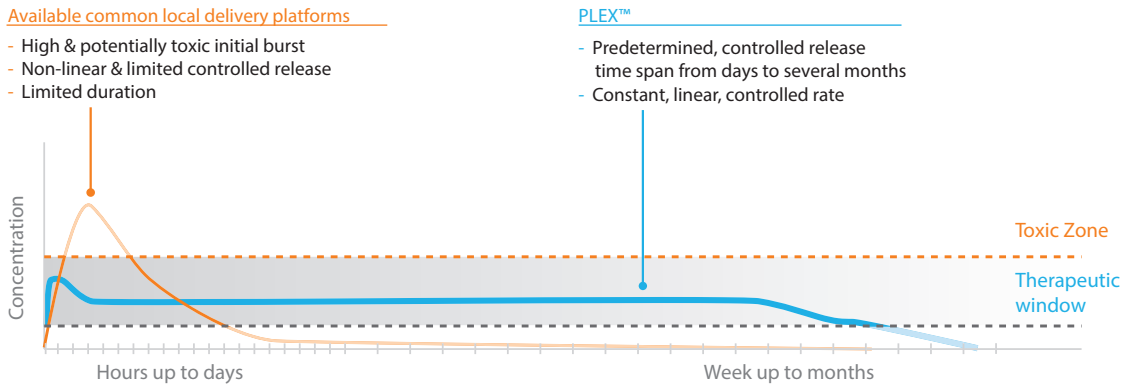
Limitations of Systemically Administered Drugs and Current Localized Delivery Systems

The systemic administration of drugs may have significant disadvantages for the treatment of localized problems, including limited efficacy due to poor penetration from the blood stream into the needed organ or other target tissues, challenges related to solubility or sensitivity to blood factors and prolonged exposure to drugs that may cause damage to non-targeted organs. Further, the increasing resistance of bacteria to antibiotics poses a major public health threat, and safety

concerns often limit or preclude the increase of dosages and/or treatment duration to address resistance.

Localized delivery of medications for localized problems can have advantages over systemic administration because it can reduce the risk of overall toxicity and adverse side effects, enable a lower amount of drug to be used in the treatment and potentially increase patient compliance. In order to address the limitations of systemic administration to treat localized medical conditions, an effective localized drug delivery system must be able to deliver the selected drug to the target site, ensure the appropriate drug concentration at the needed site and release the active drug over the entire desired treatment period.

Comparative duration of PLEX vs. available common local delivery platforms



Existing localized treatments, including extended release formulations based on polymer-, lipid- and liposomal-based technologies, generally suffer from one or more of the following limitations:

- ***Short release periods.*** An effective regimen to manage infections typically needs to span several weeks due to the persistence of bacteria; most local delivery systems, however, are able to generate local concentrations that are effective for only several days.
- ***Controllability of drug release rates.*** For a localized delivery system to be effective, it must deliver a non-toxic but adequate and constant dosage to the target site throughout the release period. Current systems based only on polymers or only on lipids have limited ability to control drug release rates. In addition, these systems release the drug with an initial high burst, followed by fast decline, which is both less effective than a steadier delivery and may cause safety issues.
- ***Susceptibility to drug reservoir degradation.*** Some drugs need to be isolated from body fluids to prevent rapid degradation. In order to effectively administer such drugs locally over prolonged periods, the implanted drug reservoir needs to be protected until released, ideally in an unhydrated form. We are not aware of any localized drug delivery systems in the market that can protect drugs from hydration inside the body over prolonged periods, and subsequently release them in their active forms.
- ***Susceptibility to drug reservoir migration.*** Drug reservoirs are more effective when anchored at the treatment site and unable to migrate after application. Many localized delivery systems are susceptible to migration away from the treatment site after application.
- ***Potential chemical modifications to underlying drug.*** Some of the currently developed localized delivery systems modify or form chemical bonds with the underlying drug, which

may modify its mechanism of action, impede the regulatory process for approval and make development longer and more expensive.

- ***Limited in applicability to different drug types.*** Many localized delivery systems are suited only to a particular drug or class of drugs, and are therefore limited in clinical scope.
- ***Difficult to use.*** Some localized delivery systems require extensive training in their application and are difficult to use. Improper use can adversely affect therapeutic benefit and physician acceptance of the product.
- ***Manufacturing complexity and cost.*** Some localized delivery systems utilize inputs and technologies that are costly or have suboptimal yields, which makes the end product more expensive and limits the system to niche or very high value applications.

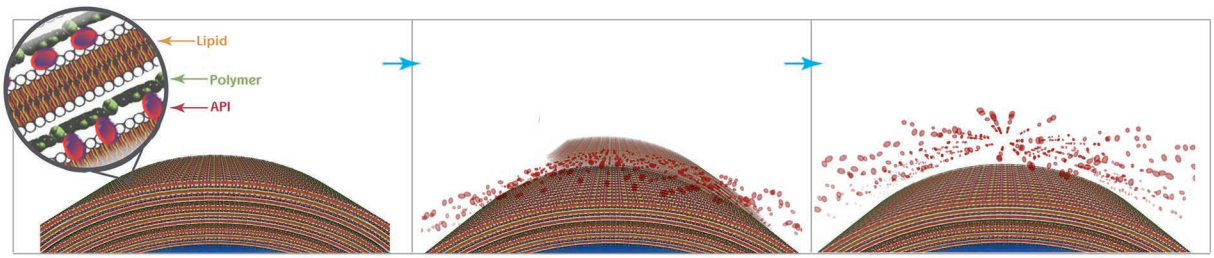
These disadvantages are particularly problematic for the management of infections, where the controlled and prolonged delivery of a drug may be more effective in managing infection than an initial high burst of drug over a shorter duration. While we believe that localized drug delivery systems are well suited to the management of SSIs, particularly in bone and soft tissue, it is important for these systems to overcome these limitations in order to change the treatment paradigm for infection management.

These limitations are particularly acute in the case of resistant bacteria. The inability to generate a high localized concentration of drug for an extended period of time limits the drug delivery systems' effectiveness in treating antibiotic-resistant infections.

Our Solution: PLEX Technology

Our PLEX technology consists of a proprietary matrix of several thousand alternating layers of chemically-inert and biodegradable polymers and lipids, which self assemble to physically entrap an API in a protected reservoir, designed to enable localized, bioavailable drug delivery at customizable, predetermined release rates and durations directly at the target site over periods ranging from days to several months. For example, our D-PLEX family of product candidates consists of thousands of layers of polymers and lipids. Drugs captured between the PLEX matrix are intended to be released over time in customizable, predetermined amounts by the gradual disintegration of the layers, from the outer layer to the inner layers, while protecting the inner drug from hydration and enzymes that would otherwise degrade the API. Natural hydration in the body triggers release of the drug in an unmodified active form similar to direct administration.

Predetermined release of API by gradual disintegration of the outer lipid and polymer layers



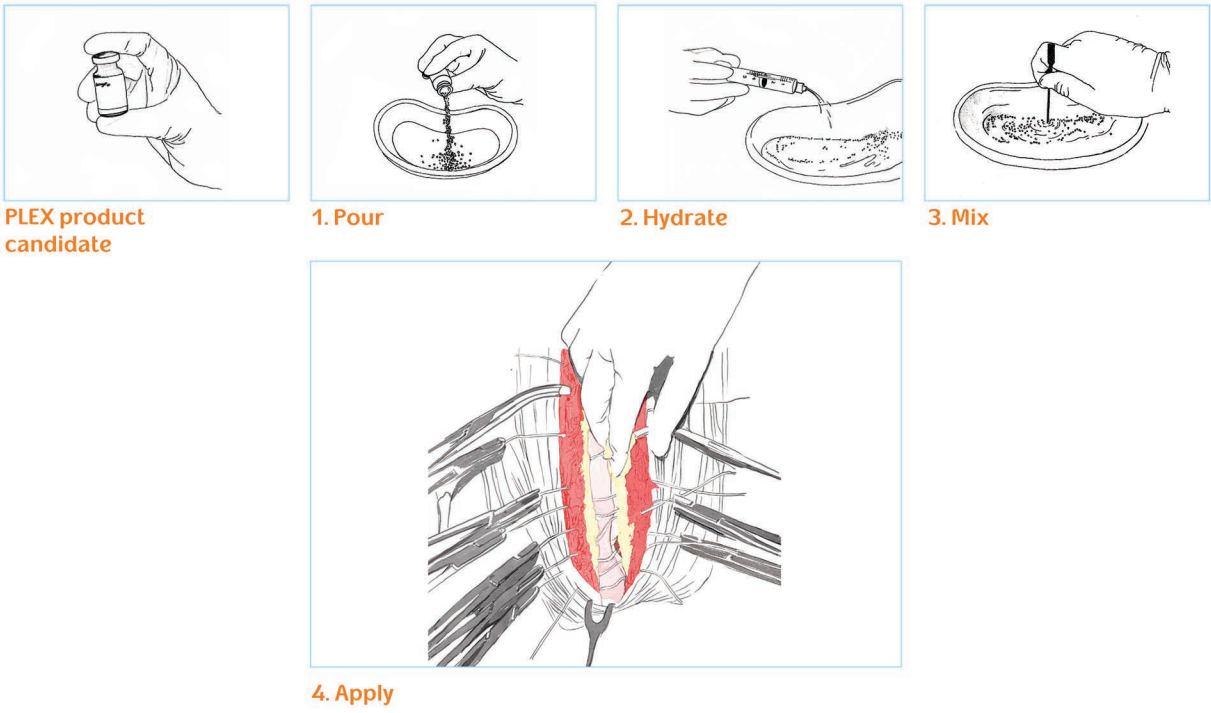
Our PLEX technology is designed to overcome the limitations of both systemic administration and current localized delivery systems. We believe PLEX has a number of key design benefits:

- ***Constant drug release rate over prolonged periods.*** PLEX enables the pre-designed constant drug release over a customizable, predetermined period to accomplish the drug's therapeutic purpose. The release rate and period can be customized to range from a few

days to several months based on the number of layers and the disintegration rate of the layers.

- ***Access to tissues that are difficult to treat through systemic administration.*** An application of our PLEX product candidates may provide long lasting treatment even in tissues that are not easily accessible to systemic or topical treatment, such as surgical sites or tissues with limited or interrupted blood supply, or where systemic administration may be limited due to toxicity.
- ***Anchored to the treatment site.*** PLEX physically encapsulates an API in a manner that anchors it to a location and allows for administration where the drug is needed during the desired period. Our PLEX product candidates have not been observed to migrate once applied to the treatment site.
- ***Potential for improved drug safety profile.*** Our PLEX product candidates use a fraction of the APIs required in systemic administration of currently marketed therapies, and these APIs are physically encapsulated in an effort to minimize systemic exposure to body fluids and prevent early degradation. Through controlled release, PLEX is designed to generate concentrations of the API that are therapeutically effective but not toxic.
- ***No chemical modification required to the encapsulated API.*** PLEX encapsulation does not require any chemical changes to the API, which we believe will streamline our development process by allowing us to rely in part on preexisting studies of safety and efficacy and maintain the already proven mechanism of action of the underlying drug.
- ***Biodegradable.*** The PLEX matrix gradually disintegrates in the body, eliminating the need for additional medical procedures to remove the drug reservoir once depleted.
- ***Broad potential applicability.*** Because PLEX is agnostic to the nature and size of the underlying drug, and no chemical bonds develop between the encapsulated drug and the PLEX components, we believe PLEX can be used for the improvement of a wide variety of drug types, including small molecules, peptides, antibodies and other proteins and nucleic acids.
- ***Efficient manufacturing process.*** Our product candidates are manufactured using a scalable process with well-defined, robust unit operations. This highly specialized and precisely controlled manufacturing process enables us to manufacture product candidates reproducibly and efficiently for clinical and commercial applications.
- ***Easy to use.*** Our D-PLEX family of product candidates are supplied as a sterile powder that can be administered locally as a powder or paste during surgery directly to a variety of tissues and solid organs, as illustrated below.

Preparation and use of D-PLEX$_{100}$ in open heart surgery



Our Initial Family of Product Candidates: D-PLEX

We are developing a family of product candidates for the management of SSIs consisting of PLEX paired with doxycycline, a widely-used, FDA-approved antibiotic, which we refer to as our D-PLEX family. Our D-PLEX family of product candidates are secure antibiotic drug reservoirs that use our PLEX technology to physically encapsulate doxycycline and release it at the local target site at predetermined rates and durations, and are designed to provide localized and prolonged infection management after surgery. The PLEX matrix in this family consists of thousands of layers of polymers and lipids that are designed to mediate the release of doxycycline for up to four weeks. The product candidates in this family are each based on the same specific PLEX formulation and are designed to be used with doxycycline. Our product candidates are supplied as sterile powders and may be administered locally as a powder or paste during surgery to a variety of tissues and solid organs. Based on results from our clinical trials to date, none of the 101 patients treated in our clinical trials of our D-PLEX product candidates developed an infection at the treatment site after treatment.

Surgical Site Infections

Hospital acquired infections, or HAIs, are infections that patients acquire when receiving medical treatment in a healthcare facility. According to the WHO, HAIs are the most frequent adverse event affecting patient safety worldwide. SSIs are the second most common HAI in both the United States and the European Union and occur in approximately 2% to 5% of patients undergoing inpatient surgery worldwide. However, these figures are likely underestimated because approximately 50% of SSIs become evident only after a patient has been discharged. The incidence and morbidity of SSIs differ based on the surgical procedure performed and patient risk factors, and the extent of the infection depends on the nature of the surgery.

According to the WHO, SSIs account for an estimated $10 billion of incremental hospital costs per year in the United States and €11 billion per year in the European Union. Directly attributable costs of SSIs range from approximately $11,000 to $26,000 per infection. In more complex infections involving a prosthetic joint or an antimicrobial-resistant organism, the costs per case can exceed $90,000. SSIs are associated with approximately seven to 11 additional post-operative hospital days, and patients with an SSI have a two to 11 times increased risk of death compared to infection-free patients. The Centers for Disease Control, or the CDC, estimates that the financial costs of treating SSIs will continue to increase, both because more surgeries are being performed and surgical patients present with increasingly complex comorbidities. Moreover, the United States, the Centers for Medicare and Medicaid Services, or CMS, track SSI rates and are increasingly using these statistics to deny reimbursement claims for certain SSIs or reduce total annual CMS payments for hospitals that CMS deems to not meet certain quality metrics for the prevention of infection. CMS also publishes the SSI incidence rate for hospitals, and therefore hospitals have economic and reputational, in addition to human, incentives to prevent SSIs.

SSIs can affect any post-operative patient, but obese patients, diabetics, smokers, patients older than 60 and patients undergoing longer duration surgeries are considered at high risk to develop SSIs. Despite the high incidence of SSIs, a large proportion of SSIs are estimated to be preventable with the use of evidence-based measures. However, the prevention of SSIs is complex and requires the implementation of a range of safety measures before, during and after surgery. Most significantly, the WHO, CDC and other health organizations recommend the almost universal systemic and/or topical administration of antibiotics and antiseptic measures prior to surgery to help prevent SSIs. When delivered systemically, these antibiotics are used in large quantities over a short period, often with adverse side effects and limited efficacy.

Market Opportunity

We are initially focused on the use of D-PLEX$_{100}$ to prevent SSIs in bone and soft tissues, where we believe there is a high unmet need, which is particularly acute in high-risk patients.

SSIs in Bone Surgeries

In our bone surgery addressable market opportunity, we include cardiac surgeries and orthopedic surgeries, which includes joint replacements and surgeries, spine surgeries and bone-related trauma surgeries.

SSIs occur in 5% to 8% of cardiac surgeries but carry a mortality rate of up to 40% for deep sternal wound infections, which are more difficult to treat than superficial infections. Deep sternal wound SSIs are associated with an average of 35 post-operative hospital days, compared with a mean of 11 days for infection-free patients. The cost of care for a patient that develops a deep sternal wound SSI can be as much as three times greater than the cost of care for an infection-free patient.

SSIs occur in 0.5% to 4.0% of orthopedic surgeries. Orthopedic SSIs are difficult to treat and associated with lifelong infection recurrence risks of 10% to 20%, particularly in the case of methicillin-resistant *Staphylococcus aureus*, or MRSA, infections. Further, often bone will not heal in the presence of infection, which can result in disabling complications, including amputation. Orthopedic SSIs have been estimated to prolong total hospital stays by a median of two weeks per patient, approximately double readmission rates and increase healthcare costs by more than 300% compared to infection-free patients.

SSIs in Soft Tissue Surgeries

In our soft tissue surgery addressable market opportunity, we include general surgeries, including intestine and bowel surgeries and selected ear, nose and throat surgeries, gynecological and urologic surgeries. SSIs are one of the most frequent complications in open abdominal surgeries, and they represent a significant cause of mortality and morbidity. SSIs occur in approximately 5% to 30% of soft tissue surgeries, including approximately 10% to 15% of abdominal surgeries, which represent the majority of the ''General Surgeries'' below, approximately 15% to 30% of colorectal surgeries, up to nearly 4% of Cesarean sections and up to 4% of hysterectomies. Patients undergoing colorectal surgeries are at particularly high risk of developing SSIs because the colon and rectal tracts contain more bacteria that are exposed during surgery. Abdominal SSIs are associated with an average of 18 additional post-operative hospital days.

The tables below provide the estimated sizes of our addressable market opportunity in these categories in the United States and the EU-5, which, for purposes of the following data, includes France, Germany, Italy, Spain and the United Kingdom, based on the number of procedures performed in 2015, according to a study we commissioned from Life Science Intelligence, Inc.:

Bone Surgeries

	Number of Surgeries
Cardiac Surgeries	
United States	889,000
EU-5	320,000
Orthopedic Surgeries	
United States	4,148,000
EU-5	2,590,000
Total	**7,947,000**

Soft Tissue Surgeries

	Number of Surgeries
General Surgeries	
United States	7,182,000
EU-5	3,290,000
Gynecological and Urologic Surgeries	
United States	2,942,000
EU-5	1,817,000
Aesthetic Surgeries	
United States	608,000
EU-5	319,000
Total	**16,158,000**

We believe that D-PLEX$_{100}$ will be used at a significantly higher rate in high-risk patients, whom we estimate to comprise approximately one-third of the total surgical patient population.

Benefits of Doxycycline

Doxycycline can be used against a variety of organisms and in a variety of settings, including for both identified and unknown bacteria.

Doxycycline has the following advantages over other antibiotics:

- broad spectrum of activity against both gram-positive and gram-negative bacteria;

- highly effective against *Staphylococcus aureus*, the most common bacteria associated with SSIs;
- potent against MRSA and community-associated MRSA strains, often with a relatively low minimal inhibitory concentration;
- low rate of resistant pathogens as compared to other antibiotics;
- good tissue and cell penetration; and
- established clinical history of safe prolonged administration.

Our D-PLEX product candidates are designed to release doxycycline locally to the surgical site at predetermined release rates and durations for up to four weeks, longer than any existing antibiotic delivery system, which we believe has the potential to be effective and safer than systemic treatment for infection management.

We believe that, by combining doxycycline with our proprietary PLEX technology, D-PLEX$_{100}$ has the potential to overcome the limitations of other available treatments and deliver significant advantages in the management of SSIs, including:

- localized delivery of an antibiotic at therapeutically effective concentrations for up to four weeks;
- applicability to a wide range of bacteria in a variety of settings, including MRSA and community-associated MRSA;
- increased penetration and access to the infection site;
- reduced risk of overall toxicity and adverse side effects due to minimization of systemic exposure and significant decrease of total drug volume delivered;
- simplicity of administration during surgery; and
- biodegradability; and
- reduction of patient compliance concerns.

D-PLEX$_{100}$ may have multiple positive impacts on the treatment paradigm for infection management. For example, we have observed in our clinical studies that surgeons applying D-PLEX$_{1000}$ directly to the contaminated or infected open long bone fracture at the first surgery can avoid repeated surgical intervention for treating a potential infection. Further, in the case of resistant bacteria, D-PLEX$_{100}$ has the potential to overcome resistant bacteria through the creation of the required local concentration at the target site, which would not be feasible using systemic antibiotic treatment regimens.

D-PLEX$_{100}$: Our Lead Product Candidate for the Prevention of SSIs

We are developing D-PLEX$_{100}$ for the prevention of SSIs in bone and soft tissue. D-PLEX$_{100}$ received QIDP designation from the FDA under the Generating Antibiotic Incentives Now, or GAIN, Act in February 2017 for the prevention of sternal infections after cardiac surgery. We plan to seek approval of D-PLEX$_{100}$ under Section 505(b)(2) of the FFDCA in the United States and the comparable regulatory pathway in the European Union. We plan to submit an IND for D-PLEX$_{100}$ to the FDA and a CTA to the European national competent authorities early in the fourth quarter of 2018, and to initiate a Phase 3 clinical trial in sternal SSIs after cardiac surgery shortly thereafter. We also plan to commence early in the fourth quarter of 2018 a Phase 2 clinical trial in Israel in patients undergoing abdominal surgery for the prevention of SSIs. Assuming a successful outcome in our Phase 2 clinical trial and subject to FDA feedback, we plan to initiate a Phase 3 clinical trial

in the same indication. Although we have not yet discussed our plans with FDA to develop D-PLEX$_{100}$ for the prevention of SSIs in patients undergoing abdominal surgery, we believe that if the results of this Phase 3 trial, together with the results from our planned Phase 3 trial for the prevention of sternal SSIs, are favorable, these two Phase 3 studies could support an NDA. We may ultimately pursue a broad label for D-PLEX$_{100}$ for the management of SSIs depending on the results of our clinical trials and further discussions with the FDA regarding this strategy.

In our pre-IND meeting in August 2017, the FDA indicated alignment on key aspects of our chemistry, manufacturing and control, or CMC, development plan of D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery, including their recommendation that we can use the proposed cGMP production process at our third-party manufacturing facility for our planned Phase 3 clinical trial. The FDA also generally accepted our proposed product specification for D-PLEX$_{100}$ and the raw materials we use to produce D-PLEX$_{100}$ for our planned IND, as well as our stability plan and the stability data we intend to submit for our planned IND. In the first quarter of 2018, we held an end of phase 2 meeting with the FDA to obtain alignment on the Phase 3 clinical trial design for the prevention of post-cardiac surgery sternal infection.

In March 2017, the EMA issued a final scientific advice letter indicating alignment with our clinical and CMC development plan for D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery for purposes of seeking Marketing Authorization Approval in the European Union.

Clinical Development of D-PLEX$_{100}$

Phase 1b/2 Clinical Trial for the Prevention of Sternal SSIs After Cardiac Surgery

In October 2016, we initiated a two-part Phase 1b/2 clinical trial of D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery in 80 patients undergoing cardiac surgery through mid-sternotomy, with no high-risk enrichment. On August 16, 2017, we completed enrollment of this trial. We are conducting this trial at four sites in Israel.

The first part of the trial was an open label, single arm study of 20 patients who received D-PLEX$_{100}$ concomitantly with the standard of care, which generally consists of a prophylactic systemic antibiotic. Based on feedback from the FDA, the second part of the trial was designed as a randomized and single blinded study of 60 patients divided in a two-to-one ratio between treatment and control arms. One arm received D-PLEX$_{100}$ concomitantly with the standard of care, and the second arm received the standard of care only. Dosing occurred during surgery, and patient follow-up continues for six months after treatment. The primary endpoint of this trial is the decrease of SSI rate as measured by the proportion of patients with at least one SSI within 90 days after cardiac surgery. An independent, blinded adjudication committee reviews all patients with infection as identified by the principal investigator. The study also follows the patients' safety for six months after surgery.

We recently announced the results of the primary efficacy endpoint from this trial observed at the three-month follow-up study period. During the three-month period after treatment, we observed no sternal wound infections in any of the patients treated with D-PLEX$_{100}$ in combination with the standard of care. In contrast, we observed a 4.5% infection rate in the control group of patients who received the standard of care alone. According to recent literature, the expected infection rate for patients receiving the standard of care alone is 5% to 8%. Patients in the D-PLEX$_{100}$ and standard of care arm had similar superficial SSI and/or significant wound secretion rates in non-treated harvesting sites as the patients in the standard of care only arm.

During the three month follow-up period, we also observed a 62% reduction in the number of patients with sternal wound discharge, as well as a 56% reduction in the duration of such discharge events, each as compared to the control group of patients who received the standard of care alone.

Moreover, in patients treated with D-PLEX$_{100}$ in combination with the standard of care, we observed reductions in re-hospitalization rates of 25%, re-hospitalization durations of 27% and overall re-hospitalization days of 44%, each as compared to the rates for the control group of patients who received the standard of care alone.

Planned Phase 3 Clinical Trial for the Prevention of Sternal SSIs After Cardiac Surgery

We held an end of Phase 2 meeting with the FDA in the first quarter of 2018 to obtain alignment on our Phase 3 clinical trial plan and regulatory approval pathway for D-PLEX$_{100}$ for the prevention of sternal SSIs after cardiac surgery. Based on feedback from the FDA, we will need to conduct two Phase 3 clinical trials of D-PLEX$_{100}$. Our first Phase 3 clinical trial will be a prospective, multinational, multicenter, randomized, two-arm, single-blinded clinical trial to evaluate the efficacy and safety of D-PLEX$_{100}$ in combination with the standard of care for the prevention of sternal SSIs after cardiac surgery. We plan to run an adaptive design clinical trial and enroll between 1,200 and 2,100 patients undergoing median sternotomy in cardiac surgery, ages 18 to 90 years old, with additional SSI-related comorbidities, such as diabetes and abnormal body mass index. Patients will be divided into two arms, one of which will be treated with D-PLEX$_{100}$ in combination with the standard of care and the other will be treated with the standard of care alone. We intend to enroll patients at clinical trial sites in the United States, Europe and Israel. The primary efficacy endpoint for this clinical trial will be sternal infection rate as measured by the proportion of subjects with a sternal wound infection event, including deep and superficial sternal wound infections, within 90 days after sternotomy for cardiac surgery. We will also evaluate secondary endpoints, including supporting health economic endpoints, as well as safety and tolerability of D-PLEX$_{100}$ over six months after surgery. The standard amount of time from initiation of a clinical trial to read-out of data is approximately two years. We are also in discussions with the FDA regarding the possibility of a waiver of pediatric studies of D-PLEX$_{100}$ for the treatment of sternal SSIs after cardiac surgery. We plan to submit an IND for D-PLEX$_{100}$ to the FDA and a CTA to the European national competent authorities early in the fourth quarter of 2018, and commence the Phase 3 clinical trial in this indication shortly thereafter.

Planned Phase 2 Clinical Trial in Patients Undergoing Abdominal Surgery for the Prevention of SSIs

We plan to commence a Phase 2 clinical trial in patients undergoing abdominal surgery for the prevention of SSIs early in the fourth quarter of 2018 in Israel. We recently submitted the clinical trial protocol for review by the Israeli Ministry of Health and the clinical sites' local ethics committees. Subject to feedback from the FDA, we intend for this clinical trial to be a double-arm, single-blinded trial to evaluate the safety and efficacy of D-PLEX$_{100}$ in combination with the standard of care for the prevention of SSIs. We expect to enroll patients undergoing abdominal surgery at four clinical trial sites in Israel. The primary efficacy endpoint for this clinical trial will be infection rate as measured by the proportion of patients with an SSI, including deep and superficial incisional SSIs, at the treatment site within 30 days after abdominal surgery. We will also evaluate safety and tolerability of D-PLEX$_{100}$. Assuming a successful outcome in our Phase 2 clinical trial and subject to FDA feedback, we plan to initiate a Phase 3 clinical trial in the same indication. Although we have not yet discussed our plans with FDA to develop D-PLEX$_{100}$ for the prevention of SSIs in patients undergoing abdominal surgery, we believe that if the results of this Phase 3 trial, together with the results from our planned Phase 3 trial for the prevention of sternal SSIs, are favorable, these two Phase 3 studies could support an NDA.

Non-Clinical Studies

We believe that the results of our non-clinical studies will be sufficient to support an IND and CTA for D-PLEX$_{100}$ for the prevention of sternal infections after cardiac surgery. In a rabbit sternal wound MRSA model, we observed that a single application of D-PLEX$_{100}$ substantially reduced bacterial content and histopathological evidence of MRSA infection in the sternal wound. In a rat intramuscular SSI model, we observed that a single application of D-PLEX$_{100}$ reduced bacterial proliferation and infection as detected in macroscopic observations, microbiological assay and histopathological evidence of infection in the wound. We have also conducted *in vitro* and *in vivo* pharmacokinetics, safety and toxicology studies, in which we observed D-PLEX$_{100}$'s ability to release doxycycline over a prolonged period and that D-PLEX$_{100}$ was generally well-tolerated.

D-PLEX$_{100}$: Potential Ability to Treat and Prevent Antibiotic-Resistant Bacteria-Related Infections

Antibiotic resistance generally takes the form of relative resistance, wherein the indicated concentrations of API from systemic delivery are no longer effective, and the required concentration of API cannot be delivered safely via systemic administration. Because PLEX is designed to enable the prolonged exposure of a high localized concentration of doxycycline directly to the target site, we believe that D-PLEX$_{100}$ may be effective in treating and preventing bacterial infections that are otherwise resistant to antibiotics. In rabbit sternal wound models, we observed that a single application of D-PLEX$_{100}$ substantially reduced bacterial content and histopathological evidence of MRSA and *Klebsiella pneumoniae* infections, each of which are doxycycline-resistant, in the sternal wound. Further, we have observed evidence suggesting the effectiveness of D-PLEX$_{1000}$ in two investigator-initiated compassionate use cases of osteomyelitis patients identified with bacterial infections, including MRSA, who were not responding to intensive conventional antibiotic treatments and other conventional treatments. After a single application of D-PLEX$_{1000}$, the infection was eradicated and bone healing resulted in both patients. D-PLEX$_{100}$ received QIDP designation from the FDA for the prevention of sternal infection after cardiac surgery. The QIDP program is designed to expedite the development of novel drugs against important pathogens, including antibiotic-resistant bacteria.

D-PLEX$_{1000}$ for the Management of SSIs and Support of Bone Recovery in Orthopedic Surgeries

We have developed D-PLEX$_{1000}$, formerly known as BonyPid-1000, for use in orthopedic surgeries for the management of SSIs and support of bone recovery. D-PLEX$_{1000}$ incorporates doxycycline and a synthetic bone void filler, comprised of resorbable beta tricalcium phosphate, or β-TCP, granules. Upon implantation in the body, PLEX is designed to release the encapsulated doxycycline in controlled, predetermined amounts for up to four weeks, while the bone filler acts as a scaffold to support osteoconductive bone recovery.

We have completed enrollment of a clinical trial of the safety and effectiveness of D-PLEX$_{1000}$ for the treatment of open tibia fractures. The trial is a randomized and single blinded standard of care-controlled study in four patients with Gustilo I and II open long bone fractures, as well as 47 patients with Gustilo IIIA and IIIB open long bone fractures, a severe clinical condition resulting from a traumatic high energy event where the bone is severely damaged and exposed and, therefore, assumed to be contaminated by environmental bacteria. The Gustilo scale is a common classification for the severity of open fractures often used to guide the treatment regimen. The standard of care generally consists of administration of a systemic antibiotic before and after surgery, as well as irrigation and debridement. This multi-center study is being conducted at six sites in Israel and three in Asia. The objective of the study is to determine the safety and efficacy in bone healing of D-PLEX$_{1000}$ in addition to the standard of care in traumatic open fracture patients over a period of six and 12 months, as compared to the standard of care alone. The

primary performance endpoint is radiographic-assessed bone healing, as assessed by the presence of a callus in three out of four cortices, to be measured at the end of a 24-week follow-up period, based on independent blinded central radiographic evaluations of X-rays of the target fracture.

We recently announced interim results from this trial of patients to reach the six-month follow-up period, which was the evaluation point for the primary efficacy endpoint for the clinical trial. Patients were assessed on a monthly basis. No patients treated with D-PLEX$_{1000}$ in combination with the standard of care developed a deep bone infection at the six-month follow-up period. We observed that 92% of the 12 evaluable patients treated with D-PLEX$_{1000}$ in addition to the standard of care reached the primary performance endpoint, the presence of solid radiographic markers for bone healing, as assessed by the establishment of a callus in three out of four cortices, at the six-month follow-up period, as compared to 62% of the 13 evaluable of patients treated with the standard of care alone. Sixty percent of the patients treated with D-PLEX$_{1000}$ in combination with the standard of care had reached the primary performance endpoint by three months post-operation, as compared to 17% of patients treated with the standard of care alone. Only 36% of patients receiving the standard of care alone showed these markers at four months. It was only at the five-month evaluation that patients in the standard of care arm showed a comparable percentage of patients with these markers as that observed in the group treated with D-PLEX$_{1000}$ in combination with the standard of care at three months post-operation. Pain-free weight bearing was demonstrated in 65% of patients treated with D-PLEX$_{1000}$ in combination with the standard of care, as compared to 32% of the patients treated with the standard of care alone. We expect to report the full results of this trial in the second half of 2018. No product-related adverse events were reported.

Pilot Clinical Trials

We conducted two pilot clinical trials that assessed the safety and effectiveness of D-PLEX$_{1000}$ in patients with infected Gustilo IIIA and IIIB open long bone fractures. These trials were both open-label single arm clinical trials of D-PLEX$_{1000}$ in addition to the standard of care. We enrolled 19 patients with open long bone fractures. At the six-month follow up date, no deaths, amputations or other serious adverse product-related events were observed. We did not observe any bone infections at the treatment site in the six months following treatment.

While we do not plan to pursue further independent development of D-PLEX$_{1000}$, as we believe the prevention of SSIs in the orthopedic market can be adequately addressed by D-PLEX$_{100}$, we will evaluate potential collaborations to further the development of D-PLEX$_{1000}$.

D-PLEX$_{500}$ for the Treatment of Peri-Implantitis (In Collaboration with MIS)

We are developing D-PLEX$_{500}$, formerly known as BonyPid-500, with our collaborator, MIS Implants Technologies Ltd., a subsidiary of Dentsply Sirona Inc., for use in periodontal and oral/maxillofacial surgeries to treat peri-implantitis, a destructive inflammatory process affecting the soft and bone tissues surrounding dental implants. D-PLEX$_{500}$ incorporates doxycycline and a synthetic bone graft substitute comprised of resorbable β-TCP granules and is designed to fill and reconstruct bone defects caused by peri-implantitis. We have observed that D-PLEX$_{500}$ gradually reabsorbs and is replaced with bone during the healing process.

In collaboration with MIS, we have completed enrollment of a pilot clinical trial to assess the safety and effectiveness of D-PLEX$_{500}$ for intrabony peri-implantitis defects in 27 patients. The trial is a prospective, randomized, dual arm, open label study. This multi-center study is being conducted at two sites in Israel. The objective of the study is to determine the safety and effectiveness of D-PLEX$_{500}$ in addition to the standard of care in healing intrabony peri-implantitis defects in subjects undergoing surgical treatment of peri-implantitis disease over a period of twelve months. The

primary efficacy endpoint of the trial is the change in depth of the periodontal pocket from baseline to six months. We expect to report results from this trial in the second half of 2018.

We will pursue further development of D-PLEX$_{500}$ in dental indications only with a collaborator.

Future Clinical Development

Our PLEX platform technology may have broad applications for localized medical conditions other than the prevention of SSIs. We are pursuing research and development programs for our PLEX platform in a variety of potential indications, including for the treatment of SSIs, pain, inflammation and cancer.

PLEX for Pain

Our next application of PLEX is the development of novel therapies for the management of chronic or post-surgical pain. We are currently in preclinical development of a product candidate that pairs PLEX with a widely-used pain API. In our preclinical studies, we have observed periods of reduced pain that are longer than those provided by the standard of care as well as approved local long-acting delivery systems that apply the same widely-used pain API.

PLEX for Other Applications

We are conducting a research and development program that pairs PLEX with a widely-used corticosteroid for the treatment of inflammation. In our preclinical studies, we have observed prolonged reduction of inflammation using a fraction of the API that would otherwise be systemically administered.

We have also conducted a number of research and development programs that paired PLEX with anti-cancer agents, proteins, peptides, nucleic acids and growth factors. We continue to evaluate these research and development programs for potential development by us or in collaboration with leading biopharmaceutical companies.

Competition

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Our potential competitors include large and experienced companies that enjoy significant competitive advantages over us, such as greater financial, research and development, manufacturing, personnel and marketing resources, greater brand recognition, and more experience and expertise in obtaining marketing approvals from the FDA and foreign regulatory authorities. These companies may develop new drugs to treat the indications that we target, or seek to have existing drugs approved for use for the treatment of the indications that we target.

These potential competitors may therefore introduce competing products without our prior knowledge and without our ability to take preemptive measures in anticipation of their commercial launch. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in this industry. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis products that are more effective, easier to administer or less costly than our product candidates.

The current standard of care for preventing SSIs involves the implementation of a range of safety measures before, during and after surgery, including prophylactic and topical antibiotic administration, antiseptic measures and wound care. We anticipate that D-PLEX$_{100}$, if approved, could be used as a complementary, rather than competitive, addition to the current standard of care for the prevention of SSIs. In addition, we are aware of other approved treatments that can be

applied locally during surgery for the prevention of SSIs, including triclosan-coated antiseptic sutures and a resorbable gentamicin-collagen sponge. In orthopedic surgeries, we are aware of approved treatments for localized SSI management that pair bone cement premixed with an antibiotic.

We may also face competition from companies that are developing localized extended release delivery systems, including Pacira Pharmaceuticals, Inc., Flexion Therapeutics, Inc. and Kala Pharmaceuticals, Inc.

MIS Memorandum of Understanding

In February 2013, we entered into a memorandum of understanding with MIS pursuant to which we are entitled to receive certain milestone-based and sales-based compensation payments from MIS related to the development of D-PLEX$_{500}$. We agreed to grant MIS an exclusive right to market a specific dental application of D-PLEX$_{500}$ for a certain period commencing after our receipt of either EMA or FDA marketing approval and the beginning of commercialized sales of D-PLEX$_{500}$ in the applicable market. In the event that the FDA imposes certain additional requirements with respect to our clinical trials on D-PLEX$_{500}$, MIS is not obligated to undertake the expenses related to these additional requirements. We will retain all rights to our existing intellectual property and any intellectual property that we develop relating to D-PLEX$_{500}$ if the agreement is terminated. We are eligible to receive payments of $2.5 million in the aggregate from MIS upon the completion of certain clinical and regulatory milestones, including the receipt of marketing approval for D-PLEX$_{500}$ in the United States and/or the European Union. MIS may terminate the MOU at any time prior to the commercialization of D-PLEX$_{500}$, in which case we would be obligated to return all milestone payments we received under the MOU. As of December 31, 2017, we had received $600,000 in the aggregate in milestone payments from MIS pursuant to the MOU.

Manufacturing

Our product candidates are manufactured using a scalable self-assembly process with well-defined, robust unit operations. This highly specialized and precisely controlled manufacturing process enables us to manufacture product candidates reproducibly and efficiently for clinical and commercial applications. We are constructing a pilot manufacturing facility for the production of our product candidates adjacent to our administrative headquarters in Petach Tikva, Israel. We currently rely on a third party to conduct our product manufacturing and intend to do so, in whole or in part, through at least 2019 when our pilot manufacturing facility is expected to be completed. Our third-party contract manufacturer has advised us that it is in compliance with cGLP and cGMP for the manufacture of drug substance and product. We use additional third-party contract manufacturers for certain raw materials necessary to manufacture our product candidates. We intend to use a portion of the net proceeds of this offering to complete the build-out of this pilot manufacturing facility. We also intend to build a larger-scale cGMP manufacturing facility in Israel in the future, for which we intend to use a portion of the net proceeds of this offering.

Marketing, Sales and Distribution

Given our stage of development, we do not currently have any internal sales, marketing or distribution infrastructure or capabilities. We have recently formed a U.S. subsidiary, PolyPid Inc., to support our U.S. development and potential commercialization efforts.

In the event that we receive regulatory approvals for our products in markets outside of the United States, we intend, where appropriate, to pursue commercialization relationships, including strategic alliances and licensing, with pharmaceutical companies and other strategic partners, which are equipped to market or sell our products through their well-developed sales, marketing and distribution organizations in such countries.

In addition, we may out-license some or all of our worldwide patent rights to more than one party to achieve the fullest development, marketing and distribution of any products we develop.

Intellectual Property

Our patent estate includes patents and patent applications with claims directed to our PLEX, D-PLEX$_{100}$, D-PLEX$_{500}$ and D-PLEX$_{1000}$ product candidates, as well as broader claims for potential future product candidates. On a worldwide basis, our patent estate includes 104 issued patents and pending patent applications for our product candidates as well as for manufacturing processes and methods of treatment, as of December 31, 2017.

Our patents and patent applications mainly relate to a polymer-lipid-based platform for sustained release of an active pharmaceutical agent at a target site such as the site of a surgery. We currently have over thirty issued patents and several pending patent applications worldwide related to compositions for sustained release of an API, including a lipid-saturated matrix formed from a biodegradable polymer, as well as methods for producing such compositions and methods of treatment through the use of such compositions. We also have five issued patents and several pending patent applications worldwide related to compositions for sustained release of an API including a lipid-saturated matrix formed from a non-biodegradable polymer, as well as methods for producing such compositions and methods of treatment through the use of such compositions. We also have seven issued patents and several pending patent applications worldwide related to compositions for sustained release of a nucleic agent including a lipid-saturated matrix formed from a biodegradable polymer, as well as methods for producing such compositions and methods of treatment through the use of such compositions. We also have an issued Australian patent and a pending Indian patent application related to compositions for sustained release of peptidic molecules, as well as methods for producing such compositions and methods of treatment through the use of such compositions. We also have nine issued patents and several pending patent applications worldwide related to methods for treating bone fractures through the use of biocompatible fillers coated with sustained release antibiotic compositions, along with several pending patent applications worldwide related to methods for treating peri-implantitis and surgical site infections through similar processes. Our patent estate includes six granted United States patents as well as granted patents and/or pending patent applications in Australia, Brazil, Canada, China, the Eurasian Patent Organization, the European Patent Office, India, Israel, Japan, Mexico, New Zealand, the Philippines, Singapore, South Africa, South Korea, and Thailand. Our issued patents are expected to remain in effect until at least 2029.

In addition to patents, we have filed for and obtained trademark registration with the United States Patent and Trademark Office, or the USPTO, for ‘‘PolyPid’’ and ‘‘BonyPid’’. Furthermore, we rely upon trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position.

Preparing and filing patent applications is a joint endeavor of our research and development team and our in-house and external patent attorneys. Our patent attorneys conduct patent prior-art searches and then analyze the data in order to provide our research and development team with recommendations on a routine basis. This results in:

- protecting our product candidates that are under development;
- encouraging pharmaceutical companies to negotiate development agreements with us; and
- preventing competitors from attempting to design-around our inventions.

We initially submit applications to the USPTO as provisional patent applications. Then typically we continue by filing non-provisional patent applications under the Patent Cooperation Treaty, or PCT, which is an international patent law treaty that provides a unified procedure for filing a single

initial patent application to later seek patent protection for an invention in any number of the member states of the PCT. Although a PCT application does not itself issue as a patent, it acts as a placeholder allowing the applicant to seek protection in any of the member states through national-phase applications.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, packaging, recordkeeping, tracking, approval, import, export, distribution, advertising and promotion of our products.

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests that must be conducted in accordance with good laboratory practices, or GLPs;
- submission of an IND, which must become effective before clinical trials may begin;
- approval by an independent institutional review board, or IRB, for each clinical site or centrally before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed product candidate for its intended use, performed in accordance with good clinical practices, or GCPs;
- submission to the FDA of an NDA and payment of user fees;
- satisfactory completion of an FDA advisory committee review, if applicable;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with current good manufacturing practices, or cGMP, and good clinical practices, or GCPs;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- FDA approval of an NDA to permit commercial marketing for particular indications for use; and

- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

The testing and approval process requires substantial time, effort and financial resources. Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. Prior to commencing the first clinical trial with a product candidate, we must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical studies may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial by imposing a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial.

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, as well as amendments to previously submitted clinical trials. Further, an independent IRB for each study site proposing to conduct the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to study subjects before the clinical trial commences at that site. The IRB must continue to oversee the clinical trial while it is being conducted, including any changes to the study plans.

Regulatory authorities, an IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, if the drug has been associated with unexpected serious harm to subjects, or based on evolving business objectives or competitive climate. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may advise us to halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1 — Studies are initially conducted to test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution and excretion in healthy volunteers or subjects with the target disease or condition. If possible, phase 1 trials may also be used to gain an initial indication of product effectiveness.
- Phase 2 — Controlled studies are conducted with groups of subjects with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 — These clinical trials are undertaken in larger subject populations to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded subject population at multiple clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for

product labeling. These trials may be done globally to support global registrations so long as the global sites are also representative of the U.S. population and the conduct of the study at global sites comports with FDA regulations and guidance, such as compliance with GCPs.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information.

Clinical trials must be conducted under the supervision of qualified investigators in accordance with GCP requirements, which includes the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, and the review and approval of the study by an IRB. Investigators must also provide information to the clinical trial sponsors to allow the sponsors to make specified financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. Information about some clinical trials, including a description of the trial and trial results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FFDCA. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if SAEs occur.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Orange Book Listing

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

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

If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the holder of the NDA for the reference listed drug and the patent owner once the application has been accepted for filing by the FDA. The applicant may also elect to submit a ''section viii'' statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the applicant or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where a 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of a 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

Exclusivity

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

If a product is not eligible for the NCE exclusivity, it may be eligible for three years of exclusivity. Three-year exclusivity is available to the holder of an NDA, including a 505(b)(2) NDA, if one or more new clinical trials, other than bioavailability or bioequivalence trials, was essential to the approval of the application and was conducted or sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the particular condition of the new drug's approval or the change to a marketed product, such as a new formulation for a previously approved drug. Five-year and three-year exclusivity will not delay the submission or approval of a 505(b)(1) NDA; however, an applicant submitting a 505(b)(1) NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

In addition, under the Generating Antibiotic Incentives Now, or GAIN, Act, which was enacted as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, which was signed into law in July 2012, the FDA may designate a product as a qualified infectious disease product, or QIDP. In order to receive this designation, a drug must qualify as an antibiotic or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either (1) an antibiotic or antifungal resistant pathogen, including novel or emerging

infectious pathogens, or (2) a so-called ''qualifying pathogen'' found on a list of potentially dangerous, drug-resistant organisms to established and maintained by the FDA. A sponsor must request such designation before submitting a marketing application. We obtained a QIDP designation in February 2017 for D-PLEX$_{100}$ for the prevention of post-cardiac surgery sternal infection and may request additional QIDP designations for D-PLEX$_{100}$ or our other product candidates prior to submitting a marketing application for such product candidates, as appropriate. Upon approving a marketing application for a QIDP-designated product, the FDA will extend by an additional five years any non-patent marketing exclusivity period awarded, such as a three-year exclusivity period awarded for new clinical investigations of previously approved products. This extension is in addition to any pediatric exclusivity extension awarded, and the extension will be awarded only to a drug first approved on or after the date of enactment of the GAIN Act. The GAIN Act prohibits the grant of an exclusivity extension where the application is a supplement to an application for which an extension is in effect or has expired, is a subsequent application for a specified change to an approved product, or is an application for a product that does not meet the definition of QIDP based on the uses for which it is ultimately approved.

Hatch Waxman Amendments and the 505(b)(2) Regulatory Approval Process

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

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, breakthrough therapy designation, accelerated approval, and priority review, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical

needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

Under the fast track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the drug candidate. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need, or that the drug qualifies as a QIDP under the GAIN Act. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides additional opportunities for interaction with the FDA's review team and may allow for rolling review of NDA components before the completed application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. The FDA may decide to rescind the fast track designation if it determines that the qualifying criteria no longer apply.

In addition, a sponsor can request breakthrough therapy designation for a drug if it is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are eligible for intensive guidance from FDA on an efficient drug development program, organizational commitment to the development and review of the product including involvement of senior managers, and, like fast track products, are also eligible for rolling review of the NDA. Both fast track and breakthrough therapy products are also eligible for accelerated approval and/or priority review, if relevant criteria are met.

Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. A drug candidate approved on this basis is subject to rigorous post marketing compliance requirements, including the completion of Phase 4 or post approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post approval studies, or confirm a clinical benefit during post marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated approval regulations are subject to prior review by FDA.

Once an NDA is submitted for a product intended to treat a serious condition, the FDA may assign a priority review designation if FDA determines that the product, if approved, would provide a significant improvement in safety or effectiveness. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the current PDUFA agreement, these six and ten month review periods are measured from the 60-day filing date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review from the date of submission. Most products that are eligible for fast track breakthrough therapy designation are also likely to be considered appropriate to receive a priority review.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, the manufacturer of an investigational drug for a serious or life threatening disease is required to make available, such as by posting on its website, its policy on responding to requests for expanded access. Furthermore, fast track designation, breakthrough therapy designation, accelerated approval and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

NDA Submission and Review by the FDA

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

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements.

The FDA must refer applications for drugs that contain active ingredients, including any ester or salt of the active ingredients, that have not previously been approved by the FDA to an advisory committee or provide in an action letter a summary of the reasons for not referring it to an advisory committee. The FDA may also refer drugs which present difficult questions of safety, purity or potency to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts who review, evaluate and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontracts, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The FDA's NDA review times may differ based on whether the application is a standard review or priority review application. The FDA may give a priority review designation to drugs that are intended to treat serious conditions and provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has set the review goal of 10 months from the 60-day filing date to complete its initial review of a standard NDA for a new molecular entity, or NME, and make a decision on the application. For non-NME standard applications, the FDA has set the review goal of 10 months from the submission date to complete its initial review and to make a decision on the application. For priority review applications, the FDA has set the review goal of reviewing NME NDAs within six months of the 60-day filing date and non-NME applications within six months of the submission date. Such deadlines are referred to as the PDUFA date. The PDUFA date is only a goal and the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding the submission.

Once the FDA's review of the application is complete, the FDA will issue either a Complete Response Letter, or CRL, or approval letter. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing, or other information or analyses in order for the FDA to reconsider the application. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission. Even with the submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a risk evaluation and mitigation strategy, or REMS, as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The FDA may prevent or limit further marketing of a product, or impose additional post-marketing requirements, based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements, FDA notification and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed or may include contraindications, warnings or precautions in the product labeling, which has resulted in a Black Box warning. The FDA also may not approve the inclusion of labeling claims necessary for successful marketing. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-marketing studies.

Post-approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including manufacturing, periodic reporting, product sampling and distribution, advertising, promotion, drug shortage reporting, compliance with any post-approval requirements imposed as a conditional of approval such as Phase 4 clinical trials, REMS and surveillance, recordkeeping and reporting requirements, including adverse experiences.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any approved products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and to list their drug products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMPs and other requirements, which impose procedural and documentation requirements upon us and our third-party manufacturers.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented, or FDA notification. FDA regulations also require investigation and correction of any deviations from cGMPs and specifications, and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in withdrawal of marketing approval, mandatory revisions to the approved labeling to add new safety information or other limitations, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program, among other consequences.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA. Physicians, in their independent professional medical judgement, may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. We, however, are prohibited from marketing or promoting drugs for uses outside of the approved labeling.

In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act also imposes obligations on manufacturers of pharmaceutical products related to product and tracking and tracing.

Failure to comply with any of the FDA's requirements could result in significant adverse enforcement actions. These include a variety of administrative or judicial sanctions, such as refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, corporate integrity agreements, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement or civil or criminal penalties, including fines and imprisonment. It is also possible that failure to comply with the FDA's requirements relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. Any of these sanctions could result in adverse publicity, among other adverse consequences.

Other Healthcare Regulations

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education and other activities are subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services and its various divisions, including CMS and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense and state and local governments. Our business activities must comply with numerous healthcare laws and regulations, including those described below.

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

The federal civil and criminal false claims laws, including the federal False Claims Act, or FCA, prohibit, among other things, any person or entity from knowingly presenting, or causing to be

presented, a false claim for payment to, or approval by, the U.S. federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes ''any request or demand'' for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to ''cause'' the submission of false or fraudulent claims. The FCA also permits a private individual acting as a ''whistleblower'' to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; engaging in promotion for ''off-label'' uses; and submitting inflated best price information to the Medicaid Rebate Program.

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

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

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

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from government funded healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Coverage and Reimbursement

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement for the procedures utilizing our product candidates, performed by health care providers, once approved, will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which procedures, and the products utilized in such procedures, they will cover and establish reimbursement levels. Assuming coverage is obtained for procedures utilizing a given product, by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who undergo procedures for the treatment of their conditions, and their treating physicians, generally rely on third-party payors to reimburse all or part of the costs associated with the procedures which utilize our products. Treating physicians are unlikely to use and order our products unless coverage is provided and the reimbursement is adequate to cover all or a significant portion of the cost of the procedures which utilize our products. Therefore, coverage and adequate reimbursement for procedures, which utilize new products, is critical to the acceptance of such new products. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Government authorities and other third-party payors are developing increasingly sophisticated methods of cost containment, such as including price controls, restrictions on coverage and reimbursement and requirements for substitution of less expensive products and procedures. Increasingly, government and other third-party payors are increasingly challenging the prices charged for health care products and procedures, examining the cost effectiveness of procedures, and the products used in such procedures, in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement. Further, no uniform policy requirement for coverage and reimbursement exists among third-party payors in the United States, which causes significant uncertainty related to the insurance coverage and reimbursement of newly approved products, and the procedures which may utilize such newly approved products. Therefore, coverage and reimbursement can differ significantly from payor to payor and health care provider to health care provider. As a result, the coverage determination process is often a time-consuming and costly process that requires the provision of scientific and clinical support for the use of new products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There may be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that a product, or the procedures which utilize such product, will be paid for in all cases or at a rate which the health care providers who purchase those products will find cost effective. Additionally, we expect pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes.

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

Healthcare Reform Measures

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the pharmaceutical industry in the United States has been affected by the passage of PPACA, which, among other things, imposed new fees on entities that manufacture or import certain branded prescription drugs and expanded pharmaceutical manufacturer obligations to provide discounts and rebates to certain government programs, expanded health care fraud and abuse laws, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, imposed an additional rebate similar to an inflation penalty on new formulations of drugs, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, expanded the 340B program which caps the price at which manufacturers can sell covered outpatient pharmaceuticals to specified hospitals, clinics and community health centers, and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the ''individual mandate''. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called ''Cadillac'' tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Congress will likely consider other legislation to replace elements of the PPACA.

Other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2.0% per fiscal year, which went into effect in April 2013, and due to subsequent legislative amendments, will remain in effect through 2027 unless additional U.S. Congressional action is taken. In addition, 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. Additional changes that may affect our business include new quality and payment programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which will be fully implemented in 2019.

In addition, there has been particular and increasing legislative and enforcement interest in the United States with respect to drug pricing practices in recent years, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of prescription drugs under Medicare and reform government program reimbursement methodologies for pharmaceutical products. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In the future, there will likely continue to be proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

The Foreign Corrupt Practices Act

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

Non-U.S. Government Regulation

To the extent that any of our product candidates, once approved, are sold in a country outside of the United States, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

In order to market our future products in the EEA (which is comprised of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein) and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

- the Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency, or EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union; and

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Data and Marketing Exclusivity

In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union during a period of eight years from the date on which the reference product was first authorized in the European Union. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the European Union until 10 years have elapsed from the initial authorization of the reference product in the European Union. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Pediatric Investigation Plan

In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the European Union and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension.

Orphan Drug Designation

In the EEA, a medicinal product can be designated as an orphan drug if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug

in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

In the EEA, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, the EMA or the member state competent authorities, cannot accept another application for a marketing authorization, or grant a marketing authorization, for a similar medicinal product for the same indication. The period of market exclusivity is extended by two years for medicines that have also complied with an agreed PIP.

This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of ''clinical superiority'' by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant are eligible for incentives made available by the European Union and its Member States to support research into, and the development and availability of, orphan drugs.

Employees

As of December 31, 2017, we had 55 full-time employees and five part-time employees, all of whom were based in Israel. Of these employees, 41 are primarily engaged in research and development activities and 14 are primarily engaged in general and administrative matters. A total of 13 employees have an M.D. or Ph.D. degree. None of our employees is represented by a labor union. We have never experienced any employment-related work stoppages and believe our relationships with our employees are good.

Israeli labor laws govern the length of the workday and workweek, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination, payments to the National Insurance Institute, and other conditions of employment and include equal opportunity and anti-discrimination laws. While none of our employees is 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 in Israel by order of the Israeli Ministry of Economy and Industry. These provisions primarily concern pension fund benefits for all employees, insurance for work-related accidents, recuperation pay and travel expenses. We generally provide our employees with benefits and working conditions beyond the required minimums.

Facilities

Our principal executive offices are located at 18 Hasivim Street, Petach Tikva 4959376, Israel, where we lease an approximately 31,000 square foot facility. This Israeli facility houses our administrative headquarters, research and development laboratories and pilot manufacturing facility. We also maintain an office at 47 Maple Street, Suite 302A, Summit, New Jersey, which serves as the headquarters for our U.S. subsidiary. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional or alternative spaces will be available in the future on

commercially reasonable terms. We also intend to build a larger-scale cGMP manufacturing facility in Israel in the future.

Environmental, Health and Safety Matters

We are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions, primarily Israel, governing, among other things: the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; chemicals, air, water and ground contamination; air emissions and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials and sewage. Our operations use chemicals and produce waste materials and sewage and require permits from various governmental authorities including, local municipal authorities, the Ministry of Environmental Protection and the Ministry of Health. The Ministry of Environmental Protection and the Ministry of Health, local authorities and the municipal water and sewage company conduct periodic inspections in order to review and ensure our compliance with the various regulations. These laws, regulations and permits could potentially require the expenditure by us of significant amounts for compliance or remediation. If we fail to comply with such laws, regulations or permits, we may be subject to fines and other civil, administrative or criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. In addition, we may be required to pay damages or civil judgments in respect of third-party claims, including those relating to personal injury (including exposure to hazardous substances we use, store, handle, transport, manufacture or dispose of), property damage or contribution claims. Some environmental, health and safety laws allow for strict, joint and several liability for remediation costs, regardless of comparative fault. We may be identified as a responsible party under such laws. Such developments could have a material adverse effect on our business, financial condition and results of operations. In addition, laws and regulations relating to environmental, health and safety matters are often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities that were previously permitted.

Legal Proceedings

We are not currently party to any material legal proceedings.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors, including their ages as of December 31, 2017:

Name	Age	Position
Executive Officers		
Amir Weisberg	62	Chief Executive Officer and Director
Dikla Czaczkes Akselbrad	44	Chief Financial Officer
Noam Emanuel, Ph.D.	58	Chief Technology Officer and Director
Jack Eitan Kyiet	48	Chief Operating Officer and Director
Dan Jacob Gelvan, Ph.D.	53	Executive Vice President
Non-Employee Directors		
Jacob Harel	62	Chairman
Yechezkel Barenholz, Ph.D.	76	Director
Eli Frydman, Ph.D.	51	Director
Chaim Hurvitz	57	Director
Anat Tsour Segal	51	Director

Our Executive Officers

Amir Weisberg has served as our Chief Executive Officer and a director since October 2010. From 2007 to 2010, Mr. Weisberg served as the chief executive officer of Implant Protection Ltd. He has over 20 years of entrepreneurial experience, including as chief executive officer of several startup companies in the life science sphere.

Dikla Czaczkes Akselbrad has served as our Chief Financial Officer since December 2016. Prior to that time, Ms. Czaczkes Akselbrad served as our Chief Strategy Officer from July 2014 to December 2016, and as chief financial officer of Compugen Ltd., a publicly-traded immuno-oncology company, from February 2008 to May 2014. She holds a BA in accounting and economics and an MBA in finance, both from Tel Aviv University, and is a certified public accountant in Israel.

Noam Emanuel, Ph.D. has served as our Chief Technology Officer and a director since October 2010. Dr. Emanuel has over 15 years of experience in drug development, drug delivery and immunology, including with respect to local, systemic and trans-dermal drug delivery systems, as well as in imaging and diagnostics. He holds a Ph.D. in immunology and drug delivery from the Hebrew University of Jerusalem.

Jack Eitan Kyiet has served as our Chief Operating Officer since June 2013 and a director since October 2013. He has held several business development and operations positions in publicly traded multi-national medical device companies. From January 2011 to July 2013, he served as director of worldwide supply chain at Biosense Webster, a Johnson & Johnson medical device company. He holds an LL.B. and an MBA from the Haifa University.

Dan Jacob Gelvan, Ph.D. has served as our Executive Vice President since April 2017. Prior to that time, Dr. Gelvan served as managing director of life science at Aurum Ventures M.K.I. Ltd. from June 2005 to December 2016. He served as a member of our board of directors from January 2014 to February 2017, as well as a member of the board of directors of Vascular Biogenics Ltd, a publicly-traded biopharmaceutical company, from May 2005 to December 2016. He holds a BA and MA in economics from The Hebrew University of Jerusalem and a Ph.D. in business economics from Roskilde University in Denmark.

Our Non-Employee Directors

Jacob Harel has served as a director since November 2017 and the chairman of our board of directors since December 2017. Mr. Harel currently serves as the chief executive officer of The Harel Group, a consulting firm that provides business development support to pharmaceutical companies, which he founded in 2014. He previously served for over 27 years in various roles at Merck & Co., Inc., most recently as the executive director of corporate business development from 2008 to April 2014. Mr. Harel currently serves as a member of the board of directors of Insuline Medical. He holds a B.S. in economics from Haifa University and an MBA from Tel Aviv University.

Prof. Yechezkel Barenholz, Ph.D. has served as a director since April 2008. Prof. Barenholz currently serves as head of the Laboratory of Membrane and Liposome Research at the Department of Biochemistry of the Hadassah Medical School at the Hebrew University of Jerusalem, a position he has held since 1978. He is a recognized world expert in the field of drug delivery, and is the co-inventor of Doxil, the first nano-delivery system approved by the FDA and marketed by major pharmaceutical companies. He holds a B.Sc., M.Sc. and Ph.D. in biochemistry from the Hebrew University of Jerusalem.

Eli Frydman, Ph.D. has served as a director since November 2016. Dr. Frydman currently serves as managing director of healthcare of Aurum Ventures M.K.I. Ltd., a position he has held since November 2016. Prior to that time, he served as chief business officer of FutuRx Ltd from September 2013 to March 2016 and vice president, chief operating officer of Aposense Ltd from March 2005 to August 2013. He currently serves as a director of Precise Bio, Inc., Beta-o2 Technologies Ltc., LifeBond Ltd. and Nucleix Ltd. He holds a B.Sc. in chemistry and physics from Tel Aviv University, a M.Sc. and Ph.D. in chemistry, materials and nanotechnology from the Weizmann Institute of Science and an MBA from the ENPC School of International Management.

Chaim Hurvitz has served as a director since February 2016. Mr. Hurvitz currently serves as chief executive officer of CH Health, a private venture capital firm, a position he has held since May 2011. He also currently serves as chairman of Galmed Pharmaceuticals Ltd. and chairman of the pharmaceuticals branch of the Manufacturer's Association of Israel. Mr. Hurvitz previously served as a member of the board of directors of UroGen Pharma Ltd. Mr. Hurvitz served as a director of Teva Pharmaceutical Industries Ltd. from 2010 to 2014 and Aposense Ltd. from 2010 to 2014. He holds a B.A. in political science and economics from Tel Aviv University.

Anat Tsour Segal has served as a director since April 2008. Ms. Segal founded Anat Segal Consulting & Technology Investments, an independent consulting and investment banking practice advising Israeli technology and healthcare companies, in January 2000. From April 2003 to February 2016, she also served as the founder, chief executive officer and a director of Xenia Venture Capital. She holds a B.A. in economics and management, an MBA in finance and an LL.B. from Tel Aviv University.

Arrangements Concerning Election of Directors; Family Relationships

Our board of directors consists of seven directors, each of whom will continue to serve pursuant to their appointment until the first annual general meeting of shareholders held after this offering. We are not a party to, and are not aware of, any voting agreements among our shareholders. In addition, there are no family relationships among our executive officers and directors.

Corporate Governance Practices

Companies incorporated under the laws of the State of Israel, whose shares are publicly traded, including companies with shares listed on The Nasdaq Global 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 the composition and responsibilities of the audit committee and the compensation committee (subject to certain exceptions that we intend to utilize), and a requirement to have an internal auditor. This is the case even if our shares are not listed on the Tel Aviv Stock Exchange, or TASE, which our shares are not expected to be. These requirements are in addition to the corporate governance requirements imposed by the Nasdaq Rules and other applicable provisions of U.S. securities laws to which we will become subject (as a foreign private issuer) upon the closing of this offering and the listing of our ordinary shares on The Nasdaq Global Market. Under the Nasdaq Rules, a foreign private issuer may generally follow its home country rules of corporate governance in lieu of the comparable requirements of the Nasdaq Rules, except for certain matters including the composition and responsibilities of the audit committee.

We intend to rely on this ''home country practice exemption'' with respect to the following Nasdaq requirements:

- *Quorum.* As permitted under the Israeli Companies Law and pursuant to our amended and restated articles of association to be effective upon the closing of this offering, 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 Israeli Companies Law, who hold at least 33⅓% of the voting power of our shares. A meeting adjourned for lack of a quorum is generally adjourned to the same day in the following week at the same time and place or to a later time or date if so specified in the summons or notice of the meeting. At the reconvened meeting, any shareholder present in person or by proxy shall constitute a lawful quorum, instead of 33⅓% of the issued share capital required under the Nasdaq Rules.
- *Proxy Statements.* We will not be required to and, in reliance on home country practice, we do not intend to comply with certain Nasdaq Rules regarding the provision of proxy statements for general meetings of shareholders. Israeli corporate law does not have a regulatory regime for the solicitation of proxies. We intend to provide notice convening an annual general meeting, including an agenda and other relevant documents.
- *Shareholder Approval.* We will not be required to and, in reliance on home country practice, we do not intend to comply with certain Nasdaq Rules regarding shareholder approval for certain issuances of securities under Nasdaq Rule 5635. In particular, under the Nasdaq Rules, 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 (or such persons collectively have a 10% or greater interest) in the target company or the assets to be acquired or the consideration to be received and the present or potential issuance of ordinary shares, or securities convertible into or exercisable for ordinary shares, could result in an increase in outstanding common shares or voting power of 5% or more; (ii) the issuance of shares leading to a change of control; (iii) adoption or amendment of a stock option or purchase plan or other equity compensation arrangements, pursuant to which stock may be acquired by officers, directors, employees or consultants (with certain limited exception); and (iv) issuances of 20% or more of the shares or voting rights (including securities convertible into, or exercisable for, equity) of a listed company via a private placement (and/or via sales by directors or 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 Israeli Companies Law, the adoption of, and material changes to, equity-based compensation plans generally require the approval of the board of directors and the compensation committee of the board of directors (for details regarding the

approvals required under the Israeli Companies Law for the approval of compensation of the chief executive officer, all other executive officers and directors, see below under ''Approval of Related Party Transactions under Israeli Law — Disclosure of Personal Interests of an Office Holder and Approval of Certain Transactions,'' and ''Approval of Related Party Transactions under Israeli Law — Disclosure of Personal Interests of a Shareholder and Approval of Certain Transactions'' respectively).

Other than as stated above, we currently intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act, the rules adopted by the SEC and The Nasdaq Global Market's listing standards. Nevertheless, we may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq corporate governance rules. Following our home country governance practices, as opposed to the requirements that would otherwise apply to a company listed on Nasdaq, may provide less protection than is accorded to investors under the Nasdaq listing requirements applicable to domestic issuers. For more information, see ''Risk Factors — As a foreign private issuer, we are permitted, and intend, to follow certain home country corporate governance practices instead of otherwise applicable Nasdaq requirements, and we will not be subject to certain U.S. securities laws including, but not limited to, U.S. proxy rules and the filing of certain Exchange Act reports.''

Board Practices

Board of Directors

Under the Israeli Companies Law, our board of directors is responsible for setting our general policies and supervising the performance of management. Our board of directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our board of directors. Our Chief Executive Officer is appointed by, and serves at the discretion of, our board of directors, subject to the terms of the employment agreement that we have entered into with him. All other executive officers are also appointed by our board of directors, and are subject to the terms of any applicable employment agreements that we may enter into with them.

Under our amended and restated articles of association, to be effective upon the closing of this offering, our board of directors must consist of at least five directors and not more than eleven directors. Our board of directors will consist of eight directors upon the closing of this offering. Other than vacancies to be filled through selection by the remaining members of our board, the Israeli Companies Law and our amended and restated articles of association provide that directors are elected at the annual general meeting of our shareholders by a vote of the majority of the total voting power of our company voting in person, by proxy or by other voting instrument at that meeting. We have only one class of directors.

Under the Israeli Companies Law, our board of directors is required to employ independent judgment and discretion when voting, and is prohibited from entering into any voting arrangements with respect to actions taken at meetings of the board. Further, the Israeli Companies Law provides that in the event a director learns about an alleged breach of law or improper conduct of business relating to a company matter, said director must promptly take action to summon a meeting of the board of directors to address any such breach.

Notwithstanding the exemptions available to foreign private issuers under Nasdaq Rules, we intend to follow the requirements of the Nasdaq Rules with regard to the process of nominating directors by means of our compensation, nominating and corporate governance committee, which is comprised of directors who our board has deemed to be independent under Nasdaq Rules.

In addition, our amended and restated articles of association allow our board of directors to appoint directors to fill vacancies on our board of directors, including filling empty board seats up to the maximum number of directors permitted under our articles of association, for a term of office equal to the remaining period of the term of office of each director whose office has been vacated. Vacancies on our board of directors may be filled by a vote of a simple majority of the directors then in office. A director so appointed will hold office until the next annual general meeting of our shareholders in which the other directors then in office are proposed to be replaced or reappointed.

Directors may be removed from office by a resolution at a general meeting of shareholders adopted by a vote of 65% of the total voting power of our company in accordance with the Israeli Companies Law and our amended and restated articles of association.

Under the Israeli Companies Law, and except as described below, we would be required to include on our board of directors at least two members, each of whom qualifies as an external director, and as to whom special qualifications and other provisions would be applicable. We would also be required to include one such external director on each of our board committees.

Under regulations promulgated under the Israeli Companies Law, Israeli companies whose shares are traded on stock exchanges such as the Nasdaq Stock Market that do not have a controlling shareholder (as defined therein) and which comply with the requirements of the jurisdiction where the company's shares are traded with respect to the appointment of independent directors and the composition of an audit committee and compensation committee, may elect not to follow the Israeli Companies Law requirements with respect to the composition of its audit committee and compensation committee and the appointment of external directors. As we do not have a controlling shareholder, we intend to comply with the requirements of the Nasdaq Stock Market with respect to the composition of our board and such committees, and therefore we will be exempt from the Israeli Companies Law requirements with respect thereto, including the appointment of external directors.

Director Independence

Although not required of foreign private issuers under Nasdaq Rules, we intend to comply with the requirements thereunder applicable to domestic listed companies that a majority of the board of directors be deemed to be independent under such rules, as well as the independence requirements that would be applicable to our audit committee and compensation, nominating and corporate governance committee if we were a domestic listed company, as described below. In light of this obligation, our board of directors has undertaken a review of the independence of our directors under current rules and regulations of the SEC and Nasdaq Rules and considered whether any of our directors has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning such director's background, employment and affiliations, including family relationships, our board of directors determined that Yechezkel Barenholz, Eli Frydman, Jacob Harel, Chaim Hurvitz and Anat Tsour Segal, representing five of our eight directors, are ''independent directors'' as defined under current rules and regulations of the SEC and Nasdaq Rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them described in ''Certain Relationships and Related Party Transactions.''

Leadership Structure of the Board

In accordance with the Israeli Companies Law and our amended and restated articles of association, our board of directors is required to appoint one of its members to serve as chairman of the board of directors. Our board of directors has appointed Jacob Harel to serve as chairman of the board of directors.

Board Committees

Under the Israeli Companies Law and our amended and restated articles of association, our board of directors is permitted to form committees, and to delegate to any such committee powers allotted to the board of directors, subject to certain exceptions. In general, the board of directors may overturn a resolution adopted by a committee it has formed; provided, however, that the board's decision shall not affect the ability of third parties, who were not aware of such decision, to rely on the committee's resolution prior to the time it is overturned. Only members of the board of directors can be members of a board committee, unless the committee is solely advisory.

Audit Committee

Following the listing of our ordinary shares on The Nasdaq Global Market, our audit committee will consist of Jacob Harel and Anat Tsour Segal.

Israeli Companies Law Requirements

Under the Israeli Companies Law, we will be required to appoint an audit committee following the closing of this offering.

Nasdaq Listing Requirements

Under the Nasdaq 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. We are permitted to phase-in our compliance with the independent audit committee requirements set forth in the Nasdaq Rules and the SEC rules, as follows: (1) we must have one independent member at the time of listing, (2) we must have a majority of independent members within 90 days of listing and (3) we must have all independent members within one year of listing. We expect that, within 90 days of our listing on the Nasdaq Stock Market, a third independent director for audit committee purposes (as determined under the Nasdaq Rules and the SEC rules) will have been added to our audit committee.

All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq Stock Market. Our board of directors has determined that is an audit committee financial expert as such term is defined by the SEC rules and has the requisite financial experience as defined by the Nasdaq Rules. Each of the members of our audit committee is ''independent'' as such term is defined in Rule 10A-3(b)(1) under the Exchange Act and satisfies the independent director requirements under the Nasdaq Rules.

Audit Committee Role

Our audit committee charter, to be effective upon the listing of our shares on The Nasdaq Global Market, sets forth the responsibilities of the audit committee consistent with the rules and

regulations of the SEC and the Nasdaq Rules, as well as the requirements for such committee under the Israeli 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 auditors are independent of management.

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

- 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;
- 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 the Israeli Companies Law) (see ''Approval of Related Party Transactions under Israeli Law — Fiduciary Duties of Directors and Executive Officers'');
- establishing the approval process for certain transactions with a controlling shareholder or in which a controlling shareholder has a personal interest;
- where the board of directors approves the working plan of the internal auditor, examining such working plan before its submission to the board of directors and proposing amendments thereto;
- examining our internal audit controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to fulfill his responsibilities;
- examining the scope of our auditor's work and compensation and submitting a recommendation with respect thereto to our board of directors, depending on which of them is considering the appointment of our auditor; and
- establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees.

Compensation, Nominating and Corporate Governance Committee and Compensation Policy

Upon the listing of our ordinary shares on The Nasdaq Global Market, we intend to establish a compensation, nominating and corporate governance committee. The composition of our compensation, nominating and corporate governance committee meets the requirements for and guidance under the Nasdaq Rules and current SEC rules and regulations applicable to domestic issuers. The members of this committee will be Eli Frydman, Jacob Harel, Chaim Hurvitz and Anat Tsour Segal, each of whom is independent in accordance with the Nasdaq rules.

Israeli Companies Law Requirements

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

The duties of the compensation committee under the Israeli Companies Law, 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, nominating and corporate governance committee, and will need to be approved by the company's shareholders, which approval requires what we refer to as a Special Majority Approval for Compensation. A Special Majority Approval for Compensation requires shareholder approval by a majority vote of the shares present and voting at a meeting of shareholders called for such purpose, provided that either: (i) 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 abstentions; or (ii) 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. Our board of directors has adopted, and our shareholders have approved, a compensation policy to be effective in connection upon the consummation of this offering, which policy will be in effect until the fifth anniversary of this offering.

The compensation policy must (subject to certain exemptions) set the framework and limitation 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 long-term objectives, business plan and policies, 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 education, 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 relationship between the terms offered and the average compensation of the company's personnel;
- the impact of disparities in salary upon work relationships in the company;
- the possibility of reducing variable compensation at the discretion of the board of directors;
- the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and
- as to severance compensation, 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 restated in the company's financial statements;
- the minimum holding or vesting period for variable, equity-based compensation; and
- maximum limits for severance compensation.

Compensation, Nominating and Corporate Governance Committee Roles

The compensation, nominating and corporate governance committee is responsible for (i) recommending the compensation policy to our board of directors for its approval (and subsequent approval by our shareholders) and (ii) duties related to the compensation policy and to the compensation of our office holders, including:

- recommending whether a compensation policy should continue in effect, if the then-current policy has a term of greater than five years from a company's initial public offering, or otherwise three years (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur five years from a company's initial public offering, or otherwise every three years);
- recommending to the board of directors periodic updates to the compensation policy;
- assessing implementation of the compensation policy;
- determining whether to approve the terms of compensation of certain office holders which, according to the Israeli Companies Law, require the committee's approval; and
- determining whether the compensation terms of a candidate for the position of the chief executive officer of the company needs to be brought to approval of the shareholders.

Our compensation, nominating and corporate governance charter, to be effective upon the closing of this offering, sets forth the responsibilities of the compensation, nominating and corporate committee, which include:

- the responsibilities set forth in the compensation policy;
- reviewing and approving the granting of options and other incentive awards to the extent such authority is delegated by our board of directors; and
- reviewing, evaluating and making recommendations regarding the compensation and benefits for our non-employee directors.

In addition, our compensation, nominating and corporate governance committee is responsible for:

- overseeing our corporate governance functions on behalf of the board;
- making recommendations to the board regarding corporate governance issues;
- identifying and evaluating candidates to serve as our directors consistent with the criteria approved by the board;
- reviewing and evaluating the performance of the board
- serving as a focal point for communication between director candidates, non-committee directors and our management;

- selecting or recommending to the board for selection candidates to the board; and
- making other recommendations to the board regarding affairs relating to our directors.

Disclosure of Compensation of Executive Officers

For so long as we qualify as a foreign private issuer, we are not required to comply with the proxy rules applicable to U.S. domestic companies, including the requirement applicable to emerging growth companies to disclose the compensation of our Chief Executive Officer, Chief Financial Officer and other three most highly compensated executive officers on an individual, rather than on an aggregate, basis. Nevertheless, under regulations promulgated under the Israeli Companies Law, we will be required, after we become a public company, to disclose the annual compensation of our five most highly compensated office holders (as defined under the Israeli Companies Law) on an individual basis. This disclosure will not be as extensive as that required of a U.S. domestic issuer. We intend to commence providing such disclosure, at the latest, in the notice (which is generally part of the proxy statement) for our first annual general meeting of shareholders following this offering, which will be furnished under cover of a Report of Foreign Private Issuer on Form 6-K, or we may elect to provide such information at an earlier date.

Internal Auditor

Under the Israeli Companies Law, the board of directors of an Israeli public company must appoint an internal auditor recommended by the audit committee. An internal auditor may not, among other things, be:

- a person (or a relative of a person) who holds 5% or more 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 its behalf.

The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures, and to report to the chief executive officer, the chairman of the board and the chairman of the audit committee. The internal auditor is entitled to receive notice of audit committee meetings and to participate in them. In addition, the internal auditor may request that the chairman of the audit committee convene a meeting within a reasonable time to discuss an issue raised by the internal auditor. The internal auditor is responsible for preparing a proposal for an annual or periodical audit plan and submit such plan to the board of directors or the audit committee for their approval. We intend to appoint an internal auditor following the closing of this offering.

Approval of Related Party Transactions under Israeli Law

Fiduciary Duties of Directors and Executive Officers

The Israeli Companies Law codifies the fiduciary duties that office holders owe to a company. Each person listed in the table under ''Executive Officers and Directors'' is an office holder under the Israeli 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 includes an obligation 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 Israeli 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 action 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 also 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 person has no personal interest in the matter. An office holder is not, however, required 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 Israeli Companies Law, an ''extraordinary transaction'' is defined as a transaction (including a unilateral decision by the company) that:

- is not in the ordinary course of business;
- is not on market terms; or
- 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, which is not an extraordinary 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. 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 his or her duty of loyalty. However, a company may not approve a transaction or action that is not in 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 first by the company's audit committee and subsequently by the board of directors.

The compensation of, or an undertaking to indemnify or insure, an office holder who is not a director generally requires approval first by the company's compensation committee, then by the company's board of directors. If such compensation arrangement or an undertaking to indemnify or insure is inconsistent with the company's stated compensation policy, or if the office holder is the chief executive officer (apart from a number of specific exceptions), then such arrangement is further subject to a Special Majority Approval for Compensation. If the shareholders of a company do not approve the compensation terms of office holders at a meeting of the shareholders, other than directors, the compensation committee and board of directors may override the shareholders' decision, subject to certain conditions. Arrangements regarding the compensation, indemnification or insurance of a director require the approval of the compensation committee, board of directors and shareholders by simple majority, in that order, and under certain circumstances, a Special Majority 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 audit 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. If a majority of the members of the audit committee or the board of directors (as applicable) has a personal interest in the approval of a transaction, then all directors may participate in discussions of the audit committee or the board of directors (as applicable) on such transaction and the voting on approval thereof, but shareholder approval is also required for such transaction.

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

Pursuant to Israeli 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, the board of directors and the shareholders of the company, in that order, is required for (i) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, (ii) the engagement with a controlling shareholder or his or her relative, directly or indirectly, for the provision of services to the company, (iii) the terms of engagement and compensation of a controlling shareholder or his or her relative who is not an office holder or (iv) the employment of a controlling shareholder or his or her relative by the company, other than as an office holder. In addition, the 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 approves 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 aggregate voting rights in the company.

To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years and under certain conditions, five years from a company's initial public offering, approval is required at the end of such period 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.

Pursuant to regulations promulgated under the Israeli Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors or other office holders, that would otherwise require approval of a company's shareholders may be exempt from shareholder approval under certain conditions.

Shareholder Duties

Pursuant to the Israeli Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the company and other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at 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.

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

In addition, certain shareholders have a duty of fairness toward the company. These shareholders include a controlling shareholder, a shareholder who knows that he or she has the power to determine the outcome of a shareholder vote and a 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 Israeli 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 Israeli 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 amended and restated articles of association which will be effective upon the closing of this offering include such a provision. A company may not exculpate in advance a director from liability arising out of a breach of the duty of care with respect to a distribution.

Under the Israeli 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:

- financial 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 (1) 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 (i) no indictment was filed against such office holder as a result of such investigation or proceeding, and (ii) no financial liability 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 (2) 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 Israeli Companies 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 the 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 financial liability imposed on the office holder in favor of a third party.

Under the Israeli 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 the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, civil fine, monetary sanction or forfeit levied against the office holder.

Under the Israeli 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 — Fiduciary Duties of Directors and Executive Officers.''

Our amended and restated articles of association to be effective upon the closing of this offering will permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by the Israeli Companies Law.

We intend to obtain directors and officers liability insurance for the benefit of our office holders and intend to increase such coverage in an amount standard for a company of our size prior to the closing of this offering. We intend to maintain such increased coverage and pay all premiums thereunder to the fullest extent permitted by the Israeli Companies Law. In addition, prior to the closing of this offering, we intend to enter into agreements with each of our directors and executive officers exculpating them from liability to us for damages caused to us as a result of a breach of duty of care and undertaking to indemnify them, in each case, to the fullest extent permitted by our amended and restated articles of association to be effective upon the closing of this offering and Israeli law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance. In the opinion of the SEC, however, indemnification of directors and office holders for liabilities arising under the Securities Act is against public policy and therefore unenforceable.

Code of Business Conduct and Ethics

We will adopt, effective upon the consummation of this offering, 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. Upon the effectiveness of the registration statement of which this prospectus forms a part, the full text of the Code of Business Conduct and Ethics will be posted on our website at www.polypid.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code 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 Form 20-F, if a waiver or amendment of the Code of Business Conduct and 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.

Compensation of Executive Officers and Directors

The aggregate compensation paid and equity-based compensation and other payments expensed by us to our directors and executive officers with respect to the year ended December 31, 2017 was $2.7 million. This amount does not include business travel, relocation, professional and business association dues and expenses reimbursed to office holders, and other benefits commonly reimbursed or paid by companies in our industry.

As of December 31, 2017, options to purchase 1,053,844 ordinary shares granted to our directors and executive officers were outstanding under our 2012 Share Option Plan at a weighted average exercise price of $4.40 per share. Such number, and the following table, excludes options to purchase up to 546,632 ordinary shares, which are contingent upon the closing of this offering.

The following table sets forth information regarding options granted to our executive officers and directors during the year ended December 31, 2017:

Name	Grant Date	Stock Options	Exercise Price	Expiration Date
Dan Jacob Gelvan	May 25, 2017	50,000	$4.00	May 25, 2027
Dan Jacob Gelvan	November 2, 2017	8,750	$7.36	November 2, 2027
Chaim Hurvitz	June 1, 2017	191,823	$3.92	June 1, 2027
Chaim Hurvitz	November 2, 2017	18,750	$7.36	November 2, 2027
Anat Tsour Segal	June 1, 2017	15,000	$3.92	June 1, 2027
Anat Tsour Segal	November 2, 2017	18,750	$7.36	November 2, 2027
Eli Frydman	November 2, 2017	18,750	$7.36	November 2, 2027

Our Chief Executive Officer, Amir Weisberg, and our Chief Technology Officer, Noam Emanuel, each will receive a bonus payment in the amount of 1.0% of the net proceeds to be received by us in connection with this offering, and to our Chief Financial Officer, Dikla Czaczkes Akselbrad, will receive a bonus payment in the amount of 0.5% of the net proceeds to be received by us in connection with this offering, in each case excluding any funds received from our existing shareholders. Upon the closing of this offering, our Chief Operating Officer, Jack Eitan Kyiet, will receive a bonus payment equal to approximately $30,000. The following table sets forth information regarding options granted to certain executive officers and directors, which options shall terminate in the event that this offering has not occurred within 11 months of the grant date:

Name	Grant Date	Stock Options	Exercise Price	Expiration Date
Amir Weisberg	November 2, 2017	162,500	$7.36	November 2, 2027
Dikla Czaczkes Akselbrad	November 2, 2017	75,000	$7.36	November 2, 2027
Noam Emanuel	November 2, 2017	162,500	$7.36	November 2, 2027
Jack Eitan Kyiet	November 2, 2017	18,750	$7.36	November 2, 2027
Chaim Hurvitz	June 1, 2017	127,882	$3.92	June 1, 2027

Our board of directors has adopted, and our shareholders have approved, a compensation policy to be effective upon the consummation of this offering, which will provide for cash and equity compensation to be paid to our non-employee directors for their service on the board and its committees. Pursuant to the compensation policy, the maximum annual cash compensation to be paid for service on our board of directors is $40,000, or $60,000 for service as the chairperson of our board. In addition, pursuant to the compensation policy, we may also provide additional compensation for service on our board committees as follows: $7,500 for service on our audit committee, or $15,000 for service as the chairperson of our audit committee, and $5,000 for service on our compensation, nominating and corporate governance committee, or $10,000 for service as the chairperson of our compensation, nominating and corporate governance committee. In addition, we intend to award equity compensation in the form of options to each of our non-employee directors who are serving as of the consummation of this offering to purchase ordinary shares with an exercise price equal to the public offering price in this offering, and for newly appointed directors thereafter, to award equity compensation in the form of options to purchase ordinary shares with an exercise price equal to the fair market value of the shares on the date of grant. We further intend to award on an annual basis equity compensation in the form of options to purchase ordinary shares with an exercise price equal to the fair market value of the shares on the date of grant to each of our non-employee directors. The ordinary shares to be issued to our non-employee directors would be awarded under our 2012 Share Option Plan and the awards to be granted thereunder will be subject to the provisions thereof, including with respect to vesting and termination.

Other than with our Chief Executive Officer, Mr. Amir Weisberg, our Chief Technology Officer, Dr. Noam Emanuel, and our Chief Operating Officer, Mr. Jack Eitan Kyiet, we do not have written agreements with any director providing for benefits upon the termination of their employment with our company. See ''— Agreements with Executive Officers.''

Agreements with Executive Officers

We currently have employment agreements with all of our executive officers. We contribute (usually following a trial period of three months) monthly amounts for the benefit and on behalf of all our employees located in Israel to a pension fund pursuant to Section 14 of Israel's Severance Pay Law. Employees covered by Section 14 are entitled to monthly deposits at a rate of 8.33% of their monthly salary, made on their behalf by us. Payments in accordance with Section 14 release us from any future severance liabilities in respect of those employees. We do not set aside or accrue any additional amounts to provide pension, severance, retirement or other similar benefits or expenses. Our executive officers do not receive benefits upon the termination of their respective employment with us, other than benefits under Section 14.

Equity Incentive Plans

Amended and Restated 2012 Share Option Plan

Our Amended and Restated 2012 Share Option Plan, or the 2012 Plan, was adopted by our board of directors on August 29, 2012 and amended on January 30, 2018. The 2012 Plan provides for the grant of options to our directors, employees, office holders, service providers and consultants. As of the date of this prospectus, a total of 898,473 shares are reserved but unissued under our 2012 Plan.

The 2012 Plan is administered by our board of directors, which, on its own or upon the recommendation of a remuneration committee or any other similar committee of the board of directors, shall determine, subject to applicable law, the identity of grantees of awards and various terms of the grant. With respect to those grantees subject to Israeli taxation, the 2012 Plan provides for granting options in compliance with Section 102 of the Israeli Income Tax Ordinance, 1961, or the Ordinance, under the capital gains track, and for grants to non-employee Israeli service providers, consultants and shareholders who hold 10% or more of our total share capital or are otherwise controlling shareholders pursuant to section 3(i) of the Ordinance, as further detailed below.

Section 102 of the Ordinance allows employees, directors and officers who are not controlling shareholders and are considered Israeli residents to receive favorable tax treatment for compensation in the form of shares or options. Our non-employee service providers and controlling shareholders may only be granted options under section 3(i) of the Ordinance, which does not provide for similar tax benefits. Section 102 includes two alternatives for tax treatment involving the issuance of options or shares to a trustee for the benefit of the grantees and also includes an additional alternative for the issuance of options or shares directly to the grantee. Section 102(b)(2) of the Ordinance, the most favorable tax treatment for the grantee, permits the issuance to a trustee under the ''capital gain track.'' However, under this track we are not allowed to deduct an expense with respect to the issuance of the options or shares.

Generally, options will not be exercisable before the first anniversary of the date of grant of options, with respect to the 33.0% of the option shares, and with respect to each additional 8.375% of the option shares, become exercisable at the end of each three-month period during the second and third years from the date of grant. Generally, options that are not exercised within ten years from the grant date shall expire.

Other than by will or laws of descent, neither the options nor any right in connection with such options are assignable or transferable. If we terminate a grantee's employment or service for cause, all of the grantee's vested and unvested options will expire on the date of termination. Also, and subject to applicable law, if the grantee's employment or services is terminated for cause, then the Company shall have a right of repurchase against any shares issued pursuant to the exercise of options. In the event that the Company shall exercise such right of repurchase, the Company shall pay such grantee for each such share being repurchased an amount equal to the price originally paid by the grantee for such share. Alternatively, the Company may assign such rights of repurchase to its shareholders pro rata to their respective holdings of the Company's issued and outstanding shares.

If we are party to a merger or consolidation, outstanding options and shares acquired under the 2012 Plan will be subject to the agreement of merger or consolidation, which will provide for one or more of the following: (i) the assumption of such options by the surviving corporation or its parent, (ii) the substitution by the surviving corporation or its parent of new options, or (iii) in the event that the successor entity neither assumes nor substitutes all outstanding options, then each respective grantee shall have a period of 15 days to exercise his or her vested options, after which all remaining options, whether vested or not shall expire. For certain individuals, if their position is terminated within a certain period after the transaction, their options shall accelerate.

In the event of any variation in our share capital, including a share dividend, share split, combination or exchange of shares, recapitalization, or any other like event, the number, class and kind of shares subject to the 2012 Plan and outstanding options, and the exercise prices of the options, will be appropriately and equitably adjusted so as to maintain the proportionate number of shares without changing the aggregate exercise price of the options.

On January 30, 2018, our board of directors adopted an appendix to the 2012 Plan for U.S. residents, which was approved by the shareholders on February 8, 2018. Under this appendix, the 2012 Plan provides for the granting of options to U.S. residents in compliance with the U.S. Internal Revenue Code of 1986, as amended.

PRINCIPAL SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of December 31, 2017 by:

- each person or entity known by us to own beneficially 5% or more of our outstanding ordinary shares;
- each of our directors and executive officers individually; and
- all of our directors and executive officers as a group.

The beneficial ownership of our ordinary shares is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power, or the right to receive the economic benefit of ownership. For purposes of the table below, we deem ordinary shares issuable pursuant to options that are currently exercisable or exercisable within 60 days of December 31, 2017 to be outstanding and to be beneficially owned by the person holding the options for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person.

The percentage of shares beneficially owned has been computed on the basis of 12,661,101 ordinary shares outstanding as of December 31, 2017, which reflects the assumed exercise for cash of all of our warrants to purchase Series A preferred shares and Series D-2 preferred shares and the subsequent conversion of all of our preferred shares into ordinary shares.

As of December 31, 2017 and based on their reported registered office, 15 of our shareholders were U.S. persons, holding in aggregate approximately 13.6% of our outstanding ordinary shares immediately prior to this offering. We have also set forth below information known to us regarding any significant change in the percentage ownership of our ordinary shares by any major shareholders during the past three years. Except where otherwise indicated, we believe, based on information furnished to us by such owners, that the beneficial owners of the ordinary shares listed below have sole investment and voting power with respect to such shares.

Certain of our existing shareholders have indicated an interest in purchasing up to an aggregate of $19.5 million in ordinary shares in this offering at the initial public offering price per share. Based on an assumed initial public offering price of $22.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, these shareholders would purchase up to an aggregate of 866,667 of the 3,333,333 ordinary shares in this offering based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, these shareholders may determine to purchase more, less or no ordinary shares in this offering. It is also possible that these shareholders could indicate an interest in purchasing more ordinary shares. In addition, the underwriters could determine to sell fewer ordinary shares to any of these shareholders than the shareholders indicate an interest in purchasing or not to sell any ordinary shares to these shareholders. The following table does not reflect any potential purchases by these shareholders.

Following the closing of this offering, all of our shareholders, including the shareholders listed below, will have the same voting rights attached to their ordinary shares, and neither our principal shareholders nor our directors and executive officers will have different or special voting rights with respect to their ordinary shares. See ''Description of Share Capital — Voting Rights.'' A description of any material relationship that our principal shareholders have had with us or any of our predecessors or affiliates within the past three years is included under ''Certain Relationships and Related Party Transactions.''

Unless otherwise noted below, the address of each shareholder, director and executive officer is c/o PolyPid Ltd., 18 Hasivim Street, P.O. Box 7126 Petach Tikva, 4959376 Israel.

Name of beneficial owner	Ordinary shares beneficially owned	Percentage of ordinary shares beneficially owned	
		Before offering	After offering
5% or Greater Shareholders			
Aurum Ventures M.K.I. Ltd.[1]	2,319,415	18.3%	14.5%
Shavit Capital Fund III (US), L.P.[2]	1,154,500	9.1%	7.2%
Xenia Venture Capital Ltd.[3]	773,460	6.1%	4.8%
Friendly Angels Club L.L.P.[4]	722,442	5.7%	4.5%
Shirat Hachaim Ltd.[5]	733,942	5.8%	4.6%
Directors and Executive Officers			
Amir Weisberg[6]	455,234	3.5%	2.8%
Dikla Czaczkes Akselbrad[7]	45,669	*	*
Chaim Hurvitz[8]	778,131	5.9%	4.9%
Anat Tsour Segal[9]	16,563	*	*
Yechezkel Barenholz, Ph.D.[10]	56,250	*	*
Noam Emanuel, Ph.D.[11]	563,227	4.3%	3.5%
Jack Eitan Kyiet.[12]	757,702	5.7%	4.7%
Eli Frydman Ph.D.[13]	1,563	*	*
Dan Jacob Gelvan, Ph.D.[14]	23,677	*	*
Jacob Harel	—	—	—
All directors and executive officers as a group (10 persons)	2,698,016	21.3%	16.9%

* Indicates beneficial ownership of less than 1% of the total ordinary shares outstanding.

(1) Consists of (i) 1,342,457 ordinary shares issuable upon conversion of preferred shares and (ii) 976,958 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and the automatic conversion thereof into ordinary shares. Cropwell Limited is the beneficial owner of the shares owned by Aurum Ventures M.K.I. Ltd. Cropwell Limited is owned in equal parts by Brock Nominees Limited and Tenby Nominees Limited, as nominees for Credit Suisse Trust as trustee of the MK Special Assets Trust, the sole beneficiary of which is The MK Trust, of which Morris Kahn is the sole beneficiary. The address of Aurum Ventures M.K.I. Ltd. is 16 Abba Hillel Silver Street, Aurec House, Ramat Gan, 52506 Israel. The percentage ownership of Aurum Ventures M.K.I. Ltd. increased from 4.7% in September 2014 to 18.3% in December 2017.

(2) Consists of (i) 536,977 ordinary shares issuable upon conversion of preferred shares and (ii) 617,523 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and the automatic conversion thereof into ordinary shares. The general partner of Shavit Capital Fund III (US), L.P. is Shavit Capital Fund GP, L.P., which is managed by Shavit Capital Management 3 (GP) Ltd. in its capacity as the general partner. The controlling shareholder of Shavit Capital Management 3 (GP) Ltd. is Rosigal Consultancy and Investments Ltd., or Rosigal. The controlling shareholder of Rosigal is Gary Leibler. The address of Shavit Capital Fund III (US), L.P. is Jerusalem Technology Park, Building 1B, Box 70, Malha, Jerusalem, 96951 Israel. Shavit Capital Fund III (US), L.P. did not own any shares in September 2014.

(3) Consists of (i) 717,210 ordinary shares issuable upon conversion of preferred shares and (ii) 56,250 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and the automatic conversion thereof into ordinary shares. Eli Sorzon is the chief executive officer of Xenia Venture Capital Ltd. The address of Xenia Venture Capital Ltd. is Igal Alon 76, Tel Aviv, Israel. The percentage ownership of Xenia Venture Capital Ltd decreased from 17.6% in September 2014 to 6.1% in December 2017.

(4) Consists of (i) 692,482 ordinary shares issuable upon conversion of preferred shares and (ii) 29,960 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and the automatic conversion thereof

into ordinary shares. Eitan Kyiet is the beneficial owner of the shares owned by Friendly Angels Club L.L.P. The address of Friendly Angels Club L.L.P. is Haifa, 34987, Rehov Frank Peleg 6, Israel. The percentage ownership of Friendly Angels Club L.L.P. decreased from 13.5% in September 2014 to 5.7% in December 2017.

(5) Consists of (i) 636,246 ordinary shares issuable upon conversion of preferred shares and (ii) 97,696 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and the automatic conversion thereof into ordinary shares. Chaim Hurvitz is the beneficial owner of Shirat Hachaim Ltd. The address of Shirat Hachaim Ltd. is 31 Yavne Street, Tel Aviv, Israel 65792. The percentage ownership of Shirat Hachaim Ltd. increased from 2.6% in September 2014 to 5.8% in December 2017.

(6) Consists of (i) 153,205 ordinary shares issuable upon conversion of preferred shares and (ii) 302,029 ordinary shares issuable upon exercise of outstanding options.

(7) Consists of 45,669 ordinary shares issuable upon exercise of outstanding options.

(8) Consists of (i) 44,190 ordinary shares issuable upon exercise of outstanding options and (ii) beneficial ownership of the shares set forth in note 5 above held by Shirat Hachaim Ltd.

(9) Consists of 16,563 ordinary shares issuable upon exercise of outstanding options.

(10) Consists of 56,250 ordinary shares issuable upon exercise of outstanding options.

(11) Consists of (i) 212,500 ordinary shares and (ii) 350,727 ordinary shares issuable upon exercise of outstanding options.

(12) Consists of (i) 35,260 ordinary shares issuable upon exercise of outstanding options and (ii) beneficial ownership of the shares set forth in note 4 above held by Friendly Angels Club L.L.P.

(13) Consists of 1,563 ordinary shares issuable upon exercise of outstanding options.

(14) Consists of (i) 13,570 ordinary shares issuable upon conversion of preferred shares, (ii) 5,211 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and conversion thereof into ordinary shares and (iii) 4,896 ordinary shares issuable upon exercise of outstanding options.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of the material terms of those transactions with related parties to which we, or our subsidiaries, are party.

Participation in this Offering

Certain of our existing shareholders have indicated an interest in purchasing up to an aggregate of $19.5 million in ordinary shares in this offering at the initial public offering price per share. Based on an assumed initial public offering price of $22.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, these shareholders would purchase up to an aggregate of 866,667 of the 3,333,333 ordinary shares in this offering based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, these shareholders may determine to purchase more, less or no ordinary shares in this offering. It is also possible that these shareholders could indicate an interest in purchasing more ordinary shares. In addition, the underwriters could determine to sell fewer ordinary shares to any of these shareholders than the shareholders indicate an interest in purchasing or not to sell any ordinary shares to these shareholders.

Private Placements of our Securities

Sale of Series B Shares

In December 2012, October 2013 and June 2014, we entered into share purchase agreements for the sale of Series B-1 preferred shares. In June 2014, we entered into a share purchase agreement with certain investors, including some of our directors, executive officers and holders of greater than 5% of our ordinary shares, pursuant to which we issued a total of 825,627 Series B-1 preferred shares for an aggregate price of $4.0 million, or the June 2014 Series B Private Placement. The following table sets forth the aggregate number of shares of Series B-1 preferred shares issued to our related parties in the June 2014 Series B Private Placement:

Participant	Series B-1 Preferred Shares
Dan Jacob Gelvan	8,256
Friendly Angels Club L.L.P.	178,792
Shirat Hachaim Ltd.	41,281
Xenia Venture Capital Ltd.	88,560
Yechezkel Berenholtz	10,694
Aurum Ventures M.K.I. Ltd.	206,407

Sale of Series C Shares

In June 2015, we entered into a share purchase agreement with certain investors, including holders of greater than 5% of our ordinary shares, pursuant to which we issued a total of 429,073 Series C-2 preferred shares for an aggregate price of $3.8 million, or the Series C Private Placement. The following table sets forth the aggregate number of shares of Series C-2 preferred shares issued to our related parties in the Series C Private Placement:

Participant	Series C-2 Preferred Shares
Aurum Ventures M.K.I. Ltd.	56,639
Dan Jacob Gelvan	783
Shirat Hachaim Ltd.	56,639

Sales of Series D Shares

In February 2016, we entered into a share purchase agreement with certain investors, including holders of greater than 5% of our ordinary shares, pursuant to which we issued a total of 2,485,889 Series D-1 preferred shares for an aggregate price of $21.9 million, or the Series D-1 Private Placement. As part of the Series D-1 Private Placement, we also issued warrants to purchase up to 20,389 Series D-1 preferred shares, at an exercise price of $10.15 per share, and warrants to purchase up to 2,506,273 Series D-2 preferred shares, at an exercise price of $10.15 per share, or the Series D-2 Warrants. The Series D-2 Warrants provided for the issuance of additional warrants to purchase Series D-2 preferred shares, and an adjustment to the exercise price, if we did not complete an initial public offering in the United States by December 31, 2016. In January 2017, we issued additional warrants to purchase up to 375,942 Series D-2 preferred shares, at an exercise price of $8.83 per share, and the exercise price of the Series D-2 Warrants was reduced to $8.83 per share. The following table sets forth the aggregate number of shares of Series D-1 preferred shares and warrants to purchase Series D-2 preferred shares issued to our related parties in the Series D-1 Private Placement:

Participant	Series D-1 Preferred Shares	Series D-2 Warrants
Aurum Ventures M.K.I. Ltd.	849,529	976,958
Dan Jacob Gelvan	4,531	5,211
Friendly Angels Club L.L.P.	26,052	29,960
Shavit Capital Fund III (US), L.P.	536,977	617,523
Shirat Hachaim Ltd.	84,953	97,696

In August 2016, we entered into a share purchase agreement with certain investors, including one of our holders of greater than 5% of our ordinary shares, pursuant to which we issued a total of 603,497 Series D-3 preferred shares for an aggregate price of $5.3 million, or the Series D-3 Private Placement. The following table sets forth the aggregate number of shares of Series D-3 preferred shares issued to our related parties in the Series D-3 Private Placement:

Participant	Series D-3 Preferred Shares
Shirat Hachaim Ltd.	37,169

Sale of Series E Shares

In the third and fourth quarters of 2017, we entered into share purchase agreements with certain investors, including one of our holders of greater than 5% of our ordinary shares, pursuant to which we issued a total of 1,178,038 Series E preferred shares for an aggregate purchase price of $15.0 million, or the Series E Private Placement. The following table sets forth the aggregate number of shares of Series E preferred shares issued to our related parties in the Series E Private Placement:

Participant	Series E Preferred Shares
Shirat Hachaim Ltd.	110,986

Convertible Loan Agreements

In December 2014 and January 2015, we entered into convertible loan agreements with certain of our holders of greater than 5% of our ordinary shares, for an aggregate principal amount

of $4.4 million, bearing an annual interest rate of 4.0%. The principal amount of the loan agreements and accrued interest converted automatically into 675,651 Series C-1 preferred shares upon the closing of the Series C Private Placement, or the Series C conversion. The following table sets forth the aggregate number of shares of Series C-2 preferred shares issued to our related parties pursuant to the Series C conversion:

Participant	Original Loan Amount	Series C-1 Preferred Shares Converted into in June 2015
Aurum Ventures MKI Ltd.	$1,500,000	229,882
Friendly Angels Club L.L.P.	$ 500,000	76,064
Shirat Hachaim Ltd.	$1,500,000	230,602

Investor Rights Agreement

We are party to an amended and restated investor rights agreement, or the IRA, with certain of our shareholders. The IRA provides that certain holders of our ordinary shares have the right to demand that we file a registration statement or request that their ordinary shares be covered by a registration statement that we are otherwise filing. The registration rights are described in more detail under ''Description of Share Capital — Registration Rights.'' All rights under the Registration Rights Agreement, other than the registration rights, will terminate upon the closing of this offering.

Agreements and Arrangements With, and Compensation of, Directors and Executive Officers

Certain of our executive officers have employment agreements with the Company. These agreements will terminate at the closing of this offering and will be replaced by new employment agreements, which will contain customary provisions and representations, including confidentiality, non-competition, non-solicitation and inventions assignment undertakings by the executive officers. Under current applicable Israeli employment laws, we may not be able to enforce (either in whole or in part) 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 ''Management — Compensation of Executive Officers and Directors.''

Indemnification Agreements

Our amended and restated articles of association permit us to exculpate, indemnify and insure each of our directors and office holders to the fullest extent permitted by the Israeli Companies Law. Upon the closing of this offering, we intend to enter into indemnification agreements with each of our directors and executive officers, undertaking to indemnify them to the fullest extent permitted by Israeli law, including with respect to liabilities resulting from a public offering of our shares, to the extent that these liabilities are not covered by insurance. We have also obtained directors and officers insurance for each of our executive officers and directors. For further information, see ''Management — Exculpation, Insurance and Indemnification of Directors and Officers.''

DESCRIPTION OF SHARE CAPITAL

The following descriptions of our share capital and provisions of our amended and restated articles of association which will be effective upon the closing of this offering are summaries and do not purport to be complete. A form of our amended and restated articles of association will be filed with the SEC as an exhibit to our registration statement, of which this prospectus forms a part. The description of the ordinary shares reflects changes to our capital structure that will occur upon the closing of this offering.

General

Upon the closing of this offering, our authorized share capital will consist of NIS 35,000,000 divided into 43,750,000 ordinary shares, with a nominal value NIS 0.80 per share, of which shares will be issued and outstanding (assuming that the underwriters do not exercise their option to purchase additional ordinary shares prior thereto).

All of our outstanding ordinary shares are validly issued, fully paid and non-assessable. Our ordinary shares are not redeemable and do not have any preemptive rights.

All ordinary shares have identical voting and other rights in all respects.

Registration Number and Purpose of the Company

Our registration number with the Israeli Registrar of Companies is 514105923. Our purpose as set forth in our amended and restated articles of association is to engage in any lawful activity. Following the completion of this offering and the resulting registration of our shares for trading, our registration number is expected to change to reflect our becoming a public company.

Conversion of Preferred Shares

Upon the closing of this offering, all of our preferred shares outstanding will automatically convert into ordinary shares, and will have no further preferences, privileges or priority rights of any kind.

Transfer of Shares

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

Election of Directors

Our ordinary shares do not have cumulative voting rights for the election of directors. As a result, the holders of a majority of the voting power represented at a meeting of shareholders have the power to elect all of our directors.

Under our amended and restated articles of association to be effective upon the closing of this offering, our board of directors must consist of at least five and not more than eleven directors. Our board of directors will consist of seven directors upon the closing of this offering.

Pursuant to our amended and restated articles of association, each of our directors, will be appointed by a vote of the majority of the total voting power of our company, participating and

voting at an annual general meeting of our shareholders. Each director will serve until the next annual general meeting following his or her election and his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal by a vote of 65% of the total voting power of our company at a general meeting of our shareholders or until his or her office expires by operation of law. In addition, our amended and restated articles of association allow our board of directors to appoint directors to fill vacancies on the board of directors, including filling empty board seats up to the maximum number of directors permitted under our articles of association, to serve until the next annual general meeting of shareholders. Our amended and restated articles of association do not have a retirement age requirement for our directors.

Dividend and Liquidation Rights

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. Under the Israeli Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the company's articles of association provide otherwise. Our amended and restated articles of association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our board of directors.

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

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

Exchange Controls

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

Shareholder Meetings

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be held no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to in our amended and restated articles of association as extraordinary meetings. Our board of directors may call extraordinary meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Israeli Companies Law provides that our board of directors is required to convene an extraordinary meeting upon the written request of (i) any two or more of our directors or one-quarter or more of the members of our board of directors, or (ii) one or more shareholders holding, in the aggregate, either (a) 5% or more of our

outstanding issued shares and 1% of our outstanding voting power, or (b) 5% or more of our outstanding voting power.

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

- amendments to our articles of association;
- appointment or termination of our auditors
- appointment of external directors (if applicable);
- approval of certain related party transactions;
- increases or reductions of our authorized share capital;
- a merger; and
- the exercise of our board of director's 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.

The Israeli Companies Law requires that a notice of any annual general meeting or extraordinary meeting be provided to shareholders 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.

Under Israeli Companies Law, whenever we cannot convene or conduct a general meeting in the manner prescribed under the law or our articles of association, the court may, upon our, shareholders' or directors' request, order that we convene and conduct a general meeting in the manner the court deems appropriate.

Voting Rights

Quorum Requirements

Pursuant to our amended and restated 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. As a foreign private issuer, the quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy or by other voting instrument in accordance with the Israeli Companies Law who hold or represent between them at least 33⅓% of the total outstanding voting rights. A meeting adjourned for lack of a quorum is generally adjourned to the same day in the following week at the same time and place or to a later time or date if so specified in the notice of the meeting. At the reconvened meeting, any shareholder present in person or by proxy shall constitute a lawful quorum.

Vote Requirements

Our amended and restated articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Israeli Companies Law or by our amended and restated articles of association. Under the Israeli Companies Law, among others, each of (i) the approval of an extraordinary transaction with a controlling

shareholder, and (ii) the terms of employment or other engagement of the controlling shareholder of the company or such controlling shareholder's relative (even if such terms are not extraordinary) requires the approval described above under ''Management — Approval of Related Party Transactions under Israeli Law — Fiduciary Duties of Directors and Executive Officers — Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions.'' Additionally, (i) the approval and extension of a compensation policy and certain deviations therefrom require the approvals described above under ''Management — Compensation Committee — Israeli Companies Law Requirements,'' and (ii) the terms of employment or other engagement of the chief executive officer of the company require the approvals described above under ''Management — Disclosure of Personal Interests of an Office Holder and Approval of Certain Transactions.'' Under our amended and restated articles of association, (i) the removal of a director from office requires the adoption of a resolution at a general meeting of shareholders by 65% of the total voting power of our company; and (ii) the alteration of the rights, privileges, preferences or obligations of any class of our shares requires a simple majority of the class so affected (or such other percentage of the relevant class that may be set forth in the governing documents relevant to such class), in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting.

Further exceptions to the simple majority vote requirement are a resolution for the voluntary winding up, or an approval of a scheme of arrangement or reorganization, of the company pursuant to Section 350 of the Israeli Companies Law, that governs the settlement of debts and reorganization of a company, which requires the approval of holders of 75% of the voting rights represented at the meeting and voting on the resolution.

Access to Corporate Records

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

Modification of Class Rights

Under the Israeli Companies Law and our amended and restated articles of association, the rights attached to any class of shares, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, as set forth in our amended and restated articles of association.

Registration Rights

We are party to the IRA with certain of our shareholders. Under the IRA, holders of a total of 12,076,950 of our ordinary shares will have the right to require us to register their ordinary shares under the Securities Act under specified circumstances and will have incidental registration rights as described below.

Demand Registration Rights

At any time beginning six months after the consummation of this offering, the holders of at least 50% of the registrable securities then outstanding may request that we file a registration statement (including, once we are eligible to use Form F-3, which we anticipate will occur twelve months following the consummation of this offering, a registration of the sale of their shares on a delayed or continuous basis under Form F-3, and in such case pursuant to a demand of at least 50% of the registrable securities then outstanding held by at least two classes of holders) with respect to the registrable securities held by them. This demand right is subject to an anticipated aggregate offering price, net of selling expenses, of at least $4.0 million in an ordinary demand registration and $1.0 million for a registration on Form F-3. Upon receipt of such registration request, we are obligated to use our best efforts to effect, as soon as practicable, the registration under the Securities Act of all registrable securities that the Holders request to be registered. Our shareholders have the right to utilize their demand rights up to two times for an ordinary demand and up to two times for registration on Form F-3.

We will not be obligated to file a registration statement at any such time if in the good faith judgment of our board of directors (as reflected in a certificate delivered by our chief executive officer or the chairman of our board of directors), such registration would be seriously detrimental to our company, provided that we do not use that exemption more than once in any 12 month period. We also have the right not to effect or take any action to effect a registration statement during the period starting with the date 60 days prior to our good faith estimate of the date of the filing of, and ending on a date 180 days following the effective date of, a Company-initiated registration statement.

Piggyback Registration Rights

In addition, if we register any of our ordinary shares in connection with the public offering of such securities solely for cash, the holders of all registrable securities are entitled to notice of the registration and to include all or a portion of their registrable securities in the registration. If the public offering that we are effecting is underwritten, the right of any shareholder to include shares in the registration related thereto is conditioned upon the shareholder accepting the terms of the underwriting as agreed between us and the underwriters. Each shareholder may furthermore only include such quantity of registrable securities as the underwriters in their sole discretion determine will not jeopardize the success of our offering.

Expenses

We will pay all registration expenses (other than underwriting discounts and selling commissions) and the reasonable fees and expenses of a single counsel for the selling shareholders, related to any demand or piggyback registration.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Israeli Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5%

of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of shares.

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

If (i) the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (ii) the shareholders who did not accept the tender offer hold 2% or more of the issued and outstanding share capital of the company (or of the applicable class), the acquirer may not acquire shares from shareholders who accepted the tender offer that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class.

Special Tender Offer

The Israeli Companies Law provides that, subject to certain exceptions, an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company. This requirement does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Israeli Companies Law provides that, subject to certain exceptions, an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company.

A special tender offer must be extended to all shareholders of a company. A special tender offer may be consummated only if (i) the offeror acquired shares representing at least 5% of the voting power in the company and (ii) the number of shares tendered by shareholders who accept the offer exceeds the number of shares held by shareholders who object to the offer (excluding the offeror, controlling shareholders, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer or any of their relatives or any entity controlled by them). 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. Shares purchased in contradiction to the tender offer rules under the Israeli Companies Law, will have no rights and will become dormant shares.

Merger

The Israeli Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Israeli Companies Law are met, by

a majority vote of each party's shareholders. In the case of the target company, approval of the merger further requires a majority vote of each class of its shares.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of shares represented at the meeting of shareholders that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same Special Majority approval that governs all extraordinary transactions with controlling shareholders (as described under ''Management — Approval of Related Party Transactions under Israeli Law — Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions'').

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the petition of holders of at least 25% of the voting rights of a company. For such petition to be granted, the court must find that the merger is fair and reasonable, taking into account the respective values assigned to each of the parties to the merger and the consideration offered to the shareholders of the target company.

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

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

Anti-Takeover Measures under Israeli Law

The Israeli 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 with respect to voting, distributions or other matters and shares having preemptive rights. As of the closing of this offering, no preferred shares will be authorized under our amended and restated articles of association. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our amended and restated articles of association, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares and voting at a general meeting. The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Israeli Companies Law as described above in ''— Voting Rights.''

Borrowing Powers

Pursuant to the Israeli Companies Law and our amended and restated articles of association, our board of directors may exercise all powers and take all actions that are not required under law

or under our amended and restated articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

Changes in Capital

Our amended and restated articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Israeli Companies Law and must be approved by a resolution duly passed by our shareholders at a general 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 or profits, require the approval of both our board of directors and an Israeli court.

Transfer Agent and Registrar

The transfer agent and registrar for our ordinary shares is American Stock Transfer & Trust Company, LLC. Its address is 6201 15th Avenue, Brooklyn, NY 11219.

Listing

Application has been made to have our ordinary shares listed on The Nasdaq Global Market under the symbol ''POLY.''

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our ordinary shares. Sales of substantial amounts of our ordinary shares following this offering, or the perception that these sales could occur, could adversely affect prevailing market prices of our ordinary shares and could impair our future ability to obtain capital, especially through an offering of equity securities. Assuming that the underwriters do not exercise in full their option to purchase additional ordinary shares with respect to this offering and assuming no exercise of options outstanding following this offering, we will have an aggregate of 13,112,219 ordinary shares outstanding upon the closing of this offering. Of these shares, the ordinary shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, unless purchased by ''affiliates'' (as that term is defined under Rule 144 of the Securities Act, or Rule 144), who may sell only the volume of shares described below and whose sales would be subject to additional restrictions described below.

The remaining ordinary shares will be held by our existing shareholders and will be deemed to be ''restricted securities'' under Rule 144. Subject to certain contractual restrictions, including the lock-up agreements described below, restricted securities may only be sold in the public market pursuant to an effective registration statement under the Securities Act or pursuant to an exemption from registration under Rule 144, Rule 701 or Rule 904 under the Securities Act. These rules are summarized below. Sales of these shares in the public market after the restrictions under the lock-up agreements lapse, or the perception that those sales may occur, could cause the prevailing market price of our ordinary shares to decrease or to be lower than it might be in the absence of those sales or perceptions.

Eligibility of Restricted Shares for Sale in the Public Market

Approximately 9,722,636 of our ordinary shares will be eligible for resale pursuant to Rule 144 after 90 days following the pricing of this offering as follows:

- with respect to non-affiliates of our company who will hold an aggregate of 8,014,633 ordinary shares upon the consummation of this offering, following the expiration of a non-affiliate's six-month holding period and subject to our compliance with the current public information requirements under Rule 144; and
- with respect to affiliates of our company who will hold an aggregate of 1,708,003 ordinary shares upon the consummation of this offering, following the expiration of an affiliate's six-month holding period and subject to our compliance with the current public information requirements under Rule 144, and subject to the volume, manner of sale and other limitations under Rule 144 applicable to securities held by affiliates.

In each case, the shares will also be subject to the contractual restrictions arising under the lock-up agreements described below.

All of the ordinary shares sold in this offering will be eligible for immediate sale upon the closing of this offering. Certain of our existing shareholders have indicated an interest in purchasing up to an aggregate of $19.5 million in ordinary shares in this offering at the initial public offering price per share. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these shareholders, or any of these shareholders may determine to purchase more, less or no shares in this offering.

Lock-Up Agreements

We, all of our directors and executive officers and holders of substantially all of our outstanding shares and our shares issuable upon the exercise of options and warrants have signed

lock-up agreements. Pursuant to such lock-up agreements, such persons have agreed, subject to certain exceptions, not to sell or otherwise dispose of ordinary shares or any securities convertible into or exchangeable for ordinary shares for a period of 180 days after the date of this prospectus without the prior written consent of Goldman Sachs & Co. LLC and Cowen and Company, LLC. Goldman Sachs & Co. LLC and Cowen and Company, LLC may, in their sole discretion, at any time without prior notice, release all or any portion of the ordinary shares from the restrictions in any such agreement.

Rule 144

Shares Held for Six Months

In general, under Rule 144 as currently in effect, and subject to the terms of any lock-up agreement, commencing 90 days after the closing of this offering, a person (or persons whose shares are aggregated), including an affiliate, who has beneficially owned our ordinary shares for six months or more, including the holding period of any prior owner other than one of our affiliates (i.e., commencing when the shares were acquired from our company or from an affiliate of our company as restricted securities), is entitled to sell our shares, subject to the availability of current public information about us. In the case of an affiliate shareholder, the right to sell is also subject to the fulfillment of certain additional conditions, including manner of sale provisions and notice requirements, and to a volume limitation that limits the number of shares to be sold thereby, within any three-month period, to the greater of:

- 1% of the number of ordinary shares then outstanding; or
- the average weekly trading volume of our ordinary shares on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

The six month holding period of Rule 144 does not apply to sales of unrestricted securities. Accordingly, persons who hold unrestricted securities may sell them under the requirements of Rule 144 described above without regard to the six-month holding period, even if they were considered our affiliates at the time of the sale or at any time during the ninety days preceding such date.

Shares Held by Non-Affiliates for One Year

Under Rule 144 as currently in effect, a person (or persons whose shares are aggregated) who is not considered to have been one of our affiliates at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than one of our affiliates, is entitled to sell his, her or its shares under Rule 144 without complying with the provisions relating to the availability of current public information or with any other conditions under Rule 144. Therefore, unless subject to a lock-up agreement or otherwise restricted, such shares may be sold immediately upon the closing of this offering.

Rule 701

In general, under Rule 701, any of our employees, directors, officers, consultants or advisors who received or purchased ordinary shares from us under our 2012 Plan or other written agreement before the closing of this offering is entitled to resell these shares.

The SEC has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of these options, including exercises after the closing of this offering.

Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described above (see ''Lock-Up Agreements''), may be sold beginning 90 days after the closing of this offering in reliance on Rule 144 by:

- persons other than affiliates, without restriction; and
- affiliates, subject to the manner-of-sale, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

Options

As of December 31, 2017, options to purchase a total of 2,019,001 ordinary shares were issued and outstanding under our 2012 Plan. Of the total number of issued and outstanding options, 1,203,114 will be vested upon the closing of this offering. See ''Management — Equity Incentive Plans — 2012 Share Option Plan.'' All of our ordinary shares issuable under these options are subject to contractual lock-up agreements with us or the underwriters.

Form S-8 Registration Statement

Following the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register up to 2,219,443 ordinary shares, in the aggregate, issued or reserved for issuance under the 2018 Plan. The registration statement on Form S-8 will become effective automatically upon filing.

Ordinary shares issued upon exercise of a share option and registered pursuant to the Form S-8 registration statement will, subject to vesting provisions and Rule 144 volume limitations applicable to our affiliates, be available for sale in the open market immediately unless they are subject to the 180 day lock-up period or, if subject to the lock-up, immediately after the 180 day lock-up period expires. See ''Management — Equity Incentive Plan — 2012 Share Option Plan.''

Registration Rights

Following the closing of this offering, holders of a total of 12,076,950 ordinary shares will have the right to require us to register these shares under the Securities Act under specified circumstances and will have incidental registration rights. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. For more information on these registration rights, see ''Description of Share Capital — Registration Rights.''

TAXATION

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences in your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

Material Israeli Tax Considerations

The following is a summary of the material Israeli income tax laws applicable to us. This section also contains a discussion of material Israeli income tax considerations concerning the ownership and disposition of our ordinary shares by holders that purchase ordinary shares pursuant to the offering and hold such ordinary shares as capital assets. This summary does not discuss all the aspects of Israeli income 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 residents of Israel or traders in securities who are subject to special tax regimes not covered in this discussion. To the extent that the discussion is based on new tax legislation that has not yet been subject to judicial or administrative interpretation, we cannot assure you that the appropriate tax authorities or the courts will accept the views expressed in this discussion. This summary is based on laws and regulations in effect as of the date of this prospectus and does not take into account possible future amendments which may be under consideration.

General Corporate Tax Structure in Israel

As of January 1, 2017, Israeli resident companies like us are generally subject to corporate tax at the rate of 24.0%. As of January 1, 2018, the corporate tax rate will be reduced to 23.0%.

Capital gains derived by an Israeli resident company are generally subject to tax at the same rate as the corporate tax rate. Under Israeli tax legislation, a corporation will be considered as an ''Israeli resident'' if it meets one of the following: (a) it was incorporated in Israel; or (b) the control and management of its business are exercised in Israel.

Taxation of our Israeli Individual Shareholders on Receipt of Dividends

Israeli residents who are individuals are generally subject to Israeli income tax for dividends paid on our ordinary shares (other than bonus shares or share dividends) at a rate of 25.0%, or 30.0% if the recipient of such dividend is a ''substantial shareholder'' (as defined below) at the time of distribution or at any time during the preceding 12-month period.

As of January 1, 2017, an additional income tax at a rate of 3.0% is imposed on high earners whose annual taxable income or gain exceeds NIS 640,000.

A ''substantial Shareholder'' is generally a person who alone, or together with his or her relative or another person who collaborates with him on a regular basis, holds, directly or indirectly, at least 10.0% of any of the ''means of control'' of the corporation. ''Means of control'' generally include the right to vote in a general meeting of shareholders, receive profits, nominate a director or an officer, receive assets upon liquidation, or instruct someone who holds any of the aforesaid rights regarding the manner in which he or she is to exercise such right(s), and whether by virtue of shares, rights to shares or other rights, or in any other manner, including by means of voting or trusteeship agreements.

The term ''Israeli resident'' for individuals is generally defined under the Israeli Income Tax Ordinance [New Version], 1961, or the Israeli Tax Ordinance, as an individual whose center of life is

in Israel. According to the Israeli Tax Ordinance, in order to determine the center of life of an individual, account will be taken of the individual's family, economic and social connections, including: (a) the place of the individual's permanent home; (b) the place of residence of the individual and the individual's family; (c) the place of the individual's regular or permanent place of business or the place of the individual's permanent employment; (d) place of the individual's active and substantial economic interests; (e) place of the individual's activities in organizations, associations and other institutions. The center of life of an individual will be presumed to be in Israel if: (a) the individual was present in Israel for 183 days or more in the tax year; or (b) the individual was present in Israel for 30 days or more in the tax year, and the total period of the individual's presence in Israel in that tax year and the two previous tax years is 425 days or more. The presumption in this paragraph may be rebutted either by the individual or by the assessing officer.

Taxation of Israeli Resident Corporations on Receipt of Dividends

Israeli resident corporations are generally exempt from Israeli corporate income tax with respect to dividends paid on our ordinary shares unless the distribution is from a Preferred Enterprise, as defined below.

Capital Gains Taxes Applicable to Israeli Resident Shareholders

The income tax rate applicable to Real Capital Gain derived by an Israeli individual from the sale of shares which had been purchased after January 1, 2012, whether listed on a stock exchange or not, is 25.0%. However, if such shareholder is considered a ''Substantial Shareholder'' (as defined above) at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30.0%. As of January 1, 2017, an additional income tax at a rate of 3% will be imposed on high earners whose annual taxable income or gain exceeds NIS 640,000.

Moreover, capital gains derived by a shareholder who is a dealer or trader in securities, or to whom such income is otherwise taxable as ordinary business income, are taxed in Israel at ordinary income rates (currently, up to 50.0% for individuals and as of January 1, 2017, the corporate tax rate is 24.0% and as of January 1, 2018, the corporate tax rate should be reduced to 23.0%).

Taxation of Non-Israeli Shareholders on Receipt of Dividends

Non-Israeli residents are generally subject to Israeli income tax on the receipt of dividends paid on our ordinary shares at the rate of 25.0% (or 30.0% for individuals, if such individual is a ''substantial shareholder'' at the time receiving the dividend or on any date in the 12 months preceding such date), which tax will be withheld at source, unless a tax certificate is obtained from the Israeli Tax Authority authorizing withholding-exempt remittances or a reduced rate of tax pursuant to an applicable tax treaty.

A non-Israeli resident who receives dividends from which tax was withheld is generally exempt from the duty to file tax returns in Israel in respect of such income, provided such income was not derived from a business conducted in Israel by such taxpayer, and such taxpayer has no other taxable sources of income in Israel.

For example, under the Convention Between the Government of the United States of America and the Government of Israel with Respect to Taxes on Income, as amended, Israeli withholding tax on dividends paid to a U.S. resident for treaty purposes may not, in general, exceed 25.0%, or 15.0% in the case of dividends paid out of the profits of an Approved Enterprise, subject to certain conditions. Where the recipient is a U.S. corporation owning 10.0% or more of the issued and outstanding voting shares of the paying corporation during the part of the paying corporation's taxable year which precedes the date of payment of the dividend and during the whole of its prior

taxable year (if any) and not more than 25.0% of the gross income of the paying corporation for such prior taxable year (if any) consists of certain interest or dividends and the dividend is not paid from the profits of an Approved Enterprise, the Israeli tax withheld may not exceed 12.5%, subject to certain conditions.

Capital Gains Income Taxes Applicable to Non-Israeli Shareholders

Provided certain conditions are met, non-Israeli resident shareholders are generally exempt from Israeli capital gains tax on any gains derived from the sale, exchange or disposition of our ordinary shares, provided that such gains were not derived from a permanent establishment or business activity of such shareholders in Israel. However, non-Israeli corporations' shareholders will not be entitled to the foregoing exemptions if Israeli residents (i) have a controlling interest of more than 25.0% in such non-Israeli corporation or (ii) are the beneficiaries of or are entitled to 25.0% or more of the revenues or profits of such non-Israeli corporation, whether directly or indirectly.

Regardless of whether shareholders may be liable for Israeli income tax on the sale of our ordinary shares, the payment of the consideration may be subject to withholding of Israeli tax at the source. Accordingly, 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.

Tax Benefits Under the 2011 Amendment

On January 1, 2011, new legislation amending the Investment Law came into effect, or the 2011 Amendment. The 2011 Amendment introduced a new status of Preferred Enterprise replacing the existing status of ''Benefited Enterprise.'' A Preferred Enterprise entitles the company to corporate tax rates without limitations on dividends and other distributions instead of full exemption from corporate tax. These preferred corporate tax rates vary from 7.5% for Preferred Enterprises residing in a ''development zone,'' or 16.0% for Preferred Enterprises residing in other zones in Israel.

In order to gain the status of Preferred Enterprise, a company must be an industrial company and at least 25.0% out of its revenues must derive from export to countries with population exceeding 14 million people.

Estate Tax

Currently, Israeli law does not impose estate taxes.

Material U.S. Federal Income Tax Consequences to U.S. Holders

The following discussion describes the material U.S. federal income tax considerations relating to the ownership and disposition of our ordinary shares by U.S. Holders (as defined below). This discussion applies to U.S. Holders that purchase ordinary shares pursuant to the offering and hold such ordinary shares as capital assets within the meaning of Section 1221 of the Code. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury regulations promulgated thereunder 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. This discussion does not address all of the U.S. federal income tax consequences that may be relevant to specific U.S. Holders in light of their particular circumstances or to U.S. Holders subject to special treatment under U.S. federal income tax law (such as certain financial institutions, insurance companies, broker-dealers and traders in securities or other persons that generally mark their securities to market for U.S. federal income tax purposes, tax-exempt entities, retirement plans, regulated investment companies, real estate investment trusts, certain former citizens or residents of the United States, persons who hold ordinary shares as part of a ''straddle,'' ''hedge,'' ''conversion

transaction,'' ''synthetic security'' or integrated investment, persons who received their ordinary shares as compensatory payments, persons that have a ''functional currency'' other than the U.S. dollar, persons that own directly, indirectly or through attribution 10% or more of our shares by vote or value, persons subject to special tax accounting rules as a result of any item of gross income with respect to the shares being taken into account in an applicable financial statement, corporations that accumulate earnings to avoid U.S. federal income tax, partnerships and other pass-through entities, and investors in such pass-through entities). This discussion does not address any U.S. state or local or non-U.S. tax consequences or any U.S. federal estate, gift or alternative minimum tax consequences.

As used in this discussion, the term ''U.S. Holder'' means a beneficial owner of ordinary shares that is, for U.S. federal income tax purposes, (1) an individual who is a citizen or resident of the United States, (2) a corporation (or entity treated 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, (3) an estate the income of which is subject to U.S. federal income tax regardless of its source or (4) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions or (y) that has elected under applicable U.S. Treasury regulations to be treated as a domestic trust for U.S. federal income tax purposes.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds ordinary shares, the U.S. federal income tax consequences relating to an investment in the ordinary shares will depend in part upon the status and activities of such entity or arrangement and the particular partner. Any such entity or arrangement should consult its own tax advisor regarding the U.S. federal income tax consequences applicable to it and its partners of the purchase, ownership and disposition of ordinary shares.

Persons considering an investment in ordinary shares should consult their own tax advisors as to the particular tax consequences applicable to them relating to the purchase, ownership and disposition of ordinary shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Passive Foreign Investment Company Consequences

In general, a corporation organized outside the United States will be treated as a passive foreign investment company, or PFIC, for any taxable year in which either (1) at least 75% of its gross income is ''passive income'', the PFIC income test, or (2) on average at least 50% of its assets, determined on a quarterly basis, are assets that produce passive income or are held for the production of passive income, the PFIC asset test. Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents, and gains from the sale or exchange of property that gives rise to passive income. Assets that produce or are held for the production of passive income generally include cash, even if held as working capital or raised in a public offering, marketable securities, and other assets that may produce passive income. Generally, 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.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets (which, assuming we are not a ''controlled foreign corporation,'' or a CFC, under Section 957(a) of the Internal Revenue Code of 1986, as amended, or the Code, for the year being tested, may be determined based on the fair market value of each asset, with the value of goodwill and going concern value being determined in large part by reference to the market value of our common shares, which may be volatile). Based upon the

expected value of our assets, including any goodwill and the expected nature and composition of our income and assets, we may be classified as a PFIC for the taxable year ended December 31, 2018 and future taxable years. In particular, so long as we do not generate revenue from operations for any taxable year and do not receive any research and development grants, or even if we receive a research and development grant, if such grant does not constitute gross income for U.S. federal income tax purposes, we likely will be classified as a PFIC for such taxable year. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. Our status as a PFIC is a fact-intensive determination made on an annual basis after the end of each taxable year. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for our taxable year ending December 31, 2018, and also expresses no opinion with regard to our expectations regarding our PFIC status in the future.

If we are a PFIC in any taxable year during which a U.S. Holder owns ordinary shares, the U.S. Holder could be liable for additional taxes and interest charges under the ''PFIC excess distribution regime'' upon (1) a distribution paid during a taxable year that is greater than 125% of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. Holder's holding period for the ordinary shares, and (2) any gain recognized on a sale, exchange or other disposition, including a pledge, of the ordinary shares, whether or not we continue to be a PFIC. Under the PFIC excess distribution regime, the tax on such distribution or gain would be determined by allocating the distribution or gain ratably over the U.S. Holder's holding period for ordinary shares. The amount allocated to the current taxable year (i.e., the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income earned in the current taxable year. The amount allocated to other taxable years will be taxed at the highest marginal rates in effect for individuals or corporations, as applicable, to ordinary income for each such taxable year, and an interest charge, generally applicable to underpayments of tax, will be added to the tax.

If we are a PFIC for any year during which a U.S. Holder holds ordinary shares, we must generally continue to be treated as a PFIC by that holder for all succeeding years during which the U.S. Holder holds the ordinary shares, unless we cease to meet the requirements for PFIC status and the U.S. Holder makes a ''deemed sale'' election with respect to the ordinary shares. If the election is made, the U.S. Holder will be deemed to sell the ordinary shares it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain recognized from such deemed sale would be taxed under the PFIC excess distribution regime. After the deemed sale election, the U.S. Holder's ordinary shares would not be treated as shares of a PFIC unless we subsequently become a PFIC.

If we are a PFIC for any taxable year during which a U.S. Holder holds ordinary shares and one of our non-U.S. corporate subsidiaries is also a PFIC (i.e., a lower-tier PFIC), such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be taxed under the PFIC excess distribution regime on distributions by the lower-tier PFIC and on gain from the disposition of shares of the lower-tier PFIC even though such U.S. Holder would not receive the proceeds of those distributions or dispositions. Each U.S. Holder is advised to consult its tax advisors regarding the application of the PFIC rules to our non-U.S. subsidiaries.

If we are a PFIC, a U.S. Holder will not be subject to tax under the PFIC excess distribution regime on distributions or gain recognized on ordinary shares if such U.S. Holder makes a valid ''mark-to-market'' election for our ordinary shares. A mark-to-market election is available to a U.S. Holder only for ''marketable stock.'' Our ordinary shares will be marketable stock as long as they remain listed on the Nasdaq Global Market and are regularly traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. If a mark-to-market election is in effect,

a U.S. Holder generally would take into account, as ordinary income for each taxable year of the U.S. holder, the excess of the fair market value of ordinary shares held at the end of such taxable year over the adjusted tax basis of such ordinary shares. The U.S. Holder would also take into account, as an ordinary loss each year, the excess of the adjusted tax basis of such ordinary shares over their fair market value at the end of the taxable year, but only to the extent of the excess of amounts previously included in income over ordinary losses deducted as a result of the mark-to-market election. The U.S. Holder's tax basis in ordinary shares would be adjusted to reflect any income or loss recognized as a result of the mark-to-market election. Any gain from a sale, exchange or other disposition of ordinary shares in any taxable year in which we are a PFIC would be treated as ordinary income and any loss from such sale, exchange or other disposition would be treated first as ordinary loss (to the extent of any net mark-to-market gains previously included in income) and thereafter as capital loss.

A mark-to-market election will not apply to ordinary shares 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. Such election will not apply to any non-U.S. subsidiaries that we may organize or acquire in the future. Accordingly, a U.S. Holder may continue to be subject to tax under the PFIC excess distribution regime with respect to any lower-tier PFICs that we may organize or acquire in the future notwithstanding the U.S. Holder's mark-to-market election for the ordinary shares.

The tax consequences that would apply if we are a PFIC would also be different from those described above if a U.S. Holder were able to make a valid qualified electing fund, or QEF, election. At this time, we do not expect to provide U.S. Holders with the information necessary for a U.S. Holder to make a QEF election. Prospective investors should assume that a QEF election will not be available.

Each U.S. person that is an investor of a PFIC is generally required to file an annual information return on IRS Form 8621 containing such information as the U.S. Treasury Department may require. The failure to file IRS Form 8621 could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax.

The U.S. federal income tax rules relating to PFICs are very complex. Prospective U.S. investors are strongly urged to consult their own tax advisors with respect to the impact of PFIC status on the purchase, ownership and disposition of ordinary shares, the consequences to them of an investment in a PFIC, any elections available with respect to the ordinary shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of ordinary shares of a PFIC.

Distributions

As described in the section entitled ''— Dividend Policy,'' we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we make a distribution contrary to the expectation, subject to the discussion above under ''— *Passive Foreign Investment Company Consequences*,'' a U.S. Holder that receives a distribution with respect to ordinary shares generally will be required to include the gross amount of such distribution in gross income as a dividend when actually or constructively received to the extent of the U.S. Holder's pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent a distribution received by a U.S. Holder is not a dividend because it exceeds the U.S. Holder's pro rata share of our current and accumulated earnings and profits, it will be treated first as a tax-free return of capital and reduce (but not below zero) the adjusted tax basis of the U.S. Holder's ordinary shares. To the extent the distribution exceeds the adjusted tax basis of the U.S. Holder's ordinary shares, the remainder will be taxed as capital gain. Because we may not account for our earnings and profits in accordance with U.S.

federal income tax principles, U.S. Holders should expect all distributions to be reported to them as dividends.

Distributions on ordinary shares that are treated as dividends generally will constitute income from sources outside the United States for foreign tax credit purposes and generally will constitute passive category income. Subject to certain complex conditions and limitations, Israeli taxes withheld on any distributions on ordinary shares may be eligible for credit against a U.S. Holder's federal income tax liability. The rules relating to the determination of the U.S. foreign tax credit are complex, and U.S. Holders should consult their tax advisors regarding the availability of a foreign tax credit in their particular circumstances and the possibility of claiming an itemized deduction (in lieu of the foreign tax credit) for any foreign taxes paid or withheld.

Dividends paid by a ''qualified foreign corporation'' are eligible for taxation to non-corporate U.S. holders at a reduced capital gains rate rather than the marginal tax rates generally applicable to ordinary income provided that certain requirements are met. Each U.S. Holder is advised to consult its tax advisors regarding the availability of the reduced tax rate on dividends with regard to its particular circumstances. Each U.S. Holder is advised to consult its tax advisors regarding the availability of the reduced tax rate on dividends with regard to its particular circumstances. Distributions on ordinary shares that are treated as dividends generally will not be eligible for the ''dividends received'' deduction generally allowed to corporate shareholders with respect to dividends received from U.S. corporations.

A non-United States corporation (other than a corporation that is classified 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 (a) 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 provision, or (b) with respect to any dividend it pays on ordinary shares that are readily tradable on an established securities market in the United States. We believe that we qualify as a resident of Israel for purposes of, and are eligible for the benefits of, the U.S.-Israel Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-Israel Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange of information provision. Therefore, subject to the discussion above under ''— *Passive Foreign Investment Company Consequences*,'' if the U.S.-Israel Treaty is applicable, such dividends will generally be ''qualified dividend income'' in the hands of individual U.S. Holders, provided that certain conditions are met, including holding period and the absence of certain risk reduction transaction requirements. Each U.S. Holder is advised to consult its tax advisors regarding the availability of the reduced tax rate on dividends with regard to its particular circumstances.

Sale, Exchange or Other Disposition of Ordinary Shares

Subject to the discussion above under ''— *Passive Foreign Investment Company Consequences*,'' a U.S. Holder generally will recognize capital gain or loss for U.S. federal income tax purposes upon the sale, exchange or other disposition of ordinary shares in an amount equal to the difference, if any, between the amount realized (i.e., the amount of cash plus the fair market value of any property received) on the sale, exchange or other disposition and such U.S. Holder's adjusted tax basis in the ordinary shares. Such capital gain or loss generally will be long-term capital gain taxable at a reduced rate for non-corporate U.S. Holders or long-term capital loss if, on the date of sale, exchange or other disposition, the ordinary shares were held by the U.S. Holder for more than one year. Any capital gain of a non-corporate U.S. Holder that is not long-term capital gain is taxed at ordinary income rates. The deductibility of capital losses is subject to limitations. Any gain or loss recognized from the sale or other disposition of ordinary shares will generally be gain or loss from sources within the United States for U.S. foreign tax credit purposes.

Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of ordinary shares. If you are a United States person that is an individual, estate or trust, you are encouraged to consult your tax advisors regarding the applicability of this Medicare tax to your income and gains in respect of your investment in ordinary shares.

Information Reporting and Backup Withholding

U.S. Holders may be required to file certain U.S. information reporting returns with the IRS with respect to an investment in ordinary shares, including, among others, IRS Form 8938 (Statement of Specified Foreign Financial Assets). As described above under ''*Passive Foreign Investment Company Consequences*'', each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information. U.S. Holders paying more than US$100,000 for ordinary shares may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) reporting this payment. Substantial penalties may be imposed upon a U.S. Holder that fails to comply with the required information reporting.

Dividends on and proceeds from the sale or other disposition of ordinary shares may be reported to the IRS unless the U.S. Holder establishes a basis for exemption. Backup withholding may apply to amounts subject to reporting if the holder (1) fails to provide an accurate United States taxpayer identification number or otherwise establish a basis for exemption (usually on IRS Form W-9), or (2) is described in certain other categories of persons. However, U.S. Holders that are corporations generally are excluded from these information reporting and backup withholding tax rules. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability if the required information is furnished by the U.S. Holder on a timely basis to the IRS.

U.S. Holders should consult their own tax advisors regarding the backup withholding tax and information reporting rules.

EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

UNDERWRITING

We have entered into an underwriting agreement with the underwriters named below with respect to the ordinary shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of ordinary shares indicated in the following table. Goldman Sachs & Co. LLC, 200 West Street, 29th Floor, New York, New York 10282 and Cowen and Company, LLC, 599 Lexington Avenue, 27th Floor, New York, New York 10022, are the representatives of the underwriters.

Underwriters	Number of Ordinary Shares
Goldman Sachs & Co. LLC	
Cowen and Company, LLC	
Cantor Fitzgerald & Co.	
Raymond James & Associates, Inc.	
Oppenheimer & Co. Inc.	
Total	3,333,333

The underwriters are committed to take and pay for all of the ordinary shares being offered, if any are taken, other than the ordinary shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 500,000 ordinary shares from the company to cover sales by the underwriters of a greater number of ordinary shares than the total number set forth in the table above. They may exercise that option for 30 days. If any ordinary shares are purchased pursuant to this option, the underwriters will severally purchase ordinary shares in approximately the same proportion as set forth in the table above.

The following table shows the per ordinary share and total underwriting discounts and commissions to be paid to the underwriters by the company. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase 500,000 additional ordinary shares.

	Paid by the Company	
	No Exercise	Full Exercise
Per ordinary share	$	$
Total	$	$

Ordinary shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover page of this prospectus. Any ordinary shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per ordinary share from the initial public offering price. After the ordinary shares are released for sale to the public, if all the ordinary shares are not sold at the initial public offering price following a bona fide effort to do so, the underwriters may change the initial public offering price and other selling terms. The offering of the ordinary shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

The company, its directors, executive officers and holders of substantially all of its outstanding shares and shares issuable upon the exercise of options and warrants have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their ordinary shares or securities convertible into or exchangeable for ordinary shares during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with

the prior written consent of the representatives. This agreement does not apply to any existing employee benefit plans. See ''Shares Available for Future Sale'' for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the ordinary shares. The initial public offering price has been negotiated among the company and the representatives. Among the factors to be considered in determining the initial public offering price of the ordinary shares, in addition to prevailing market conditions, will be the company's historical performance, estimates of the business potential and earnings prospects of the company, an assessment of the company's management and the consideration of the above factors in relation to market valuation of companies in related businesses.

Application has been made to list the ordinary shares on The Nasdaq Global Market under the symbol ''POLY.''

In connection with the offering, the underwriters may purchase and sell the ordinary shares in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of ordinary shares than they are required to purchase in the offering, and a short position represents the amount of such sales that has not been covered by subsequent purchases. A ''covered short position'' is a short position that is not greater than the amount of additional ordinary shares for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional ordinary shares or purchasing ordinary shares in the open market. In determining the source of ordinary shares to cover the covered short position, the underwriters will consider, among other things, the price of ordinary shares available for purchase in the open market as compared to the price at which they may purchase additional ordinary shares pursuant to the option described above. ''Naked'' short sales are any short sales that create a short position greater than the amount of additional ordinary shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing ordinary shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ordinary shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of ordinary shares made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased ordinary shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the company's ordinary shares, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the ordinary shares. As a result, the price of the ordinary shares may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on The Nasdaq Global Market, in the over-the-counter market or otherwise.

The underwriters do not expect sales to discretionary accounts to exceed five percent of the total number of ordinary shares offered.

The company estimates that its share of the total expenses of the offering, excluding estimated underwriting discounts and commissions, will be approximately $2.0 million. The company has also agreed to reimburse the underwriters for certain of their expenses in an amount up to $45,000.

The company has agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. The underwriters and their respective affiliates may in the future provide a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, each, a Relevant Member State, an offer to the public of the ordinary shares may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of the ordinary shares may be made at any time under the following exemptions under the Prospectus Directive:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive;

provided that no such offer of ordinary shares shall require the company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an ‘‘offer of ordinary shares to the public’’ in relation to the company’s ordinary shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the ordinary shares to be offered so as to enable an investor to decide to purchase the ordinary shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression ‘‘Prospectus Directive’’ means Directive 2003/71/EC (as amended), including by Directive 2010/73/EU and includes any relevant implementing measure in the Relevant Member State.

This European Economic Area selling restriction is in addition to any other selling restrictions set out below.

United Kingdom

In the United Kingdom, this prospectus is only addressed to and directed at qualified investors who are (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the Order); or (ii) high net worth entities and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as ''relevant persons''). Any investment or investment activity to which this prospectus relates is available only to relevant persons and will only be engaged with relevant persons. Any person who is not a relevant person should not act or relay on this prospectus or any of its contents.

Canada

The ordinary shares may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the ordinary shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The ordinary shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong), or the Companies (Winding Up and Miscellaneous Provisions) Ordinance, or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the Securities and Futures Ordinance, or (ii) to ''professional investors'' as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a ''prospectus'' as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to ''professional investors'' in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ordinary shares may not be circulated or distributed, nor may the ordinary shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the ordinary shares are subscribed or purchased under Section 275 by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the ordinary shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore, or Regulation 32.

Where the ordinary shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

Australia

No prospectus or other disclosure document (as defined in the Corporations Act 2001 (Cth) of Australia, or the 'Corporations Act, in relation to the ordinary shares has been or will be lodged with the Australian Securities & Investments Commission, or ASIC. This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia:

- you confirm and warrant that you are either:
  - a ''sophisticated investor'' under section 708(8)(a) or (b) of the Corporations Act;
  - a ''sophisticated investor'' under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
  - a person associated with the company under section 708(12) of the Corporations Act; or
  - a ''professional investor'' within the meaning of section 708(11)(a) or (b) of the Corporations Act, and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this document is void and incapable of acceptance; and
- you warrant and agree that you will not offer any of the ordinary shares for resale in Australia within 12 months of those ordinary shares being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (''FINMA''), and the offer of the securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (''CISA''). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer

of the ordinary shares is directed only at, (i) a limited number of 35 persons or entities in accordance with the Securities Law and the regulations thereunder and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds (all as defined under the Israeli Law), entities with equity in excess of NIS 50 million (other than entities formed for the acquisition of securities from a certain offer) and ''qualified individuals,'' each as defined in the Addendum (as it may be amended from time to time), collectively referred to as Qualified Investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified Investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it. Certain Qualified Investors may be required to submit additional confirmations.

EXPENSES OF THIS OFFERING

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by us in connection with the sale of our ordinary shares being registered. All amounts are estimates except for the SEC registration fee, the FINRA filing fee and The Nasdaq Global Market listing fee.

Item	Amount to be Paid
SEC registration fee	$ 10,738
FINRA filing fee	13,438
The Nasdaq Global Market listing fee	125,000
Printing and engraving expenses	150,000
Legal fees and expenses	1,339,317
Accounting fees and expenses	240,000
Miscellaneous expenses	61,507
Total	$2,000,000

LEGAL MATTERS

The validity of the issuance of our ordinary shares offered in this prospectus and certain other matters of Israeli law will be passed upon for us by Zysman, Aharoni, Gayer & Co., Tel Aviv, Israel. Certain matters of U.S. federal law will be passed upon for us by Cooley LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Yigal Arnon & Co., Tel-Aviv, Israel, with respect to Israeli law, and Latham & Watkins LLP with respect to U.S. federal law.

EXPERTS

The consolidated financial statements as of December 31, 2017 and 2016 and for each of the two years in the period ended December 31, 2017 appearing in this Prospectus and Registration Statement have been audited by Kost, Forer, Gabbay & Kasierer, Certified Public Accountants (Israel), an independent registered public accounting firm and a member firm of Ernst & Young Global, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing. The address of Kost, Forer, Gabbay & Kasierer is Menachem Begin 144, Tel Aviv, Israel.

ENFORCEMENT OF CIVIL LIABILITIES

We are incorporated under the laws of the State of Israel. Service of process upon us and upon our directors and officers and the Israeli experts named in this registration statement, most of whom reside outside of the United States, may be difficult to obtain within the United States. Furthermore, because substantially all of our assets and substantially all of our directors and officers are located outside of the United States, any judgment obtained in the United States against us or any of our directors and officers may not be collectible within the United States.

We have been informed by our legal counsel in Israel, Zysman, Aharoni, Gayer & Co., that it may be difficult to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not 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.

We have irrevocably appointed PolyPid Inc. as our agent to receive service of process in any action against us in any U.S. federal or state court arising out of this offering or any purchase or sale of securities in connection with this offering. Subject to specified time limitations and legal procedures, Israeli courts may enforce a U.S. judgment in a civil matter which, subject to certain exceptions, is non-appealable, including a judgment based upon the civil liability provisions of the Securities Act and the Exchange Act and including a monetary or compensatory judgment in a non-civil matter, provided that among other things:

- the judgment was obtained after due process before a court of competent jurisdiction, according to the laws of the state in which the judgment was given and the rules of private international law currently prevailing in Israel;
- the prevailing law of the foreign state in which the judgment was rendered allows for the enforcement of judgments of Israeli courts;
- adequate service of process has been effected and the defendant has had a reasonable opportunity to be heard and to present his or her evidence;
- the judgment is not contrary to public policy of Israel, and the enforcement of the civil liabilities set forth in the judgment is not likely to impair the security or sovereignty of Israel;
- the judgment was not obtained by fraud and do not conflict with any other valid judgments in the same matter between the same parties;
- an action between the same parties in the same matter is not pending in any Israeli court at the time the lawsuit is instituted in the foreign court; and
- the judgment is enforceable according to the laws of Israel and according to the law of the foreign state in which the relief was granted.

If a foreign judgment is enforced by an Israeli court, it generally will be payable in Israeli currency, which can then be converted into non-Israeli currency and transferred out of Israel. The usual practice in an action before an Israeli court to recover an amount in a non-Israeli currency is for the Israeli court to issue a judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment, but the judgment debtor may make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily will be linked to the Israeli consumer price index plus interest at the annual statutory rate set by Israeli regulations prevailing at the time. Judgment creditors must bear the risk of unfavorable exchange rates.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act relating to this offering of our ordinary shares. This prospectus does not contain all of the information contained in the registration statement. The rules and regulations of the SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

You may read and copy the registration statement, 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, D.C. 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, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains a 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*.

Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers, and under those requirements will file reports with the SEC. These other reports or other information may be inspected without charge at the locations described above. 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. In addition, we will not be required under the Exchange Act to file reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We maintain a corporate website at *http://www.polypid.com*. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus.

POLYPID LTD.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2017

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Building a better working world

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders' and Board of Directors of

POLYPID LTD.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Polypid Ltd. (the ''Company'') as of December 31, 2017 and 2016 and the related consolidated statements of operations, changes in convertible preferred shares and shareholders' deficiency and cash flows for each of the two years in the period ended December 31, 2017 and the related notes (collectively referred to as the ''consolidated financial statements''). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

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

We have served as the Company's auditor since 2010.
Tel-Aviv, Israel
February 8, 2018 except for Notes 1(d), 2(j), 7, 9, 10, 12, 13, 14 and 15, to which the date is March 14, 2018

POLYPID LTD AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	December 31,		Pro forma as of December 31,
	2016	2017	2017
			(Unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$10,221	$ 3,907	$ 3,920
Short-term deposits	7,530	14,031	14,031
Prepaid expenses and other receivables	503	792	792
Total current assets	18,254	18,730	18,743
Long-term assets:			
Property and equipment, net	847	2,926	2,926
Deferred equity offering costs	—	1,088	—
Other long-term assets	136	240	240
Total long-term assets	983	4,254	3,166
Total assets	$19,237	$22,984	$21,909

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

POLYPID LTD AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS (Continued)

U.S. dollars in thousands (except share and per share data)

	December 31,		Pro forma as of December 31,
	2016	2017	2017
			(Unaudited)
Liabilities, Convertible Preferred Shares and Shareholders' Deficiency			
Current liabilities:			
Trade payables	$ 778	$ 2,019	$ 2,019
Other payables and accrued expenses	920	1,345	1,345
Total current liabilities	1,698	3,364	3,364
Long-term liabilities:			
Advances on account of collaboration agreement	600	600	600
Other liabilities	256	284	284
Convertible preferred shares warrant liability	6,616	47,399	—
Total long-term liabilities	7,472	48,283	884
Commitments and Contingencies			
Convertible preferred shares:			
Preferred A, A-1, B, B-1, C-1, C-2, D-1, D-2, D-3 and E shares of NIS 0.8 par value — Authorized: 12,741,017 and 11,553,517 shares at December 31, 2017 and 2016, respectively; Issued and outstanding: 9,138,485 and 7,960,447 shares at December 31, 2017 and 2016, respectively; Aggregate liquidation preference of $84,895 at December 31, 2017	44,026	59,983	—
Shareholders' deficiency:			
Share capital —			
Ordinary shares of NIS 0.8 par value — Authorized: 15,687,500 and 14,500,000 shares at December 31, 2017 and 2016, respectively; Issued and outstanding: 584,151 and 568,078 shares at December 31, 2017 and 2016	126	129	2,251
Additional paid-in capital	2,487	3,540	107,725
Accumulated deficit	(36,572)	(92,315)	(92,315)
Total shareholders' deficiency	(33,959)	(88,646)	17,661
Total liabilities, convertible preferred shares and shareholders' deficiency	$ 19,237	$ 22,984	$ 21,909

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

POLYPID LTD AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

U.S. dollars in thousands (except share and per share data)

	Year ended December 31,	
	2016	2017
Operating expenses:		
Research and development, net	$ 7,708	$ 9,736
General and administrative	2,551	4,064
Operating loss	10,259	13,800
Financial expenses, net	1,133	40,688
Net loss	$ 11,392	$ 54,488
Deemed dividend	—	1,255
Net loss attributable to Ordinary shares	$ 11,392	$ 55,743
Basic and diluted net loss per Ordinary share	$ (24.64)	$ (102.00)
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	568,078	584,176
Pro forma basic and diluted net loss per Ordinary share (unaudited)		$ (6.32)
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share — pro forma (unaudited)		8,822,250

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

POLYPID LTD AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED SHARES AND CHANGES IN SHAREHOLDERS' DEFICIENCY

U.S. dollars in thousands (except share data)

	Convertible Preferred shares			Shareholders' deficiency				
	Number of Preferred shares	Amount	Total	Number of Ordinary shares	Amount	Additional paid-in capital	Accumulated deficit	Total shareholders' deficiency
Balances as of January 1, 2016	4,871,061	$22,934	$22,934	568,078	$126	$1,889	$(25,180)	$(23,165)
Issuance of series D-1 Preferred shares, net(*)	2,485,889	16,039	16,039	—	—	—	—	—
Issuance of series D-3 Preferred shares, net(**)	603,497	5,053	5,053	—	—	—	—	—
Share-based compensation	—	—	—	—	—	598	—	598
Net loss	—	—	—	—	—	—	(11,392)	(11,392)
Balances as of December 31, 2016	7,960,447	44,026	44,026	568,078	126	2,487	(36,572)	(33,959)
Exercise of options	—	—	—	16,073	3	65	—	68
Issuance of series E Preferred shares, net(***)	1,178,038	14,315	14,315	—	—	—	—	—
Deemed dividend related to Series E Preferred Shares (Note 9c)	—	1,255	1,255	—	—	—	(1,255)	(1,255)
Share-based compensation (Note 9c)	—	387	387	—	—	—	—	—
Share-based compensation	—	—	—	—	—	988	—	988
Net loss	—	—	—	—	—	—	(54,488)	(54,488)
Balances as of December 31, 2017	9,138,485	$59,983	$59,983	584,151	$129	$3,540	$(92,315)	$(88,646)

(*) Net of $5,215 fair value of warrants liability issued to investors and issuance costs of $787 (cash and share-based).

(**) Net of issuance costs of $275 in cash.

(***) Net of issuance costs of $665 in cash and share-based.

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

POLYPID LTD AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,	
	2016	2017
Cash flows from operating activities:		
Net loss	$(11,392)	$(54,488)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	127	205
Re-evaluation of warrants	1,171	40,783
Share-based compensation	598	1,375
Changes in assets and liabilities:		
Increase in receivables and prepaid expenses	(276)	(705)
Decrease (increase) in other long-term assets	3	(104)
Increase in trade payables	199	385
Increase (decrease) in other payables and accrued expenses and other liabilities	(163)	237
Net cash used in operating activities	(9,733)	(12,312)
Cash flows from investing activities:		
Short-term deposits, net	(7,530)	(6,501)
Purchase of property and equipment	(539)	(1,884)
Net cash used in investing activities	(8,069)	(8,385)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred shares and warrants, net	26,344	14,315
Proceeds from exercise of options	—	68
Net cash provided by financing activities	26,344	14,383
Increase (decrease) in cash and cash equivalents	8,542	(6,314)
Cash and cash equivalents at the beginning of the year	1,679	10,221
Cash and cash equivalents at the end of the year	$ 10,221	$ 3,907
Non cash activity:		
Purchase of property and equipment	—	400
Deferred equity offering costs	—	672

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

NOTE 1:- GENERAL

a. Polypid Ltd. (the ''Company'') was incorporated under the laws of Israel and commenced its operations on February 28, 2008. The Company is a clinical-stage pharmaceutical company focused on developing and commercializing novel, locally administered therapies using its PLEX (Polymer-Lipid Encapsulation matriX) technology. The Company's product candidates are designed to address unmet medical needs by delivering active pharmaceutical ingredients, or APIs, locally at predetermined release rates and durations over extended periods ranging from days to several months. The Company is initially focused on the development of its lead product candidate, D-PLEX$_{100}$, which incorporates an antibiotic, for the prevention of surgical site infection in bone and soft tissue.

In October 2017, the Company established a wholly-owned subsidiary in the Unites States of America.

Through December 31, 2017, the Company has been primarily engaged in research and development.

b. The Company's activities since inception have consisted of performing research and development activities. Successful completion of the Company's development programs and, ultimately, the attainment of profitable operations are dependent on future events, including, among other things, its ability to obtain marketing approval from regulatory authorities; access potential markets; secure financing; conclude a customer base; attract, retain and motivate qualified personnel; and develop strategic alliances. The Company's operations are funded by its shareholders and research and development grants and the Company intends to seek further private or public financing as well as make applications for further research and development grants for continuing its operations. Although management believes that the Company will be able to successfully fund its operations, there can be no assurance that the Company will be able to do so or that the Company will ever operate profitably.

The Company expects to continue to incur substantial losses over the next several years during its development phase. To fully execute its business plan, the Company will need to complete certain research and development activities, clinical studies and validate the pilot manufacturing plant. Further, the Company's product candidates will require regulatory approval prior to commercialization as well as establish sales, marketing and logistic infrastructures. These activities may span many years and require substantial expenditures to complete and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company.

As of December 31, 2017, the Company had cash and cash equivalents and short-term deposits of $3,907 and $14,031, respectively. During the year ended December 31, 2017, the Company incurred a net loss of $54,488 and had negative cash flows from operating activities of $12,312. In addition, the Company had an accumulated deficit of $92,315 at December 31, 2017. Management plans to seek additional equity financing through private and public offerings or strategic partnerships and, in the longer term, by generating revenues from product sales.

The Company's future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above; (ii) the

NOTE 1:- GENERAL (Continued)

success of its research and development; activities; (iii) completion of all required clinical studies; (iv) completion of construction of the pilot manufacturing facility and validate such plant; (v) marketing approval by the relevant regulatory authorities; and (vi) market acceptance of the Company's products candidates.

There can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all.

c. In February, 2013, the Company signed a memorandum of understanding (the ''MOU''), with MIS Implants Technologies Ltd. (''MIS''). The MOU grants MIS an exclusive right to market a specific dental application of the Company's technology for a period of at least 5 years, starting after receipt of either European Medicines Agency (''EMA'') marketing approval or U.S. Food and Drug Administration (''FDA'') regulatory approval and beginning of commercialized sales in the applicable market, accordingly.

Under the terms of the MOU, the Company is entitled to receive up to $2,500, subject to meeting certain milestones, as specified in the MOU. Under the terms of the MOU, 45 days following the publication of the results of the clinical study report by the principal investigator, MIS is obligated to inform the Company of its intention to either continue the commercialization of the product or terminate the MOU. In event of termination by MIS, the Company is obligated to return all milestone payments received until such notification. In addition, under the terms of the MOU, within 30 days of notification of FDA requirements for the performance of a clinical trial, MIS may choose to decline to undertake such clinical trial, in which case the license to MIS granted by the Company shall exclude the U.S. territory, MIS shall not be obligated to make additional milestone payments and the Company will be obligated to return any such milestone payment, to the extent received. See Note 2l.

In the event of termination of the MOU, the Company shall retain all rights to the existing intellectual property and all intellectual property developed during the term of the MOU and shall be obligated to return all milestones received until such termination.

d. On February 21, 2018 the Board of Directors resolved to consolidate the Company's share capital by applying a reverse share split at a ratio of 8:1 (the ''Reverse Split Ratio'') such that every 8 Ordinary shares of NIS 0.10 par value, will be substituted by 1 ordinary share, NIS 0.8 par value (the ''Split''). The Split will be applied in the same proportion and manner to all of the Company's authorized, issued and outstanding securities, including preferred shares, options and warrants. See Note 10a.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements are prepared according to United States generally accepted accounting principles (''U.S. GAAP'').

a. Use of estimates:

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, the

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

Company's management evaluates estimates, including those related to fair values of convertible preferred shares warrants, fair values of share-based awards, deferred taxes, and contingent liabilities. Such estimates are based on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities at the dates of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

b. Consolidated Financial statements in U.S. dollars:

The accompanying consolidated financial statements have been prepared in U.S. dollars.

A substantial portion of the Company's expenses are incurred in New Israeli Shekels. However, the Company finances its operations mainly in U.S. dollars, a substantial portion of its expenses are incurred in U.S. dollars and potential revenues from its primary markets are anticipated to be generated in U.S. dollars. As such, the Company's management believes that the U.S. dollar is the currency of the primary economic environment in which the Company operates. Thus, the functional and reporting currency of the Company is the U.S. dollar.

Transactions and balances denominated in U.S. dollars are presented at their original amounts. Monetary accounts maintained in currencies other than the dollar are re-measured into dollars in accordance with Accounting Standards Codification No. 830, ''Foreign Currency Matters'' (''ASC 830''). All transaction gains and losses of the re-measurement of monetary balance sheet items are reflected in the statements of operations as financial income or expenses, as appropriate.

c. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its subsidiary. Intercompany balances have been eliminated upon consolidation.

d. Cash equivalents:

Cash equivalents are short-term, highly liquid investments that are readily convertible into cash with an original maturity of three months or less, at the date acquired.

e. Restricted cash:

Restricted cash is primarily invested in certificates of deposit and is used as security for the Company's lease commitments.

f. Short-term deposits

A short-term bank deposit is a deposit with a maturity of more than three months but less than one year. Deposits in U.S. dollars bear interest at rates ranging from 1.39% - 1.65% and 0.35% - 1.39%, per annum, as of December 31, 2017 and 2016, respectively. The Company had no short-term deposits in NIS as of December 31, 2017. Short-term deposits are presented at cost, which approximates market value due to their short maturities.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

g. Property and equipment, net:

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets at the following rates:

	%
Computers, software and laboratory equipment	15 - 33
Furniture and office equipment	7 - 15
Leasehold improvements	Over the shorter of the term of the lease or its useful life

h. Impairment of long-lived assets:

The Company's long-lived assets are reviewed for impairment in accordance with ASC 360, ''Property, Plant and Equipment'' (''ASC 360''), whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. During the years ended December 31, 2017 and 2016, no impairment losses have been identified.

i. Research and development expenses:

Research and development expenses consist of personnel costs (including salaries, benefits and share-based compensation), materials, consulting fees and payments to subcontractors, chemical, manufacturing and control activities, costs associated with obtaining regulatory approvals, executing pre-clinical and clinical studies and maintenance and prosecution of the Company's intellectual property rights. In addition, research and development expenses include overhead allocations consisting of various administrative and facilities related costs. The Company charges research and development expenses as expenses when incurred. Grants from the Israeli Innovation Authority (IIA) and the European Commission's Seventh Framework Programme for Research (FP7) are offset against research and development costs at the later of when grant receipt is assured or the expenses are incurred.

j. Accounting for share-based payments:

The Company accounts for share based compensation in accordance with ASC No. 718, ''Compensation — Stock Compensation'' that requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The Company recognizes compensation expenses for the value of its awards granted based on the straight-line attribution method over the requisite service period of each of the awards. The Company recognizes forfeitures of awards as they occur.

The Company selected the Black-Scholes-Merton Option-Pricing Model (OPM) as the most appropriate fair value method for its option awards. The OPM requires a number of

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

assumptions, of which the most significant are the expected share price, volatility and the expected option term.

The fair value of Ordinary shares underlying the options has historically been determined by management and the board of directors. As there has been no public market for the Company's Ordinary shares, the board of directors has determined fair value of an Ordinary share at the time of grant of the option by considering a number of objective and subjective factors including data from other comparable companies, sales of convertible preferred shares to unrelated third parties, operating and financial performance, the lack of liquidity of share capital and general and industry specific economic outlook, amongst other factors. The fair value of the underlying Ordinary shares will be determined by the board of directors until such time as the Company's Ordinary shares are listed on an established share exchange or national market system. The Company's board of directors determined the fair value of Ordinary shares based on valuations performed using the OPM method for the years ended December 31, 2017 and 2016.

The computation of expected volatility is based on actual historical share price volatility of comparable companies. Expected term of options granted is calculated using the average between the vesting period and the contractual term to the expected term of the options in effect at the time of grant. The Company has historically not paid dividends and has no foreseeable plans to pay dividends and, therefore, uses an expected dividend yield of zero in the option pricing model. The risk-free interest rate is based on the yield of U.S. treasury bonds with equivalent terms as the expected term of the options.

The fair value for options granted to employees during 2017 is estimated at the date of grant using the Black-Scholes-Merton Option Pricing Model with the following assumptions: expected volatility of 75% - 94%, risk free interest rates of 2.25% - 3.03%, dividend yield of 0%, and an expected term of 7 - 10 years. During 2017, the Company's board of directors deemed the fair value of the Company's Ordinary shares to be $3.92 - $9.52 per share as of the grant date of the options.

The fair value for options granted to employees during 2016 was estimated at the date of grant using the Black-Scholes-Merton Option Pricing Model with the following assumptions: expected volatility of 75% - 89%, risk free interest rates of 2.16% - 2.69%, dividend yield of 0%, and an expected term of 7 - 10 years. The Company's board of directors deemed the fair value of the Company's Ordinary shares to be $2.96 - $3.92 per share as of the grant date of the options.

The Company accounts for options granted to consultants and other service providers under ASC 718 and ASC 505, ''Equity-based payments to non-employees.'' The fair value of these options was estimated using the Black-Scholes Option Pricing Model. The fair value is re-measured at each reporting date for all unvested options in accordance with ASC 505.

Total share-based compensation expenses related to employees, consultants and other service providers for the years ended December 31, 2017 and 2016, amounted to $ 1,375 (out of which $667 were related to non-employees) and $598 (out of which $18 were related to non-employees), respectively.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

k. Grants and participations:

Royalty-bearing grants from the Israeli Innovation Authority (''IIA'') (previously known as Office of the Chief Scientist) of the Ministry of Economy and Industry in Israel for funding of approved research and development projects are recognized at the time the Company is entitled to such grants, on the basis of the costs incurred, and are presented as a deduction from research and development expenses. Non-royalty-bearing grants from the IIA MAGNET program and from European Commission's Seventh Framework Programme for Research (FP7) for funding approved research and development projects are recognized at the time the Company is entitled to such grants, on the basis of the costs incurred, and are presented as a deduction from research and development expenses.

Since the payment of royalties is not probable when the grants are received, the Company does not record a liability for amounts received from IIA until the related revenues are recognized. In the event of failure of a project that was partly financed by IIA, the Company will not be obligated to pay any royalties or repay the amounts received.

The Company recognizes participations in R&D development, as a reduction from R&D expenses. The excess of the recognized amount received over the amount of research and development expenses incurred during the period is recognized as other income within operating income.

l. Advance on account of collaboration agreement

Through December 31, 2017, milestone payments totaling $600 were received by the Company from MIS (see Note 1c). These amounts were recorded as an advance on account of the collaboration agreement. To date, no amounts were recognized in the statements of operations with respect to the collaboration agreement, as all the amounts are refundable.

m. Convertible preferred shares and convertible preferred shares warrant liability:

The terms of the convertible preferred A, A-1, B, B-1, C-1, C-2, D-1, D-3 and E shares allow the holders to redeem shares, under certain circumstances, outside of the Company's control. Therefore, these shares are classified as mezzanine equity on the balance sheet and are not included as a component of shareholders' deficiency. The carrying value of the convertible preferred shares is equal to cost. The Company has not adjusted the carrying value to redemption value since it is not probable that the convertible preferred shares will be redeemed.

Warrants to purchase the Company's convertible preferred shares are classified as a liability on the balance sheet, and measured at fair value, as the underlying shares are contingently redeemable (upon a deemed liquidation event) and, therefore, may obligate the Company to transfer assets at some point in the future. The warrants are subject to re-measurement to fair value at each balance sheet date and any change in fair value is recognized as a component of financial expenses, net, in the statement of operation. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants, or the completion of a deemed liquidation event (see Note 10).

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

n. Fair value of financial instruments:

The Company applies ASC 820, ''Fair Value Measurements and Disclosures'' (''ASC 820''), pursuant to which fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the ''exit price'') in an orderly transaction between market participants at the measurement date.

In determining fair value, the Company uses various valuation approaches. ASC 820 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company.

Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

Fair value is an exit price, representing the amount that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

A three tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

- Level 1 — Observable inputs that reflect quoted prices (unadjusted) in active markets for identical assets and liabilities.
- Level 2 — Include other inputs that are directly or indirectly observable in the marketplace.
- Level 3 — Unobservable inputs which are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The financial instruments carried at fair value on the Company's balance sheet as of December 31, 2017 and 2016 are convertible preferred shares warrants classified as a liability. See Note 7.

The following methods and assumptions were used by the Company in estimating their fair value disclosures for financial instruments:

The carrying amounts of cash and cash equivalents, short-term deposits, prepaid expenses and other receivables, trade payables, advances on account of collaboration agreement and other accounts payable and accrued expenses approximate their fair value due to the short-term maturity of such instruments.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

o. Basic and diluted net loss per share:

Basic loss per share is computed based on the weighted average number of Ordinary shares outstanding during each year. Diluted loss per share is computed based on the weighted average number of Ordinary shares outstanding during each year, plus the dilutive effect of options considered to be outstanding during each year, in accordance with ASC 260, ''Earnings Per Share'' (''ASC 260'').

For the years ended December 31, 2017 and 2016, all outstanding options have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive for the periods presented.

p. Income taxes:

The Company accounts for income taxes in accordance with ASC 740, ''Income Taxes'' (''ASC 740''). ASC 740 prescribes the use of the liability method whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, to reduce deferred tax assets to their estimated realizable value, if needed.

ASC 740 contains a two-step approach to recognizing and measuring a liability for uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. As of December 31, 2017, and 2016 no liability for unrecognized tax benefits was recorded as a result of ASC 740.

The Company's policy is to accrue interest and penalties related to unrecognized tax benefits in its taxes on income.

q. Concentration of credit risks:

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents.

Cash, cash equivalents and short-term deposits are deposited in major banks in Israel. Such investments in Israel may be in excess of insured limits and are not insured in other jurisdictions. Generally, cash and cash equivalents may be redeemed upon demand and, therefore, bear minimal risk (see note 2f).

The Company has no off-balance sheet concentration of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

r. Severance pay:

All the Company's employees have subscribed to Section 14 of Israel's Severance Pay Law, 5723-1963 (''Section 14''). Pursuant to Section 14, employees covered by this section are entitled to monthly deposits at a rate of 8.33% of their monthly salary, made on their behalf by the Company. Payments in accordance with Section 14 release the Company from any future severance liabilities in respect of those employees.

Neither severance pay liability nor severance pay fund under Section 14 for such employees is recorded on the Company's balance sheet.

Through February 2016, several employees also provided services to the Company as service providers. The Company has recorded a provision for severance pay liability for such service providers.

Severance pay expense for the years ended December 31, 2017 and 2016 amounted to $307 and $249, respectively.

s. Contingent liabilities

The Company accounts for its contingent liabilities in accordance with ASC 450, ''Contingencies'' (''ASC 450''). A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter.

The Company is occasionally a party to routine claims or litigation incidental to its business. The Company does not believe that it is a party to any pending legal proceeding that is likely to have a material adverse effect on its business, financial condition or results of operations. The Company recorded an accrual in the consolidated statement of operations, which it deems appropriate.

t. Recently adopted accounting pronouncements

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, Compensation — Stock Compensation (Topic 718): Improvement to Employee Share-based Payment Accounting (ASU 2016-09), to simplify the accounting for share-based payment transactions, including the income tax consequences, an option to recognize gross share-based compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. Upon adoption of ASU 2016-09, the Company elected to change its accounting policy to account for forfeitures as they occur. The guidance was applied on a modified, retrospective basis in the first quarter of fiscal 2017 and did not have a material impact on the Company's financial results.

u. New pronouncements not yet effective

In February 2016, the FASB issued ASU 2016-02, ''Leases (Topic 842)'' (''ASU 2016-02''), whereby, lessees will be required to recognize for all leases at the commencement date a

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. Under the new guidance, lessor accounting is largely unchanged. A modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the consolidated financial statements must be applied. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Companies may not apply a full retrospective transition approach. ASU 2016-02 is effective for annual and interim periods beginning after December 15, 2018. Early application is permitted.

In November 2016, the FASB issued Accounting Standards Update No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (ASU 2016-18), which requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This guidance will be effective for us in the first quarter of 2018 and early adoption is permitted. The Company does not expect the guidance to have a material impact on its financial results.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260); (Part I) Accounting for Certain Financial Instruments with Down Round Features. The ASU allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be classified as liabilities.

A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, such as warrants, an entity will treat the value of the effect of the down round, when triggered, as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. The guidance in ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, and the guidance is to be applied using a full or modified retrospective approach. The Company is evaluating the impact of the revised guidance and does not expect it to have a material impact on its financial results.

v. Pro forma balance sheet and pro forma net loss per ordinary share:

The Company is contemplating the filing of a Registration Statement with the U.S. Securities and Exchange Commission to register the offer and sale of the Company's Ordinary shares in connection with the Company's planned qualified initial public offering (''Qualified IPO'') in accordance with the Company's Amended and Restated Articles of Association.

A Qualified IPO is defined as a closing of an offering by the Company of its securities to the public in a bona fide underwriting arrangement under the U.S. Securities Act of 1933, the Israeli Securities Law or similar securities law of another jurisdiction, with gross offering proceeds of not less than $22,000.

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

Immediately prior to the closing of the Qualified IPO, all of the issued and outstanding preferred shares will be automatically converted into ordinary shares. The unaudited pro forma balance sheet as of December 31, 2017 has been prepared assuming the automatic conversion of all outstanding preferred shares and A warrants into 9,194,735 ordinary shares and the classification of D-2 warrants into shareholders' equity. Pro forma net loss per ordinary share is disclosed in the consolidated statements of operations, which also gives effect to the assumed conversion of the preferred shares as described above.

NOTE 3:- PREPAID EXPENSES AND OTHER RECEIVABLES

	December 31,	
	2016	2017
Government authorities	$170	$355
Prepaid expenses	258	305
Grants receivable from IIA	47	100
Lease deposits	28	28
Others	—	4
	$503	$792

NOTE 4:- PROPERTY AND EQUIPMENT, NET

	December 31,	
	2016	2017
Cost:		
Computers and software	$ 148	$ 191
Laboratory equipment	809	1,613
Furniture and office equipment	110	133
Leasehold improvements	341	1,755
	1,408	3,692
Accumulated depreciation	(561)	(766)
Depreciated cost	$ 847	$2,926

Depreciation expenses amounted to $205 and $127 for the years ended December 31, 2017 and 2016, respectively.

U.S. dollars in thousands (except share and per share data)

NOTE 5:- OTHER PAYABLES AND ACCRUED EXPENSES

	December 31,	
	2016	2017
Employees and payroll accruals	$439	$ 507
Accrued expenses	377	730
Other expenses	104	108
	$920	$1,345

NOTE 6:- COMMITMENTS AND CONTINGENT LIABILITIES

a. The facilities of the Company are leased under operating lease agreements for periods ending no later than 2028. The Company also leases motor vehicles under various operating leases, the latest of which expires in 2020.

Future minimum lease payments under operating leases as of December 31, 2017 are as follows:

As of December 31, 2017	
2018	1,068
2019	1,061
2020	1,021
2021	1,021
2022	1,017
Thereafter	2,905
	$8,093

As of December 31, 2017, the Company made advance payments on account of car leases in the amount of $103.

Rental and lease expenses for the years ended December 31, 2017 and 2016 were $785 and $626, respectively.

b. In connection with its research and development programs, through December 31, 2017, the Company received and accrued participation payments from the IIA in the aggregate amount of $4,652. In return for IIA's participation, the Company is committed to pay royalties at a rate of 3% of sales of the developed product, up to 100% of the amount of grants received plus interest at LIBOR rate. Through December 31, 2017, no royalties have been paid or accrued.

c. On December 22, 2016, the Company received a written demand for a finder's fee in amount of $250, in connection with 2nd 2016 SPA. In September 2017, a suit was filed against the Company in the Tel-Aviv Magistrates Court in amount of $250.

The Company believes it has strong defense claims and intends to vigorously defend its position. The Company cannot assess the outcome of this claim due its early stage. The Company included a provision in its consolidated financial statements, which management believe it sufficient.

U.S. dollars in thousands (except share and per share data)

NOTE 7:- FAIR VALUE MEASUREMENTS

Financial instruments measured at fair value on a recurring basis include convertible preferred shares warrants. The warrants are classified as a liability in accordance with ASC 480-10-25 (see Note 9). These warrants were classified as level 3 in the fair value hierarchy since some of the inputs used in the valuation (the share price) were determined based on management's assumptions. The fair value of the warrants on the issuance date and on subsequent reporting dates was determined using the OPM model. The fair value of the underlying convertible preferred share price was determined by the board of directors considering, among others, a third party valuation. The valuation of the Company was performed using a DCF model. The Company's enterprise value was determined based on financing transactions with third parties and price indications from bankers. The OPM method was then employed to allocate the enterprise value among the Company's various equity classes, deriving a fully marketable value per share for the convertible preferred shares.

The underlying share price was $22.16 for the convertible preferred D-2 shares. The following assumptions were used to estimate the value of the Series D-2 Preferred share warrants as of December 31, 2017: expected volatility of 95.4%, risk free interest rates of 2.69%, dividend yield of 0% and expected term of 4.25 years.

The underlying share price was $21.92 for the convertible preferred A shares. The following assumptions were used to estimate the value of the Series A Preferred share warrants as of December 31 2017: expected volatility of 95.4%, risk free interest rates of 2.69%, dividend yield of 0% and expected term of 4.25 years.

In respect with the issuance warrants during 2016, see also Note 9d.

The change in the fair value of the preferred share warrants liability is summarized below:

	2016	2017
Beginning of year	$ 193	$ 6,616
Issuance of warrants	5,252	—
Expiration of warrants C-1, C-2 and D-1	—	(70)
Change in fair value	1,171	40,853
End of year	$6,616	$47,399

NOTE 8:- INCOME TAXES

a. Corporate tax rates:

The corporate tax rate in Israel in 2016 and 2017 was 26.5% and 24%, respectively.

On January 4, 2016, the Israeli Parliament's approved the Bill for Amending the Income Tax Ordinance (No. 217) (Reduction of Corporate Tax Rate), 2015, which consists of the reduction of the corporate tax rate from 26.5% to 25%.

In December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), 2016,

U.S. dollars in thousands (except share and per share data)

NOTE 8:- INCOME TAXES (Continued)

which reduces the corporate income tax rate to 24% (instead of 25%) effective from January 1, 2017 and to 23% effective from January 1, 2018.

b. Net operating losses carry forward:

The Company has accumulated losses for tax purposes as of December 31, 2017 in the amount of approximately $40,206 which may be carried forward and offset against taxable income in the future for an indefinite period.

c. Deferred taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's deferred tax assets are comprised of operating loss carryforwards and other temporary differences.

Significant components of the Company's deferred tax assets are as follows:

	December 31,	
	2016	2017
Reserves and allowances	$ 108	$ 148
Temporary differences	735	941
Loss carryforward	5,749	9,248
Deferred tax assets before valuation allowance	6,592	10,337
Less — valuation allowance	(6,592)	(10,337)
Net deferred tax assets	$ —	$ —

Management currently believes that since the Company has a history of losses, and uncertainty with respect to future taxable income, it is more likely than not that the deferred tax assets will not be utilized in the foreseeable future. Thus, a full valuation allowance was provided to reduce deferred tax assets to their realizable value.

In 2017 and 2016, the main reconciling item of the statutory tax rate of the Company, 24% and 26.5%, respectively, to the effective tax rate of 0%, is tax loss carryforwards for which a full valuation allowance was provided.

d. Tax assessment:

The Company received final tax assessments through 2013.

U.S. dollars in thousands (except share and per share data)

NOTE 9:- CONVERTIBLE PREFERRED SHARES AND WARRANTS

a. The Composition of the Company's Convertible Preferred shares is as follows:

	December 31, 2016		December 31, 2017	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Series A Convertible Preferred shares of NIS 0.8 par value	562,500	506,250	562,500	506,250
Series A-1 Convertible Preferred shares of NIS 0.8 Par value	937,500	835,721	937,500	835,721
Series B Convertible Preferred shares of NIS 0.8 par value	625,000	592,454	625,000	592,454
Series B-1 Convertible Preferred shares of NIS 0.8 par value	1,953,517	1,831,912	1,953,517	1,831,912
Series C-1 Convertible Preferred shares of NIS 0.8 par value	750,000	675,651	750,000	675,651
Series C-2 Convertible Preferred shares of NIS 0.8 par value	475,000	429,073	475,000	429,073
Series D-1 Convertible Preferred shares of NIS 0.8 par value	2,625,000	2,485,889	2,625,000	2,485,889
Series D-2 Convertible Preferred shares of NIS 0.8 par value	3,000,000	—	3,000,000	—
Series D-3 Convertible Preferred shares of NIS 0.8 par value	625,000	603,497	625,000	603,497
Series E Convertible Preferred shares of NIS 0.8 par value	—	—	1,187,500	1,178,038
Total	11,553,517	7,960,447	12,741,017	9,138,485

The Company issued Series A, A-1, B, B-1, C-1, C-2, D-1, D-3 and E convertible preferred shares between the years 2008 and 2017. The Company classifies the convertible preferred shares outside of shareholders' equity (deficiency) as required by ASC 480-10-S99-3A and ASR 268, since these convertible preferred shares are entitled to liquidation preferences which may trigger a distribution of cash or assets that is not solely within the Company's control.

Pursuant to the Company's Amended and Restated Articles of Incorporation (the ''AoA''), a deemed liquidation event would occur, inter alia, upon the closing of the transfer of the Company's securities to a person or a group of affiliated persons, in one or a series of related transactions, if immediately after such transaction, such person or group of affiliated persons would hold 50% or more of the outstanding voting shares of the Company and upon the occurrence of the events listed in the AoA. For the years ended December 31, 2017 and 2016, the Company did not adjust the carrying values of the convertible preferred shares to the deemed liquidation values of such shares since a deemed liquidation event was not probable at each balance sheet date. Subsequent adjustments to increase the carrying values to the ultimate liquidation values will be made only when it becomes probable that such a deemed liquidation event will occur.

NOTE 9:- CONVERTIBLE PREFERRED SHARES AND WARRANTS (Continued)

b. Preferred shares rights:

Series A, A-1, B, B-1, C-1,C-2, D-1,D-3 and E convertible preferred shares confer upon their holders all the rights conferred by Ordinary shares, in addition to certain rights stipulated in the Company's AOA, inter alia, the following:

Dividend rights — the holders of Series A, A-1, B, B-1, C-1, C-2 , D-1, D-3 and E convertible preferred shares shall be entitled to receive on a pari passu basis, prior and in preference to the declaration or payment of any dividend or distribution to the holders of any other class of shares on an as-converted basis if any dividend or distribution is declared by the Company's board of directors, an amount equal to 6% of the applicable original issue price for such preferred shares per annum (the ''Preference Dividend'').

The preference order is such that Series E, Series D, Series C-2, Series C-1, Series B-1, Series B, Series A-1 and Series A shareholders shall be entitled, in their respective order, to receive, prior and in preference to the above order, any distribution of any asset, capital, earnings or surplus funds of the Company. After the Preference Dividend has been paid in full, the preferred shareholders' shall participate pro-rata and pari-passu, on an as converted basis with the Ordinary shareholders' in the receipt of any additional dividend distributed.

Liquidation rights — In the event of any event of liquidation or deemed liquidation event, the Company shall distribute to the holders of convertible preferred shares, prior to and in preference to any payments to any of the holders of any other classes of shares, a per share amount equal to the original issuance price plus 6% annual interest compounded annually from the date of issuance and up to the date of liquidation for each of their shares. Holders of Series E preferred shares and D preferred shares shall receive an amount equal to the original issuance price thereof, times 1.3, plus 6% annual interest, on the original issue price, compounded annually from the date of issuance and up to the date of liquidation for each of their shares plus an amount equal to the declared but unpaid dividends, less the amount any dividend preference previously declared and actually paid.

The liquidation order is such that Series E, Series D, Series C-2 and Series C-1, Series B-1, Series B Series A-1, and Series A shareholders' shall be entitled, in their respective order, to receive, prior and in preference to the above order any distribution of any asset, capital, earnings or surplus funds of the Company.

All remaining assets shall be distributed among all the shareholders pro rata in proportion to the number of Ordinary shares held by them on an as converted basis. The original issue price of the Series A, A-1, B, B-1 and C-1 Preferred shares is $1.44, $1.68, $3.44, $4.84, and $6.64 per share, respectively, Series C-2, D-1 and D-3 is $8.83 per share and Series E is $12.72 per share.

Voting rights — each holder of Series A, A-1, B, B-1, C-1, C-2, D-1, D-3 and E Convertible Preferred share is entitled to one vote per each share held by it (on an as converted basis).

Conversion — each preferred share is convertible into ordinary shares, at the holder's option, or automatically upon a Qualified Initial Public Offering (''Qualified IPO'') of the Company or upon written demand of the Investor Majority (as defined in the AoA).

NOTE 9:- CONVERTIBLE PREFERRED SHARES AND WARRANTS (Continued)

At the current conversion prices, each share of Series A, A-1, B, B-1, C-1, C-2, D-1, D-3 and E will convert to ordinary shares on a 1-for-1 ratio. The current conversion price per preferred share will be adjusted in the event of recapitalizations, splits, Ordinary share dividends and standard anti-dilution events.

c. Financing rounds:

On February 4, 2016, the Company entered into a Share Purchase Agreement (the ''2016 SPA'') with new and existing investors, the closing of which was consummated on February 24, 2016. According to the 2016 SPA, the Company shall issue to the investors up to 2,548,586 series D-1 Preferred shares for an aggregate amount of up to $22,500, at a price per share of $8.83 and shall grant to the investors and/or any other individuals or entities as instructed by the investors, warrants to purchase up to 2,548,586 D-2 Preferred shares at a price per share of $10.15 against payment of a total exercise amount of up to $25,875.

The Company issued to the investors 2,485,889 series D-1 convertible preferred shares and warrants for an aggregate consideration of $15,944 (net of $5,215 fair value of warrants liability issued to investors and issuance costs as described below). Issuance costs consisting of: (1) $570 in cash, (2) $180 settled as issuance of Preferred D-1 shares to MarketBridges, and (3) $37 value of warrants issued to MarketBridges (as described below).

On August 24, 2016, the Company entered into a Securities Purchase Agreement (the ''2nd 2016 SPA '') with new and existing investors, the closing of which was consummated on November 8, 2016. According to the 2nd 2016 SPA and the joinder thereto, the Company shall issue to the investors 603,497 Series D-3 Preferred Shares for an aggregate amount of $5,328 at a price per share of $8.83 ($5,053, net of $275 issuance costs in cash).

During August to October 2017, the Company entered into a Securities Purchase Agreement (the ''2017 SPA'') with new and existing investors for an aggregate amount of up to $15,000. The Company received $13,410 as part of the initial closing and issued to the investors 1,054,581 Series E Preferred Shares (net of $620 issuance costs) at a price per share of $12.72. Issuance costs consisting of: (1) $102 in cash and (2) $518 settled as issuance of Preferred E shares as a finder fee.

During November to December, as part of the deferred closing, the Company entered into Joinder Agreements to the 2017 SPA with new and existing investors, and received an additional amount of $1,570 (net of $45 issuance costs) and issued to the investors 123,457 Series E Preferred Shares, at a price per share of $12.72. The fair value of the Series E Preferred Shares issued in the deferred closing to the 2017 SPA was higher than value of the Series Preferred Shares issued in the initial closing to the 2017 SPA, and accordingly, the Company measured a beneficial feature of $1,255 for the deferred closing investors which was accounted for as a deemed dividend and was recorded as mezzanine equity for the year ended December 31, 2017.

The Company recorded compensation expenses of $387 against mezzanine equity for the year ended December 31, 2017 in respect of a shareholder and director who participated in the deferred closing to the 2017 SPA (see Note 14).

NOTE 9:- CONVERTIBLE PREFERRED SHARES AND WARRANTS (Continued)

The terms of the convertible preferred E shares allow the holders to redeem shares, under certain circumstances, outside of the Company's control. Therefore, these shares are classified as mezzanine equity on the balance sheet and are not included as a component of shareholders' deficiency. The carrying value of the convertible preferred shares is equal to cost. The Company has not adjusted the carrying value to redemption value since it is not probable that the convertible preferred shares will be redeemed.

d. Warrants to purchase preferred shares:

In March 2008, in connection with the March 2008 Founders and Share Purchase Agreement, the Company granted to the investor warrants to purchase preferred A shares, with an exercise price of NIS 0.80.

The A warrants may be converted at any time until the earlier of (1) consummation of an initial public offering on certain stock exchanges as set forth in the warrant terms, with net proceeds to the Company of at least $15,000 (and pre-money valuation of at least $75,000), (2) merger or consolidation of the Company with another company, and (3) the sale of substantially all of the Company's assets or substantially all of the shares to another party. The Company anticipates that the A warrants will be exercised prior to the closing of this offering.

In January 2015, in connection with the receipt of convertible loans in the amount of $1,500 to a certain investor (the ''Investor''), the Company issued warrants to purchase preferred shares to Market Bridges Ltd. (''MarketBridges''). The C-1 warrants expired on June 11, 2017 prior to any exercise.

In September 2015, in connection with the issuance of C-2 shares in the amount of $500 to a certain investor (the ''New Investor''), the Company issued warrants to purchase preferred shares to MarketBridges. The C-2 warrants expired on September 2, 2017 prior to any exercise.

On February 23, 2016, in connection with 2016 SPA the Company granted to the investors and/or any other individuals or entities as instructed by the investors, warrants to purchase up to 20,389 D-1 Preferred shares and up to 2,506,273 D-2 Preferred shares at a price per share of $10.15 against payment of a total exercise amount of up to $25,875 (see b above).

The 2016 SPA, as amended, provided that the Company shall issue additional D-2 warrants to purchase preferred D-2 shares if the Company did not complete an initial public offering (''IPO'') by December 31, 2016 of its shares in the United States, which yields gross proceeds to the Company of at least $22 million. In such event, the exercise price of all the D-2 warrants shall concurrently be reduced to $8.83 per preferred D-2 share. Accordingly, during January 2017, the Company issued an additional 375,942 warrants to purchase preferred D-2 shares with an exercise price of $8.83, 6,117 of which were issued as part of the issuance expenses to MarketBridges (see below).

In February 2016, in connection with 2016 SPA and in accordance with the terms of the Service Finance Agreement with MarketBridges, the Company included the following as part of its issuance costs: (1) $360, representing 5% of the investment made by the New Investor (out of which, $180 was settled in cash and $180 as payment for issuance of 20,389 Preferred D-1

U.S. dollars in thousands (except share and per share data)

NOTE 9:- CONVERTIBLE PREFERRED SHARES AND WARRANTS (Continued)

shares and issuance of 20,389 warrants to purchase D-1 Preferred shares) and (2) 40,777 issuance of D-2 warrants with an exercise price of $10.15 representing 5% of the shares to be received by the New Investor (see also b above).

All outstanding A and D-2 warrants are classified as a long-term liability and are re-measured at each reporting date, as the underlying shares may be redeemed upon an event which is not solely in the control of the Company.

The D-1 warrants expired on February 4, 2017 prior to any exercise.

The survival of D-2 warrants shall be limited to a period ending upon the earlier of: (i) the lapse of 5 years from closing; or (ii) deemed liquidation event.

The D-2 warrants will be exercised automatically if they are still outstanding on the final day of the warrant period as defined in the warrants grant letter, and if the fair market value of a warrant share is more than the exercise price for such share.

As of December 31, 2017, 2,882,215 D-2 warrants and 56,250 A warrants are outstanding.

NOTE 10:- SHAREHOLDERS' DEFICIENCY

a. General:

All Ordinary shares, Convertible Preferred shares, options, convertible loans, warrants, exercise prices, per share data and loss per share amounts have been adjusted retroactively for all periods presented in these financial statements, to reflect the eight-to-one reverse share split approved by the Company's board of directors on February 21, 2018 and par value adjustment from NIS 0.1 to NIS 0.8.

b. Ordinary share capital is composed as follows:

	December 31, 2016		December 31, 2017	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Ordinary shares of NIS 0.08 par value	14,500,000	568,078	15,687,500	584,151

c. Ordinary shares rights:

The Ordinary shares confers upon its holders the right to participate in the general meetings of the Company, to vote at such meetings (each share represents one vote), and to participate in any distribution of dividends or any other distribution of the Company's property, including the distribution of surplus assets upon liquidation.

U.S. dollars in thousands (except share and per share data)

NOTE 10:- SHAREHOLDERS' DEFICIENCY (Continued)

d. Share option plans:

The Company has authorized through its 2012 Share Option Plan, the grant of options to officers, directors, advisors, management and other key employees of up to 2,219,443 Ordinary shares. The options granted generally have a three-year vesting period and expire ten years after the date of grant. Options granted under the Company's option plan that are cancelled or forfeited before expiration become available for future grant. As of December 31, 2017, 200,442 of the Company's options were available for future grants.

On July 19, 2015, the board of directors approved that if any transaction (merger, acquisition, reorganization of the company with one or more other entities pursuant to which the company is not the surviving entity or sale of all or substantially all of the assets or shares of the company) is consummated by the Company, then the vesting schedule of the options granted to its senior management shall be accelerated so that 50% of the unvested options shall be fully vested immediately prior to the transaction, and the remaining 50% of the then unvested options shall continue to vest in accordance with the same vesting schedule.

A summary of the status of options to employees under the Company's option plan as of December 31, 2017 and changes during the relevant period ended on that date is presented below:

	Year ended December 31, 2017			
	Number of options	Weighted average exercise price	Aggregate intrinsic value	Weighted average remaining contractual life (years)
Outstanding at beginning of year	1,120,280	4.00	1,306	7.43
Granted	592,312	6.88		
Exercised	(16,073)	4.24		
Forfeited and cancelled	(1,337)	2.96		
Outstanding at end of year	1,695,182	4.96	22,596	7.60
Exercisable options	973,288	3.68	14,272	6.14
Vested and expected to vest	1,695,182	4.96	22,596	7.60

On November 2, 2017, the Company's compensation committee and board of directors resolved to recommend before the shareholders to grant to the Company's CEO, CFO and CTO options to purchase 162,500, 75,000 and 162,500 shares, respectively, at an exercise price of $7.36 per share, which was the fair market value known at such date.

The options shall vest quarterly and become exercisable during a three-year period as of the vesting commencement date (1/12 at the end of each quarter). It is hereby clarified that if the IPO does not accrue until the eleven month anniversary of the vesting commencement date, any and all options hereby granted shall expire immediately.

U.S. dollars in thousands (except share and per share data)

NOTE 10:- SHAREHOLDERS' DEFICIENCY (Continued)

A summary of options to employees under the Company's option plan as of December 31, 2016 and changes during the relevant period ended on that date is presented below:

	Year ended December 31, 2016			
	Number of options	Weighted average exercise price	Aggregate intrinsic value	Weighted average remaining contractual life (years)
Outstanding at beginning of year	1,034,932	2.72	877	8.16
Granted	114,356	3.44		
Exercised	—	—		
Forfeited and cancelled	(29,008)	4.96		
Outstanding at end of year	1,120,280	4.00	1,306	7.43
Exercisable options	820,092	3.12	1,259	6.79
Vested and expected to vest	1,120,280	4.00	1,306	7.43

The total equity-based compensation expense related to all of the Company's equity-based awards recognized for the year ended December 31, 2016 and 2017, was comprised as follows:

	Year ended December 31,	
	2016	2017
Research and development	289	393
General and administrative	309	982
Total share-based compensation expense	598	1,375

General and administrative costs include compensation expenses of $387 related to the deferred closing of 2017 SPA (see Note 9c).

As of December 31, 2017, there were unrecognized compensation costs of $5,630, which are expected to be recognized over a weighted average period of approximately 2.7 years.

The weighted average grant date fair value of the Company's options granted during the year ended December 31, 2017, and 2016 was $6.88 and $3.44, respectively.

16,073 options were exercised during the year ended December 31, 2017, no options were exercised during the year ended December 31, 2016. The Company's board of directors deemed the fair value of the Company's Ordinary shares to be $18.32 per share as of December 31, 2017.

U.S. dollars in thousands (except share and per share data)

NOTE 10:- SHAREHOLDERS' DEFICIENCY (Continued)

The options outstanding as of December 31, 2017 are comprised, as follows:

Exercise price(*)	Options outstanding as of December 31, 2017	Weighted average exercise price	Weighted average remaining contractual term	Options exercisable as of December 31, 2017	Weighted average exercise price	Weighted average remaining contractual term
			(years)			(years)
0.24	261,047	0.24	5.22	261,047	0.24	5.04
1.68	112,870	1.68	5.22	112,870	1.68	5.22
3.44	87,346	3.44	5.33	87,346	3.44	5.33
4.84	308,213	4.84	6.33	308,213	4.84	6.33
8.83	221,319	8.83	7.87	151,905	8.83	7.86
2.96	39,575	2.96	8.41	19,275	2.96	8.40
3.76	72,500	3.76	8.98	24,167	3.76	8.98
3.92	23,875	3.92	9.19	5,969	3.92	9.19
4.00	58,750	4.00	9.40	2,496	4.00	9.40
7.36	509,687	7.36	9.84	—	7.36	—
	1,695,182	4.96	7.60	973,288	3.68	6.14

(*) The exercise price of the options is denominated in NIS and was translated to USD in the table above using the exchange rate as of the issuance date of the options. The options were granted at the Ordinary share par value.

e. Options issued to non-employees:

Outstanding options granted to consultants as of December 31, 2017 were as follows:

Grant date	Options outstanding as of December 31, 2017	Exercise price per share	Options exercisable as of December 31, 2017	Exercisable through
March 2013	23,282	$1.68	23,282	March 2023
October 2013	5,982	$4.84	5,982	October 2023
June 2014	5,875	$4.84	5,875	June 2024
September 2014	5,982	$4.84	5,982	September 2024
April 2016	6,250	$2.96	3,633	April 2026
December 2016	7,500	$3.76	3,103	March 2023
June 2017	206,823	$3.92	52,299	June 2027
August 2017	5,875	$8.88	3,415	August 2027
November 2017	56,250	$7.36	—	March 2027
	323,819		103,571	

U.S. dollars in thousands (except share and per share data)

NOTE 11:- FINANCIAL EXPENSES, NET

	Year ended December 31,	
	2016	2017
Financial expenses:		
Revaluation of warrants	1,171	40,783
Others	108	16
Total financial expenses, net	1,279	40,799
Financial income:		
Interest from deposits	(71)	(90)
Foreign currency transaction gains, net	(75)	(21)
Total financial income:	(146)	(111)
Financial expenses, net	$1,133	$40,688

NOTE 12:- BASIC AND DILUTED NET LOSS PER SHARE

The following table sets forth the computation of the Company's basic and diluted net loss per Ordinary share:

	Year ended December 31,	
	2016	2017
Numerator:		
Net loss attributable to Ordinary shares as reported	$ (11,392)	$ (54,488)
Preferred share preference	(2,608)	(3,399)
Deemed dividend	—	(1,255)
Net loss applicable to Ordinary shareholders	$ (14,000)	$ (59,142)
Denominator:		
Weighted average shares used in computing net loss per Ordinary share, basic and diluted:		
Ordinary share — basic	568,078	579,676
Ordinary share equivalents	—	—
Ordinary share — dilutive	568,078	579,676
Net loss per ordinary share, basic and diluted	$ (24.64)	$ (102.00)

The impact of share-based options, warrants, and the convertible preferred shares on earnings per share is anti-dilutive as the Company had a net loss in 2017 and 2016.

U.S. dollars in thousands (except share and per share data)

NOTE 13:- PRO FORMA BASIC AND DILUTED NET LOSS PER SHARE

The following table sets forth the computation of the Company's pro forma basic and diluted net loss per ordinary share (unaudited):

	Year ended December 31, 2017
	Unaudited
Net loss attributable to ordinary shares as reported	$ (55,743)
Shares used in computing net loss per ordinary share, basic and diluted	579,676
Pro forma adjustments to reflect assumed conversion of convertible preferred shares and exercise of warrants A	8,242,844
Shares used in computing pro forma net loss per ordinary share, basic and diluted	8,822,520
Pro forma net loss per ordinary share, basic and diluted	$ (6.32)

The A warrants will expire upon the consummation of the Company's initial public offering. Accordingly, the Company assumes, considering the exercise price of the A warrants and the fair value of the Company's Ordinary Shares at present, and the increase in fair value following the Company's initial public offering, that the investors will exercise the A warrants prior to the warrants' expiration.

The D-2 warrants, on the other hand, do not expire upon the consummation of the Company's initial public offering. Accordingly, no assumptions are made regarding exercise by investors. Furthermore, pursuant to their terms, if at any time the entire class of Series D-2 preferred shares is converted into Ordinary Shares, then the warrant shall automatically be deemed exercisable into Ordinary Shares. Pursuant to the Company's articles of association currently in effect, upon the consummation of the Company's initial public offering, the entire class of Series D-2 preferred shares shall be converted into Ordinary Shares.

NOTE 14:- RELATED PARTY TRANSACTIONS

a. The Company executed a transaction with a related party as detailed below.

As described in Note 9c, on December 20, 2017, as part of the deferred closing of the 2017 SPA a shareholder and director of the Company invested $370 for the issuance of 29,087 Series E Preferred Shares. In this respect, the Company recorded general and administrative compensation expenses of $387 against mezzanine equity for the year ended December 31, 2017.

NOTE 15:- SUBSEQUENT EVENTS

a. The Company evaluates events or transactions that occur after the balance sheet date but prior to the issuance of the consolidated financial statements to identify matters that require

NOTE 15:- SUBSEQUENT EVENTS (Continued)

additional disclosure. For its annual consolidated financial statements as of December 31, 2017 and for the year then ended, the Company evaluated subsequent events through March 14, 2018, the date that the consolidated financial statements were issued. Except as described below, the Company has concluded that no subsequent event has occurred that require disclosure.

b. On January 30, 2018, the Board of Directors approved to increase the option pool by 750,000 options.

c. On January 30, 2018, the Board of Directors approved a grant of 16,563 options to certain employees. 33% of the options shall vest on the first anniversary of the vesting commencement date, and additional 8.375% of the options shall vest upon the lapse of each full additional three months of the vesting commencement date, for an additional period of two years.

d. On January 30, 2018, the Board of Directors of the Company recommended to the Company's shareholders to approve the grant of 37,500 options to Jacob Harel, the Chairman of the Board of Directors. On February 8, 2018, the shareholders of the Company approved this grant.

- - - - - - - - - - - - -

3,333,333 Shares

PolyPid Ltd.

Ordinary Shares

Goldman Sachs & Co. LLC **Cowen**

Cantor

Raymond James **Oppenheimer & Co.**

Through and including , 2018 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.