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[POLYPID LTD. FINANCIAL STATEMENTS AS OF AND FOR THE YEARS ENDED DECEMBER 31, 2015 AND 2016 \(U.S. DOLLARS IN THOUSANDS\)](#)

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As confidentially submitted to the Securities and Exchange Commission on November 8, 2017

Registration No. 333-

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

FORM F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

PolyPid Ltd.

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

State of Israel

(State or other jurisdiction of
incorporation or
organization)

2834

(Primary Standard Industrial
Classification Code Number)

Not Applicable

(I.R.S. Employer
Identification Number)

**18 Hasivim Street
Petach Tikva 4959376, Israel
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(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this Registration Statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	Proposed Maximum Aggregate Offering Price ⁽¹⁾	Amount of Registration Fee ⁽²⁾
Ordinary Shares, par value NIS 0.10 per share	\$	\$

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes the ordinary shares that the underwriters have the option to purchase.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion. Dated November 8, 2017

Shares



PolyPid Ltd.

Ordinary Shares

This is an initial public offering of the ordinary shares of PolyPid Ltd. All of the 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 \$ and \$. Application will be 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 10 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 163 for additional information regarding underwriting compensation.

The underwriters have the option to purchase up to an additional 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

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 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 0.10 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. We are initially focused on the development of our lead product candidate, D-PLEX, which incorporates doxycycline, a versatile antibiotic, for the management of surgical site infections, or SSIs, in bone and soft tissue. We recently completed patient enrollment of a Phase 1b/2 clinical trial of D-PLEX for the prevention of sternal SSIs after cardiac surgery. In the first half of 2018, we plan to submit an Investigational New Drug, or IND, application for D-PLEX to the U.S. Food and Drug Administration, or FDA, and a clinical trial application, or CTA, to the European national competent authorities, and to commence a Phase 3 clinical trial in this indication shortly thereafter. In the first half of 2018, we also plan to commence a Phase 2 clinical trial of D-PLEX for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery. 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 received a designation of Qualified Infectious Disease Product, or QIDP, from the FDA for D-PLEX 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 €7 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 initial family of product candidates pairs PLEX with the widely-used antibiotic doxycycline, which we refer to as the PLEX-doxycycline family. Based on data read out to date, none of the 32 patients treated in our clinical trials of BonyPid-1000, a member of our PLEX-doxycycline family, developed an infection after treatment for open long bone fractures.

We believe that, by combining doxycycline with our proprietary PLEX technology, D-PLEX 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, which is being developed to manage 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 completed patient enrollment of a Phase 1b/2 clinical trial of D-PLEX in 81 patients in this indication. We expect to report the results of this trial by the end of 2017, and we intend to hold 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. In the first half of 2018, we plan to submit an IND for D-PLEX to the FDA and a CTA to the European national competent authorities 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 for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery in the first half of 2018. We plan to seek approval of D-PLEX in the United States under Section 505(b)(2) of the Federal Food, Drug, and

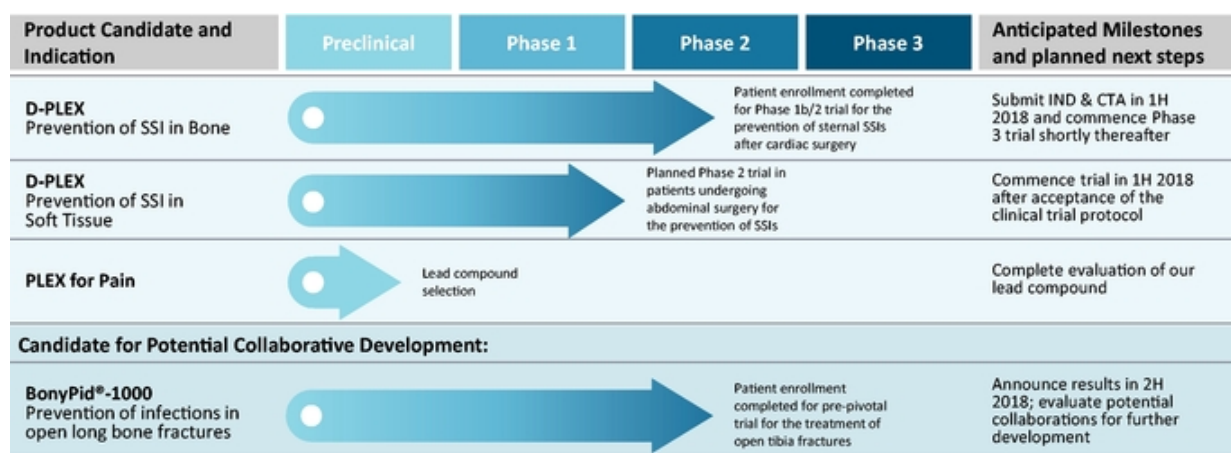
Cosmetic Act, or the FFDCa, which is administered by the FDA, and the comparable hybrid application pathway in the European Union.

We have developed BonyPid-1000, another product candidate from the PLEX-doxycycline family, for use in connection with orthopedic surgeries for the prevention of SSIs and support of bone recovery. Often, bone will not heal in the presence of infection. Based on data read out from our clinical trials of BonyPid-1000 to date, none of the 32 patients treated with BonyPid-1000 developed infections in the target fracture. We have completed enrollment of a clinical trial in 51 patients of the safety and effectiveness of BonyPid-1000 for the treatment of open tibia fractures. We have announced interim results that indicated statistically significant reductions in self-assessments of pain using the Visual Analogue Scale twelve weeks after surgery. We expect to report the full results of this trial in the second half of 2018. We do not currently plan to pursue further independent development of BonyPid-1000, as we believe the orthopedic SSI market can be adequately addressed by D-PLEX.

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 for the management 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	ordinary shares
Ordinary shares to be outstanding immediately after this offering	ordinary shares (or 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 ordinary shares.
Use of proceeds	<p>We estimate that the net proceeds to us from this offering will be approximately \$ million, or approximately \$ million if the underwriters exercise their option to purchase 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 \$ per ordinary share, which is the midpoint of the price range set forth on the cover page of this prospectus.</p> <p>We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents and short-term deposits: (i) to fund clinical development of our product candidates, including our planned Phase 3 clinical trial of D-PLEX for the prevention of sternal SSIs after cardiac surgery, and our planned Phase 2 clinical trial of D-PLEX for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery, (ii) to continue construction of our pilot manufacturing facility and initiate preparations for our larger commercial-scale cGMP compliant manufacturing facility and (iii) for general corporate purposes and working capital.</p> <p>See "Use of Proceeds" for more information about the intended use of proceeds from this offering.</p>
Tax 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, 2017 or in future taxable years. If we do not receive non-passive income, or, if certain Israeli tax grants, credits or subsidies that we receive do not constitute gross income for purposes of the PFIC test, we likely will be classified as a PFIC for 2017 and future years. However, we are still assessing our PFIC classification for our taxable year ending December 31, 2017, and may not be able to take a position on our classification for such taxable year until January 2018.

Proposed Nasdaq Global Market
symbol

Application will be 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 72,859,110 ordinary shares outstanding as of September 30, 2017, and excludes the following as of such date:

- 11,755,506 ordinary shares reserved for issuance under our 2012 Share Option Plan, including 11,624,470 ordinary shares reserved for issuance upon the exercise of outstanding options at a weighted average exercise price of \$0.49 per share; and
- 23,057,712 ordinary shares issuable upon the exercise of outstanding warrants to purchase Series D-2 preferred shares, at a weighted average exercise price of \$1.10 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 \$ 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 67,735,899 ordinary shares, which will occur upon the closing of this offering;
- the automatic exercise of warrants to purchase 450,000 Series A preferred shares, and the automatic conversion thereof into 450,000 ordinary shares, which will occur upon the closing of this offering;
- a -for- reverse share split to be effected on , 2018, by means of distribution of a share dividend of ordinary shares for each ordinary share then outstanding; 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.

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, 2015 and 2016 from our audited financial statements included elsewhere in this prospectus. We have derived the following statements of operations data for the nine month periods ended September 30, 2016 and 2017 and the balance sheet data as of September 30, 2017 from our unaudited interim financial statements included elsewhere in this prospectus, which have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited interim financial statements reflect all adjustments, consisting only of normal, recurring adjustments, necessary for a fair statement of the of the financial information in those statements. 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 financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,		Nine Months Ended September 30,	
	2015	2016	2016	2017
			(unaudited)	
	(in thousands, except share and per share amounts)			
Statements of Operations Data:				
Research and development, net	\$ 5,634	\$ 7,708	\$ 5,299	\$ 6,494
General and administrative	2,933	2,551	1,771	2,291
Operating loss	8,567	10,259	7,070	8,785
Financial expenses, net	1,181	1,133	2,179	5,562
Net loss	<u>\$ 9,748</u>	<u>\$ 11,392</u>	<u>\$ 9,249</u>	<u>\$ 14,347</u>
Basic and diluted net loss per ordinary share	<u>\$ (2.40)</u>	<u>\$ (3.08)</u>	<u>(2.50)</u>	<u>(3.62)</u>
Weighted average number of ordinary shares, basic and diluted	<u>4,518,056</u>	<u>4,544,628</u>	<u>4,544,628</u>	<u>4,625,635</u>
Pro forma basic and diluted net loss per ordinary share ⁽¹⁾		<u>\$ (0.17)</u>		<u>\$ (0.20)</u>
Pro forma weighted average number of ordinary shares, basic and diluted		<u>68,954,530</u>		<u>72,811,534</u>

⁽¹⁾ See Note 8 to our 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 September 30, 2017

	Actual	Pro Forma⁽¹⁾	Pro Forma As Adjusted⁽²⁾
		(unaudited)	
	(in thousands)		
Balance Sheet Data:			
Cash and cash equivalents	\$ 6,412	\$ 6,425	\$
Working capital ⁽³⁾	13,683	13,696	
Total assets	17,232	17,245	
Convertible preferred shares	50,133	—	
Convertible preferred shares warrant liability	12,266	—	
Total shareholders' equity (deficiency)	(47,699)	14,713	

- (1) Pro forma balance sheet data give effect to: (i) the automatic conversion of all outstanding preferred shares into 67,735,899 ordinary shares upon the closing of this offering and (ii) the automatic exercise of warrants to purchase 450,000 Series A preferred shares, and the automatic conversion thereof into 450,000 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 _____ ordinary shares in this offering at the assumed initial public offering price of \$ _____ 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 \$ _____ 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 and cash equivalents, total assets and shareholders' equity (deficiency) by \$ _____ 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 and cash equivalents, total assets and shareholders' equity (deficiency) by \$ _____ 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 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 \$9.7 million and \$11.4 million for the years ended December 31, 2015 and 2016, respectively, and \$14.3 million for the nine months ended September 30, 2017. As of September 30, 2017, we had an accumulated deficit of \$50.9 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 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 products 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 products 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 completed patient enrollment of a Phase 1b/2 clinical trial of our lead product candidate, D-PLEX, for the prevention of sternal SSIs after cardiac surgery. In the first half of 2018, we plan to submit an Investigational New Drug, or IND, application for D-PLEX to the FDA, and a clinical trial application, or CTA, to the European national competent authorities, and to commence a Phase 3 clinical trial in this indication shortly thereafter. In the first half 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 September 30, 2017, we had cash and cash equivalents of \$6.4 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 and our other future product candidates;
- the cost, timing and outcomes of regulatory review of D-PLEX 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, 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 in the first half of 2018, for our planned Phase 3 clinical trial of D-PLEX 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 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 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 single pivotal Phase 3 clinical trial, even if successfully completed, will be sufficient to support approval of a New Drug Application, or 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 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 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 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 FDCA, 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. 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 product 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 for sternal SSIs after cardiac surgery, but we have not yet conducted a clinical trial of D-PLEX 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 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 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.

If the FDA does not conclude that D-PLEX satisfies the requirements under Section 505(b)(2) of the FDCA, 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 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 for the prevention of sternal SSIs after cardiac surgery and the prevention of SSIs in patients undergoing abdominal surgery in the future. 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 FDCA. 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 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 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 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, and complications and risks associated with D-PLEX, 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 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.

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 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. 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. 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. 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 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 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 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 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. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and Budget on April 5, 2017, the administration

indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. Moreover, on February 24, 2017, President Trump issued an Executive Order requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification, and on September 8, 2017, the FDA published notices in the Federal Register soliciting broad public comment to identify regulations that could be modified in compliance with these Executive Orders. It is difficult to predict how these requirements 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. 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. The Trump administration has also announced that it will discontinue the payment of cost-sharing reduction (CSR) payments to insurance companies until Congress approves the appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. A bipartisan bill to appropriate funds for CSR payments has been introduced in the Senate, but the future of that bill is uncertain. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the PPACA for plans sold through such marketplaces. Further, each chamber of Congress has put forth multiple bills this year designed to repeal or repeal and replace portions of the PPACA. Although none of these measures have been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the PPACA. Congress will likely consider other legislation to replace elements of the PPACA. 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 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 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 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 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.

We initially intend to seek marketing approval for D-PLEX 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-cleared 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 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 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. 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. 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 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 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 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. 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 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. 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 September 30, 2017, our portfolio of owned patents and patent applications consists of seven families that protect our technology, including 52 issued patents, one allowed patent application and 51 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 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, 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, price 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 as well as our financial condition.

Before we can begin to commercially manufacture D-PLEX 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 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 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 _____ ordinary shares in this offering (or _____ shares if the underwriters exercise their option to purchase additional shares in full), 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 _____ % 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 \$ _____ 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 \$ _____ 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 _____ % of the aggregate price paid by all purchasers of our stock but will own only approximately _____ % 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.

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 _____ 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.

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 depository institutions. These investments may not yield a favorable return to our shareholders.

We may be classified as a passive foreign investment company for the current taxable year and in the foreseeable future. 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) from time to time. 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, 2017 or in future taxable years. However, we are still assessing our PFIC classification for our taxable year ending December 31, 2017, and may not be able to take a position on our classification for such taxable year until January 2018.

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 September 30, 2017, we had 52 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 \$4.6 million that we received from the IIA as of September 30, 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 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 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 \$ _____ 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 \$ _____ 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 _____ additional ordinary shares in full, we estimate that the net proceeds to us from this offering will be approximately \$ _____ 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 \$ _____ 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 \$ _____ 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 \$ _____ 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 and cash equivalents and short-term deposits, as follows:

- to fund clinical development of our product candidates, including our planned Phase 3 clinical trial of D-PLEX for the prevention of sternal SSIs after cardiac surgery, and our planned Phase 2 clinical trial of D-PLEX for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery;
- to fund our manufacturing activities, 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 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 from this offering, will be sufficient for the completion of _____. 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 and cash equivalents and capitalization as of September 30, 2017, on:

- an actual basis;
- a pro forma basis to give effect to (i) the automatic conversion of all outstanding preferred shares into 67,735,899 ordinary shares upon the closing of this offering and (ii) the automatic exercise of warrants to purchase 450,000 Series A preferred shares, and the automatic conversion thereof into 450,000 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 _____ ordinary shares in this offering at the assumed initial public offering price of \$ _____ 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 interim 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 September 30, 2017		
	Actual	Pro Forma	Pro Forma As Adjusted
		(unaudited)	
		(in thousands)	
Cash and cash equivalents ⁽¹⁾	\$ 6,412	\$ 6,425	\$ _____
Convertible preferred shares warrant liability	12,226	—	_____
Preferred A, A-1, B, B-1, C-1, C-2, D-1, D-3 and E shares of NIS 0.10 par value: 101,928,140 shares authorized, actual; no shares authorized, pro forma and pro forma as adjusted; 67,735,899 shares issued and outstanding, actual; no shares issued and outstanding, pro forma and pro forma as adjusted	50,133	—	_____
Shareholders' (deficiency) equity:			
Ordinary shares of NIS 0.10 par value: 125,500,000 shares authorized, actual; _____ shares authorized pro forma; _____ shares authorized pro forma as adjusted; 4,673,211 issued and outstanding, actual; 72,859,110 shares issued and outstanding, pro forma; _____ shares issued and outstanding, pro forma as adjusted	129	2,061	_____
Additional paid-in capital	3,091	63,571	_____
Accumulated deficit	(50,919)	(50,919)	_____
Total shareholders' (deficiency) equity ⁽¹⁾	(47,699)	14,713	_____
Total capitalization ⁽¹⁾	\$ 14,660	\$ 14,713	\$ _____

⁽¹⁾ Each \$1.00 increase or decrease in the assumed initial public offering price of \$ _____ 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 and cash equivalents, total shareholders' (deficiency) equity and total capitalization

by \$ 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 and cash equivalents, total shareholders' (deficiency) equity and total capitalization by \$ 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:

- 11,755,506 ordinary shares reserved for issuance under our 2012 Share Option Plan, including 11,624,470 ordinary shares reserved for issuance upon the exercise of outstanding options at a weighted average exercise price of \$0.49 per share; and
- 23,057,712 ordinary shares issuable upon the exercise of outstanding warrants to purchase Series D-2 preferred shares, at a weighted average exercise price of \$1.10 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 September 30, 2017, we had a historical net tangible book value of \$14.7 million, or \$3.15 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 September 30, 2017.

Our pro forma net tangible book value as of September 30, 2017 was \$14.7 million, or \$0.20 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 September 30, 2017, after giving effect to the automatic conversion of all outstanding preferred shares into ordinary shares and the automatic exercise of warrants to purchase 450,000 Series A preferred shares, and the automatic conversion thereof into 450,000 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 \$ _____ 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 automatic exercise of warrants to purchase 450,000 Series A preferred shares, and the automatic conversion thereof into 450,000 ordinary shares, which will occur upon the closing of this offering, our pro forma as adjusted net tangible book value at September 30, 2017 would have been \$ _____ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ _____ per share to existing shareholders and immediate dilution of \$ _____ per ordinary share to new investors. The following table illustrates this dilution per ordinary share:

Assumed initial public offering price per ordinary share		\$ _____
Historical net tangible book value per ordinary share as of September 30, 2017	\$ 3.15	
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	\$ (2.95)	
Pro forma net tangible book value per ordinary share as of September 30, 2017	\$ 0.20	
Increase in pro forma net tangible book value per ordinary share attributable to new investors	\$ _____	
Pro forma as adjusted net tangible book value per ordinary share after this offering		\$ _____
Dilution per ordinary share to new investors participating in this offering		\$ _____

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ 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 September 30, 2017 after this offering by approximately \$ _____ per ordinary share, and would increase (decrease) dilution to investors in this offering by \$ _____ 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 September 30, 2017 after this offering by approximately \$ _____ per ordinary share, and would decrease (increase) dilution to investors in this offering by approximately \$ _____ 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 \$ _____ per ordinary share, representing an immediate increase in pro forma as adjusted net tangible book value to existing shareholders of \$ _____ per ordinary share and an immediate dilution of \$ _____ 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 September 30, 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 \$ _____ 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	Share
Existing shareholders			%\$		%\$
Investors participating in this offering					
Total		100%	\$	100%	\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ 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 \$ _____ million, \$ _____ million and \$ _____ million, 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 \$ _____ million, \$ _____ million and \$ _____ million, respectively, assuming the assumed initial public offering price of \$ _____ 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 72,859,110 ordinary shares outstanding as of September 30, 2017, after giving effect to the automatic conversion of all outstanding preferred shares into ordinary shares and the automatic exercise of warrants to purchase 450,000 Series A preferred shares, and the automatic conversion thereof into 450,000 ordinary shares, each of which will occur upon the closing of this offering, and excludes:

- 11,755,506 ordinary shares reserved for issuance under our 2012 Share Option Plan, including 11,624,470 ordinary shares reserved for issuance upon the exercise of outstanding options at a weighted average exercise price of \$0.49 per share; and
- 23,057,712 ordinary shares issuable upon the exercise of outstanding warrants to purchase Series D-2 preferred shares, at a weighted average exercise price of \$1.10 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.

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, 2015 and 2016 from our audited financial statements included elsewhere in this prospectus, which have been prepared in accordance with U.S. GAAP. We have derived the following statements of operations data for the nine month periods ended September 30, 2016 and 2017 and the balance sheet data as of September 30, 2017 from our unaudited interim financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited interim financial statements reflect all adjustments, consisting only of normal, recurring adjustments, necessary for a fair statement of the financial information in those statements. 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 financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,		Nine Months Ended September 30,	
	2015	2016	2016	2017
			(unaudited)	
	(in thousands of dollars, except share and per share amounts)			
Statements of Operations Data:				
Research and development, net	\$ 5,634	\$ 7,708	\$ 5,299	\$ 6,494
General and administrative	2,933	2,551	1,771	2,291
Operating loss	8,567	10,259	7,070	8,785
Financial expenses, net	1,181	1,133	2,179	5,562
Net loss	\$ 9,748	\$ 11,392	\$ 9,249	\$ 14,347
Basic and diluted net loss per ordinary share	\$ (2.40)	\$ (3.08)	\$ (2.50)	\$ (3.62)
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	4,518,056	4,544,628	4,544,628	4,625,635
			As of	As of
			December 31,	September 30,
			2015	2017
				(unaudited)
	(in thousands of U.S. dollars)			
Balance Sheet Data:				
Cash and cash equivalents	\$ 1,679	\$ 10,221	\$ 10,221	\$ 6,412
Working capital ⁽¹⁾	232	16,556	16,556	13,683
Total assets	2,480	19,237	19,237	17,232
Convertible preferred shares	22,934	44,026	44,026	50,133
Convertible preferred shares warrant liability	193	6,616	6,616	12,266
Total shareholders' equity (deficiency)	(23,165)	(33,959)	(33,959)	(47,699)

⁽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 financial statements and our unaudited interim financial statements, including, in each case, 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, 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 were \$9.7 million and \$11.4 million for the years ended December 31, 2015 and 2016, respectively, and \$9.2 million and \$14.3 million for the nine months ended September 30, 2016 and 2017, respectively. As of September 30, 2017, we had an accumulated deficit of \$50.9 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 for the prevention of sternal SSIs after cardiac surgery and our Phase 2 clinical trial of D-PLEX in patients undergoing abdominal surgery for the prevention of SSIs;
- file an NDA seeking regulatory approval for D-PLEX 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 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 September 30, 2017, we have raised an aggregate of \$55.1 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 August and September 2017, we received an aggregate of \$6.1 million in gross proceeds from the sale of our Series E preferred shares. In October and November 2017, we received an aggregate of \$5.3 million in gross proceeds from the sale of our Series E preferred 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 through September 30, 2017, we have incurred approximately \$30.0 million in research and development expenses to advance the development of our product candidates and

preclinical research and development programs. As of September 30, 2017, we have received grants of \$4.6 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 September 30, 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, 2015 and 2016 and the nine months ended September 30, 2016 and 2017 were related to the development of the PLEX-doxycycline 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 and cash equivalents and our foreign exchange gains and losses.

Results of Operations

Comparison of the Nine Months Ended September 30, 2016 and 2017

The following table summarizes our results of operations for the nine months ended September 30, 2016 and 2017:

	Nine Months Ended September 30,	
	2016	2017
	(unaudited)	
	(in thousands)	
Research and development expenses, net	\$ 5,299	\$ 6,494
General and administrative expenses	1,771	2,291
Operating loss	7,070	8,785
Financial expenses, net	2,179	5,562
Net loss	<u>\$ 9,249</u>	<u>\$ 14,347</u>

Research and Development Expenses, Net

Research and development expenses, net increased by \$1.2 million during the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016. The increase in research and development expenses resulted primarily from increases in expenses related to the clinical development of our PLEX-doxycycline family. More specifically, this amount included increases in third party clinical and manufacturing research and development expense and preclinical and clinical trial costs for our PLEX-doxycycline family product candidates, salaries and personnel-related expenses, driven by increased headcount across all research and development functions from 29 employees as of September 30, 2016 to 40 employees as of September 30, 2017 and costs associated with the maintenance and prosecution of our intellectual property portfolio. These increases were partially offset by decreases in regulatory expenses related to submissions to the FDA and third-party consultant costs as we hired consultants as employees and share-based compensation to research and development employees and consultants. These increases were further offset by an increase in IIA grants.

General and Administrative Expenses

General and administrative expenses increased by \$0.5 million during the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016. The increase in general and administrative expenses resulted primarily from increases in salaries and personnel-related expenses for employees not performing research and development functions and share-based compensation expense, facility and maintenance costs, legal and professional costs and third-party consultant costs.

Financial Expenses, Net

Financial expenses, net increased by \$3.4 million during the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016. The increase in financial expenses, net resulted primarily from an increase related to the reevaluation of our preferred share warrant liability, partially offset by an increase in financial income.

Comparison of the Years Ended December 31, 2015 and 2016

The following table summarizes our results of operations for the years ended December 31, 2015 and 2016:

	Year Ended December 31,	
	2015	2016
	(in thousands)	
Research and development expenses, net	\$ 5,634	\$ 7,708
General and administrative expenses	2,933	2,551
Operating loss	8,567	10,259
Financial expenses, net	1,181	1,133
Net loss	<u>\$ 9,748</u>	<u>\$ 11,392</u>

Research and Development Expenses, Net

Research and development expenses, net increased by \$2.0 million during the year ended December 31, 2016 compared to the year ended December 31, 2015. The increase in research and development expenses resulted primarily from increases in expenses related to the research and clinical development of D-PLEX. More specifically, this amount included increases in third party clinical and manufacturing research and development expenses and preclinical and clinical trial costs for our PLEX-doxycycline family product candidates and salaries and personnel-related expenses, driven by increased headcount across all research and development functions from 29 employees as of December 31, 2015 to 31 employees as of December 31, 2016. These increases were partially offset by decreases in share-based compensation to research and development employees and consultants and third-party consultant costs, costs associated with the maintenance and prosecution of our intellectual property portfolio and regulatory expenses. These increases were further offset by an increase in IIA grants.

General and Administrative Expenses

General and administrative expenses decreased by \$0.4 million during the year ended December 31, 2016 compared to the year ended December 31, 2015. The decrease in general and administrative expenses resulted primarily from decreases in third-party consultant costs as we hired consultants as employees of the Company, share-based compensation expense and facility

and maintenance costs, partially offset by increases in salaries and personnel-related expenses, driven by increased headcount across all general and administrative functions from 10 employees as of December 31, 2015 to 12 employees as of December 31, 2016, and legal and professional costs. During the year ended December 31, 2015, we incurred expenses associated with a previously planned U.S. initial public offering process that were written off in 2016.

Financial Expenses, Net

Financial expenses, net decreased by \$0.1 million during the year ended December 31, 2016 compared to the year ended December 31, 2015. The decrease in financial expenses, net resulted primarily from a decrease in financial expenses related to convertible loans, partially offset by increases related to the reevaluation of our preferred share warrant liability and financial income.

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 September 30, 2017, we raised an aggregate of \$55.1 million from private placements of equity securities and convertible debt. In October and November 2017, we received an aggregate of \$5.3 million in gross proceeds from the sale of our Series E preferred shares. As of September 30, 2017, we had \$6.4 million in cash and cash equivalents.

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,		Nine Months Ended September 30,	
	2015	2016	2016	2017
			(unaudited)	
			(in thousands)	
Net cash used in operating activities	\$ (6,573)	\$ (9,733)	\$ (7,492)	\$ (8,487)
Net cash used in investing activities	(102)	(8,069)	(8,764)	(1,497)
Net cash provided by financing activities	6,188	26,344	21,291	6,175
Net increase (decrease) in cash and cash equivalents	<u>\$ (487)</u>	<u>\$ 8,542</u>	<u>\$ 5,035</u>	<u>\$ (3,809)</u>

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, accretion of interest on convertible loans and share-based compensation.

Net cash used in operating activities was \$9.7 million for the year ended December 31, 2016, as compared to \$6.6 million for the year ended December 31, 2015, respectively. Net cash used in operating activities was \$8.5 million for the nine months ended September 30, 2017, as compared

to \$7.5 million for the nine months ended September 30, 2016, respectively. In all periods, 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 PLEX-doxycycline 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 \$8.1 million for the year ended December 31, 2016, as compared to \$0.1 million for the year ended December 31, 2015. The increase in net cash used in investing activities in 2016 primarily related to the acquisition of short-term deposits and for the purchase of equipment.

Net cash used in investing activities was \$1.5 million for the nine months ended September 30, 2017, as compared to \$8.8 million for the nine months ended September 30, 2016. The decrease in net cash used in investing activities during the nine months ended September 30, 2017 related to a decrease in short-term deposits and an increase in the purchase of equipment as compared to the nine months ended September 30, 2016.

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 \$26.3 million for the year ended December 31, 2016, related to the issuance of shares of our Series D-1 and Series D-3 preferred shares, as compared to \$6.2 million for the year ended December 31, 2015, related to the issuance of convertible debt and shares of our Series C-2 preferred shares.

Net cash provided by financing activities was \$6.2 million for the nine months ended September 30, 2017, related to the issuance of shares of our Series E preferred shares, as compared to \$21.3 million for the nine months ended September 30, 2016, related to the issuance of shares of our Series D-1 and Series 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 and our future product candidates. In addition, if we obtain marketing approval for D-PLEX 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 and 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. 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;
- 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 and our future product candidates;
- the costs and timing of establishing and validating manufacturing processes and facilities for development and commercialization of D-PLEX 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, 2016:

	<u>Less than 1 Year</u>	<u>1 to 3 Years</u>	<u>4 to 5 Years</u>	<u>More than 5 Years</u>	<u>Total</u>
	(in thousands)				
Operating lease obligations ⁽¹⁾	\$ 513	\$ 1,257	\$ 794	\$ 795	\$ 3,359

⁽¹⁾ Operating lease obligation consist of payments pursuant to lease agreements for our Israeli facility 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 financial statements are prepared in accordance with accepted accounting principles generally accepted in the United States. The preparation of our 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 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 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, 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 September 30, 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:

	Nine Months Ended September 30, 2017	Year Ended December 31, 2016
Expected term (in years)	7 - 10	7 - 10
Expected volatility	75.2% - 94.0%	75.0% - 89.0%
Risk-free rate	2.1% - 3.2%	2.2% - 2.7%
Dividend yield	0.0%	0.0%

We incurred non-cash share-based compensation expense of \$0.6 million during the year ended December 31, 2016 and non-cash share-based compensation expense of \$0.5 million for the nine months ended September 30, 2017. 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 summarize by grant date the number of ordinary shares subject to share option awards granted between January 1, 2016 and September 30, 2017, 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	264,000	\$ 0.37	\$ 0.37	\$ 81,890
August 24, 2016	120,845	\$ 0.37	\$ 0.37	\$ 43,927
December 21, 2016	640,000	\$ 0.47	\$ 0.47	\$ 232,202
March 8, 2017	191,000	\$ 0.49	\$ 0.49	\$ 65,629
May 25, 2017	470,000	\$ 0.50	\$ 0.50	\$ 168,990
June 1, 2017	1,654,586	\$ 0.49	\$ 0.49	\$ 215,030
August 5, 2017	47,000	\$ 1.11	\$ 1.11	\$ 20,900

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

Based upon the assumed initial public offering price of \$ _____ 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 September 30, 2017 was \$ _____ million, of which \$ _____ million related to vested options and \$ _____ 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* (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;
- the prices, rights, preferences and privileges of our convertible preferred shares;
- current business conditions and projections;
- our stage of development;
- 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 preliminary 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 our value using a market approach, based on the backsolve method. The backsolve method involves assumptions for the time to liquidity, volatility, and risk free rate and then solving for the value of equity such that value for the most recent financing equals the amount paid. In order to estimate the value of our equity value, including both ordinary and preferred shares, we relied upon the share price of our Series E preferred shares determined in our private placements of shares of Series E preferred shares, or the Series E Rounds, which we believed to be the most indicative of our value.

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 backsolve method we used recent share purchase transactions to solve our implied equity value. This approach takes into account the economic rights of the various classes of shares such as liquidation preferences, conversion rights and dividend rights and

then allocates the value accordingly to the rights and privileges of each class of shares. Since the Series E Rounds were led by unrelated investors and were arms-length transactions, we determined the Series E Rounds were the most appropriate method to determine the fair value of our ordinary shares given the early stage nature of the company.

- 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.

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 redeemable 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 and price indications from bankers. 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 September 30, 2017, we have received royalty-bearing grants totaling \$4.6 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 financial statements beginning on page F-1 of this prospectus for a description of recent accounting pronouncements applicable to our 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, 2016.

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, 2015 and 2016 or the nine months ended September 30, 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. We are initially focused on the development of our lead product candidate, D-PLEX, which incorporates doxycycline, a versatile antibiotic, for the management of surgical site infections, or SSIs, in bone and soft tissue. We recently completed patient enrollment of a Phase 1b/2 clinical trial of D-PLEX for the prevention of sternal SSIs after cardiac surgery. In the first half of 2018, we plan to submit an Investigational New Drug, or IND, application for D-PLEX to the U.S. Food and Drug Administration, or FDA, and a clinical trial application, or CTA, to the European national competent authorities, and to commence a Phase 3 clinical trial in this indication shortly thereafter. In the first half of 2018, we also plan to commence a Phase 2 clinical trial of D-PLEX for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery. 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 received a designation of Qualified Infectious Disease Product, or QIDP, from the FDA for D-PLEX 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 €7 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 initial family of product candidates pairs PLEX with the widely-used antibiotic doxycycline, which we refer to as the PLEX-doxycycline family. Based on data read out to date, none of the 32 patients treated in our clinical trials of BonyPid-1000, a member of our PLEX-doxycycline family, developed an infection after treatment for open long bone fractures.

Our lead product candidate from this family, D-PLEX, which is being developed to manage 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 completed patient enrollment of a Phase 1b/2 clinical trial of D-PLEX in 81 patients in this indication. We expect to report the results of this trial by the end of 2017, and we intend to hold 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. In the first half of 2018, we plan to submit an IND for D-PLEX to the FDA and a CTA to the European national competent authorities 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 for the prevention of SSIs, to be conducted in patients undergoing abdominal surgery for the prevention of SSIs in the first half of 2018. We plan to seek approval of D-PLEX 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 BonyPid-1000, another product candidate from the PLEX-doxycycline family, for use in connection with orthopedic surgeries for the prevention of SSIs and support of bone recovery. Often, bone will not heal in the presence of infection. We have completed enrollment of a clinical trial in 51 patients of the safety and effectiveness of BonyPid-1000 for the treatment of open tibia fractures. We have announced interim results that indicated statistically significant reductions in self-assessments of pain using the Visual Analogue Scale twelve weeks after surgery. We expect to report the full results of this trial in the second half of 2018. We do not currently plan to pursue further independent development of BonyPid-1000, as we believe the orthopedic SSI market can be adequately addressed by D-PLEX.

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 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:

Product Candidate and Indication	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones and planned next steps
D-PLEX Prevention of SSI in Bone				Patient enrollment completed for Phase 1b/2 trial for the prevention of sternal SSIs after cardiac surgery	Submit IND & CTA in 1H 2018 and commence Phase 3 trial shortly thereafter
D-PLEX Prevention of SSI in Soft Tissue			Planned Phase 2 trial in patients undergoing abdominal surgery for the prevention of SSIs		Commence trial in 1H 2018 after acceptance of the clinical trial protocol
PLEX for Pain		Lead compound selection			Complete evaluation of our lead compound
Candidate for Potential Collaborative Development:					
BonyPid®-1000 Prevention of infections in open long bone fractures			Patient enrollment completed for pre-pivotal trial for the treatment of open tibia fractures		Announce results in 2H 2018; evaluate potential collaborations for further development

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 for the management of bone and soft tissue SSIs in the United States and the European Union.** We recently completed patient enrollment of a Phase 1b/2 clinical trial of D-PLEX for the prevention of sternal SSIs after cardiac surgery. In the first half of 2018, we plan to submit an IND for D-PLEX to the FDA and a CTA to the European national competent authorities and to commence a Phase 3 clinical trial in this indication shortly thereafter. We also plan to commence in the first half of 2018 a Phase 2 clinical trial in patients undergoing abdominal surgery for the prevention of SSIs. We are planning to pursue a broad label for D-PLEX 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 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 is eligible for fast track designation upon request and priority review once we submit a New Drug Application, or 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 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 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 September 30, 2017, we owned 52 issued patents, and we had two allowed patent applications and 50 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.

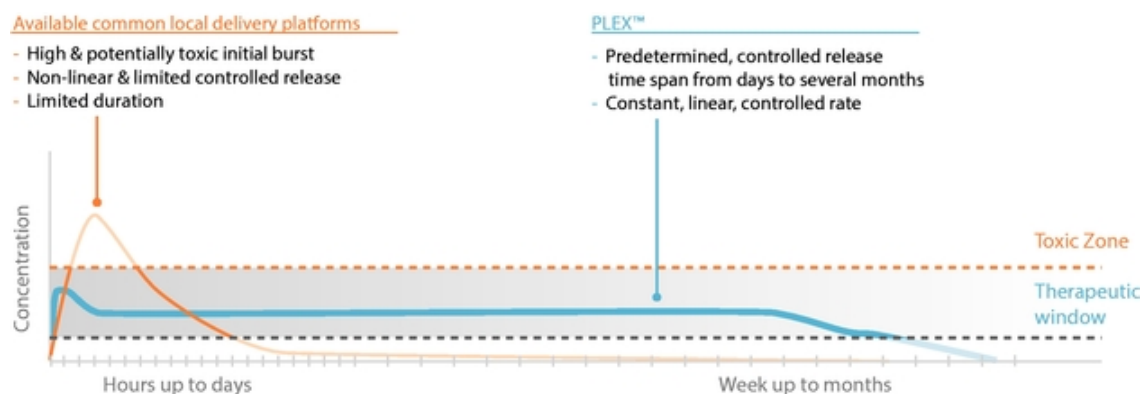
Limitations of Systemically Administered Drugs and Current Localized Delivery Systems

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 it in its active form.
- **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.

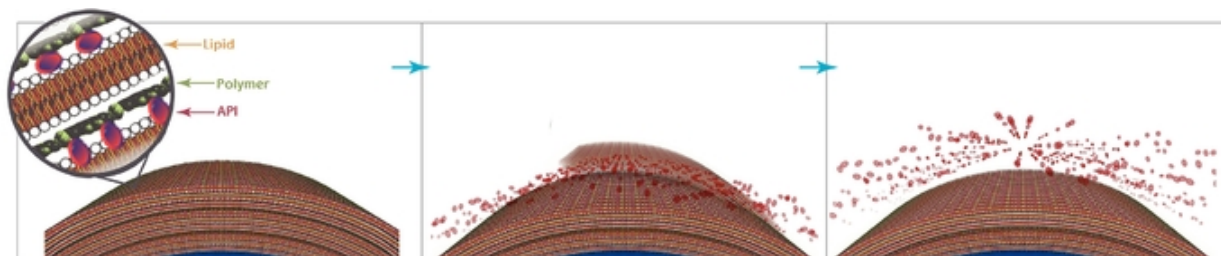
These disadvantages are particularly problematic for the management of infections, where the controlled and prolonged delivery of a drug may be more effective in managing infection than an initial high burst of drug over a shorter duration. While we believe that localized drug delivery systems are well 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 PLEX-doxycycline 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



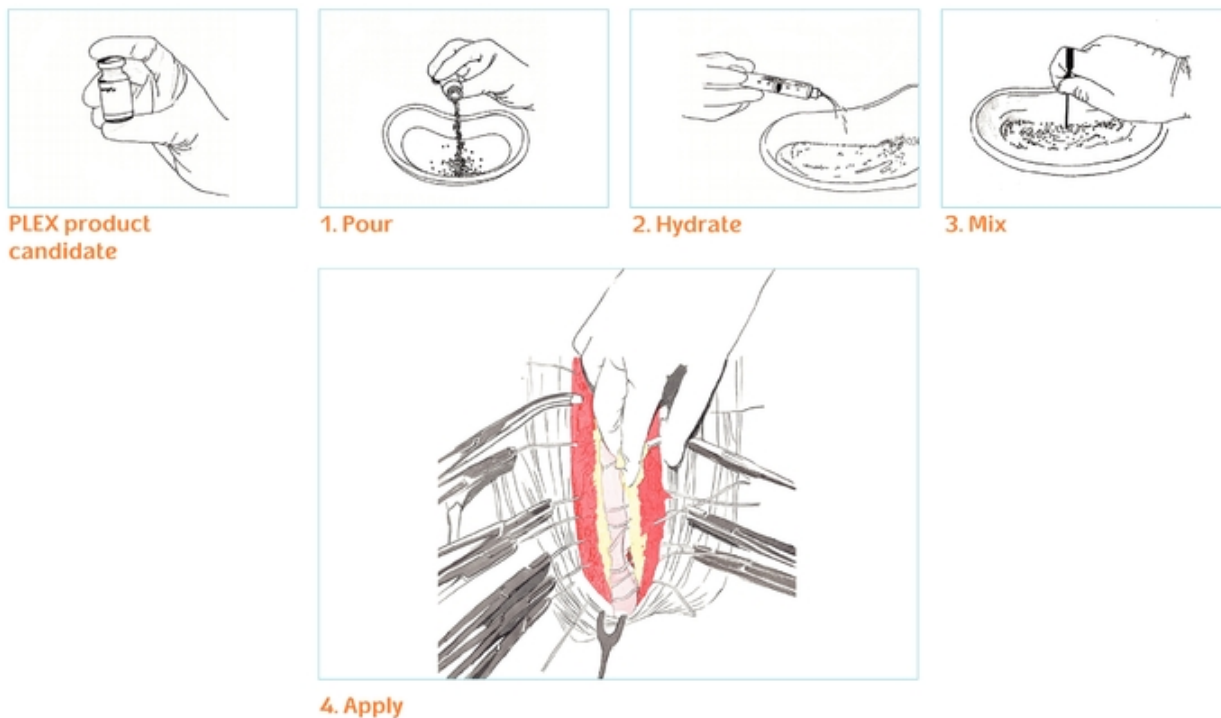
Our PLEX technology is designed to overcome the limitations of both systemic administration and current localized delivery systems. We believe PLEX has a number of key design benefits:

- **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 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 in open heart surgery



Our Initial Family of Product Candidates: PLEX-Doxycycline

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 PLEX-doxycycline family. Our PLEX-doxycycline 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 data read out to date, none of the 32 patients treated in our clinical trials of BonyPid-1000 developed an infection after treatment for open long bone fractures.

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 €7 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 reduce or deny reimbursement claims for SSIs in 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, up to 60% 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. These antibiotics are administered systemically, in large quantities and over a short period, often with adverse side effects and limited efficacy.

Market Opportunity

We are initially focused on the use of D-PLEX to manage 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 up to 5% 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 additional 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 select 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 up to nearly 4% of Cesarean sections, up to 4% of hysterectomies and approximately 15% to 30% of colorectal surgeries. 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. Colorectal SSIs are associated with an average of 31 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:

Bone Surgeries

	<u>Number of Surgeries</u>
<i>Cardiac Surgeries</i>	
United States	889,000
EU-5	320,000
<i>Orthopedic Surgeries</i>	
United States	4,148,000
EU-5	2,590,000
Total	7,947,000

Soft Tissue Surgeries

	<u>Number of Surgeries</u>
<i>General Surgeries</i>	
United States	7,182,000
EU-5	3,062,000
<i>Gynecological Surgeries</i>	
United States	2,942,000
EU-5	1,817,000
<i>Urologic Surgeries</i>	
United States	608,000
EU-5	319,000
Total	15,930,000

We believe that D-PLEX 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 PLEX-doxycycline 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 is highly effective and safer than systemic treatment for infection management.

We believe that, by combining doxycycline with our proprietary PLEX technology, D-PLEX 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 may have multiple positive impacts on the treatment paradigm for infection management. For example, we have observed in our clinical trials that BonyPid-1000 enabled surgeons to apply an antibiotic directly to the contaminated injury during the initial surgery, rather than requiring multiple surgeries to treat infection consistent with the current treatment protocol of open long bone fractures. Further, in the case of resistant bacteria, D-PLEX 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: Our Lead Product Candidate for the Management of SSIs

We are developing D-PLEX from our PLEX-doxycycline family for the management of SSIs in bone and soft tissue. D-PLEX 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 under Section 505(b)(2) of the FDCA in the United States and the comparable regulatory pathway in the European Union. In the first half of 2018, we plan to submit an IND for D-PLEX to the FDA and a CTA to the European national competent authorities and to initiate a Phase 3 clinical trial in sternal SSIs after cardiac surgery shortly thereafter. We also plan to commence in the first half of 2018 a Phase 2 clinical trial in Israel in patients undergoing abdominal surgery for the prevention of SSIs.

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 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 and the raw materials we use to produce D-PLEX for our planned IND, as well as our stability plan and the stability data we intend to submit for our planned IND.

In March 2017, the EMA issued a final scientific advice letter indicating alignment with our clinical and CMC development plan for D-PLEX 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

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 for the prevention of sternal SSIs after cardiac surgery in 81 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 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 61 patients divided in a two-to-one ratio between treatment and control arms. One arm received D-PLEX 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 expect to report the results of the primary efficacy endpoint from this trial by the end of 2017.

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

We expect to hold 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 for the prevention of sternal SSIs after cardiac surgery. Subject to the results from our Phase 1b/2 clinical trial, we plan to submit an IND for D-PLEX to the FDA and a CTA to the European national competent authorities in the first half of 2018 and commence a 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 in the first half 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.

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 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 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 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's ability to release doxycycline over a prolonged period and a safety profile that was generally well-tolerated.

D-PLEX: 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 may be effective in treating and preventing bacterial infections that are otherwise resistant to antibiotics. In a rabbit sternal wound MRSA model, we observed that a single application of D-PLEX substantially reduced bacterial content and histopathological evidence of MRSA infection in the sternal wound. Further, we have observed evidence suggesting the effectiveness of BonyPid-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 BonyPid-1000, the infection was eradicated and full bone healing resulted in both patients. D-PLEX 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.

BonyPid-1000 for the Management of SSIs and Support of Bone Recovery in Orthopedic Surgeries

We have developed BonyPid-1000 for use in orthopedic surgeries for the management of SSIs and support of bone recovery. BonyPid-1000 is a member of our PLEX-doxycycline family that also incorporates 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 BonyPid-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 BonyPid-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.

In March 2017, we announced interim results from this trial of the first group of patients to reach the 16-week follow-up period. We observed that in the 12 patients treated with BonyPid-1000 in addition to the standard of care, median time from surgery to the initiation of bone healing, as assessed by the presence of a callus in one out of four cortices, was reduced by approximately 31%, as compared to 12 patients in the standard of care only group. Median time from surgery to the primary endpoint, the presence of solid radiographic markers for bone healing, as assessed by the presence of a callus in three out of four cortices, was reduced by 20%, as compared to the standard of care only group. As of March 8, 2017, more than 30% of patients treated with the standard of care alone had not reached the primary endpoint, as compared to approximately 8% of patients treated with BonyPid-1000 and the standard of care. Pain-free weight bearing was demonstrated in 63% of patients treated with BonyPid-1000 and the standard of care, as compared to none of the patients treated with the standard of care alone. We have announced interim results that indicated statistically significant reductions in self-assessments of pain using the Visual Analogue Scale twelve weeks after surgery. 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 BonyPid-1000 in patients with infected Gustilo IIIA and IIIB open long bone fractures. These trials were both open-label single arm clinical trials of BonyPid-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 BonyPid-1000, as we believe the orthopedic market can be adequately addressed by D-PLEX, we will evaluate potential collaborations to further the development of BonyPid-1000.

BonyPid-500 for the Treatment of Peri-Implantitis (In Collaboration with MIS)

We are developing 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. BonyPid-500 is a member of our PLEX-doxycycline family that incorporates 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 BonyPid-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 BonyPid-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 BonyPid-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 quarter of 2018.

We will pursue further development of BonyPid-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 could be used as a complementary, rather than competitive, addition to the current standard of care for the management 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 BonyPid-500. We agreed to grant MIS an exclusive right to market a specific dental application of BonyPid-500 for a certain period commencing after our receipt of either EMA or FDA marketing approval and the beginning of commercialized sales of BonyPid-500 in the applicable market. In the event that the FDA imposes certain additional requirements with respect to our clinical trials on BonyPid-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 BonyPid-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.

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, BonyPid-500, and BonyPid-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 September 30, 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 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 six issued patents, one allowed patent application, 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 eight issued patents, one allowed patent application, 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 FDCA, 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 for the prevention of post-cardiac surgery sternal infection and may request additional QIDP designations for D-PLEX 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 FDCA 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 of up to an aggregate of \$1.5 million per year for "knowing failures."

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. The Trump administration has also announced that it will discontinue the payment of cost-sharing reduction (CSR) payments to insurance companies until Congress approves the appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. A bipartisan bill to appropriate funds for CSR payments has been introduced in the Senate, but the future of that bill is uncertain. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the PPACA for plans sold through such marketplaces. Further, each chamber of Congress has put forth multiple bills this year designed to repeal or repeal and replace portions of the PPACA. Although none of these measures have been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the PPACA. 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 2025 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 September 30, 2017, we had 47 full-time employees and five part-time employees, all of whom were based in Israel. Of these employees, 40 are primarily engaged in research and development activities and 12 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 September 30, 2017:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<i>Executive Officers</i>		
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
<i>Non-Employee Directors</i>		
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

Prof. Yechezkel Barenholz, Ph.D. has served as a director since April 2008. Prof. Barenholz currently serves 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 Ltd., 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 a director of UroGen Pharma Ltd., as well as chairman of the pharmaceuticals branch of the Manufacturer's Association of Israel. 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 33¹/₃% 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 two or more shareholders present in person or by proxy shall constitute a lawful quorum, instead of 33¹/₃% 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 (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 seven 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 65% 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 _____ and _____, representing _____ of our seven 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 _____ 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 _____, and _____ will serve as chairman of the audit committee.

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.

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 _____, _____ and _____, each of whom is independent in accordance with the Nasdaq rules. _____ will serve as chairman of such committee.

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. We intend to adopt a compensation policy in conjunction with our listing on the Nasdaq Stock Market, which policy would be in effect until the fifth anniversary of this offering.

Even if the company's shareholders do not approve the compensation policy, the board of directors may resolve to approve the compensation policy if and to the extent the board determines, in its judgment following internal discussions, that approval of the compensation policy is in the best interests of the company.

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 be:

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

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

If it is determined that an office holder has a personal interest in a transaction, 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.

The Companies Law defines an extraordinary transaction as a transaction (including a unilateral decision by a company) to provide a right or other benefit to a third party which has at least one of the following characteristics: (i) is not in the ordinary course of business of the company, (ii) is not at market terms; or (iii) which may materially affect a company's profits, assets or obligations). 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 intend to adopt 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, 2016 was \$1.6 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, 2016, options to purchase 6,897,476 ordinary shares granted to our directors and executive officers were outstanding under our 2012 Share Option Plan at a weighted average exercise price of \$0.53 per share. Such number excludes options to purchase up to 3,350,000 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, 2016:

<u>Name</u>	<u>Grant Date</u>	<u>Stock Options</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
Dikla Czaczkes Akselbrad	April 5, 2016	70,000	\$ 0.37	April 5, 2026
Dikla Czaczkes Akselbrad	August 24, 2016	57,345	\$ 0.37	August 24, 2026
Dikla Czaczkes Akselbrad	December 21, 2016	430,000	\$ 0.47	December 21, 2026
Eitan Kyiet	April 5, 2016	25,000	\$ 0.37	April 5, 2026
Eitan Kyiet	December 21, 2016	150,000	\$ 0.47	December 21, 2026

Our board of directors has granted bonus payments to our Chief Executive Officer, Amir Weisberg, and our Chief Technology Officer, Noam Emanuel, 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, 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.

We anticipate that our board of directors will adopt a director 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. Following the consummation of this offering, we intend to pay annual cash compensation of \$ _____ per year for service on the board, an additional \$ _____ for service as chairperson and \$ _____ for service as a member of the audit committee, and an additional \$ _____ for service as chairperson and \$ _____ for service as a member of the 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.

Upon the closing of this offering, we will enter into new written employment agreements with all of our executive officers. These agreements contain standard provisions for a company in our industry regarding non-solicitation, confidentiality of information, non-competition and assignment of inventions. Our executive officers will not receive benefits upon the termination of their respective employment with us, other than benefits under Section 14 as described above. See "Certain Relationships and Related Party Transactions — Agreements and Arrangements with, and Compensation of, Directors and Executive Officers" for additional information.

Equity Incentive Plans

2012 Share Option Plan

Our 2012 Share Option Plan, or the 2012 Plan, was adopted by our board of directors on August 29, 2012. 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 1,532,036

shares are reserved but unissued under our 2012 Plan. We intend to amend and restate the 2012 Plan to allow for the issuance of options that qualify as incentive stock options under the U.S. Internal Revenue Code.

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.

PRINCIPAL SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of September 30, 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 September 30, 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 95,916,822 ordinary shares outstanding as of September 30, 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 September 30, 2017 and based on their reported registered office, 13 of our shareholders were U.S. persons, holding in aggregate approximately 15.7% 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.

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⁾	18,555,314	19.3%	%
Shavit Capital Fund III (US), L.P. ⁽²⁾	9,236,002	9.6%	%
Xenia Venture Capital Ltd. ⁽³⁾	6,187,682	6.5%	%
Friendly Angels Club L.L.P. ⁽⁴⁾	5,779,535	6.0%	%
Shirat Hachaim Ltd. ⁽⁵⁾	5,015,099	5.2%	%
Directors and Executive Officers			
Amir Weisberg ⁽⁶⁾	3,469,560	3.6%	%
Dikla Czaczkes Akselbrad ⁽⁷⁾	268,881	*	%
Chaim Hurvitz ⁽⁸⁾	5,313,490	5.5%	%
Anat Tsour Segal ⁽⁹⁾	120,000	*	%
Yechezkel Barenholz, Ph.D. ⁽¹⁰⁾	450,000	*	%
Noam Emanuel, Ph.D. ⁽¹¹⁾	4,333,505	4.5%	%
Jack Eitan Kyiet. ⁽¹²⁾	6,034,535	6.3%	%
Eli Frydman Ph.D.	—	—	%
Dan Jacob Gelvan, Ph.D. ⁽¹³⁾	166,915	*	%
All directors and executive officers as a group (9 persons)	20,156,886	21.0%	%

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

- (1) Consists of (i) 10,739,649 ordinary shares issuable upon conversion of preferred shares and (ii) 7,815,665 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and the automatic conversion thereof into ordinary shares. is the beneficial owner of the shares owned by Aurum Ventures M.K.I. Ltd. 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 19.3% in September 2017.
- (2) Consists of (i) 4,295,815 ordinary shares issuable upon conversion of preferred shares and (ii) 4,940,187 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) 5,737,682 ordinary shares issuable upon conversion of preferred shares and (ii) 450,000 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and the automatic conversion thereof into ordinary shares. is the beneficial owner of the shares owned by 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 6.5% in September 2017.
- (4) Consists of (i) 5,539,854 ordinary shares issuable upon conversion of preferred shares and (ii) 239,681 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 6.0% in September 2017.

- (5) Consists of (i) 4,233,533 ordinary shares issuable upon conversion of preferred shares and (ii) 781,566 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 5.2% in September 2017.
- (6) Consists of (i) 1,225,635 ordinary shares issuable upon conversion of preferred shares and (ii) 2,243,925 ordinary shares issuable upon exercise of outstanding options.
- (7) Consists of 268,881 ordinary shares issuable upon exercise of outstanding options.
- (8) Consists of (i) 298,391 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 120,000 ordinary shares issuable upon exercise of outstanding options.
- (10) Consists of 450,000 ordinary shares issuable upon exercise of outstanding options.
- (11) Consists of (i) 1,700,000 ordinary shares and (ii) 2,633,505 ordinary shares issuable upon exercise of outstanding options.
- (12) Consists of (i) 255,000 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 (i) 108,564 ordinary shares issuable upon conversion of preferred shares, (ii) 41,684 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and conversion thereof into ordinary shares and (iii) 16,667 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.

Private Placements of our Securities

Sale of Series B 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 6,605,019 Series B-1 preferred shares for an aggregate price of \$4.0 million, or the 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 Series B Private Placement:

<u>Participant</u>	<u>Series B-1 Preferred Shares</u>
Amir Weisberg	23,118
Dan Gelvan	66,050
Friendly Angels Club L.L.P.	133,166
Shirat Hachaim Ltd.	349,243
Xenia Venture Capital Ltd.	698,487
Yechezkel Berenholtz	232,829

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 3,432,570 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:

<u>Participant</u>	<u>Series C-2 Preferred Shares</u>
Aurum Ventures M.K.I. Ltd.	453,110
Dan Jacob Gelvan	6,267
Shirat Hachaim Ltd.	453,110

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 19,887,076 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 163,109 Series D-1 preferred shares, at an exercise price of \$1.27 per share, and warrants to purchase up to 20,050,185 Series D-2 preferred shares, at an exercise price of \$1.27 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 3,007,527 Series D-2 preferred shares, at an exercise price of \$1.10 per share, and the exercise price of the Series D-2 Warrants

was reduced to \$1.10 per share. The following table sets forth the aggregate number of shares of Series C-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.	6,796,230	7,815,665
Dan Jacob Gelvan	36,247	41,684
Friendly Angels Club L.L.P.	208,418	239,681
Shavit Capital Fund III (US), L.P.	4,295,815	4,940,187
Shirat Hachaim Ltd.	679,623	781,566

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 4,827,975 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 C-2 preferred shares issued to our related parties in the Series D-3 Private Placement:

Participant	Series D-3 Preferred Shares
Shirat Hachaim Ltd.	297,348

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 \$4,410,000, bearing an annual interest rate of 4.0%. The principal amount of the loan agreements and accrued interest converted automatically into 5,405,210 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	1,839,054
Friendly Angels Club L.L.P.	\$ 500,000	608,513
Shirat Hachaim Ltd.	\$ 1,500,000	1,844,814

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 _____ ordinary shares, par value NIS 0.10 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 65% 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 the majority of the aggregate 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 33¹/₃% 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 two or more shareholders 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 a majority of the aggregate voting rights 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 _____ of our ordinary shares, which reflects the assumed exercise for cash of all of our warrants to purchase preferred shares and the subsequent conversion of all of our preferred shares into 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 . Its address is .

Listing

Application will be 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 _____ 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

The following indicates approximately when the ordinary shares that are not being sold in this offering, but which will be outstanding at the time at which this offering is complete, will be eligible for sale into the public market under the provisions of Rule 144 and Rule 701 (but subject to the further contractual restrictions arising under the lock-up agreements described below):

- upon the closing of this offering, ordinary shares held by non-affiliates of our company that have been held for at least one year will be available for resale under Rule 144(b)(1)(ii);
- beginning 90 days after the closing of this offering, up to approximately _____ ordinary shares, constituting shares issuable upon exercise of outstanding options under our 2012 Plan that have vested as of _____, or within 60 days of _____, may be eligible for resale under Rule 701 and Rule 144, of which approximately _____ are held by our affiliates and would therefore be subject to the volume, current public information, manner of sale and other limitations under Rule 144; and
- approximately _____ ordinary shares will be eligible for resale pursuant to Rule 144 upon the expiration of various six month holding periods, so long as at least 90 days have elapsed after the closing of this offering, and subject to the current public information requirement under Rule 144 and, in the case of affiliates of our company, such eligibility will also be subject to the volume, manner of sale and other limitations under Rule 144.

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 September 30, 2017, options to purchase a total of 11,624,470 ordinary shares were issued and outstanding under our 2012 Plan. Of the total number of issued and outstanding options, 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 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 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 the voting power of our shares, 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.

We may be classified as a PFIC for the year ending December 31, 2016. If we do not receive non-passive income, or, if certain Israeli tax grants, credits or subsidies that we receive do not constitute gross income for purposes of the PFIC test, we likely will be classified as a PFIC for 2017 and future taxable years. However, we are still assessing our PFIC classification for our taxable year ending December 31, 2017, and may not be able to take a position on our classification for such taxable year until January 2018. 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, 2017, 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.

<u>Underwriters</u>	<u>Number of Ordinary Shares</u>
Goldman Sachs & Co. LLC	
Cowen and Company, LLC	
Total	

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 _____ 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 _____ additional ordinary shares.

	<u>Paid by the Company</u>	
	<u>No Exercise</u>	<u>Full Exercise</u>
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 initial offering of the ordinary shares, the representatives may change the offering price and the 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 will be 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 \$. The company has also agreed to reimburse the underwriters for certain of their expenses in an amount up to \$.

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. Certain of the underwriters and their respective affiliates have provided, and 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 rely 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	\$ *
FINRA filing fee	650
The Nasdaq Global Market listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous expenses	*
Total	\$ *

* To be completed by amendment.

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 financial statements as of December 31, 2016 and 2015 and for each of the two years in the period ended December 31, 2016 included in this prospectus have been so included in reliance on the report of Kost, Forer, Gabbay & Kasierer, Certified Public Accountants (Israel), an independent registered public accounting firm and a member firm of Ernst & Young LLP, given on the authority of said firm as experts in auditing and accounting. 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.
FINANCIAL STATEMENTS
AS OF AND FOR THE YEARS ENDED DECEMBER 31, 2015 AND 2016
(U.S. DOLLARS IN THOUSANDS)

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POLYPID LTD.
INTERIM FINANCIAL STATEMENTS
AS OF AND FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2017
(U.S. DOLLARS IN THOUSANDS)

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the Shareholders' and Board of Directors of
POLYPID LTD.**

We have audited the accompanying balance sheets of Polypid Ltd. (the "Company") as of December 31, 2016 and 2015 and the related 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, 2016. These financial statements are the responsibility of Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2016 and 2015, and the related results of its operations and its cash flows for each of the two years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ Kost Forer Gabbay & Kasierer

Tel-Aviv, Israel
March 8, 2017

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

POLYPID LTD.**BALANCE SHEETS****U.S. dollars in thousands**

	December 31,	
	2015	2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,679	\$ 10,221
Short-term deposits	—	7,530
Prepaid expenses and other receivables	227	503
Total current assets	<u>1,906</u>	<u>18,254</u>
Long-term assets:		
Property and equipment, net	435	847
Other long-term assets	139	136
Total long-term assets	<u>574</u>	<u>983</u>
Total assets	<u>\$ 2,480</u>	<u>\$ 19,237</u>

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

POLYPID LTD.

BALANCE SHEETS (Continued)

U.S. dollars in thousands (except share and per share data)

	December 31,	
	2015	2016
Liabilities, Convertible Preferred Shares and Shareholders' Equity (Deficiency)		
Current liabilities:		
Trade payables	\$ 579	\$ 778
Other payables and accrued expenses	1,095	920
Total current liabilities	<u>1,674</u>	<u>1,698</u>
Long-term liabilities:		
Advances on account of collaboration agreement	600	600
Other liabilities	244	256
Convertible preferred shares warrant liability	193	6,616
Total long-term liabilities	<u>1,037</u>	<u>7,472</u>
Commitments and Contingencies		
Convertible preferred shares:		
Preferred A, A-1, B, B-1, C-1, C-2, D-1 and D-3 shares of NIS 0.1 par value —		
Authorized: 92,428,140 and 42,428,137 shares at December 31, 2016 and 2015, respectively; Issued and outstanding: 63,683,516 and 38,968,465 shares at December 31, 2016 and 2015, respectively; Aggregate liquidation preference of \$62,023 at December 31, 2016		
	<u>22,934</u>	<u>44,026</u>
Shareholders' deficiency:		
Share capital —		
Ordinary shares of NIS 0.1 par value — Authorized: 116,000,000 and 57,571,863 shares at December 31, 2016 and 2015, respectively; Issued and outstanding: 4,544,628 shares at December 31, 2016 and 2015		
	126	126
Additional paid-in capital	1,889	2,487
Accumulated deficit	(25,180)	(36,572)
Total shareholders' deficiency	<u>(23,165)</u>	<u>(33,959)</u>
Total liabilities, convertible preferred shares and shareholders' deficiency	<u>\$ 2,480</u>	<u>\$ 19,237</u>

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

POLYPID LTD.**STATEMENTS OF OPERATIONS****U.S. dollars in thousands (except share and per share data)**

	Year ended December 31,	
	2015	2016
Operating expenses:		
Research and development, net	\$ 5,634	\$ 7,708
General and administrative	2,933	2,551
Operating loss	8,567	10,259
Financial expenses, net	1,181	1,133
Net loss	\$ 9,748	\$ 11,392
Basic and diluted net loss per Ordinary share	\$ (2.40)	\$ (3.08)
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	4,518,056	4,544,628

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

POLYPID LTD.

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
Balance as of January 1, 2015	30,048,122	\$ 13,134	13,134	4,500,000	\$ 125	\$ 1,146	\$ (15,432)	\$ (14,161)
Exercise of B-1 warrants	82,563	123	123	—	—	—	—	—
Exercise of options	—	—	—	44,628	1	26	—	27
Issuance of Series C-1 Preferred shares, net ^(*)	5,405,210	5,943	5,943	—	—	—	—	—
Issuance of Series C-2 Preferred shares, net ^(**)	3,432,570	3,734	3,734	—	—	—	—	—
Share-based compensation	—	—	—	—	—	717	—	717
Net loss	—	—	—	—	—	—	(9,748)	(9,748)
Balances as of December 31, 2015	38,968,465	22,934	22,934	4,544,628	126	1,889	(25,180)	(23,165)
Issuance of series D-1 Preferred shares, net ^(***)	19,887,076	16,039	16,039	—	—	—	—	—
Issuance of series D-3 Preferred shares, net ^(****)	4,827,975	5,053	5,053	—	—	—	—	—
Share-based compensation	—	—	—	—	—	598	—	598
Net loss	—	—	—	—	—	—	(11,392)	(11,392)
Balances as of December 31, 2016	<u>63,683,516</u>	<u>\$ 44,026</u>	<u>44,026</u>	<u>4,544,628</u>	<u>\$ 126</u>	<u>\$ 2,487</u>	<u>\$ (36,572)</u>	<u>\$ (33,959)</u>

(*) Conversion of convertible loan to series C-1 Preferred shares.

(**) Net of issuance costs of \$54, out of which \$44 settled in cash and \$10 fair value of warrant liability.

(***) 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.

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

POLYPID LTD.

STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,	
	2015	2016
Cash flows from operating activities:		
Net loss	\$ (9,748)	\$ (11,392)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	108	127
Re-evaluation of warrants	(500)	1,171
Share-based compensation	717	598
Write-off of deferred equity offering costs	438	—
Changes in assets and liabilities:		
Increase in receivables and prepaid expenses	(15)	(276)
Decrease in other long-term assets	12	3
Accretion of interest on convertible loans	1,533	—
Increase in advances on account of R&D reimbursement	233	—
Increase in trade payables	59	199
Increase (decrease) in other payables and accrued expenses and other liabilities	590	(163)
Net cash used in operating activities	<u>(6,573)</u>	<u>(9,733)</u>
Cash flows from investing activities:		
Short-term deposits, net	—	(7,530)
Purchase of property and equipment	(113)	(539)
Decrease in restricted cash	11	—
Net cash used in investing activities	<u>(102)</u>	<u>(8,069)</u>
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred shares and warrants, net	3,794	26,344
Issuance expenses in connection with convertible loans	57	—
Proceeds from convertible loans	2,310	—
Proceeds from exercise of options	27	—
Net cash provided by financing activities	<u>6,188</u>	<u>26,344</u>
Increase (decrease) in cash and cash equivalents	(487)	8,542
Cash and cash equivalents at the beginning of the year	2,166	1,679
Cash and cash equivalents at the end of the year	<u>\$ 1,679</u>	<u>\$ 10,221</u>
Non cash activity:		
Issuance of warrants to purchase convertible preferred shares	<u>(10)</u>	<u>—</u>
Exercise of warrants to convertible preferred B-1 shares	<u>73</u>	<u>—</u>
Conversion of convertible loans to Series C-1 convertible preferred shares	<u>5,943</u>	<u>—</u>

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

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

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 pairing PLEX with active pharmaceutical ingredients, or APIs, with PLEX, which are delivered locally at customizable, predetermined release rates and durations over periods ranging from days to several months. The Company is initially focused on the development of its lead product candidate, D-PLEX, which incorporates doxycycline for the prevention of surgical site infections in bone and soft tissue.

Through December 31, 2016, 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; develop 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 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 and clinical studies. Further, the Company's product candidates will require regulatory approval prior to commercialization. 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, 2016, the Company had cash and cash equivalents and short-term deposits of \$10,221 and 7,530, respectively. During the year ended December 31, 2016, the Company incurred a net loss of \$11,392 and had negative cash flows from operating activities of \$9,743. In addition, the Company had an accumulated deficit of \$36,572 at December 31, 2016. Management intends to continue its research and development efforts and clinical and regulatory activities and to finance operations of the Company through equity financings. 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 success of its research and development; and (iii) regulatory approval and market acceptance of the Company's proposed future products.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 1:- GENERAL (Continued)

There can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all.

Regarding the financing rounds in February and November 2016, please refer to Note 10c.

- 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 2j.

Upon 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The financial statements are prepared according to United States generally accepted accounting principles ("U.S. GAAP").

- a. Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the 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 financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

POLYPID LTD.**NOTES TO FINANCIAL STATEMENTS (Continued)****U.S. dollars in thousands (except share and per share data)****NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)**

b. Financial statements in U.S. dollars:

The accompanying financial statements have been prepared in U.S. dollars.

A substantial portion of the Company's costs are incurred in New Israeli Shekels. However, the Company finances its operations mainly in U.S. dollars and a substantial portion of its costs and revenues from its primary markets are anticipated to be incurred and 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. 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.

d. Restricted cash:

Restricted cash is primarily invested in certificates of deposit and is used as security for the Company's lease commitments.

e. 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 0.35% - 1.39% and 0.35%, per annum, as of December 31, 2016 and 2015, respectively. The Company had no short-term deposits in NIS as of December 31, 2016. Short-term deposits are presented at cost, which approximates market value due to their short maturities.

f. 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

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

g. 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, 2016 and 2015, no impairment losses have been identified.

h. Research and development costs:

Research and development costs 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 costs include overhead allocations consisting of various administrative and facilities related costs. The Company charges research and development costs as expenses when incurred. Grants from the Israeli Innovation Authority (IIA) and the European Commission's Seventh Framework Programme for Research (FP7) and participation from third-parties related to such research and development expenses are offset against research and development costs at the later of when grant receipt is assured or the expenses are incurred.

i. Accounting for share-based payments:

The Company accounts for share-based compensation to employees and directors in accordance with ASC 718, "Compensation — Share Compensation" ("ASC 718"). ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. 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 the Company's statements of operations.

The Company recognizes 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. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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 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

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 2016 and 2015.

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 2016 is 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.

During 2016, the Company's board of directors deemed the fair value of the Company's Ordinary shares to be \$0.37 - \$0.487 per share in accordance with the grant date of the options.

The fair value for options granted to employees during 2015 was estimated at the date of grant using the Black-Scholes-Merton Option Pricing Model with the following assumptions: expected volatility of 89% - 112%, risk free interest rates of 2.32% - 3.7%, dividend yield of 0%, and an expected term of 6 years. The Company's board of directors deemed the fair value of the Company's Ordinary shares to be \$0.37 - \$1.11 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 compensation expenses related to employees, consultants and other service providers for the years ended December 31, 2016 and 2015, amounted to \$598 (out of which \$18 were related to non-employees) and \$717 (out of which \$24 were related to non-employees), respectively.

j. 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

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

Through December 31, 2016, 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.

k. 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 and D-3 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).

l. 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.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 2016 and 2015 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, other receivables, trade payables, advances on account of R&D reimbursement and other accounts payable and accrued expenses approximate their fair value due to the short-term maturity of such instruments.

m. 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").

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

For the years ended December 31, 2016 and 2015, all outstanding options and convertible preferred shares warrants have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive for the periods presented.

n. 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. The Company classifies interest related to unrecognized tax benefits in taxes on income. As of December 31, 2016 and 2015 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.

o. 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 2e).

The Company has no off-balance sheet concentration of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

p. 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.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 2016 and 2015 amounted to \$249 and \$171, respectively.

q. 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 statement of operations, which it deems appropriate.

r. Recently issued accounting pronouncements

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15"). The standard requires management to evaluate, at each interim and annual reporting period, whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the issuance date of the financial statements, and provide related disclosures. The Company adopts ASU 2014-15, and believes it has no impact on its consolidated results of operations, financial position or cash flows. Management's plans concerning these matters are also described in Note 1b to the consolidated financial statements.

s. New pronouncements not yet effective

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 is evaluating the effect that this guidance will have on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), aimed at making leasing activities more transparent and comparable. The new standard requires substantially all leases

POLYPID LTD.**NOTES TO FINANCIAL STATEMENTS (Continued)****U.S. dollars in thousands (except share and per share data)****NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)**

be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including today's operating leases.

The standard is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. The Company is evaluating the possible impact of ASU 2016-02 but is presently unable to assess its effect, if any, on the financial statements.

NOTE 3:- PREPAID EXPENSES AND OTHER RECEIVABLES

	December 31,	
	2016	2015
Government authorities	\$ 170	\$ 68
Prepaid expenses	257	39
Grants receivable from IIA	47	59
Lease deposits	28	44
Others	1	17
	<u>\$ 503</u>	<u>\$ 227</u>

NOTE 4:- PROPERTY AND EQUIPMENT, NET

	December 31,	
	2016	2015
Cost:		
Computers and software	\$ 148	\$ 133
Laboratory equipment	809	362
Furniture and office equipment	110	91
Leasehold improvements	341	283
	<u>1,408</u>	<u>869</u>
Accumulated depreciation	(561)	(434)
Depreciated cost	<u>\$ 847</u>	<u>\$ 435</u>

Depreciation expenses amounted to \$127 and \$108 for the years ended December 31, 2016 and 2015, respectively.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 5:- OTHER PAYABLES AND ACCRUED EXPENSES

	December 31,	
	2016	2015
Employees and payroll accruals	\$ 439	\$ 506
Accrued expenses	377	589
Other expenses	104	—
	<u>\$ 920</u>	<u>\$ 1,095</u>

NOTE 6:- COMMITMENTS AND CONTINGENT LIABILITIES

- a. The facilities of the Company are leased under various operating lease agreements for periods ending no later than 2024. The Company also leases motor vehicles under various operating leases, which expire on various dates, the latest of which is in 2018.

Future minimum lease payments under operating leases as of December 31, 2016 are as follows:

<u>As of December 31, 2016</u>	
2017	\$ 513
2018	456
2019	404
2020	397
2021	397
Thereafter	1,192
	<u>\$ 3,359</u>

As of December 31, 2016, the Company made advance payments on account of car leases in the amount of \$100.

Rental and lease expenses for the years ended December 31, 2016 and 2015 were \$626 and \$624, respectively.

- b. In connection with its research and development programs, through December 31, 2016, the Company received and accrued participation payments from the IIA in the aggregate amount of \$2,972. 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, 2016, no royalties have been paid or accrued.

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 10). 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

POLYPID LTD.**NOTES TO FINANCIAL STATEMENTS (Continued)****U.S. dollars in thousands (except share and per share data)****NOTE 7:- FAIR VALUE MEASUREMENTS (Continued)**

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 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 prices were \$1.18 for the convertible preferred D-1 and D-2, \$0.77 for the convertible preferred C-2 shares, \$0.73 for the convertible preferred C-1 shares and \$0.61 for the convertible preferred A shares as of December 31, 2016. During February 2015, all the warrants to purchase convertible preferred B-1 shares were exercised into convertible preferred B-1 shares.

In respect with the issuance warrants during 2016, see also Note 10d.

The change in the fair value of the preferred share warrants liability is summarized below:

	2016	2015
Beginning of year	\$ 193	\$ 699
Issuance of warrants	5,252	67
Exercise of warrant	—	(73)
Change in fair value	1,171	(500)
End of year	<u>\$ 6,616</u>	<u>\$ 193</u>

NOTE 8:- INCOME TAXES**a. Corporate tax rates:**

The corporate tax rate in Israel in 2015 and 2016 is 26.5%.

On January 4, 2016, the Israeli Parliament's Plenum approved by a second and third reading 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, 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.

The deferred tax balances as of December 31, 2016 have been calculated based on the revised tax rates.

b. Net operating losses carry forward:

The Company has accumulated losses for tax purposes as of December 31, 2016 in the amount of approximately \$25,000 which may be carried forward and offset against taxable income in the future for an indefinite period.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 8:- INCOME TAXES (Continued)

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	2015
Reserves and allowances	\$ 108	\$ 81
Temporary differences	735	808
Loss carryforward	5,749	4,873
Deferred tax assets before valuation allowance	6,592	5,762
Less — valuation allowance	(6,592)	(5,762)
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 2016 and 2015, the main reconciling item of the statutory tax rate of the Company, 26.5% in 2016 and in 2015, 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 2012.

NOTE 9:- CONVERTIBLE LOANS

During December 2014, the Company entered into convertible loan agreements in the aggregate principal amount of \$4,410, of which an amount of \$2,100 was received by December 31, 2014 and an additional amount of \$2,310 was received during 2015.

The convertible loans bear interest of 4% per annum, compounded annually. The Company paid issuance expenses of \$75 in cash and issued 90,622 warrants in connection with convertible loans in the amount of \$1,500.

According to the terms of the agreement, the convertible loans shall be automatically converted upon the earliest of (i) a consummation of a financing round occurring prior to the lapse of twelve months from the closing, into the most senior class of shares issued in such financing round, or (ii) an IPO, into ordinary shares, at a 25% discount applied to the price per share reflected in such financing round or the price per share as determined for such shares in an IPO, as applicable.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 9:- CONVERTIBLE LOANS (Continued)

The convertible loans shall become due and payable only upon an event of default (defined as bankruptcy or final liquidation of the company). The conversion features related to a financing round and/or IPO continuously reset as the underlying share price increases or decreases to provide a fixed value of shares (i.e., "share settled debt").

The conversion features upon a financing round or an IPO were determined to be the predominant events and therefore the entire instrument was considered as a liability pursuant to ASC No. 480 "Distinguishing Liabilities from Equity". The convertible loans are presented at their redemption amount, which includes the principal amount of the convertible loans, the accumulated interest and additional redemption amount accrued over the term of the convertible loans, using the interest method.

On June 11, 2015, all convertible loans were automatically converted into 5,405,210 Series C-1 preferred shares as a result of a Series C-2 preferred shares financing round (refer to Note 10c). The redemption value of the convertible loans, in the amount of \$5,943, was reclassified into preferred C-1 shares upon their conversion. Until the conversion of the loan, the Company had accrued an amount of \$1,533 on the account of redemption amount and accumulated interest expense.

NOTE 10:- CONVERTIBLE PREFERRED SHARES AND WARRANTS

a. The Composition of the Company's Convertible Preferred shares is as follows:

	December 31, 2016		December 31, 2015	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Series A Convertible Preferred shares of NIS 0.1 par value	4,500,000	4,050,000	4,500,000	4,050,000
Series A-1 Convertible Preferred shares of NIS 0.1 Par value	7,500,000	6,685,770	7,500,000	6,685,770
Series B Convertible Preferred shares of NIS 0.1 par value	5,000,000	4,739,629	5,000,000	4,739,629
Series B-1 Convertible Preferred shares of NIS 0.1 par value	15,628,137	14,655,286	15,628,137	14,655,286
Series C-1 Convertible Preferred shares of NIS 0.1 par value	6,000,000	5,405,210	6,000,000	5,405,210
Series C-2 Convertible Preferred shares of NIS 0.1 par value	3,800,000	3,432,570	3,800,000	3,432,570
Series D-1 Convertible Preferred shares of NIS 0.1 par value	21,000,000	19,887,076	—	—
Series D-2 Convertible Preferred shares of NIS 0.1 par value	24,000,003	—	—	—
Series D-3 Convertible Preferred shares of NIS 0.1 par value	5,000,000	4,827,975	—	—
Total	<u>92,428,140</u>	<u>63,683,516</u>	<u>42,428,137</u>	<u>38,968,465</u>

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 10:- CONVERTIBLE PREFERRED SHARES AND WARRANTS (Continued)

The Company issued Series A, A-1, B, B-1, C-1,C-2, D-1 and D-3 convertible preferred shares between the years 2008 and 2016. 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 Association (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, 2016 and 2015, 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.

b. Preferred shares rights:

Series A, A-1, B, B-1, C-1,C-2, D-1 and D-3 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 and D-3 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 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 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

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 10:- CONVERTIBLE PREFERRED SHARES AND WARRANTS (Continued)

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 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 \$0.18, \$0.21, \$0.43, \$0.61, and \$0.83 per share, respectively, and Series C-2, D-1 and D-3 is \$1.10 per share.

Voting rights — each holder of Series A, A-1, B, B-1, C-1, C-2, D-1 and D-3 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 ("IPO") of the Company or upon written demand of the Investor Majority (as defined in the AoA).

At the current conversion prices, each share of Series A, A-1, B, B-1, C-1, C-2, D-1 and D-3 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:

In June 2015, the Company entered into a Share Purchase Agreement (the "2015 SPA") with new and existing investors. According to the 2015 SPA, the Company shall issue to the investors up to 3,624,848 Series C-2 preferred shares, for an aggregate amount of up to \$4,000 at a price per shares of \$1.10.

As of December 31, 2015, the Company issued to the investors 3,432,570 Series C-2 preferred shares, for an aggregate consideration of \$3,788 (net of issuance costs of \$54). Concurrent with the 2015 SPA, all outstanding convertible loans in the principal amount of \$4,410 were converted into 5,405,210 Series C-1 preferred shares, at a price per share of \$0.83 (refer also to Note 9).

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 20,388,689 series D-1 Preferred shares for an aggregate amount of up to \$22,500, at a price per share of \$1.10 and shall grant to the investors and/or any other individuals or entities as instructed by the investors, warrants to purchase up to 20,388,689 D-2 Preferred shares at a price per share of \$1.27 against payment of a total exercise amount of up to \$25,875.

The Company issued to the investors 19,887,076 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:

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 10:- CONVERTIBLE PREFERRED SHARES AND WARRANTS (Continued)

(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 4,827,975 Series D-3 Preferred Shares for an aggregate amount of \$5,328 at a price per share of \$1.10 (\$5,053, net of \$275 issuance costs in cash).

d. Warrants to purchase preferred shares:

In January 2015, in connection with the receipt of convertible loans (see Note 9) 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"). According to the terms of the Service Finance Agreement with MarketBridges, they are entitled to payment of (1) \$75 in cash, representing 5% of the investment made by the Investor and (2) issuance of 90,622 of C-1 warrants with an exercise price of \$0.83 representing 5% of the shares to be received by the Investor upon conversion of the investor loan, with an exercise price of \$0.83.

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. According to the terms of the Service Finance Agreement with MarketBridges, they are entitled to a payment of (1) \$25 in cash, representing 5% of the investment made by the New Investor and (2) 22,655 C-2 warrants with an exercise price of \$1.10 representing 5% of the shares to be received by the New Investor.

The survival of C-1 and C-2 warrants shall be limited to a period ending upon the earlier of: (i) 24 months following the Effective date; or (ii) consummation of an initial public offering.

On February 4, 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 163,109 D-1 Preferred shares and up to 20,050,185 D-2 Preferred shares at a price per share of \$1.27 against payment of a total exercise amount of up to \$25,875 (see b above).

In addition, the 2016 SPA, provides that the Company shall issue up to 3,007,527 additional warrants to purchase preferred D-2 shares if the Company failed to complete an initial public offering ("IPO") of its shares in the United States, which yields gross proceeds to the Company of at least \$22 million by December 31, 2016. In such event, the exercise price of all the warrants shall concurrently be reduced to \$1.10 per preferred D-2 share (see also Note 14b).

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 163,100 Preferred D-1 shares and issuance of 163,109 warrants to purchase D-1 Preferred shares) and (2) 326,219 issuance of D-2 warrants with an exercise price of \$1.27 representing 5% of the shares to be received by the New Investor (see also b above).

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 10:- CONVERTIBLE PREFERRED SHARES AND WARRANTS (Continued)

All outstanding D 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 survival of D-1 warrants shall be limited to a period ending upon the lapse of twenty-four (24) months from the Closing.

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-1 and D-2 warrants will exercise automatically if it is still outstanding on the final day of the warrant period as defined in warrants grant letter, and if the fair market value of a warrant share is more than the exercise price for such share.

NOTE 11:- SHAREHOLDERS' EQUITY (DEFICIENCY)

- a. Ordinary share capital is composed as follows:

	<u>December 31, 2016</u>		<u>December 31, 2015</u>	
	<u>Authorized</u>	<u>Issued and outstanding</u>	<u>Authorized</u>	<u>Issued and outstanding</u>
	Number of shares			
Ordinary shares of NIS 0.01 par value	<u>116,000,000</u>	<u>4,544,628</u>	<u>57,571,863</u>	<u>4,544,268</u>

- b. 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.

- c. 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 10,293,467 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, 2016, 892,301 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.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 11:- SHAREHOLDERS' EQUITY (DEFICIENCY) (Continued)

On November 19, 2015, the board of directors approved the grant of 1,535,386 options to the Company's CEO and CTO, 767,693 each. The options shall vest over 3 years and have an exercise price per share of \$1.1032.

On December 21, 2016, the board of directors approved the grant of 430,000 and 150,000 options to the Company's CFO and COO, respectively. The options shall vest over 3 years and have an exercise price per share of \$0.47.

A summary of the status of 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	8,279,411	0.34	877	8.159
Granted	914,845	0.43		
Exercised	—	—		
Forfeited and cancelled	(232,064)	0.62		
Outstanding at end of year	8,962,192	0.50	1,306	7.425
Exercisable options	6,560,734	0.39	1,259	6.789
Vested and expected to vest	8,962,192	0.50	1,306	7.425

A summary of the status of the Company's option plan as of December 31, 2015 and changes during the relevant period ended on that date is presented below:

	Year ended December 31, 2015			
	Number of options	Weighted average exercise price	Aggregate intrinsic value	Weighted average remaining contractual life (years)
Outstanding at beginning of year	6,546,370	0.34	5,046	8.172
Granted	1,810,541	1.10		
Exercised	(44,628)	0.61		
Forfeited and cancelled	(32,872)	0.61		
Outstanding at end of year	8,279,411	0.51	877	8.159
Exercisable options	5,270,745	0.29	875	7.453
Vested and expected to vest	8,279,411	0.51	877	8.159

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 11:- SHAREHOLDERS' EQUITY (DEFICIENCY) (Continued)

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 2015, was comprised as follows:

	Year ended December 31, 2016	Year ended December 31, 2015
Research and development	\$ 289	\$ 342
General and administrative	309	375
Total share-based compensation expense	<u>\$ 598</u>	<u>\$ 717</u>

As of December 31, 2016, there were unrecognized compensation costs of \$686, which are expected to be recognized over a weighted average period of approximately 0.99 years.

The weighted average grant date fair value of the Company's options granted during the year ended December 31, 2016 was \$0.43.

During the year ended December 31, 2016, no options were exercised and 44,628 options were exercised during the year ended December 31, 2015. The Company's board of directors deemed the fair value of the Company's Ordinary shares to be \$0.49 per share as of December 31, 2016.

The options outstanding as of December 31, 2016 are comprised, as follows:

Exercise price ^(*)	Options outstanding as of December 31, 2016	Weighted average exercise price	Weighted average remaining contractual term (years)	Options exercisable as of December 31, 2016	Weighted average exercise price	Weighted average remaining contractual term (years)
\$0.03	2,088,368	\$ 0.03	6.22	2,088,368	\$ 0.03	6.01
\$0.21	902,960	\$ 0.21	6.22	902,960	\$ 0.21	6.22
\$0.43	744,798	\$ 0.43	6.33	744,798	\$ 0.43	6.33
\$0.61	2,540,680	\$ 0.61	7.32	2,168,158	\$ 0.61	7.31
\$1.10	1,770,541	\$ 1.10	8.87	636,450	\$ 1.10	8.84
\$0.37	334,845	\$ 0.37	9.41	20,000	\$ 0.37	9.27
\$0.47	580,000	\$ 0.47	9.98	—	\$ 0.47	—
	<u>8,962,192</u>	\$ 0.50	7.42	<u>6,560,734</u>	\$ 0.39	6.79

(*) 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.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 11:- SHAREHOLDERS' EQUITY (DEFICIENCY) (Continued)

d. Options issued to consultants:

Outstanding options granted to consultants as of December 31, 2016 were as follows:

Grant date	Options outstanding as of December 31, 2016	Exercise price per share	Options exercisable as of December 31, 2016	Exercisable through
March 2013	186,258	\$ 0.61	186,258	March 2023
October 2013	47,858	\$ 0.61	47,858	October 2023
June 2014	47,000	\$ 0.61	39,128	June 2024
September 2014	47,858	\$ 0.61	47,858	September 2024
April 2016	50,000	\$ 0.37	—	April 2026
December 2016	60,000	\$ 0.47	—	March 2023
	<u>438,974</u>		<u>321,102</u>	

NOTE 12:- FINANCIAL EXPENSES, NET

	Year ended December 31,	
	2016	2015
Financial expenses:		
Accretion of interest on convertible loans	\$ —	\$ 1,533
Revaluation of warrants	1,171	—
Others	108	153
Total financial expenses, net	<u>1,279</u>	<u>1,686</u>
Financial income:		
Interest from deposits	(71)	—
Foreign currency transaction gains, net	(75)	(5)
Revaluation of warrants	—	(500)
Total financial income:	<u>(146)</u>	<u>(505)</u>
Financial expenses, net	<u>\$ 1,133</u>	<u>\$ 1,181</u>

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 13:- 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	2015
Numerator:		
Net loss attributable to Ordinary shares as reported	\$ (11,392)	\$ (9,748)
Preferred share dividend	(2,957)	(1,114)
Net loss applicable to Ordinary shareholders	<u>(14,349)</u>	<u>(10,862)</u>
Denominator:		
Weighted average shares used in computing net loss per Ordinary share, basic and diluted:		
Ordinary share — basic	4,544,628	4,518,056
Ordinary share equivalents	—	—
Ordinary share — dilutive	<u>4,544,628</u>	<u>4,518,056</u>
Net loss per ordinary share, basic and diluted	<u>\$ (3.16)</u>	<u>\$ (2.40)</u>

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 2016 and 2015.

NOTE 14:- SUBSEQUENT EVENTS

- a. The Company evaluates events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to identify matters that require additional disclosure. For its annual financial statements as of December 31, 2016 and for the year then ended, the Company evaluated subsequent events through March 8, 2017, the date that the financial statements were issued. Except as described below, the Company has concluded that no subsequent event has occurred that require disclosure
- b. During January 2017, the Company issued additional 3,007,527 warrants to purchase preferred D-2 shares with an exercise price of \$1.10 (see also Note 10d).

POLYPID LTD.**BALANCE SHEETS**

U.S. dollars in thousands

	December 31, 2016	September 30, 2017	Pro forma as of September 30, 2017
	<u>Audited</u>	<u>Unaudited</u>	<u>Unaudited</u>
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	\$ 10,221	\$ 6,412	\$ 6,425
Short-term deposits	7,530	8,035	8,035
Prepaid expenses and other receivables	503	889	889
Total current assets	<u>18,254</u>	<u>15,336</u>	<u>15,349</u>
LONG-TERM ASSETS:			
Property and equipment, net	847	1,697	1,697
Other long-term assets	136	199	199
Total long-term assets	<u>983</u>	<u>1,896</u>	<u>1,896</u>
Total assets	<u>\$ 19,237</u>	<u>\$ 17,232</u>	<u>\$ 17,245</u>

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

POLYPID LTD.

BALANCE SHEETS (Continued)

U.S. dollars in thousands (except share and per share data)

	December 31, 2016	September 30, 2017	Pro forma as of September 30, 2017
	Audited	Unaudited	Unaudited
LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIENCY)			
Current liabilities:			
Trade payables	\$ 778	\$ 907	\$ 907
Other payables and accrued expenses	920	746	746
Total current liabilities	<u>1,698</u>	<u>1,653</u>	<u>1,653</u>
Long-term liabilities:			
Advances on account of collaboration agreement	600	600	600
Other liabilities	256	279	279
Convertible preferred shares warrant liability	6,616	12,266	—
Total long-term liabilities	<u>7,472</u>	<u>13,145</u>	<u>879</u>
Convertible preferred shares:			
Preferred A, A-1, B, B-1, C-1, C-2, D-1, D-3 and E shares of NIS 0.1 par value —			
Authorized	101,928,140 and 92,428,140		
shares at pro forma as of September 30, 2017 (unaudited), September 30, 2017 (unaudited) and December 31, 2016, respectively; Issued and outstanding:	67,735,899 and 63,683,516		
shares at pro forma as of September 30, 2017 (unaudited), September 30, 2017 (unaudited) and December 31, 2016, respectively; Aggregate liquidation preference of \$72,795 at September 30, 2017 (unaudited)	44,026	50,133	—
Shareholders' equity (deficiency):			
Share capital —			
Ordinary shares of NIS 0.1 par value —			
Authorized:	125,500,000 and 116,000,000		
shares at pro forma as of September 30, 2017 (unaudited), September 30, 2017 (unaudited) and December 31, 2016, respectively; Issued and outstanding:	4,673,211 and 4,544,628		
shares at pro forma as of September 30, 2017 (unaudited), September 30, 2017 (unaudited) and December 31, 2016, respectively	126	129	2,061
Additional paid-in capital	2,487	3,091	63,571
Accumulated deficit	<u>(36,572)</u>	<u>(50,919)</u>	<u>(50,919)</u>
Total shareholders' equity (deficiency)	<u>(33,959)</u>	<u>(47,699)</u>	<u>14,713</u>
Total liabilities, convertible preferred shares and shareholders' equity (deficiency)	<u>\$ 19,237</u>	<u>\$ 17,232</u>	<u>\$ 17,245</u>

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

POLYPID LTD.

STATEMENTS OF OPERATIONS

U.S. dollars in thousands (except share and per share data)

	Nine months ended September 30,	
	2016	2017
	Unaudited	
Operating expenses:		
Research and development, net	\$ 5,299	\$ 6,494
General and administrative	1,771	2,291
Operating loss	7,070	8,785
Financial expenses, net	2,179	5,562
Net loss	\$ 9,249	\$ 14,347
Basic and diluted net loss per Ordinary share	\$ (2.50)	\$ (3.62)
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	4,544,628	4,625,635
Pro forma basic and diluted net loss per Ordinary share (unaudited)		\$ (0.20)
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share — pro forma (unaudited)		72,811,534

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

POLYPID LTD.

STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED SHARES AND 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	38,968,465	\$ 22,934	\$ 22,934	4,544,628	\$ 126	\$ 1,889	\$ (25,180)	\$ (23,165)
Issuance of series D-1 Preferred shares, net ^(*)	19,887,076	16,039	16,039	—	—	—	—	—
Issuance of series D-3 Preferred shares, net ^(**)	4,827,975	5,053	5,053	—	—	—	—	—
Share-based compensation	—	—	—	—	—	598	—	598
Net loss	—	—	—	—	—	—	(11,392)	(11,392)
Balances as of December 31, 2016	63,683,516	44,026	44,026	4,544,628	126	2,487	(36,572)	(33,959)
Exercise of options	—	—	—	128,583	3	65	—	68
Issuance of series E Preferred shares, net ^(***)	4,052,383	6,107	6,107	—	—	—	—	—
Share-based compensation	—	—	—	—	—	539	—	539
Net loss	—	—	—	—	—	—	(14,347)	(14,347)
Balances as of September 30, 2017 (unaudited)	<u>67,735,899</u>	<u>\$ 50,133</u>	<u>\$ 50,133</u>	<u>4,673,211</u>	<u>\$ 129</u>	<u>\$ 3,091</u>	<u>\$ (50,919)</u>	<u>\$ (47,699)</u>

(*) 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 \$334 in cash and share-based.

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

POLYPID LTD.

STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Nine months ended September 30,	
	2016	2017
	Unaudited	
Cash flows from operating activities:		
Net loss	\$ (9,249)	\$ (14,347)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	90	142
Re-evaluation of warrants	2,193	5,650
Share-based compensation	445	539
Changes in assets and liabilities:		
Increase in receivables and prepaid expenses	(38)	(386)
Increase in other long-term assets	(3)	(63)
Increase (decrease) in trade payables	(372)	129
Decrease in other payables and accrued expenses and other liabilities	(558)	(151)
Net cash used in operating activities	(7,492)	(8,487)
Cash flows from investing activities:		
Short-term deposits, net	(8,553)	(505)
Purchase of property and equipment	(211)	(992)
Net cash used in investing activities	(8,764)	(1,497)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred shares and warrants, net	21,291	6,107
Proceeds from exercise of options	—	68
Net cash provided by financing activities	21,291	6,175
Increase (decrease) in cash and cash equivalents	5,035	(3,809)
Cash and cash equivalents at the beginning of the period	1,679	10,221
Cash and cash equivalents at the end of the period	\$ 6,714	\$ 6,412

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

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

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 pairing PLEX with active pharmaceutical ingredients, or APIs, with PLEX, which are delivered locally at customizable, 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, which incorporates doxycycline, for the prevention of surgical site infections in bone and soft tissue.

Through September 30, 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; develop 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 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 and clinical studies and obtain regulatory approvals. Further, the Company's product candidates will require regulatory approval prior to commercialization. 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 September 30, 2017, the Company had cash and cash equivalents of \$6,412. During the nine months period ended September 30, 2017, the Company incurred a net loss of \$14,347 and had negative cash flows from operating activities of \$8,487. In addition, the Company had an accumulated deficit of \$50,919 at September 30, 2017. Management intends to continue its research and development efforts and clinical and regulatory activities and to finance operations of the Company through equity financings. Management plans to seek additional equity financing through private and public offerings, 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 success of its research and development activities; (iii) successful conclusion of clinical studies for its lead product candidates; (iv) regulatory approval for its lead product candidates; and (v) market acceptance of the Company's lead products candidates.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 1:- GENERAL (Continued)

There can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation:

The unaudited interim financial statements should be read in conjunction with the audited financial statements and notes for the year ended December 31, 2016.

These unaudited interim financial statements of the Company, as of September 30, 2017 and for the nine months period then ended, have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP").

The unaudited interim financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information. Accordingly, they do not include all the information and footnotes required by generally accepted accounting principles for annual financial statements. In the opinion of our management, all material adjustments considered necessary for a fair presentation of the financial information as of and for the periods presented have been included.

b. Accounting policies:

The significant accounting policies followed in the preparation of these unaudited interim financial statements are consistent to those applied in the preparation of the latest annual financial statements.

c. Use of estimates:

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

d. Unaudited 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 initial qualified 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.

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 September 30, 2017 has been prepared assuming the automatic conversion of all outstanding preferred shares and A warrants into 68,185,899 ordinary shares

POLYPID LTD.**NOTES TO FINANCIAL STATEMENTS (Continued)****U.S. dollars in thousands (except share and per share data)****NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)**

and the classification of D-2 warrants into shareholders' equity. Pro forma net loss per ordinary share is disclosed in the statement of operations which also gives effect to the assumed conversion of the preferred shares as described above.

e. 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.

f. 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 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 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. The Company is evaluating the potential impact of this pronouncement.

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

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 believes that this will not have a material impact on its consolidated financial statements.

NOTE 3:- COMMITMENTS AND CONTINGENT LIABILITIES

- a. The facilities of the Company are leased under various operating lease agreements for periods ending no later than 2024. The Company also leases motor vehicles under various operating leases, which expire on various dates, the latest of which is in 2018.

As of September 30, 2017 (unaudited), an amount of \$175 was restricted in favor of long term lease deposits and classified in the balance sheet as other long-term assets.

Future minimum lease payments under non-cancelable operating leases as of September 30, 2017 (unaudited) are as follows:

	As of September 30, 2017
	Unaudited
2017	\$ 224
2018	871
2019	818
2020	785
2021	744
Thereafter	2,723
Total	<u>\$ 6,165</u>

As of September 30, 2017 (unaudited), the Company made advance payments on account of installments on car leases in the amount of \$99.

Lease and rental expenses for the nine months ended September 30, 2017 (unaudited) were \$539.

- b. In connection with its research and development programs, the Company received participation payments from the Israel Innovation Authority of the Ministry of Economy in Israel ("IIA") of \$4,594 for industrial research and development projects as of September 30, 2017 (unaudited). In return for the IIA's participation, the Company is committed to pay royalties at a rate of 3% of sales of the developed products, up to 100% of the amount of grants received plus interest at LIBOR. During the nine months ended September 30, 2017 (unaudited) and for the year ended December 31, 2016, 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.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 3:- COMMITMENTS AND CONTINGENT LIABILITIES (Continued)

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 financial statements, which management believes is sufficient.

NOTE 4:- FAIR VALUE MEASUREMENTS

Financial instruments measured at fair value on a recurring basis include warrants to purchase preferred A and D-2 shares. The warrants are classified as a liability in accordance with ASC 480-10-25. 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 Option Pricing Method ("OPM") model. The fair value of the underlying preferred share price was determined by the board of directors with the assistance of a third party valuator. The Company's enterprise value was determined based on financing transactions with third parties. 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 preferred shares. The underlying share prices were \$1.24 for the convertible preferred D-2 shares and \$1.12 for the convertible preferred A shares as of September 30, 2017 (unaudited).

The change in the fair value of the preferred share warrant liability is summarized below:

	December 31, 2016	September 30, 2017
	Audited	Unaudited
Beginning of period	\$ 193	\$ 6,616
Expiration of warrants C-1, C-2 and D-1	—	(70)
Issuance of warrants	5,252	—
Change in fair value	1,171	5,720
End of period	<u>\$ 6,616</u>	<u>\$ 12,266</u>

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 5:- CONVERTIBLE PREFERRED SHARES AND WARRANTS

a. The composition of the Company's convertible preferred shares is as follows:

	December 31, 2016		September 30, 2017	
	Audited		Unaudited	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Series A Convertible Preferred shares of NIS 0.1 par value	4,500,000	4,050,000	4,500,000	4,050,000
Series A-1 Convertible Preferred shares of NIS 0.1 par value	7,500,000	6,685,770	7,500,000	6,685,770
Series B Convertible Preferred shares of NIS 0.1 par value	5,000,000	4,739,629	5,000,000	4,739,629
Series B-1 Convertible Preferred shares of NIS 0.1 par value	15,628,137	14,655,286	15,628,137	14,655,286
Series C-1 Convertible Preferred shares of NIS 0.1 par value	6,000,000	5,405,210	6,000,000	5,405,210
Series C-2 Convertible Preferred shares of NIS 0.1 par value	3,800,000	3,432,570	3,800,000	3,432,570
Series D-1 Convertible Preferred shares of NIS 0.1 par value	21,000,000	19,887,076	21,000,000	19,887,076
Series D-2 Convertible Preferred shares of NIS 0.1 par value	24,000,003	—	24,000,003	—
Series D-3 Convertible Preferred shares of NIS 0.1 par value	5,000,000	4,827,975	5,000,000	4,827,975
Series E Convertible Preferred shares of NIS 0.1 par value	—	—	9,500,000	4,052,383
Total	92,428,140	63,683,516	101,928,140	67,735,899

The Company issued Series A, A-1, B, B-1, C-1, C-2, D-1, D-3 and E preferred shares between February 2008 and September 30, 2017. The Company classifies the convertible preferred shares outside of shareholders' deficiency as required by ASC 480-10-S99-3A and ASR 268, since these 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.

b. Financing round:

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 20,388,689 series D-1 Preferred shares for an aggregate amount of up to \$22,500, at a price per share of \$1.10 and shall grant to the investors and/or any other individuals or entities as instructed by the investors, warrants to purchase up to 20,388,689 D-2 Preferred shares at a price per share of \$1.27 against payment of a total exercise amount of up to \$25,875.

POLYPID LTD.**NOTES TO FINANCIAL STATEMENTS (Continued)****U.S. dollars in thousands (except share and per share data)****NOTE 5:- CONVERTIBLE PREFERRED SHARES AND WARRANTS (Continued)**

The Company issued to the investors 19,887,076 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). An amount of \$95 relating to MarketBridges was deducted from issuance costs and classified to financial expenses.

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 4,827,975 Series D-3 Preferred Shares for an aggregate amount of \$5,328 at a price per share of \$1.10 (\$5,053, net of \$275 issuance costs in cash).

During August and September 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. As of the balance sheet date, the company received \$6,107 and issued to the investors 4,052,383 Series E Preferred Shares net of \$334 issuance costs, at a price per share of \$1.59. Issuance costs consisting of: (1) \$30 in cash and (2) \$304 settled as issuance of Preferred E shares as a finder fee. The terms and conditions of the convertible preferred E shares are similar to preferred shares D-2.

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.

c. Warrants:

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 20,050,185 D-2 preferred shares at a price per share of \$1.27 against payment of a total exercise amount of up to \$25,464 (See note 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

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 5:- CONVERTIBLE PREFERRED SHARES AND WARRANTS (Continued)

("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 \$1.10 per preferred D-2 share. Accordingly, during January 2017, the Company issued an additional 3,007,527 warrants to purchase preferred D-2 shares with an exercise price of \$1.10, 48,933 of which were issued as part of the issuance expenses to MarketBridges (see below).

In February 2016, in connection with the 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 was settled by issuing 163,110 D-1 preferred shares and 163,109 D-1 warrants) and (2) 326,219 of D-2 warrants with an exercise price of \$1.27 representing 5% of the shares to be received by the New Investor (see also b above). During January 2017, the Company issued an additional 48,933 warrants to purchase preferred D-2 shares with an exercise price of \$1.1

All outstanding 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 September 30, 2017, there were outstanding warrants to purchase 450,000 Series A preferred shares and warrants to purchase 23,057,712 Series D-2 preferred shares.

NOTE 6:- SHAREHOLDERS' DEFICIENCY

- a. Ordinary share capital is composed as follows:

	December 31, 2016		September 30, 2017	
	Audited		Unaudited	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Ordinary shares of NIS 0.1 par value	116,000,000	4,544,628	125,500,000	4,673,211

- b. Share option plans:

The Company authorized through its 2012 Share Option Plan the grant of options to officers, directors, advisors, management and other key employees of up to 11,755,506 ordinary

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 6:- SHAREHOLDERS' DEFICIENCY (Continued)

shares, of which 11,624,470 were granted as of September 30, 2017. 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 September 30, 2017 (unaudited), 131,036 of the Company's options were available for future grants.

The total equity-based compensation expense related to all of the Company's equity-based awards recognized for the nine months ended September 30, 2017 (unaudited) was comprised as follows:

	Nine months ended September 30, 2017
	Unaudited
Research and development	\$ 190
General and administrative	349
Total share-based compensation expense	<u>\$ 539</u>

128,583 options were exercised during the nine months ended September 30, 2017 (unaudited).

The Company's board of directors deemed the fair value of the Company's ordinary shares to be \$ 0.92 per share as of September 30, 2017 (unaudited).

c. Options issued to employees:

A summary of the status of the options issued to employees as of September 30, 2017 (unaudited), and changes during the period then ended is presented below:

	Nine months ended September 30, 2017		
	Number of options	Weighted average exercise price	Aggregate intrinsic value
		Unaudited	
Outstanding at beginning of period	8,962,192	\$ 0.50	\$ 1,306
Granted	661,000	\$ 0.50	
Exercised	(128,583)	\$ 0.53	
Forfeited or expired	(10,699)	\$ 0.37	
Outstanding at end of period	<u>9,483,910</u>	\$ 0.50	\$ 4,325
Exercisable options	<u>7,562,325</u>	\$ 0.45	\$ 3,771
Vested and expected to vest	<u>9,483,910</u>	\$ 0.50	\$ 4,325

As of September 30, 2017 (unaudited), there were unrecognized compensation costs of \$636, which are expected to be recognized over a weighted average period of approximately 1.7 years.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 6:- SHAREHOLDERS' DEFICIENCY (Continued)

The options outstanding as of September 30, 2017 (unaudited) have been separated into ranges of exercise prices, as follows:

Exercise price ^(*)	Options outstanding as of September 30, 2017	Weighted average exercise price ^(*)	Weighted average remaining contractual term (years)	Options exercisable as of September 30, 2017	Weighted average exercise price ^(*)	Weighted average remaining contractual term (years)
\$0.03	2,088,368	\$0.03	5.47	2,088,368	\$0.03	5.29
\$0.21	902,960	\$0.21	5.47	902,960	\$0.21	5.47
\$0.43	698,766	\$0.43	5.59	698,766	\$0.43	5.59
\$0.61	2,465,680	\$0.61	6.58	2,493,180	\$0.61	6.58
\$1.10	1,770,541	\$1.10	8.12	1,073,669	\$1.10	8.11
\$0.37	316,595	\$0.37	8.67	128,549	\$0.37	8.65
\$0.47	580,000	\$0.47	9.23	145,000	\$0.47	9.23
\$0.49	191,000	\$0.49	9.44	31,833	\$0.49	9.44
\$0.50	470,000	\$0.50	9.65	—	\$0.50	—
	<u>9,483,910</u>			<u>7,562,325</u>		

(*) The exercise price as per the option terms was denominated in NIS and translated to US\$ in the table above using the exchange rate as of the grant date. The options were granted at ordinary share par value.

d. Options issued to directors and consultants:

The outstanding options granted to consultants as of September 30, 2017 (unaudited) were as follows:

	Options outstanding as of September 30, 2017	Exercise price per share	Options exercisable as of September 30, 2017	Exercisable through
March 2013	186,258	\$ 0.61	186,258	March 2023
October 2013	47,858	\$ 0.61	47,858	October 2023
June 2014	47,000	\$ 0.61	47,000	June 2024
September 2014	47,858	\$ 0.61	47,858	September 2024
April 2016	50,000	\$ 0.37	24,875	April 2026
December 2016	60,000	\$ 0.47	19,800	March 2023
June 2017	1,654,586	\$ 0.49	375,764	June 2027
August 2017	47,000	\$ 1.11	23,383	August 2027
	<u>2,140,560</u>		<u>772,796</u>	

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 7:- 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:

	Nine months ended September,	
	2016	2017
Numerator:		
Net loss attributable to ordinary shares as reported	\$ (9,249)	\$ (14,347)
Preferred share dividend	(2,091)	(2,398)
Net loss applicable to ordinary shareholders	<u>(11,340)</u>	<u>(16,745)</u>
Denominator:		
Weighted average shares used in computing net loss per ordinary share, basic and diluted:		
Ordinary share — basic	4,544,628	4,625,635
Ordinary share equivalents	—	—
Ordinary share — dilutive	<u>4,544,628</u>	<u>4,625,635</u>
Net loss per ordinary share, basic and diluted	<u>\$ (2.50)</u>	<u>\$ (3.62)</u>

NOTE 8:- PRO FORMA BASIC AND DILUTED NET LOSS PER SHARE (UNAUDITED)

The following table sets forth the computation of the Company's pro forma basic and diluted net loss per ordinary share (unaudited):

	Nine months ended September 30, 2017
	Unaudited
Net loss attributable to ordinary shares as reported	<u>\$ (14,347)</u>
Shares used in computing net loss per ordinary share, basic and diluted	4,625,635
Pro forma adjustments to reflect assumed conversion of convertible preferred shares and exercise of warrants A	<u>68,185,899</u>
Shares used in computing pro forma net loss per ordinary share, basic and diluted	<u>72,811,534</u>
Pro forma net loss per ordinary share, basic and diluted	<u>\$ (0.20)</u>

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS (Continued)

U.S. dollars in thousands (except share and per share data)

NOTE 9:- SUBSEQUENT EVENTS

- a. The Company evaluates events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to identify matters that require additional disclosure. For its financial statements as of September 30, 2017 and for the nine months then ended, the Company evaluated subsequent events through November 8, 2017 the date that the financial statements were issued. Except as described below, the Company has concluded that no subsequent event has occurred that require disclosure.
- b. As part of 2017 SPA (see note 5b), the Company received during October and November an additional \$5,288 in cash proceeds and issued to the investors 3,326,832 series E preferred shares.
- c. In October 2017, the Company established a wholly-owned subsidiary in the United States (US), PolyPid Inc. (the "Subsidiary"). The Subsidiary was established in order to efficiently facilitate the conduct of its expected business operations in the US.
- d. On November 2, 2017, the Board of Directors approved an increase of 6,000,000 ordinary shares to the 2012 Share Option Plan option pool.
- e. On November 2, 2017, the Board of Directors approved the grant of options to purchase 4,559,000 ordinary shares to directors, officers, employees and consultants.

Shares

PolyPid Ltd.

Ordinary Shares



Goldman Sachs & Co. LLC

Cowen

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.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 6. Indemnification of Directors, Officers and Employees.

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 to 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 with respect to 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 "Management — 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 continue to maintain such 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.

Insofar as the indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or persons controlling the registrant, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 7. Recent Sales of Unregistered Securities.

The following list sets forth information as to all securities we have sold since January 1, 2014, which were not registered under the Securities Act.

- In June 2014, we issued an aggregate of 6,605,019 Series B-1 preferred shares pursuant to a private placement, at a price per share of \$0.61.
- In June 2015, we issued 3,432,570 Series C-2 preferred shares pursuant to a private placement, at a price per share of \$1.10.
- In June 2015, we issued an aggregate of 5,405,210 Series C-1 preferred shares pursuant to convertible loan agreements, at a price per share of \$0.83.
- In September 2015, we issued warrants to purchase up to 22,655 Series C-2 preferred shares, at an exercise price per share of \$1.10.
- In February 2016, we issued in connection with a private placement: (i) an aggregate of 19,887,076 Series D-1 preferred shares at a price per share of \$1.10, (ii) warrants to

purchase up to 163,109 Series D-1 preferred shares, at an exercise price per share of \$1.10, and (iii) warrants to purchase up to 20,050,185 Series D-2 preferred shares, which was subsequently adjusted to up to 23,057,712 Series D-2 preferred shares, at an exercise price per share of \$1.27.

- In November 2016, we issued an aggregate of 4,827,975 Series D-3 preferred shares pursuant to a private placement, at a price per share of \$1.10.
- In August, September, October and November 2017, we issued an aggregate of 7,379,215 Series E preferred shares pursuant to a private placement, at a price per share of \$1.59.

The sales of the above securities were deemed to be exempt from registration under the Securities Act because they were made outside of the United States of America to certain non-U.S. individuals or entities pursuant to Regulation S or, in reliance upon the exemption from registration provided under Section 4(a)(2) of the Securities Act and the regulations promulgated thereunder.

Additionally, we granted share options to employees, directors, consultants and service providers under our 2012 Plan covering an aggregate of 16,223,470 ordinary shares, with exercise prices ranging from \$0.03 to \$1.1035 per share. Such number excludes options to purchase up to 3,350,000 ordinary shares, which are contingent upon the closing of this offering.

We claimed exemption from registration under the Securities Act for these option grants described above under Section 4(a)(2), Regulation S, or under Rule 701 of the Securities Act as transactions pursuant to written compensatory plans or pursuant to a written contract relating to compensation.

No underwriters were employed in connection with the securities issuances set forth in this Item.

Item 8. Exhibits and Financial Statement Schedules.

- (a) **Exhibits.** See the Exhibit Index attached to this registration statement, which is incorporated by reference herein.
- (b) **Financial Statement Schedules.** Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 9. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

- (1) for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective; and
- (2) for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

EXHIBIT INDEX

EXHIBIT NUMBER	EXHIBIT DESCRIPTION
1.1*	Form of Underwriting Agreement
3.1*	Amended and Restated Articles of Association of the Registrant, as currently in effect
3.2*	Form of Articles of Association of the Registrant to be effective upon the closing of this offering
4.1	Warrant to purchase Series A Preferred Shares
4.2	Form of Warrant to purchase Series D-2 Preferred Shares
5.1*	Opinion of Zysman, Aharoni, Gayer & Co., Israeli counsel to the Registrant, as to the validity of the ordinary shares
10.1*	Form of Officer Indemnity and Exculpation Agreement
10.2	PolyPid Ltd. 2012 Share Option Plan, as amended to date
10.3*	Amended and Restated Investors' Rights Agreement, dated November , 2017, among the Registrant and the shareholders named therein
21.1	Subsidiaries of the Registrant
23.1*	Consent of Kost, Forer, Gabbay & Kasierer, Certified Public Accountants (Israel), an independent registered public accounting firm and a member firm of Ernst & Young LLP
23.2*	Consent of Zysman, Aharoni, Gayer & Co. (included in Exhibit 5.1)
24.1	Power of Attorney (included in signature pages of Registration Statement)

* To be provided by amendment.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Petach Tikva, Israel on this day of , .

POLYPID LTD.

By:

Amir Weisberg
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Amir Weisberg and Dikla Czaczkes Akselbrad, and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Registration Statement, including post-effective amendments or any abbreviated registration statement and any amendments thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
_____ Amir Weisberg	Chief Executive Officer and Director (Principal Executive Officer)	,
_____ Dikla Czaczkes Akselbrad	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	,
_____ Yechezkel Barenholz, Ph.D.	Director	,

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
_____ Noam Emanuel, Ph.D.	Director	,
_____ Eli Frydman Ph.D.	Director	,
_____ Chaim Hurvitz	Director	,
_____ Jack Eitan Kyiet	Director	,
_____ Anat Tsour Segal	Director	,
PolyPid Inc.		
By: _____	AUTHORIZED U.S. REPRESENTATIVE	,
Name: Amir Weisberg		
Title: <i>President</i>		

THIS WARRANT AND THE SECURITIES EVIDENCED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), THE ISRAELI SECURITIES LAW 5728 — 1968, AS AMENDED, OR ANY STATE OR FOREIGN SECURITIES LAWS. SUCH SECURITIES MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF SUCH REGISTRATION UNLESS SUCH SALE, OFFER, PLEDGE OR HYPOTHECATION IS EXEMPT FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF THE ACT AND OF ANY APPLICABLE SECURITIES LAWS.

No. 1
ISSUED: April 7, 2008

WARRANT TO PURCHASE
PREFERRED A SHARES

Polypid Ltd. Warrant

THIS WARRANT is issued to Xenia Venture Capital Ltd. or its assigns (the "**Holder**") by Polypid Ltd., an Israeli corporation (the "**Company**"), pursuant to the terms of that certain Founders' and Share Purchase Agreement dated March 16, 2008 (the "**Agreement**") according to which the Holder is issued this Warrant to purchase 450,000 Series A Preferred Shares, par value NIS 0.10 each, of the Company (the "**Warrant Shares**"), as adjusted or readjusted pursuant to Section 3 hereof, on the terms set forth herein, representing (as reflected in the Cap Table attached to the Agreement as Exhibit 2.1(a)) 4.50% of the Company's share capital on a Fully Diluted Basis (as defined in the Agreement) immediately after the Closing (as defined in the Agreement).

1. Exercise Price and Number of Warrant Shares

- (a) The per share exercise price for the Warrant Shares shall be the par value thereof, i.e. Ten Israeli Agrot (NIS 0.10) (the "**Exercise Price**"). The number of shares and type of security are subject to adjustment for the protection of the Holder as provided below.
- (b) This Warrant may be exercised by the Holder at any time during the period commencing with the date hereof and ending upon the consummation of the earlier of the following events: (i) the Company's initial public offering of its shares offering on the NASDAQ National Market, the New-York Stock Exchange, the London Stock Exchange, the AIM, the Tel Aviv Stock Exchange, the Hong Kong Stock Exchange, the Toronto Stock Exchange, the Moscow Stock exchange and the Ireland Stock Exchange, reflecting a pre-money valuation of the Company of at least seventy five million United States dollars (US\$ 75,000,000) with net proceeds to the Company of not less than fifteen million United States Dollars (US\$ 15,000,000) ("**QIPO**"); (ii) a merger or consolidation of the Company with or into another company, and (iii) the sale of all or substantially all of the Company's properties and assets or the sale of all or substantially all of the Company's shares to another party (each of the events in (ii) and (iii) an "**M&A**") (the "**Exercise Period**") provided, however, that the Company shall provide written notice to the Holder of an intended QIPO or M&A not less than 45 days prior to the intended closing of such QIPO or M&A. The Warrant may be exercised by the Holder in whole or in part, by delivering to the Company (a) this Warrant certificate, (b) an amount equal to the Exercise Price multiplied by the number of Warrant Shares for which this Warrant is being exercised

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(the "**Purchase Price**"), and (c) the Notice of Exercise attached as Exhibit A duly completed and executed by the Holder. Upon exercise, the Holder shall be entitled to receive from the Company a share certificate in proper form representing the number of Warrant Shares so purchased.

- (c) The Holder may condition its exercise hereof in connection with a QIPO or M&A on the completion of such QIPO or M&A.

2. Delivery of Share Certificates; No Fractional Shares

- (a) Within 10 days after the payment of the Purchase Price following the exercise of this Warrant (in whole or in part), the Company at its expense shall (1) issue in the name of the Holder the number of fully paid and nonassessable Warrant Shares to which the Holder shall be entitled upon such exercise; and (2) register the Holder in the Company's shareholders registrar as the holder of the Warrant Shares to which the Holder shall be entitled upon such exercise, and deliver to the Holder: (i) a certificate or certificates thereof, and (ii) a new Warrant of like tenor to purchase up to that number of Warrant Shares, if any, as to which this Warrant has not been exercised.
- (b) If, upon exercise of this Warrant, a fraction of a share results, the Company will round up the number of Warrant Shares deliverable hereunder to the next whole number of such shares.

3. Adjustments

The number and kind of securities purchasable upon the exercise of this Warrant, and the Exercise Price therefor, shall be subject to adjustment from time to time upon the occurrence of certain events, as follows:

- (a) Reclassification. In case of any reclassification or change of the Warrant Shares (other than as a result of a subdivision or combination), the Company shall execute a new Warrant, providing that the Holder of this Warrant shall have the right to exercise such new Warrant, and procure upon such exercise and payment of the same aggregate Exercise Price, in lieu of the Warrant Shares theretofore issuable upon exercise of this Warrant, the kind and amount of shares, other securities, money and property receivable upon such reclassification or change, by a holder of an equivalent number of Warrant Shares. Such new Warrant shall provide for adjustments that shall be as nearly equivalent as may be practicable to the adjustments provided for in this Section 3. The provisions of this Section 3(a) shall similarly apply to successive reclassifications or changes.
- (b) Share Splits and Combinations. In the event that the Company shall at any time subdivide the Warrant Shares, the number of Warrant Shares issuable upon exercise of this Warrant immediately prior to such subdivision shall be proportionately increased, and in the event that the Company shall at any time combine the Warrant Shares, the number of Warrant Shares issuable upon exercise of this Warrant immediately prior to such combination shall be proportionately decreased, effective at the close of business on the date of such subdivision or combination, as the case may be.

- (c) Adjustments for Certain Dividends and Distributions. In the event the Company at any time or from time to time makes, or fixes a record date for the determination of holders of the Warrant Shares entitled to receive, a dividend or other distribution payable in securities of the Company, then in each such event provision shall be made so that the

Holder shall receive upon exercise of this Warrant, in addition to the number receivable thereupon of Warrant Shares, the amount of securities of the Company that the Holder would have received had this Warrant been exercised immediately prior to such event (or the record date for such event) and had the Holder thereafter, during the period from the date of such event to and including the date of exercise, retained such securities receivable by it as aforesaid during such period, subject to all other adjustments called for during such period under this Section.

- (d) Reorganization. If at any time there is a capital reorganization the Company's shares (other than a recapitalization, subdivision, combination or reclassification provided for elsewhere in this section), then, as a part of such reorganization, provision shall be made so that the Holder shall thereafter be entitled to receive upon exercise of this Warrant, the number of shares or other securities or property of the Company to which a holder of shares deliverable upon conversion would have been entitled on such capital reorganization. In any such case, appropriate adjustment shall be made in the application of the provisions of this Section 3(d) and the Company's Articles with respect to the rights of the Holder after the reorganization to the end that the provisions of this Section 3(d) and the Company's Articles (including adjustment of the number of shares issuable upon exercise of this Warrant) shall be applicable after that event and be as nearly equivalent to the provisions hereof as may be practicable.
- (e) Other Transactions. In the event that the Company shall issue shares to its shareholders as a result of a split-off, spin-off or the like, then the Company shall only complete such issuance or other action if, as part thereof, allowance is made to protect the economic interest of the Holder either by increasing the number of Warrant Shares or by procuring that the Holder shall be entitled, on economically proportionate terms, to acquire additional shares of the spun-off or split-off entities.
- (f) General Protection. The Company will not, by amendment of its Articles or through any reorganization, recapitalization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed hereunder, or impair the economic interest of the Holder, but will at all times in good faith assist in the carrying out of all the provisions hereof and in taking of all such actions and making all such adjustments as may be necessary or appropriate in order to protect the rights and the economic interests of the Holder against impairment.

4. Notice of Adjustments

- (a) Upon the occurrence of each adjustment or readjustment pursuant to Section 3, the Company at its expense shall promptly compute such adjustment or readjustment in accordance with the terms hereof and provide notice to the Holder signed by the Company's Chief Financial Officer or Chief Executive Officer setting forth, in reasonable detail, the event requiring the adjustment or readjustment, the amount of the adjustment or readjustment, the method by which such adjustment or readjustment was calculated, and the number and class of Warrant Shares which may be purchased after giving effect to such adjustment or readjustment.
- (b) If at any time the Company shall offer for subscription pro rata to the holders of Ordinary Shares (or other stock or securities at the time receivable upon the exercise of this Warrant) any additional shares of any class, other rights or any equity security of

any kind, or there shall be any public offering, capital reorganization or reclassification of the capital shares of the Company, or consolidation or merger of the Company with, or sale of all or substantially all of its assets to another company or there shall be a voluntary or involuntary dissolution, liquidation or winding up of the Company, or other transaction described in Section 3, then, in any one or more of said cases, the Company shall give the Holder prior written notice, by registered or certified mail, postage prepaid, of the date on which (i) a record shall be taken for such subscription rights or (ii) such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding up or other transaction shall take place, as the case may be. Such notice shall also specify the date as of which the holders of record of Ordinary Shares (or other stock or securities at the time receivable upon the exercise of this Warrant) shall participate in such subscription rights, or shall be entitled to exchange their securities for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding up, etc. as the case may be. Such written notice shall be given at least fourteen (14) days prior to the action in question and not less than fourteen (14) days prior to the record date in respect thereto.

5. Representations, Warranties, and Covenants of the Company

The Company represents, warrants, and covenants to the Holders as follows:

- (a) The Company represents that all corporate actions on the part of the Company, its officers, directors and shareholders necessary for the sale and issuance of this Warrant and the Warrant Shares and the performance of the Company's obligations hereunder were taken prior to and are effective as of the effective date of this Warrant.
- (b) The execution and delivery of this Warrant are not, and the issuance of the Warrant Shares upon exercise of this Warrant in accordance with the terms hereof will not be, inconsistent with the Company's Articles, do not contravene any material law, governmental rule or regulation, judgment or order applicable to the Company, and, except for consents that have already been obtained by the Company, do not and will not conflict with or contravene any provision of, or constitute a default under, any indenture, mortgage, contract or other instrument of which the Company is a party or by which it is bound.
- (c) The Company represents and covenants that at all times during the Exercise Period there shall be reserved for issuance and delivery upon exercise of this Warrant such number of Warrant Shares as is necessary for exercise in full of this Warrant and, from time to time, it will take all steps necessary to amend its Articles to provide sufficient reserves of Warrant Shares. All Warrant Shares issued pursuant to the exercise of this Warrant will, upon their issuance, be validly issued and outstanding, fully paid and nonassessable, free and clear of all liens and other encumbrances or restrictions on sale and free and clear of all preemptive rights, except restrictions arising (a) under applicable securities laws, (b) not by or through the Company, or (c) by agreement between the Company and the Holder or its successors.

6. Rights of Shareholders

- (a) No holder of this Warrant shall be entitled, as a Warrant holder, to vote or receive dividends or be deemed the holder of the Warrant Shares or any other securities of the Company which may at any time be issuable on the exercise hereof for any purpose, nor

shall anything contained herein be construed to confer upon the holder of this Warrant, as such, any of the rights of a shareholder of the Company or any right to vote for the election of directors or upon any matter submitted to shareholders at any meeting thereof, or to give or withhold consent to any corporate action (whether upon any recapitalization, issuance of shares, reclassification of shares, change of par value, consolidation, merger, conveyance, or otherwise) or to receive notice of meetings, or to receive dividends or subscription rights or otherwise until the Warrant shall have been exercised and the Warrant Shares purchasable upon the exercise hereof shall have become deliverable, as provided herein.

- (b) Notwithstanding the provisions of Section 6(a) hereof, the Warrant Shares shall be deemed to have been issued in full to the Holder for the purpose of calculating the Holder's pro-rata share of the Company's issued and outstanding share capital under any rights offering by the Company, including pursuant to Article 29 (pre-emptive rights) of the Company's Articles.

7. Holder's Representations

The Holder's representation in Section 6.3 to the Agreement is hereby incorporated herein by reference and forms an integral part hereof binding as among the parties hereto.

8. Notices

All notices and other communications required or permitted hereunder shall be in writing and shall be effective (a) if mailed, seven (7) business days after mailing by registered or certified mail, (b) if sent by messenger, upon delivery, and (c) if sent via fax or e-mail, upon transmission and electronic confirmation of receipt or (if transmitted and received on a non-business day) on the first business day following transmission and electronic confirmation of receipt. Notices to the Company shall be sent to the principal office of the Company (or at such other place as the Company shall notify the Holder hereof in writing). Notices to the Holder shall be sent to the address of the Holder in the Books of the Company (or at such other place as the Holder shall notify the Company in writing).

9. Loss, Theft, Destruction or Mutilation of Warrant

Upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of any Warrant or share certificate, and in case of loss, theft or destruction, of indemnity, or security reasonably satisfactory to it, and upon reimbursement to the Company of all reasonable expenses incidental thereto, and upon surrender and cancellation of such Warrant or share certificate, if mutilated, the Company will make and deliver a new Warrant or share certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or share certificate.

10. Miscellaneous

10.1 Amendments and Waivers

Any term of this Warrant may be amended and the observance of any term may be waived (either generally or in a particular instance and either retroactively or prospectively) only with the written consent of the Company and the Holder. Any amendment or waiver effected in accordance with this Section 10.1 shall be binding on the Holder, each future Holder and the Company.

10.2 Governing Law; Jurisdiction; Venue

This Warrant shall be governed by and construed under the laws of Israel, without regard to principles of conflict of laws. All controversies, claims or differences that may arise between the Parties hereto out of or in connection with this Agreement, shall be exclusively settled by the competent courts of Tel Aviv, Israel.

10.3 Successors and Assigns; Transfer

The terms and conditions of this Warrant shall inure to the benefit of and be binding on the respective successors and assigns of the parties. This Warrant may be transferred or assigned without the consent of the Company or other third parties pursuant to an Assignment in the form of Exhibit B hereto, provided that such assignment shall be subject to and made in accordance with the provisions of the Company's Articles applying to transfer of shares in the Company, including without limitations, the requirement of Board's approval provided under Article 44.1 of the Company's Articles,

IN WITNESS WHEREOF, the Company has executed this Warrant as of the date first written above.

We hereby agree to the foregoing terms of the Warrant:

Polypid Ltd.

By: Noam Emanuel
Title: CEO

/s/ Noam Emanuel

By: Noam Emanuel

/s/ Anat Segal

Xenia Venture Capital Ltd.

Anat Segal

Exhibit A

NOTICE OF EXERCISE

To: Polypid Ltd.

The undersigned hereby irrevocably elects to purchase _____ Series A Preferred Shares of Polypid Ltd. issuable upon the exercise of the attached Warrant and requests that certificates for such shares be issued in the name of the undersigned and delivered to the address of the undersigned, at the address stated below and, if such number of shares shall not be all the shares that may be purchased pursuant to the attached Warrant, that a new Warrant evidencing the right to purchase the balance of such shares be registered in the name of, and delivered to, the undersigned at the address stated below.

Payment enclosed in the amount of NIS _____

Dated: _____

Name of Holder of Warrant: _____ (please print)

Address: _____

Signature: _____

Exhibit B

ASSIGNMENT

For value received the undersigned sells, assigns and transfers to the transferee named below the attached Warrant, together with all right, title and interest, to hold by the transferee, subject to the terms and conditions under which we held the same immediately before the execution hereof, and does irrevocably constitute and appoint the corporate secretary or transfer agent of Polypid Ltd. (the "**Company**") as the undersigned's attorney-in-fact, to transfer such Warrant on the books of the Company, with full power of substitution in the premises, and I the transferee, do hereby agree to accept and take the attached Warrant subject to the conditions aforesaid.

Dated: _____

Name of Holder of Warrant: _____ (please print)

Address: _____

Signature: _____

Name of transferee: _____

Address of transferee: _____ (please print)

THIS WARRANT AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS WARRANT HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT") OR QUALIFIED UNDER ANY STATE OR FOREIGN SECURITIES LAW, AND MAY NOT BE SOLD, TRANSFERRED, ASSIGNED OR HYPOTHECATED UNLESS THERE IS AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT COVERING THIS WARRANT AND/OR SUCH SECURITIES, OR THE HOLDER RECEIVES AN OPINION OF COUNSEL FOR THE HOLDER OF THE WARRANT AND/OR SUCH SECURITIES SATISFACTORY TO THE COMPANY STATING THAT SUCH SALE, TRANSFER, ASSIGNMENT OR HYPOTHECATION IS EXEMPT FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF THE SECURITIES ACT AND THE QUALIFICATION REQUIREMENTS UNDER APPLICABLE STATE OR FOREIGN LAW.

POLYPID LTD.

WARRANT

To purchase
Series D-2 Preferred Shares (as defined below) (subject to adjustment hereunder) of
PolyPid Ltd. (the "**Company**")
at a per share price and subject to the terms detailed below
VOID AFTER 20:00 local Israel time
on the last day of the Warrant Period (as defined below)

THIS IS TO CERTIFY THAT (the "**Holder**"), is entitled to purchase from the Company, during the Warrant Period, an aggregate of up to Series D-2 Preferred Shares of the Company, nominal value NIS 0.10 per share (the "**Series D Preferred Shares**"), as may be adjusted hereunder, at a price per share of US\$ 1.27 (as may be adjusted hereunder) (the "**Exercise Price**") (it being acknowledged that the amount of Series D-2 Preferred Shares that the Holder is entitled to purchase from the Company pursuant to this Warrant and the Exercise Price thereof, are subject to further adjustments in accordance herewith and in accordance with the provisions of the Articles of Association of the Company (as in effect from time to time) ("**Amended AOA**") and the provisions of the SPA).

Unless otherwise is specifically set forth herein, all capitalized terms used but not defined herein shall have the meanings ascribed to them in that certain Securities Purchase Agreement dated as of February , 2016 (the "**SPA**"), by and among the Company and the Investors (as such term is defined in the SPA).

1. EXERCISE OF WARRANT

1.1. Number of Warrant Shares.

1.1.1. In General. The number of Series D-2 Preferred Shares into which this Warrant may be exercised at any time (the "**Warrant Shares**") shall equal the aggregate number of Ordinary Shares of the Company, nominal value NIS 0.10 per share (the

"**Ordinary Shares**") into which the Base Number (as defined below) may be converted, in accordance with the Amended AOA (the "**Conversion Ratio**"). For the avoidance of doubt, the Base Number, and (whether or not the Base Number is adjusted) the number of Warrant Shares, shall be subject to adjustment in accordance with the provisions hereof (including but not limited to Sections 1.2.5 and 4), the Amended AOA (principally, Article 9), and the provisions of the SPA.

1.1.2. As of Closing. The Company hereby represents and warrants that, as of the Closing: (a) the "**Base Number**" (which shall initially be the number of Warrant Shares which the Holder is to be granted the right to purchase, at the Closing, as reflected on the Capitalization Table attached to the SPA) is Series D-2 Preferred Shares, (b) the aggregate Base Number of Series D-2 Preferred Shares are convertible into an equal number of Ordinary Shares, and (c) the number of Warrant Shares is thus equal to Series D-2 Preferred Shares.

1.1.3. Adjustment Upon Trigger Event. Upon the occurrence of a Trigger Event, the Base Number shall automatically, and for no additional consideration, be increased (and, for the avoidance of doubt, in no event decreased) so that it equals the aggregate number of Warrant Shares as reflected in the "Trigger Event" column in the Capitalization Table attached to the SPA, and the Exercise Price under the Warrants shall be reduced to equal the Adjusted Investors' Conversion Price (as defined in the Amended AOA and as may be adjusted from time to time thereunder) of the Series D-2 Preferred Shares , so that the aggregate exercise price hereunder (i.e., US\$) remains the same.

1.2. Exercise Price. Without derogating from, and in addition to, any other provision hereof (including but not limited to Section 4), the Exercise Price shall be, and shall be adjusted, as follows:

1.2.1. In General. Except in case of exercise of the Warrant at any time upon or following a Trigger Event, in which case, the provisions of Sections 1.1.3, 1.2.3, and 1.2.4 hereof will apply, the Exercise Price hereunder shall at all times equal 15% more than the Adjusted Investors' Conversion Price, as determined in accordance with the Amended AOA.

1.2.2. As of Closing. The Company hereby represents and warrants that, as of the Closing, (A) the Adjusted Investors' Conversion Price equals the Price Per Share under the SPA, i.e. US\$1.1036, and (B) as such, the Exercise Price equals US\$1.27 (i.e. the Price Per Share times 1.15).

1.2.3. Adjustments. Upon each adjustment to the Adjusted Investors' Conversion Price under the Amended AOA, the Exercise Price shall concurrently be reduced (and, for the avoidance of doubt, not increased) to equal (i) if prior to, and not in conjunction with, a Trigger Event, 15% more than the new Adjusted Investors' Conversion Price thereunder, and (ii) if upon or at any time following a Trigger Event, such Adjusted Investors' Conversion Price.

1.2.4. Increase of Warrant Shares. Upon each reduction to the Exercise Price, the number of Warrant Shares shall be correspondingly increased, with the intent that, as a result of such adjustments, the aggregate exercise price of this Warrant shall remain the same.

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1.2.5. Exercise Upon Certain Transactions. If this Warrant is exercised in the context of an IPO (including, for the purposes of this Warrant, any other public offering) or a Deemed Liquidation (as such capitalized terms are defined in the Amended AOA), then, even if the exercise of this Warrant in such case shall be required to occur no later than immediately prior to the closing of such transaction, the Adjusted Investors' Conversion Price shall be deemed to be the Adjusted Investors' Conversion Price as it would have been adjusted in accordance with the Amended AOA upon an issuance by the Company of shares (in this clause, the "**Exit Shares**"), in each case as if such Exit Shares were issued by the Company prior to such transaction. In such event, the Exercise Price and the number of Warrant Shares shall be adjusted accordingly, as of immediately prior to such transaction.

1.3. Warrant Period. This Warrant may be exercised, subject to the terms and conditions hereof, in whole or in part, at one time or from time to time during the period commencing upon the Closing until the 4th anniversary of the Closing; provided, however, that if a Trigger Event occurs, then such period shall terminate upon the 5th anniversary of the Closing; provided further, however, that in the event of a Deemed Liquidation, this Warrant will expire immediately prior to the closing of the Deemed Liquidation, subject to such closing and the application of the terms hereof to such transaction, including but not limited to Section 1.2.5; provided further, however, that if such Deemed Liquidation is a transaction with a private company, then this Warrant shall expire upon the closing of such Deemed Liquidation, if so required by the acquiring entity, but only if the Investors receive their entire Series D Preference (as such capitalized terms are defined in the Amended AOA) in such transaction, in liquid proceeds (cash or publicly-tradable shares). The above period shall be referred to herein as the "**Warrant Period**".

1.4. Exercise for Cash. The Holder may elect to exercise this Warrant in whole or in part and from time to time during the Warrant Period, by presentation and surrender thereof to the Company at its principal office or at such other office or agency as it may designate from time to time, accompanied by:

1.4.1. A duly executed notice of exercise, in the form attached hereto as Schedule 1.4.1 (the "**Exercise Notice**"); and

1.4.2. Payment to the Company, for the account of the Company, of the aggregate Exercise Price for the Warrant Shares being acquired upon such exercise, payable in immediately available funds by wire transfer to the Company's bank account.

1.5. Exercise on Net Issuance Basis. In lieu of payment to the Company as set forth in Section 1.4 above, the Holder may elect to convert this Warrant into the number of Warrant Shares calculated pursuant to the formula below, by presentation and surrender thereof to the Company at its principal office or at such other office or agency it may designate from time to time, accompanied by a duly executed notice of cashless exercise, in the form attached hereto as Schedule 1.5 (the "**Net Issuance Notice**");

$$X = \frac{Y*(A - B)}{A}$$

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Where:

X = the number of Warrant Shares to be issued to the Holder;

Y = the number of Warrant Shares otherwise purchasable upon exercise of this Warrant (or such lesser number of shares as Holder may designate in case of a partial exercise of this Warrant);

A = the fair market value of one Warrant Share (or of any securities into which Warrant Shares have been converted in accordance with the Company's organizational documents and applicable law) at the time the net issuance election under this Section 1.5 is made; and

B = the Exercise Price per Warrant Share.

For purposes hereof, the "**fair market value**" of one (1) Warrant Share as of a particular date shall be: (a) if applicable, the average of the closing bid and asked prices of Warrant Shares (or of any securities into which the Warrant Shares have been converted in accordance with the Company's organizational documents and applicable law) quoted in the over-the-counter market summary or the closing price quoted on any exchange on which the Warrant Share (or any securities into which the Warrant Shares have been converted in accordance with the Company's organizational documents and applicable law) is listed, whichever is applicable, for the five (5) trading days immediately prior to but not including the date of determination of fair market value; (b) if the exercise pursuant to this Section 1.5 is as of immediately prior to the consummation of an M&A Event (or other similar corporate transaction), then (without, for the avoidance of doubt, derogating from the adjustment provisions hereof) the fair market value of one (1) Warrant Share (or of any securities into which the Warrant Shares have been converted in accordance with the Company's governing documents, this Warrant, and applicable law) in such transaction (*i.e.* the price per share paid by the surviving or acquiring entity in such transaction, as set forth in Section 1.2.5 above). In the event that the price in the transaction is not in cash, then the applicable fair market value of the non-cash consideration shall be determined by the Company's auditors; (c) if the exercise pursuant to this Section 1.5 is immediately prior to the closing of an IPO of a corporate successor of the Company's equity interests, then the public offering price (before deduction of discounts, commissions or expenses) in such offering; or (d) if the Company's

shares are not publicly traded or registered on any stock exchange at the time of exercise and clauses (b) and (c) are not applicable, then as determined by the Company's auditors.

For the avoidance of doubt, the Holder may effect partial exercise(s) of this Warrant pursuant to this Section 1.5. Any exercise under this Section 1.5 shall, for the avoidance of doubt, be for no further consideration by the Holder.

- 1.6. Issuance of Warrant Shares. Upon presentation and surrender of this Warrant, accompanied by (a) the duly executed Exercise Notice and the payment of the applicable aggregate Exercise Price pursuant to Section 1.4 above; or (b) the duly executed Net Issuance Notice pursuant to Section 1.5 above, as the case may be, the Company shall promptly (i) issue to the Holder the Warrant Shares to which the Holder is entitled; and (ii) deliver to the Holder the share certificate evidencing such Warrant Shares, and (iii) in any event, the Holder shall be deemed to be the holder of record of the Warrant Shares issuable upon such exercise,

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notwithstanding that the share transfer books of the Company shall then be closed or that certificates representing such shares shall not then be actually delivered to the Holder.

- 1.7. Fractional Shares. No fractions of Warrant Shares shall be issued in connection with the exercise of this Warrant, and the number of shares issued shall be rounded to the nearest whole number.
- 1.8. Automatic Exercise. If this Warrant or any portion hereof is still outstanding on the final day of the Warrant Period, then if, at such time, the fair market value of a Warrant Share is more than the Exercise Price for such share, this Warrant shall be deemed automatically exercised by the Holder in full immediately prior to the conclusion of the Warrant Period, on a net issuance basis pursuant to Section 1.5 hereof.
- 1.9. Loss or Destruction of Warrant. Upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant, and (in the case of loss, theft or destruction) of reasonable expense reimbursement and indemnification, and upon surrender and cancellation of this Warrant, if mutilated, the Company will execute and deliver a new Warrant of like tenor and date.
- 1.10. Partial Exercise; Effective Date of Exercise. In case of any partial exercise of this Warrant, the Company shall cancel this Warrant upon surrender hereof and shall execute and deliver a new Warrant of like tenor and date for the balance of the Warrant Shares purchasable hereunder. This Warrant shall be deemed to have been exercised immediately prior to the close of business on the date of its surrender for exercise as provided above. The person entitled to receive the Warrant Shares shall be treated for all purposes as the holder of record of such shares as of the close of business on the date the Holder is deemed to have exercised this Warrant.
- 1.11. Conditional Exercise. If this Warrant is exercised in the context of an IPO or Deemed Liquidation, then such exercise shall be deemed conditional on the closing of such transaction, and for the avoidance of doubt, if such transaction does not close, then this Warrant shall not be considered exercised at such time (unless the Holder explicitly notifies the Company otherwise).
- 1.12. Right to Exercise into Ordinary Shares. The Holder shall have the right, at its sole discretion, to exercise this Warrant into the number of Ordinary Shares into which the Warrant Shares otherwise purchasable hereunder could be converted at such time in accordance with the provisions of the Amended AOA (as in effect from time to time). If at any time the entire class of Series D-2 Preferred Shares is converted into Ordinary Shares or another class of shares pursuant to the provisions of the Amended AOA, then this Warrant shall automatically be deemed to be exercisable for such number of Ordinary Shares or shares of such other class, into which the Warrant Shares would have been converted had the Warrant Shares been issued and outstanding on the date of such conversion, and the Exercise Price shall equal the Exercise Price in effect as of immediately prior to such conversion divided by the number of Ordinary Shares or shares of such other class into which one Warrant Share would have been converted, all subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant.

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2. TAXES

- 2.1. The Holder acknowledges that the grant of the Warrant, the issue of the Warrant Shares and the execution and/or performance of this Warrant may have tax consequences to the Holder.
- 2.2. The Company shall pay all of the applicable taxes and other charges payable by the Company in connection with the issuance of the Warrant Shares and the preparation and delivery of share certificates pursuant to Section 1 in the name of the Holder, if any, but shall not pay any taxes payable by the Holder by virtue of the holding, issuance, exercise or sale of this Warrant or the Warrant Shares by the Holder, which shall be the obligation of the Holder.
- 2.3. The Company shall withhold taxes, if and as required according to the requirements under the applicable laws, rules, and regulations for withholding taxes at source, provided that the Company shall inform the Holder of such withholding requirement at least 5 (five) business days prior to such anticipated withholding, so as to allow the Holder to obtain and provide the Company with an appropriate certificate of exemption, if available. No withholding shall be made if an exemption, satisfactory to the Company, is obtained and delivered to the Company, for as long as it is valid in accordance with applicable law. Holder shall indemnify the Company, its shareholders, directors and/or officers, as applicable, and hold them harmless from and against any and all liability for any such tax or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax from any payment made to the Holder, provided that they acted in due care.

3. RESERVATION OF SHARES; PRESERVATION OF RIGHTS OF HOLDER

- 3.1. Reservation of Shares. The Company hereby agrees that, at all times prior to the expiration or exercise of this Warrant, it will maintain and reserve, free from pre-emptive or similar rights, (a) such number of authorized but unissued Series D-2 Preferred Shares, and (b) such number of Ordinary Shares into which such Series D-2 Preferred Shares shall, at any time, be convertible, so that this Warrant may be exercised into Series D-2 Preferred

Shares and/or (at the Holder's discretion, or in case of automatic conversion pursuant to the Articles) into Ordinary Shares, without additional authorization of shares.

- 3.2. **Preservation of Rights.** Subject to the provisions of Section 8.1 below, the Company will not, by amendment of its organizational documents or through reorganization, recapitalization, consolidation, merger, dissolution, transfer of assets, issue or sale of securities or any other voluntary act, avoid or seek to avoid the observance or performance of any of the covenants, stipulations, conditions or terms to be observed or performed hereunder, but will at all times in good faith assist in the carrying out of all the provisions hereof and in the taking of all such actions and making all such adjustments as may be necessary or appropriate in order to fulfill the provisions hereof.

4. **ADJUSTMENT**

- 4.1. In addition to, and without derogating from, the other provisions hereof, the Amended AOA and the SPA, the number of Warrant Shares purchasable upon the exercise of this Warrant and the Exercise Price shall be subject to adjustment from time to time or upon exercise, as follows:

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- 4.1.1. **Bonus Shares.** In the event that during the Warrant Period the Company shall declare or distribute to all of its shareholders, and/or to the holders of Warrant Shares, bonus shares or other securities or non-cash property (except for any securities distributed as dividends) (in this Section, "bonus shares"), then this Warrant shall represent the right to acquire, in addition to the number of Warrant Shares into which it was exercisable as of immediately prior to such event, the amount of such bonus shares that are distributed to all shareholders of the Company, and/or to the holders of Warrant Shares, without payment of any additional consideration therefor, to which the Holder would have been entitled had this Warrant been exercised prior to the issuance of the bonus shares.
- 4.1.2. **Consolidation and Division.** In the event that during the Warrant Period the Company consolidates its entire share capital and/or the class of shares representing the Warrant Shares into shares of greater par value, or subdivides them into shares of lesser par value, then the number of Warrant Shares to be allotted on exercise of this Warrant after such consolidation or subdivision shall be reduced or increased accordingly, as the case may be, and in each case the Exercise Price shall be adjusted appropriately such that the aggregate consideration hereunder to the Company shall not change.
- 4.1.3. **Capital Reorganization.** In the event that during the Warrant Period a reorganization of the share capital of the Company is effected (other than as provided for elsewhere in this Section 4), including any recapitalization, reclassification or similar event resulting in a change of the Series D-2 Preferred Shares and/or number of the Series D-2 Preferred Shares and/or the Ordinary Shares into a different number of shares of the same class or any other class or classes of shares, then, as part of such transaction, provision shall be made so that the Holder shall be entitled to purchase, upon exercise of this Warrant, such kind and number of shares or other securities of the Company to which the Holder would have been entitled had this Warrant been exercised immediately prior to such transaction. In such case the Exercise Price shall be adjusted appropriately such that the aggregate consideration hereunder to the Company shall not change.
- 4.2. **Certificate of Adjustment.** Whenever an adjustment is effected under this Warrant, the Company shall promptly compute such adjustment and deliver to the Holder a certificate setting forth the number of Warrant Shares (or any other securities) for which this Warrant is exercisable and the Exercise Price as a result of such adjustment, a brief statement of the facts requiring such adjustment and the computation thereof and when such adjustment has or will become effective.
- 4.3. **Parallel Adjustments.** For the avoidance of any doubt, it is the intention of the parties that any adjustments made to the exercise price and the number of warrant shares purchasable pursuant to the warrants granted by the Company to the Investors under the SPA, shall also be made to the Exercise Price and the number of Warrant Shares purchasable hereunder even if the Holder did not actually invest funds under the SPA.

5. **NOTICE OF CERTAIN EVENTS**

- 5.1. If at any time during the Warrant Period, any of the Notice Events set forth in Section 5.2 below shall occur, then, in any one or more of such events, the Company shall deliver to the Holder written notice thereof, including the date on which (a) a record shall be taken in

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connection with such event (if applicable); and (b) such event is to be consummated. Such written notice shall be delivered to the Holder at least fourteen (14) days prior to the consummation of the applicable event and not less than fourteen (14) days prior to the record date in respect thereof.

- 5.2. For the purposes hereof, a "Notice Event" shall mean any of the following: (i) an IPO by the Company or a corporate successor of its equity interests; or (ii) a Liquidation (as defined in the Amended AOA) or Deemed Liquidation, or (iii) the date on which the Company shall distribute a cash or other dividend.
- 5.3. Notwithstanding the aforementioned, in the event that any notice pursuant to Section 5.1 shall lawfully be delivered by the Company to its shareholders within a shorter period, then such shorter period shall apply and the notice above shall be required to be delivered contemporaneously to the Holder with the delivery of such notice by the Company to its shareholders.

6. **RIGHTS OF THE HOLDER**

- 6.1. **No Current Rights as Shareholder.** This Warrant shall not entitle the Holder, by virtue hereof, to any voting rights or other rights as a shareholder of the Company, except for the rights expressly set forth herein.
- 6.2. **Certain Restrictions.** The Holder acknowledges that the Warrant Shares shall be subject to certain rights, privileges, restrictions and limitations as set forth in this Warrant, and the Amended AOA (as in effect from time to time).

- 6.3. **Registration Rights.** All Warrant Shares which are, at any time, issuable upon exercise of this Warrant, and all and Ordinary Shares which are, at any time, issuable upon exercise hereof and/or conversion of the Warrant Shares, shall be “Registrable Securities” pursuant to the Investors’ Rights Agreement, dated on even date herewith, by and among the Company, the Holder, the other Investors and the other parties named therein (the “**Investors’ Rights Agreement**”), and shall be entitled, subject to the terms and conditions of the Investors’ Rights Agreement, as an Investor thereunder, to all registration rights granted to holders of Registrable Securities thereunder.
- 6.4. **Conversion of Series D-2 Preferred Shares.** In the event that the entire class of Series D-2 Preferred Shares is converted into Ordinary Shares in accordance with the terms of the Amended AOA, this Warrant shall become exercisable for Ordinary Shares.
- 6.5. **Lockup.** The Holder understands that in the event of any registration of the Company’s shares on any stock exchange, the underwriters may request, or it may be required under applicable law and/or by any governmental authority, that the Warrant Shares shall be subject to a lock up period of up to 180 days. If, in connection with an IPO, the underwriter will request the shareholders of the Company and the Holder of this Warrant to be subject to a lock-up period of up to 180 days, (a) the Holder shall not be allowed to sell or transfer any of the Warrant Shares, provided that in any case, any “lock-up” restrictions applicable to this Warrant and/or the Warrant Shares which may be acquired hereunder, shall terminate no later than upon the end of the “lock-up” period applicable to the Investors Shares (or the Ordinary Shares into which they may be converted) in such registration; and (b) the Holder shall sign a customary lock up agreement as required by the underwriter or the Company with respect to the lock up restriction specified in this Section 6.5.

7. **REPRESENTATIONS OF THE COMPANY**

The Company represents and warrants to the Holder as follows: (i) this Warrant has been duly authorized and executed by the Company and is a valid and binding obligation of the Company enforceable in accordance with its terms; (ii) the Warrant Shares (and the Ordinary Shares into which such Warrant Shares are convertible) are duly authorized and reserved for issuance by the Company and, when issued in accordance with the terms hereof, will be validly issued, fully paid (subject to the full payment of the exercise price, or valid net issuance exercise, by the Holder) and non-assessable and not subject to any third party rights or liens, except as set forth in the Amended AOA and any agreement entered into between the Company and the holders of Preferred D-1 Shares; and (iii) the execution and delivery of this Warrant are not, and the issuance of the Warrant Shares upon exercise of this Warrant in accordance with the terms hereof and the issuance of the Ordinary Shares into which such Warrant Shares are convertible in accordance with the terms hereof and the Amended AOA (as in effect from time to time), will not be, inconsistent with the Company’s governing documents, do not and will not conflict with or contravene with all applicable laws and will be issued in compliance with all applicable laws, and do not and will not conflict with or contravene any provision of, or constitute a default under, any indenture, mortgage, contract or other instrument of which the Company is a party or by which it is bound or require the consent or approval of, the giving of notice to, the registration with or the taking of any action in respect of or by, any government authority or agency or other person, other than those consents or approvals that shall have been previously obtained and reports of issuance to the Israeli Registrar of Companies and to OCS (if applicable).

8. **MISCELLANEOUS**

- 8.1. **Entire Agreement; Amendment.** This Warrant, and the provisions of the SPA and the Amended AOA relating hereto, set forth the entire understanding of the parties with respect to the subject matter hereof and supersedes all existing agreements among them concerning such subject matter. All section headings herein are inserted for convenience only and shall not modify or affect the construction or interpretation of any provision of this Warrant. No modification or amendment of this Warrant will be valid unless executed in writing by the Company and the Holder; *provided however* that in the event that the Majority Investors (as defined in the Amended AOA) agree with the Company to make an amendment which will apply to the Warrants granted pursuant to the SPA, then this Warrant shall be amended in accordance with such amendment, without the need for further action or approval on the part of the Holder.
- 8.2. **Waiver.** No failure or delay on the part of any of the parties in exercising any right, power or privilege hereunder and/or under any applicable laws or the exercise of such right or power in a manner inconsistent with the provisions of this Warrant or applicable law shall operate as a waiver thereof. Any waiver must be evidenced in writing signed by the party against whom the waiver is sought to be enforced.
- 8.3. **Successors and Assigns.** Except as otherwise expressly limited herein, this Warrant shall inure to the benefit of, be binding upon, and be enforceable by the Holder and its respective successors, and administrators.
- 8.4. **Assignment.** This Warrant and all rights hereunder are transferable by the Holder, subject to compliance with applicable securities laws and the Amended AOA, provided that the assignee will sign and provide to the Company an undertaking to be bound by all of the terms of this Warrant. Without derogating from the foregoing it is clarified that the Holder may transfer this Warrant to its Permitted Transferees under the Amended AOA. Within a

reasonable time after the Company’s receipt of an executed Assignment Form in the form attached hereto as Schedule 8.4, the transfer shall be recorded on the books of the Company upon the surrender of this Warrant, properly endorsed, to the Company at its principal offices. In the event of a transfer hereunder which is only a partial transfer hereof, the Company shall issue to the holders one or more appropriate new warrants in accordance with the provisions of Section 1.10.

- 8.5. **Governing Law.** This Warrant shall be exclusively governed and construed in accordance with the laws of the State of Israel, without regard to conflicts of laws provisions thereof.
- 8.6. **Jurisdiction.** The competent courts in Tel Aviv shall have sole and exclusive jurisdiction over all matters relating to this Agreement.
- 8.7. **Notices.** All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified; (b) when sent by facsimile or email with confirmation of transmission if sent during normal business hours of the recipient, if not, then

on the next business day; (c) ten (10) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) two business days after deposit with an internationally-recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent out as set forth in the SPA or as otherwise notified by the parties.

- 8.8. **Severability.** In the event one or more of the provisions of this Warrant should, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions of this Warrant, which shall remain enforceable, to the fullest extent permitted by law. Furthermore, to the fullest extent possible, the provisions of this Warrant (including, without limitation, the portion of this Warrant containing any provision held to be invalid, illegal or unenforceable that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested by the provision held invalid, illegal or unenforceable.
- 8.9. **Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 8.10. **Titles and Subtitles.** The titles of the sections and subsections of this Agreement are for convenience of reference only and are not to be considered in construing this Agreement.
- 8.11. **Preamble.** The preamble hereto is an integral part hereof.

[THE REMAINDER OF THIS PAGE WAS INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, PolyPid Ltd. has caused this Warrant to be executed by its officer thereunto duly authorized.

Dated: _____

POLYPID LTD.

By: _____
Name: _____
Title: _____

AGREED AND ACCEPTED:

By: _____
Name: _____
Title: _____

Schedule 1.4.1

Exercise Notice

Date:

To: PolyPid Ltd. (the "Company")

The undersigned, pursuant to the provisions set forth in the Warrant to which this Exercise Notice is attached (the "Warrant"), hereby elects to purchase Series D-2 Preferred Shares of the Company pursuant to Section 1.4 of the Warrant, and herewith makes payment of US\$ _____, representing the full Exercise Price for such shares in accordance with the Warrant. The undersigned makes again here, with respect to the securities it is acquiring upon the exercise of the Warrant as contemplated hereby, the same representations, warranties and acknowledgements for the benefit of the Company, as it made in the Warrant.

Please issue a certificate representing the Warrant Shares in the name of the undersigned or as otherwise indicated below and deliver it to the address stated below, and if the number of Warrant Shares shall not be all the Warrant Shares purchasable upon exercise of the Warrant, then please also issue a new Warrant for the balance of the Warrant Shares purchasable upon exercise of this Warrant in the name of the undersigned or as otherwise indicated below and deliver it to the address stated below:

Name:

Address:

ID / Social Security No./ company number:

Signature: _____

Schedule 1.5

Net Issuance Notice

Date:

To: PolyPid Ltd. (the “Company”)

The undersigned, pursuant to the provisions set forth in the Warrant to which this Exercise Notice is attached (the “Warrant”), hereby elects to exercise the Warrant, for no additional consideration, for the purchase of Series D-2 Preferred Shares of the Company, pursuant to the provisions of Section 1.5 of the Warrant (net issuance).

The undersigned makes again here, with respect to the securities it is receiving upon the exercise of the Warrant as contemplated hereby, the same representations, warranties and acknowledgements for the benefit of the Company, as it made in the Warrant.

Please issue a certificate representing the Warrant Shares in the name of the undersigned or as otherwise indicated below and deliver it to the address stated below, and if the number of Warrant Shares shall not be all the Warrant Shares purchasable upon exercise of the Warrant in its entirety via net issuance, then please also issue a new Warrant for the balance of the Warrant Shares purchasable upon exercise of this Warrant in the name of the undersigned or as otherwise indicated below and deliver it to the address stated below:

Name:

Address:

ID / Social Security No./ company number:

Signature: _____

Schedule 8.4

Assignment Form

(To assign the foregoing Warrant to purchase shares of PolyPid Ltd., execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to the undersigned transferee, who will assume all obligations of the Holder under the Warrant and under the SPA and all of the schedules and exhibits attached thereto and contemplated thereby:

Name: _____
(Please Print)

Address: _____
(Please Print)

Dated: _____

Holder’s
Signature: _____

Holder’s
Address: _____

Transferee’s
signature: _____

Transferee’s
address: _____

**POLYPID LTD.
2012 SHARE OPTION PLAN**

1. Definitions

As used herein capitalized terms shall have the meanings set forth in Annex A hereto, unless the context clearly indicates to the contrary.

2. The Plan

2.1 Purpose

The purpose and intent of the Plan is to advance the interests of the Company by affording to selected employees, officers, directors, consultants and other services providers of the Company or Affiliated Companies an opportunity to acquire a proprietary interest in the Company or to increase their proprietary interest therein, as applicable, by the grant in their favor, of Options, thus providing such Grantee an additional incentive to become, and to remain, employed or engaged by the Company or Affiliated Company, as the case may be, and encouraging such Grantee's sense of proprietorship and stimulating his or her active interest in the success of the Company and the Affiliated Company by which such Grantee is employed or engaged.

2.2 Effective Date and Term

The Plan shall become effective as of the day it was adopted by the Board, and shall continue in effect until the earlier of (a) its termination by the Board; or (b) the date on which all of the Options available for issuance under the Plan have been granted and exercised; or (c) the lapse of ten (10) years from the date the Plan is adopted by the Board.

3. Administration

3.1 This Plan and any Sub-Plans shall be administered by the Board. The Board may appoint a committee which, subject to any applicable limitations imposed by the Companies Law, and/or by any other applicable Law, shall have all of the powers of the Board granted herein (in which event of such limitations, such committee may make recommendations to the Board). Subject to the above, the term "Board" whenever used herein, shall mean the Board or such appointed committee, as applicable.

3.2 Unless specifically required otherwise under applicable Mandatory Law, the Board shall have sole and full discretion and authority, without the need to submit its determinations or actions to the shareholders of the Company for their approval or authorization, to administer the Plan and any Sub-Plans and all actions related thereto, including without limitation the performance, at any time and from time to time, of any and all of the following:

3.2.1 the designation of Grantees;

3.2.2 the determination of the terms of each grant of Options (which need not be identical), including without limitation the number of Options to be granted in favor of each Grantee and the vesting schedule and the Exercise Price thereof and the documents to be executed by the Grantee;

3.2.3 the determination of the applicable tax regimes to which the Options will be subject;

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3.2.4 the determination of the terms and form of the Option Agreements (which need not be identical), whether a general form or a specific form with respect to a certain Grantee;

3.2.5 the modification or amendment of the Exercise Period, vesting schedules (including by way of acceleration) and/or of the Exercise Price of Options, including without limitation the reduction thereof, either prior to or following their grant; the repricing of Options or any other action which is or may be treated as repricing under generally accepted accounting principles; the grant to the holder of an outstanding Option, in exchange for such Option, of a new Option having a purchase price equal to, lower than or higher than the Exercise Price provided in the Option so surrendered and canceled, and containing such other terms and conditions as the Board may prescribe;

3.2.6 any other action and/or determination deemed by the Board to be required or advisable for the administration of the Plan and/or any Sub-Plan or Option Agreement;

3.2.7 the determination of the Fair Market Value of the Shares, and the mechanism of such determination;

3.2.8 the interpretation of the Plan, any Sub-Plans, and the Option Agreements;

3.2.9 the adoption of Sub-Plans, including without limitation the determination, if the Board sees fit to so determine, that to the extent any terms of such Sub-Plan are inconsistent with the terms of this Plan, the terms of such Sub-Plan shall prevail; and

3.2.10 the extension of the period of the Plan or any Sub-Plans.

3.3 The Board may, without shareholder approval, amend, modify (including by adding new terms and rules), and/or cancel or terminate this Plan, any Sub-Plans, and any Options granted under this Plan or any Sub-Plans, any of their terms, and/or any rules, guidelines or policies relating thereto. Notwithstanding the foregoing (a) material amendments to the Plan or any Sub-Plans (but not the exercise of discretion under the Plan or any Sub-Plans) shall be subject to shareholder approval to the extent so required by applicable Mandatory Law; and (b) no termination or amendment of the Plan or any Sub-Plan shall affect any then outstanding Options nor the Board's ability to exercise its powers with respect to such outstanding Options granted prior to the date of such termination, unless expressly provided by the Board.

3.4 Unless otherwise determined by the Board, any amendment or modification of this Plan and/or any applicable Sub-Plan and/or Option Agreement shall apply to the relationship between the Grantee and the Company; and such amendment or modification shall be deemed to have been included, *ab initio*, in the Plan and any such applicable Sub-Plan and/or Option Agreement, and shall have full force and effect with respect to the relationship between the Company and the Grantee.

4. **Eligibility**

The persons eligible for participation in the Plan as Grantees include employees, officers, directors, consultants, and other service providers of the Company or any Affiliated Company (including persons who are responsible for or contribute to the management, growth or profitability of, or who provide substantial services to, the Company or any Affiliated Company). The Board, in its sole discretion shall select from time to time the individuals,

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from among the persons eligible to participate in the Plan, who shall receive Options. In determining the persons in favor of whom Options are to be granted, the number of Options to be granted thereto and the terms of such grants, the Board may take into account the nature of the services rendered by such person, his/her present and future potential contribution to the Company or to the Affiliated Company by which he/she is employed or engaged, and such other factors as the Board in its discretion shall deem relevant.

5. **Option Pool**

The total number of Options to be granted pursuant to this Plan shall be Seventeen Million Seven Hundred and Fifty Five Thousand Five Hundred and Six (17,755,506) and the Company has reserved Seventeen Million Seven Hundred and Fifty Five Thousand Five Hundred and Six (17,755,506) authorized but unissued Shares for the purpose of the Plan, subject to adjustment as set forth in Section 12 below, and as shall be amended by the Board from time to time.

The Company shall at all times until the expiration or termination of this Plan keep reserved a sufficient number of Shares to meet the requirements of this Plan. Any of such Shares, which, as of the expiration or termination of this Plan, remain unissued and not subject to outstanding Options, shall at such time cease to be reserved for the purposes of this Plan. Should any Option for any reason expire or be canceled prior to its exercise or relinquishment in full, such Option may be returned to said pool of Options and may again be granted under this Plan.

6. **Grant of Options**

6.1 The Options shall be granted for no consideration.

6.2 Each Option granted pursuant to the Plan shall be evidenced by an Option Agreement.

6.3 Each Grantee shall be required to execute, in addition to the Option Agreement, any and all other documents required by the Company or any Affiliated Company, whether before or after the grant of the Options (including without limitation any customary documents and undertakings towards a trustee, if any, and/or the tax authorities). Notwithstanding anything to the contrary in this Plan or in any Sub-Plan, no Option shall be deemed granted unless all documents required by the Company or any Affiliated Company to be signed by the Grantee prior to or upon the grant of such Option, shall have been duly signed and delivered to the Company or such Affiliated Company.

7. **Terms of Options**

Option agreements between the Company and a Grantee will be in such form approved by the Board, which may be a general form or a specific form with respect to a certain Grantee.

Unless otherwise determined by the Board (which determination shall not require shareholder approval, unless so required in order to comply with the provisions of applicable Mandatory Law) and provided accordingly in the applicable Option Agreement, such Option Agreement shall set forth, by appropriate language, the number of Options granted thereunder and the substance of all of the following provisions:

7.1 **Exercise Price**: The Exercise Price for each Grantee shall be as determined by the Board and specified in the applicable Option Agreement. Without derogating from and in addition to the provisions of Section 18 of the Plan, the Exercise Price shall be denominated in the currency of the primary economic environment of, at the Company's discretion, either the Company or the Grantee (that is the functional currency of the Company or the currency in which the Grantee is paid).

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7.2 **Vesting**: Unless otherwise determined by the Board with respect to any specific Grantee and/or to any specific grant (which determination shall not require shareholder approval unless so required in order to comply with the provisions of applicable Mandatory Law) and provided accordingly in the applicable Option Agreement, the Options shall vest (become exercisable) according to the following 3 year vesting schedule:

Period of Grantee's Continuous Service from the Start Date:	Portion of Total Number of Options that becomes Vested and Exercisable
Upon the completion of a full twelve (12) months of continuous Service	33%
Upon the lapse of each full additional three month(s) of the Grantee's continuous Service thereafter, until all the Options are vested (i.e. 100% of the grant will be vested after 3 years)	8.375%

For the purposes hereof, the "Start Date" shall mean the Date of Grant, unless otherwise determined by the Board (which determination shall not require shareholder approval unless so required in order to comply with the provisions of the Companies Law), and provided accordingly in the

For the purposes hereof, the term “**Service**” means a Grantee’s employment or engagement by the Company or an Affiliated Company. Service shall be deemed terminated upon the effective date of the termination of the employment/engagement relationship. A Grantee’s Service shall not be deemed terminated or interrupted solely as a result of a change in the capacity in which the Grantee renders Service to the Company or an Affiliated Company (i.e., as an employee, officer, director, consultant, etc.); nor shall it be deemed terminated or interrupted due solely to a change in the identity of the specific entity (out of the Company and its Affiliated Companies) to which the Grantee renders such Service, provided that there is no actual interruption or termination of the continuous provision by the Grantee of such Service to any of the Company and its Affiliated Companies. Furthermore, a Grantee’s Service with the Company or Affiliated Company shall not be deemed terminated or interrupted as a result of any military leave, sick leave, or other bona fide leave of absence taken by the Grantee and approved by the Company or such Affiliated Company by which the Grantee is employed or engaged, as applicable; provided, however, that if any such leave exceeds ninety (90) days, then on the ninety-first (91st) day of such leave the Grantee’s Service shall be deemed to have terminated unless the Grantee’s right to return to Service with the Company or such Affiliated Company is secured by statute or contract. Notwithstanding the foregoing, unless otherwise designated by the Company or Affiliated Company, as the case may be, or required by law, time spent in a leave of absence shall not be treated as time spent providing Service for the purposes of calculating accrued vesting rights under the vesting schedule of the Options. Without derogating from the aforesaid, the Service of a Grantee to an Affiliated Company shall also be deemed terminated in the event that such Affiliated Company for which the Grantee performs Service ceases to fall within the definition of an “Affiliated Company” under this Plan, effective as of the date said Affiliated Company ceases to be such. In all other cases in which any doubt may arise regarding the termination of a Grantee’s Service or the effective date of such termination, or the implications of absence from Service on vesting, the Corporation, in its discretion, shall determine whether the Grantee’s Service has terminated and the effective date of such termination and the implications, if any, on vesting.

The Board shall be entitled, but not obliged, at its sole discretion, to accelerate, in whole or in part, the vesting schedule of any Option, including, without limitation, in connection with a Merger Transaction and/or an IPO.

7.3 Expiration Date: Unless expired earlier pursuant to either Section 7.4 or Section 9 below, unexercised Options shall expire and terminate and become null and void upon the lapse of ten (10) years from the Date of Grant (the “**Expiration Date**”).

7.4 Exercise Period:

7.4.1 Each Option shall be exercisable from the date upon which it becomes vested until the Expiration Date of such Option (the “**Exercise Period**”).

7.4.2 Notwithstanding anything to the contrary contained in this Plan, in the event of a merger of the Company with or into another corporation, or the sale of all or substantially all the assets or the shares of the Company (such merger or sale: a “**Merger Transaction**”), the surviving or the acquiring entity, as the case may be, or its respective parent company or subsidiary (the “**Successor Entity**”) may either assume the Company’s rights and obligations under outstanding Options or substitute the outstanding Options, as follows:

- (a) For purposes of this Section 7.4.2, the outstanding Options shall be deemed assumed or substituted by the Successor Entity if, following the consummation of the Merger Transaction, the outstanding Options confer the right to receive, for each share underlying any outstanding Option immediately prior to the consummation of the Merger Transaction, the same consideration (whether shares, cash or other securities or property) to which an existing holder of a Share on the effective date of consummation of the Merger Transaction was entitled; provided, however, that if the consideration to which such existing holder is entitled comprises consideration other than or in addition to securities of the Successor Entity, then the Board may determine, with the consent of the Successor Entity, that the consideration to be received by the Grantees for their outstanding Options will comprise solely securities of the Successor Entity equal in their market value to the per share consideration received by the holders of Shares in the Merger Transaction.
- (b) In the event that the Successor Entity neither assumes nor substitutes all of the outstanding Options of a Grantee, then such Grantee shall have a period of 15 days (or if so decided by the Board, such longer period as the Board may determine in its sole discretion) from the date designated by the Company in a written notice given to the Grantee (such date to be no earlier than the date upon which said notice is delivered to the Grantee) to exercise his or her Vested Options.
- (c) All Options, whether vested or not, which are neither assumed or substituted by the Successor Entity, nor exercised by the end of the said 15-day period, shall expire effective as of the date of the consummation of the Merger Transaction, whereupon they shall become null and void and shall no longer entitle the Grantee to any right in or towards the Company or the Successor Entity.

7.5 Exercise Notice and Payment:

Vested Options may be exercised at one time or from time to time during the Exercise Period, by giving a written notice of exercise (the “**Exercise Notice**”) to the Company, at their principal offices, in accordance with the following terms, or such other procedures as shall be determined from time to time by the Board and notified in writing to the Grantees:

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- (a) The Exercise Notice must be signed by the Grantee and must be delivered to the Company, prior to the termination of the Options, by certified or registered mail - return receipt requested, with a copy delivered to the Chief Financial Officer (or such other authorized representative) of the Affiliated Company with which the Grantee is employed or engaged, if applicable.
 - (b) The Exercise Notice will specify the number of Vested Options being exercised.
 - (c) The Exercise Notice will be accompanied by payment in full of the Exercise Price for the exercised Options and by such other representations and agreements as required by the Company with respect to the Grantee’s investment intent regarding the Exercised Shares. Payment will be

made by personal check or cashier's check payable to the order of the Company, or at the discretion of the Board, payment of such other lawful consideration as the Board may determine (such as, by way of example, cashless exercise), provided however, that in case of payment by check, the Options shall not be deemed exercised, and the Company shall not issue the Exercised Shares in respect thereof, until the check shall have been fully and irrevocably honored by the bank on which it was drawn.

7.6 Conditions of Issuance

No Options shall be deemed exercised nor shall any Share be issued thereunder, until the Company has been provided with confirmation by the applicable tax authorities or is otherwise under a tax arrangement, which either: **(a)** waives or defers the tax withholding obligation with respect to such exercise and issuance; or **(b)** confirms receipt of the payment of all the tax due with respect to such exercise; or **(c)** confirms the conclusion of another arrangement with the Grantee regarding the tax amounts, if any, that are to be withheld by the Company or any Affiliated Company under Law with respect to such exercise, and which arrangement is satisfactory to the Company. If such confirmations/exemptions/arrangements are not available under the tax objections of the Grantee, the Company shall be entitled to require as a condition of issuance that the Grantee remit an amount sufficient to satisfy all federal, state and other governmental withholding tax requirements related thereto. A determination of the Company's counsel that a withholding tax is required in connection with the exercise of Options shall be conclusive for the purposes of this requirement condition.

Furthermore, notwithstanding any other provision of this Plan, the Company shall have no obligation to issue or deliver Shares under the Plan unless the exercise of the Option and the issuance and delivery of the underlying Shares comply with, and do not result in a breach of, all applicable Laws, to the satisfaction of the Company in its sole discretion, and have received, if deemed desirable by the Company, the approval of legal counsel for the Company with respect to such compliance. The Company may further require the Grantee to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with applicable Laws.

As a condition to the exercise of an Option, the Company may require, among other things, that: **(a)** the Grantee represent and warrant at the time of any exercise that the underlying Shares are being purchased only for investment and without any present intention to sell or distribute such Shares, and make such other representations, warranties and covenants as may be reasonably required to comply with applicable laws; **(b)** a legend be stamped on the certificates representing such underlying Shares indicating that they may not be pledged, sold or otherwise transferred unless an opinion of legal counsel (acceptable by the Company's counsel) stating that such transfer is not in violation of any applicable Law, is provided; and

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(c) the Grantee execute and deliver to the Company such an agreement as may be in use by the Company setting forth certain terms and conditions applicable to the Shares.

8. Transferability

8.1 The Options are not publicly traded.

8.2 Other than by will or laws of descent, neither the Options nor any of the rights in connection therewith shall be assignable, transferable, made subject to attachment, lien or encumbrance of any kind, and the Grantee shall not grant with respect thereto any power of attorney or transfer deed, whether valid immediately or in the future.

8.3 Following the exercise of Vested Options, the Exercised Shares shall be transferable; provided, however, that Exercised Shares may be subject to applicable securities regulations, a right of first refusal, one or more repurchase options, market stand-off provisions, lock up periods and such other conditions and restrictions as may be included in the Company's Articles, the Plan, any applicable Sub-Plan, the applicable Option Agreement, and/or any conditions and restrictions included in the Company's Securities Law Compliance Manual/Insider Trade Policy, or similar document, if any, all as determined by the Board in its discretion, provided however, that if the Options are subject to a right of first refusal or a repurchase option, then for as long as the Company is not publicly traded, a Grantee shall not transfer any Exercised Shares, prior to the lapse of six (6) months and one day from the date on which s/he exercised the Options. The Company shall have the right to assign at any time any repurchase or right of first refusal right it may have, whether or not such right is then exercisable, to one or more persons as may be selected by the Company. Upon request by the Company, the Grantee shall execute any agreement or document evidencing such transfer restrictions prior to the receipt of Exercised Shares hereunder, and shall promptly present to the Company any and all certificates representing Exercised Shares for the placement on such certificates of appropriate legends evidencing any such transfer restrictions.

The Grantee may transfer or sell only Exercised Shares, or any part thereof, to any third party, provided that all of the following conditions have been met prior to such transfer: **(a)** the transfer is made in accordance with and subject to the provisions of the Company's Articles (including, without limitation, any rights of first refusal provided therein, if any); and **(b)** the transferee confirmed in writing its acceptance of the terms and conditions of the Plan, any applicable Sub-Plan and the applicable Option Agreement with respect to the Exercised Shares being transferred, instead of the Grantee, to the satisfaction of the Board (including the execution of the proxy referred to in Section 10.2 below); and **(c)** actual payment of all taxes required to be paid upon such sale and transfer of the Exercised Shares has been made to the tax assessor, and the trustee (if applicable) received confirmation from the tax assessor that all taxes required to be paid upon such sale and transfer have been paid.

Any transfer that is not made in accordance with the Plan, any applicable Sub-Plan or the applicable Option Agreement shall be null and void.

8.4 No transfer of an Exercised Share or Option by the Grantee by will or by the laws of descent shall be effective against the Company, unless and until: **(a)** the Company shall have been furnished with written notice thereof, accompanied by an authenticated copy of probate of a will together with the will or inheritance order and/or such other evidence as the Board may deem necessary to establish the validity of the transfer; and **(b)** the contemplated transferee(s) shall have confirmed to the Company in writing its acceptance of the terms and conditions of

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the Plan, any applicable Sub-Plan and Option Agreement, with respect to the Exercised Share or Options being transferred, to the satisfaction of the Board.

8.5 In the event that prior to an IPO, holders holding in the aggregate no less than a controlling interest in the Company (“**Selling Shareholders**”) elect to sell all or substantially all of their shares in the Company either to a third party or to one shareholder of the Company, then, if so requested by the purchaser, the Grantee shall be obligated to join the sale and sell all of his/her Shares in the Company (and if requested, also his/her unexpired Vested Options), all under the same terms under which the Selling Shareholders have agreed to sell their shares (provided that with respect to Vested Options, the Exercise Price shall be deducted from the purchase price paid for the shares in such transaction) and in accordance with the provisions of the Articles of the Company.

9. Termination of Options and Repurchase of Exercised Shares

9.1 Notwithstanding anything to the contrary, any Option granted in favor of any Grantee but not exercised by such Grantee within the Exercise Period and in strict accordance with the terms of the Plan, any applicable Sub-Plan and the applicable Option Agreement, shall, upon the lapse of the Exercise Period, immediately expire and terminate and become null and void.

9.2 Upon the termination of a Grantee’s Service, for any reason whatsoever, any Options granted in favor of such Grantee, which are not Vested Options, shall immediately expire and terminate and become null and void.

9.3 Additionally, in the event of the termination of a Grantee’s Service for Cause (a) all of such Grantee’s Vested Options shall also, upon such termination for Cause, immediately expire and terminate and become null and void; and (b) any and all of such Grantee’s Exercise Shares shall be subject to the Company’s “Repurchase Right”, as described below.

For the purposes hereof the term “**Cause**” shall mean (a) the conviction of the Grantee for any felony involving moral turpitude or affecting the Company or any Affiliated Company; (b) the embezzlement of funds of the Company or any Affiliated Company; (c) any breach of the Grantee’s fiduciary duties or duties of care towards the Company or any Affiliated Company (including without limitation any disclosure of confidential information of the Company or any Affiliated Company or any breach of a non-competition undertaking); (d) any conduct in bad faith reasonably determined by the Board to be materially detrimental to the Company or, with respect to any Affiliated Company, reasonably determined by the Board of Directors of such Affiliated Company to be materially detrimental to either the Company or such Affiliated Company; or (e) any other event classified under any applicable agreement between the Grantee and the Company or the Affiliated Company, as applicable, as a “cause” for termination or by other language of similar substance.

The Company’s “**Repurchase Right**” shall be as follows: If any Grantee’s Service is terminated by the Company for Cause, then, within 180 days after such termination, the Company shall have the right, but not the obligation, to repurchase from the Grantee, or his or her legal representative, as the case may be, all or part of the Shares s/he exercised pursuant to the Options, if any. The Repurchase Right shall be exercised by the Company by giving the Grantee, or his/her legal representative written notice, within said 180 days, of its intention to exercise the Repurchase Right, indicating the number of such Exercised Shares to be repurchased and the date on which the repurchase is to be effected, and shall pay the Grantee for each such Exercised Share being repurchased, an amount equal to the price originally paid by the Grantee for such Exercised Shares, subject to adjustments as provided in Section 12 below. The certificate(s) representing such Exercised Shares to be repurchased shall, prior to

the close of business on the date specified for the repurchase, be delivered to the Company together with a duly endorsed stock assignment certificate. Payment shall be made in cash, cash equivalents, or in any other way of payment allowed under any applicable Law, and authorized by the Board. Concurrently with the exercise of the Repurchase Right, if exercised, the Grantee (or the holder of the Exercised Shares so repurchased) shall no longer have any rights as a holder of such repurchased Exercised Shares. Such repurchased Exercised Shares shall be deemed to have been repurchased, whether or not the certificate(s) therefor have been delivered. If the Grantee fails to deliver such stock certificate(s), the Company shall be entitled to take such action as may be necessary to remove the requisite number of Shares registered in the name of the Grantee from the books and records of the Company. The Repurchase Right shall be in addition to any and all other rights and remedies available to the Company.

In the event that the Company shall be prohibited, on account of any applicable Mandatory Law, from repurchasing Exercised Shares, the Company may assign the Repurchase Right to its wholly owned subsidiary, or if the same is not possible on account of any applicable Law, to all of the stockholders of the Company at the time of the exercise of said right (excluding other shareholders pursuant to the exercise of Options), on a pro-rata, as converted basis, all under the same terms and conditions set forth in this Plan, in which event the Company portion shall inform the Grantee of the identity of the particular assignee in the Company’s Notice, and the provisions of this Section regarding the Company shall apply to such assignee(s), *mutatis mutandis*.

In the event that at the time the Company wishes to exercise its Repurchase Right, the Grantee does not own a sufficient number of Exercised Shares to satisfy the Company’s Repurchase Right, in addition to performing any obligations necessary to satisfy the Company’s Repurchase Right, the Company may require the Grantee to deliver to the Company, for each Exercised Share that is the subject of the Repurchase Right and is not available for repurchase as it has been sold or transferred, an aggregate cash amount, equal to the difference between the fair market value of each such missing Share and the price originally paid by the Grantee to the Company for each such Exercised Share, as adjusted.

9.4 Unless otherwise determined by the Board (which determination shall not require shareholder approval, unless so required in order to comply with the provisions of applicable Mandatory Law), following termination of Grantee’s Service other than for Cause, the Expiration Date of such Grantee’s Vested Options shall be deemed the earlier of: (a) the Expiration Date of such Vested Options as was in effect immediately prior to such termination; or (b) 3 (three) calendar months following the date of such termination or, if such termination is the result of death or disability of the Grantee, 12 (twelve) calendar months from the date of such termination.

9.5 Notwithstanding anything to the contrary herein, upon the issuance of a court order declaring the bankruptcy of a Grantee, or the appointment of a receiver or a provisional receiver for a Grantee over all of his assets, or any material part thereof, or upon making a general assignment for the benefit of his creditors, any outstanding Options issued in favor of such Grantee (whether vested or not) shall immediately expire and terminate and become null and void and shall entitle neither the Grantee nor the Grantee’s receiver, successors, creditors or assignees to any right in or towards the Company or any Affiliated Company in connection with the same, and all interests and rights of the Grantee or the Grantee’s receiver, successors, creditors or assignees in and to the same, shall expire.

10. Rights as Shareholder, Voting Rights, Dividends and Bonus Shares

- 10.1 It is hereby clarified that a Grantee shall not, by virtue of this Plan, any applicable Sub-Plan or the applicable Option Agreement or any Option granted to the Grantee, have any of the rights of a shareholder with respect to the Shares underlying the Options, until the Options have been exercised and the Exercised Shares issued in the Grantee's name.
- 10.2 Prior to the closing of an IPO, the Board shall be entitled to require, as a condition to the exercise of any Option, that the Grantee (and the trustee, if there is a trustee who is the holder of the Exercised Shares) sign and deliver to such person as may be designated by the Board (the "Nominee") an irrevocable proxy, in a form to be provided by the Company, appointing the Nominee as the sole person entitled to exercise the voting rights conferred by such shares. The Nominee shall not exercise the voting rights conferred by the Exercised Shares held by him or with respect to which the Nominee has been given an irrevocable proxy as aforesaid, in any way whatsoever, and shall not issue a proxy to any person or entity to vote such shares, unless otherwise instructed by the Board, and in accordance with such instructions. Unless instructed otherwise by the Board, the Nominee shall vote such Exercised Shares in a manner pro-rata to the votes of the other voting shares, such that the votes of the Exercised Shares shall not affect the end result of the vote. The Nominee shall be indemnified and held harmless by the Company, to the extent permitted by applicable law, against any cost or expense (including counsel fees) reasonably incurred by him/it, or any liability (including any sum paid in settlement of a claim with the approval of the Company) arising out of any act or omission to act in connection with the voting of the aforesaid proxy unless arising out of such Nominee's own fraud or bad faith. Such indemnification shall be in addition to any rights of indemnification the Nominee(s) may have as a director or otherwise under the Company's Articles, any agreement, any vote of shareholders or disinterested directors, insurance policy or otherwise.
- 10.3 Notwithstanding anything to the contrary herein or in the Company's Articles, none of the Grantees shall have (and they hereby waive the right to have), any pre-emptive rights to purchase, along with the other shareholders in the Company, a pro rata portion of any securities proposed to be offered by the Company prior to the offering thereof to any third party or any rights of first refusal to purchase any securities of the Company offered by the other shareholders of the Company.
- 10.4 Cash dividends paid or distributed, if any, with respect to the Exercised Shares shall be remitted to the Trustee and the Trustee shall make reasonable efforts to remit to the Grantee who is entitled to the Exercised Shares for which the dividends are being paid or distributed, subject to any applicable taxation and laws on such distribution of dividend, and the withholding thereof.
- 10.5 All bonus shares to be issued by the Company, if any, with regard to the Exercised Shares held by a trustee, if any, shall be registered in the name of such trustee and all provisions applying to such Exercised Shares, shall apply to the bonus shares issued by virtue thereof, *mutatis mutandis*.

11. Liquidation

In the event that the Company is liquidated or dissolved while unexercised Options remain outstanding under the Plan, then all or part of such outstanding Options may be exercised in full by the Grantees as of immediately prior to the effective date of such liquidation or dissolution of the Company, without regard to the vesting terms thereof.

12. Adjustments

The number of Shares to which each outstanding Option is exercisable, together with those Shares otherwise reserved for the purposes of the Plan for Options not yet exercised as provided under Section 5 above, shall be proportionately adjusted for any increase or decrease in the number of Shares resulting from a stock split, reverse stock split, combination or reclassification of the Shares, as well as for any distribution of bonus shares. Such adjustment shall be made by the Board, whose determination in that respect shall be final, binding and conclusive.

All provisions applying to the Exercised Shares shall apply to all Shares received as a result of an adjustment as described above.

No adjustment shall be made by virtue of the distribution, if any, of any cash or similar dividend.

13. No Interference

Neither the Plan nor any applicable Sub-Plan or Option Agreement shall affect, in any way, the rights or powers of the Company or its shareholders to make or to authorize any sale, transfer or change whatsoever in all or any part of the Company's assets, obligations or business, or any other business, commercial or corporate act or proceeding, whether of a similar character or otherwise; any adjustments, recapitalizations, reorganizations or other changes in the Company's capital structure or business; any merger or consolidation of the Company; any issue of bonds, debentures, shares (including preferred or prior preference shares ahead of or affecting the existing shares of the Company including the shares into which the Options granted hereunder are exercisable or the Exercised Shares or the rights thereof, etc.); or the dissolution or liquidation of the Company; and none of the above acts or authorizations shall entitle the Grantee to any right or remedy, including without limitation, any right of compensation for any dilution resulting from any issuance of any shares or of any other securities in the Company to any person or entity whatsoever.

14. No Employment/Engagement/Continuance of Service Obligations

Nothing in the Plan, in any applicable [ILLEGIBLE] Sub-Plan or Option Agreements, or in any Option granted hereunder shall be construed as guaranteeing the Grantee's continuous employment, engagement or service with the Company or any Affiliated Company, and no obligation of the Company or any Affiliated Company as to the length of the Grantee's employment, engagement or service shall be implied by the same. The Company and its Affiliated Companies reserve the right to terminate the employment, engagement or service of any Grantee pursuant to such Grantee's terms of employment, engagement or service and any law.

15. No Representation

The Company does not and shall not, through this Plan, any applicable Sub-Plan or the applicable Option Agreement, make any representation towards any Grantee with respect to the Company, its business, its value or either its shares in general or the Exercised Shares in particular.

Each Grantee, upon entering into the applicable Option Agreement, shall represent and warrant toward the Company that his/her consent to the grant of the Options issued in his/her favor and the exercise (if so exercised) thereof, neither is nor shall be made, in any respect, upon the basis of any representation or warranty made by the Company or by any of its directors, officers, shareholders or employees, and is and shall be made based only upon his/her examination and expectations of the Company, on an "as is" basis. Each Grantee shall waive any claim whatsoever of "non-conformity" of any kind, and any other cause of action or claim of any kind with respect to the Options and/or their underlying Shares.

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16. Tax Consequences

- 16.1 Any and all tax and/or other mandatory payment consequences arising from the grant or exercise of any Option, the payment for or the transfer of the Exercised Shares to the Grantee, or the sale of the Exercised Shares by the Grantee, or from any other event or act in connection therewith (including without limitation, in the event that the Options do not qualify under the tax classification/tax track in which they were intended) (whether of the Company, any Affiliated Company, a trustee, if applicable, or the Grantee), shall be borne solely by the Grantee.
- 16.2 The Company, any Affiliated Company and a trustee, if applicable, may each withhold (including at source), deduct and/or set-off, from any payment made to the Grantee, the amount of the tax and/or other mandatory payment the withholding of which is required with respect to the Options and/or the Exercised Shares under any applicable Law. The Company or an Affiliated Company may require the Grantee, through payroll withholding, cash payment or otherwise, to make adequate provision for any such tax withholding obligations of the Company, Affiliated Company or a trustee, if applicable, arising in connection with the Options or the Exercised Shares. Without derogating from the aforesaid, each Grantee shall provide the Company and/or any applicable Affiliated Company with any executed documents, certificates and/or forms that may be required from time to time by the Company or such Affiliated Company in order to determine and/or establish the tax liability of such Grantee.
- 16.3 Furthermore, each Grantee shall indemnify the Company, any applicable Affiliated Company and a trustee, if applicable, or any one thereof, and hold them harmless from and against any and all liability in relation with any such tax and/or other mandatory payments or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax and/or other mandatory payments from any payment made to the Grantee.

17. Non-Exclusivity of the Plan

The adoption by the Board of this Plan and any Sub-Plans shall not be construed as amending, modifying or rescinding any previously approved incentive arrangements, or as creating any limitations on the power of the Board to adopt such other incentive arrangements as it may deem desirable, including without limitation the grant of options for shares in the Company otherwise than under the Plan, and such arrangements may be either applicable generally or only in specific cases.

18. Currency Exchange Rates

Except as otherwise determined by the Board, all monetary values with respect to Options granted pursuant to this Plan, including without limitation the fair market value and the Exercise Price of each Option, shall be stated in United States Dollars. In the event that the Exercise Price is in fact to be paid in New Israeli Shekels, the conversion rate shall be the last known representative rate of the US Dollar to the New Israeli Shekels on the date of payment.

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ANNEX A

Capitalized Terms used in the 2012 Share Option Plan, shall have the meanings set forth below:

- 1.1 "**Affiliated Company**" — means any present or future entity *(a)* which holds a controlling interest in the Company; *(b)* in which the Company holds a controlling interest; *(c)* in which a controlling interest is held by another entity, who also holds a controlling interest in the Company; or *(d)* which has been designated an "Affiliated Company" by resolution of the Board.
- 1.2 "**Board**" — means the Board of Directors of the Company.
- 1.3 "**Cause**" — as defined in Section 9.3 of the Plan.
- 1.4 "**Company**" — PolyPid Ltd.
- 1.5 "**Companies Law**" — the State of Israel's Companies Law, 5759 — 1999, as amended from time to time, and the rules and regulations promulgated thereunder.
- 1.6 "**Date of Grant**" — the date determined by the Board to be the effective date of the grant of Options to a Grantee, or, if the Board has not determined such effective date, the date of the resolution of the Board approving the grant of such Options.
- 1.7 "**Exercise Notice**" - as defined in Section 7.5 of the Plan.
- 1.8 "**Exercise Period**" - as defined in Section 7.4 of the Plan.

- 1.9 “**Exercise Price**” - the price to be paid for the exercise of each Option.
- 1.10 “**Exercised Shares**” - the Shares that are issued upon the exercise of the Options.
- 1.11 “**Expiration Date**” - as defined in Section 7.3 of the Plan.
- 1.12 “**Fair Market Value**” means as of any date, the value of a Share determined as follows:
- (i) If the Shares are listed on any established stock exchange or a national market system, including without limitation the Tel -Aviv Stock Exchange, the NASDAQ National Market System or the NASDAQ SmallCap Market, the Fair Market Value shall be the last reported sale price for such Shares (or the highest closing bid, if no sales were reported), as quoted on such exchange or system for the last market trading day prior to time of determination, as reported in The Wall Street Journal, or such other source as the Board deems reliable;
 - (ii) If the Shares are regularly quoted by one or more recognized securities dealers, but selling prices are not reported, the Fair Market Value shall be the mean between the highest bid and lowest asked prices for the Shares on the last market trading day prior to the day of determination; or
 - (iii) In the absence of an established market for the Shares, the Fair Market Value thereof shall be determined in good faith by the Board.
- 1.13 “**Grantee**” — a person or entity to whom Options are granted.

- 1.14 “**IPO**” — an initial public offering of securities of the Company in a recognized stock exchange market or the listing thereof on NASDAQ or another recognized automated quotation system.
- 1.15 “**Law**” — federal, state and/or foreign, laws, rules and/or regulations and/or rules, regulations, guidelines and/or requirements of any relevant securities and exchange and/or tax commission and/or authority and/or any relevant stock exchange or quotations systems.
- 1.16 “**Mandatory Law**” — provisions of Law, which may not be contrarily addressed or regulated by the determination and/or consent of the Company and/or other parties.
- 1.17 “**Merger Transaction**” - as defined in Section 7.4 of the Plan.
- 1.18 “**Option(s)**” - an option(s) granted within the framework of this Plan, each of which imparts the right to purchase one Share.
- 1.19 “**Option Agreement**” — with respect to any Grantee — a written option agreement or a written instrument, executed by and between the Company and the Grantee, which shall set forth the terms and conditions with respect to the Options.
- 1.20 “**Plan**” - this Company’s 2012 Israeli Share Option Plan, as may be amended from time to time as set forth herein.
- 1.21 “**Service**” — as defined in Section 7.2 of the Plan.
- 1.22 “**Share(s)**” — Ordinary Share(s) of the Company, par value of NIS 0.10 each, to which, subject to the provisions herein, are attached the rights specified in the Company’s Articles, as may be amended from time to time.
- 1.23 “**Start Date**” — as defined in Section 7.2 of the Plan.
- 1.24 “**Sub-Plan**” - any supplements or sub-plans to the Plan adopted by the Board, applicable to Grantees employed in a certain country or region or subject to the laws of a certain country or region, as deemed by the Board to be necessary or desirable to comply with the laws of such region or country, or to accommodate the tax policy or custom thereof, which, if and to the extent applicable to any particular Grantee, shall constitute an integral part of the Plan.
- 1.25 “**Vested Option(s)**” — that portion of the Options which the Grantee is entitled to exercise in accordance with the provisions of Section 7.2 of the Plan or, if inconsistent with the provisions of Section 7.2 of the Plan - the provisions of the Option Agreement of such Grantee.

PolyPid Ltd.
Subsidiaries of the Registrant
(as of September 30, 2017)

PolyPid Pharma SRL, a company organized and existing under the laws of Romania.

PolyPid Inc., a Delaware corporation.
