As confidentially submitted to the Securities and Exchange Commission on September 24, 2014
pursuant to the Jumpstart Our Business Startups Act of 2012. All information herein is strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Amendment No. 1
to
Form F-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

PolyPid Ltd.

(Exact name of registrant as specified in its charter)

State of Israel	**2834**	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification Number)*

Amir Weisberg, Chief Executive Officer
PolyPid Ltd.
18 Hasivim Street

Petach Tikva 4917002 Israel
Tel: +972-74-7195700
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Zysman, Aharoni, Gayer and
Sullivan & Worcester LLP
1633 Broadway
New York, NY 10019
Tel: 212.660.5000
(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 hereof.

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, check the following box. o

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. o

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. o

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. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Proposed Maximum Aggregate Offering Price[(1)]**	**Amount of Registration Fee**
Ordinary shares, par value NIS 0.01 per share[(2)(3)]	$	$
Representative's warrants to purchase ordinary shares[(4)]		
Ordinary shares underlying Representative's warrants[(5)]		
TOTAL	$	$

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended.

(2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional securities as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(3) Includes shares of ordinary shares which may be issued upon exercise of a 45-day option granted to the underwriters to cover over-allotments, if any.

(4) In accordance with Rule 457(g) under the Securities Act, because the shares of the registrant's ordinary shares underlying the Representative's warrants are registered hereby, no separate registration fee is required with respect to the warrants registered hereby.

(5) As estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act, the warrants are exercisable at a per share exercise price equal to 125% of the public offering price, and the proposed maximum aggregate offering price of the representative's warrants is $.

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 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 prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED SEPTEMBER 24, 2014

Ordinary Shares

PolyPid Ltd. is offering its ordinary shares in an initial public offering. No public market currently exists for our ordinary shares. The estimated initial public offering price is between $ and $ per share.

We have applied to list our ordinary shares on the NASDAQ Capital Market under the symbol "PLPD."

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and, therefore, will be subject to reduced public company reporting requirements.

Investing in our ordinary shares involves a high degree of risk. See "Risk Factors" beginning on page 9 of this prospectus for a discussion of information that should be considered in connection with an investment in our ordinary shares.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to us (before expenses)	$	$

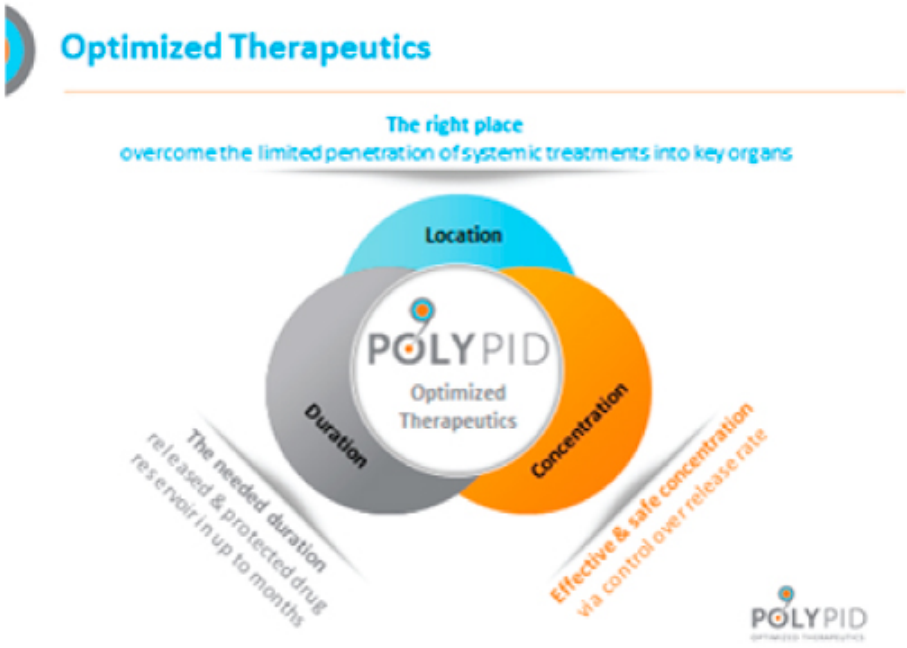
(1) The underwriters will receive compensation in addition to the underwriting discounts and commissions, including warrants to purchase up to of our ordinary shares at a per share exercise price equal to 125% of the initial public offering price of the ordinary shares sold in this offering. See "Underwriting" for a description of the compensation payable to the underwriters.

We have granted a 45-day option to the underwriters to purchase up to additional ordinary shares solely to cover over-allotments, if any.

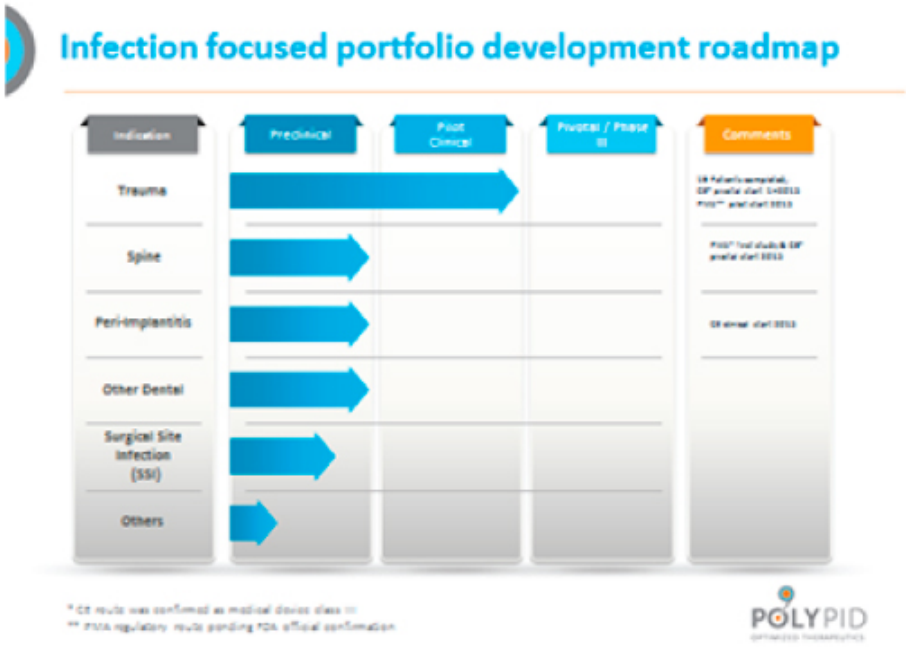
The underwriters expect to deliver the shares to purchasers in the offering on or about , 2014.

Aegis Capital Corp

The date of this prospectus is , 2014.



The graphic above illustrates the potential benefits of PolyPid's advanced PLEX drug release technology, including the ability to effectively treat areas in the body where systemic treatment is ineffective or to improve the safety and performance of localized treatment.



Our most advanced orthopedic lead product candidate, BonyPid-1000, is used as a bone healing scaffold that is protected by local release of antibiotics for use in trauma such as open (through the skin) bone fractures and other bone voids. BonyPid-500 is used to support bone recovery around dental implants in challenging infected or contaminated areas. BonyPid-1000 and BonyPid-500 are planned for regulatory submission in Europe as early as the second half of 2016.

TABLE OF CONTENTS

You should rely only on the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with information that is different. We are offering to sell our ordinary shares, and seeking offers to buy our ordinary shares, only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our ordinary shares.

Until and including , 2014, 25 days after the date of this prospectus, all dealers that buy, sell or trade our ordinary shares, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

For investors outside of the United States: Neither we nor any of the underwriters have done anything that would 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.

BonyPid, BonyPid-1000, BonyPid-500, PLEX™, and D-PLEX are trademarks of PolyPid Ltd.

Our reporting currency and functional currency is the U.S. dollar.

PROSPECTUS SUMMARY

The items in the following summary are described in more detail later in this prospectus. This summary provides an overview of selected information and does not contain all of the information you should consider before buying our ordinary shares. Therefore, you should read the entire prospectus carefully, especially the "Risk Factors" section beginning on page 9 and our financial statements and the related notes appearing at the end of this prospectus before deciding to invest in our ordinary shares.

We are an emerging specialty pharmaceutical company engaged in research and development of our product candidates based on PLEX, our proprietary drug delivery technology. PLEX (abbreviation for **P**olymer-**L**ipid **E**ncapsulation Matri**X**) is able to encapsulate many types of drugs to enable targeted, localized drug delivery into the body over periods of time ranging from days to several months without changing the chemistry of the drug. The application of our PLEX technology in our product candidates enables us to optimize drug treatment regimens with release rates and durations that are pre-determined by us, a combination of attributes not currently available. We are a clinical stage company, meaning that our product candidates are yet to be approved for sale by any regulatory agency.

The localized (as opposed to systemic), controlled and constant release of drugs over extended periods is essential in many treatment regimens, such as the treatment of infections, inflammation and pain. Our PLEX technology platform is a matrix of several thousand alternating layers of polymers (plastics) and lipids (fatty substances) that entrap a therapeutic drug between them. Our preliminary studies show that our product candidates are effective using a very small fraction of the active pharmaceutical ingredients required in systemic administration. One vial of BonyPid-1000, one of our lead product candidates, utilizes slightly more than 1% of the accepted 30-day systemic regimen for the same antibiotic. One vial of BonyPid-500, one of our other lead product candidates, utilizes approximately 1.5% of the normal 10-day antibiotic regimen used in dental applications.

Our most advanced product candidates, BonyPid-1000 and BonyPid-500, address current treatment problems in orthopedics and dental implants that are not adequately addressed by current treatments (either local or systemic). Our additional product candidate D-PLEX addresses the prevention and treatment of surgical site infections generally. BonyPid-1000 and BonyPid-500 are specifically directed at combatting bacterial colonization on implanted bone substitutes and the resulting complications, as well as supporting bone recovery around dental implants, in each case by releasing a broad-spectrum antibiotic at the site to enhance healing. We expect to begin a confirmatory clinical trial for BonyPid-1000 in the second half of 2015 for a CE Mark authorizing marketing in Europe. We expect to begin a pilot clinical trial for BonyPid-500 in the second half of 2015. Both studies are expected to serve as a safety and preliminary effectiveness study as part of the approval process of the U.S. Food and Drug Administration (FDA). We expect, assuming continued favorable clinical results, that both BonyPid-1000 and BonyPid-500 will be ready for commercial release in Europe during the first half of 2017. We are also planning to begin a pilot clinical trial for D-PLEX shortly after our BonyPid-1000 and BonyPid-500 trials. Our estimates of the funds required to achieve these goals are set forth under "Use of Proceeds."

The attributes of our PLEX platform can be used in a wide variety of products and indications in addition to orthopedics and dental implants, including infection treatment and prevention more generally. Based on our current clinical data, we believe that our product candidates have the capability to reduce the number of surgical procedures, side effects, hospitalizations and recovery times, while improving clinical and patient outcomes, thus significantly impacting health economics.

Background and Market Focus

Infection resulting from trauma or surgery remains a major health problem despite the intensive use of systemically administered antibiotics both pre- and post-surgery. Infection causes medical complications that may be fatal, and creates a significant public health burden. Furthermore, according to the FDA and its international counterparts, the increasing resistance of bacteria to antibiotics and similar drugs — called antimicrobials — is a major public health threat. Additionally, systemic administration of antimicrobials frequently involves high dosing that causes safety concerns and potential side effects, in addition to increasing the likelihood of the development of antibacterial resistance. Existing localized treatments are limited by one or several or the following factors that can affect safety or effectiveness: short maximum release periods;

controllability of the drug release; no mechanism to prevent drug degradation; applicability to a limited number of drugs; and difficulties in bonding between the drug and the delivery mechanism.

Our current market focus is to create a range of effective, extended release pharmaceutical products for medicating tissues locally with antibiotics for infection treatment and prevention in surgical procedures. Our studies suggest that our product candidates are effective in a number of cases where systemic administration or other localized solutions have either little or no effect, are too toxic, or both. Based on our clinical and pre-clinical experience, we believe that use of our product candidates will reduce overall surgical infection rates and reduce bacterial resistance, thus benefiting patients, hospitals and healthcare organizations.

Lead Product Candidates

Our three lead product candidates are as follows:

- BonyPid-1000 is a conventional bone substitute used in orthopedic surgery that has been coated with our PLEX technology and contains antibiotics. Bone substitutes are inserted into severe open bone fractures to promote bone healing, and the antibiotics protect the implants from bacterial adhesion by releasing a broad-spectrum antibiotic. This combination has also been designed for use in other orthopedic surgical procedures, such as spine surgeries and joint replacements that require the filling of bone voids and that are also prone to infection.

  Penetration of antibiotics and other drugs from the blood stream into bone can be ineffective due to limited blood supply which results in inadequate delivery of sufficient dosages. The most severe open bone fracture cases frequently become infected and may require amputation of the limb despite the best available treatment and medications, both local and systemic. The antibiotics that are encapsulated by BonyPid-1000 are directly applied to the surgical site instead of being delivered through the blood supply. The entrapped antibiotics are released at an effective rate over a period of three to four weeks. In our clinical trials to date with BonyPid-1000, there have been no bone infection complications and no amputations despite the severity of the treated cases, suggesting a substantial improvement over current success rates. Additionally, the ability of BonyPid-1000 to permit immediate or early closure of the wound is an advance over current procedures and promotes earlier healing and reduces the risk of hospital-related bacterial contaminations. As a result, we believe that BonyPid-1000 has the potential to significantly reduce treatment costs because it can reduce the number of required recurring surgical procedures and the number, length and cost of hospitalizations. BonyPid-1000 also has the potential to be used in dental applications.

- BonyPid-500 allows bone regrowth in bacterially-infected dental sites surrounding dental implants. Current treatments of bone resorption around these dental implants are largely ineffective and often require implant removal. BonyPid-500 acts as a scaffold to support bone recovery and delivers antibiotics locally over a prolonged period to prevent local development of device-related microbial colonization, which subsequently may result in infections and bone resorption. We expect BonyPid-500 to reduce implant procedure costs and prevent prolonged and painful follow-on dental procedures. We are currently collaborating with MIS Implants Ltd. for the development and future commercialization of BonyPid-500 in the field of peri-implantitis — one of the potential applications of BonyPid-500 in the maxiofacial market. BonyPid-500 may also potentially be used in other dental applications such as periodontitis, ridge augmentation and sinus lifts. See “Business — Collaborations.”

- D-PLEX is in active development to treat infection and is directed at preventing and treating surgical site infections (known as SSI) addressing medical needs that are currently lacking effective solutions and that are of great concern to the medical community. D-PLEX is designed to provide localized infection treatment and prevention of soft tissues that will be administered locally during surgical procedures. SSI occur in varying percentages of surgical procedures despite administration of systemic antibiotics, depending on the procedure type. D-PLEX is expected to reduce the overall infection rate and overcome or reduce existing infections, including hospital-acquired resistant bacteria. D-PLEX is planned to be applied into a variety of tissues and solid organs to treat and prevent infections that may exist prior to, or appear after, surgery. Some possible examples include

abdominal surgeries such as colectomy, appendectomy and chronic bone infection (osteomyelitis). We expect, in 2015, to begin a limited clinical trial in Asia and to enter discussions with the FDA as to our clinical path in the United States.

Target Markets

Orthopedics. According to multiple published Millennium Research Group reports, in 2013 approximately one million annual orthopedic surgical procedures on open fractures requiring bone grafts were performed worldwide, with over 335,000 procedures in the United States. In a 2007 article in The Internet Journal of Orthopedic Surgery, it was reported that, depending on severity, up to 50% of these procedures result in bone infections. It was also reported that approximately 1,550,000 thoracolumbar and cervical spine procedures take place globally, of which around 720,000 were conducted in the United States. Two studies published in 2012 by the European Spine Journal show that between 2 – 10% of these shall incur infection, despite systemic antibiotic administration. Per the Millennium reports, approximately 328,500 hip and knee replacement revision surgeries took place, of which a total of 136,200 occurred in the United States. Almost all of these revision treatments, which are complications of primary hip and knee replacement surgeries, are expected to benefit from our product candidates.

Dental. According to multiple Millennium Research Group reports, there were over 12 million dental implants worldwide in 2013, and approximately 10 – 20% of dental implants become infected up to five years after implantation. Millennium also reports that approximately 4.2 million dental procedures such as sinus lifts, ridge augmentation and expansion surgeries and socket extractions took place in 2013 with the United States accounting for approximately 1,4500,000 of them.

SSI. According to the a datasheet published by the U.S. Centers for Disease Control and Prevention (CDC) in 2010 and several Millennium reports, of the 100 million interventional procedures conduced in the United States, approximately 30 million carry a risk of incurring surgical site infections (SSI) despite systemic antibiotic administration. In a 2001 report prepared for the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, 80 – 90% of surgeries use systemic antibiotic administration. As an example, according to numerous Millennium reports, there were approximately 1,500,000 primary hip replacements conducted globally during 2013, of which approximately 300,000 took place in the United States. Although almost all of these procedures are accompanied by antibiotic administration, around 11% of these procedures will still incur infections according to the American Journal of Health-System Pharmacy published in February 2013. Similarly, according to the above CDC report, approximately 305,000 colectomy procedures are performed annually in the United States. According to a 2014 Journal of Hospital Infection review, 14 – 18% of colectomy procedures result in infections despite systemic antibiotic treatment. These are just a few of many examples of the need for an effective, localized and prolonged antibiotic treatment that our product candidates are intended to address.

Research Programs

The following programs, based on our PLEX platform, are in the early research phase:

- Anti-Inflammatory Research Program. Systemic treatments are very effective for the treatment of inflamed conditions. However, wide use of anti-inflammatory agents is limited due to serious systemic side effects that include liver damage, heart disease, addiction and pain. We are developing a localized and controlled delivery of a very small, yet effective dose with minimal systemic side effects.
- Anti-Cancer Research Program. Systemic anti-cancer treatments have serious side effects. Our program is designed to treat cancer by extended localized release of common chemotherapeutic agents. The program is aimed at reducing the overall dose of toxic agents for a prolonged, local delivery while achieving effectiveness that is at least comparable to systemic administration.

Intellectual Property

Various aspects of our technology are protected by five patent families, including two issued patents (U.S. and China), 2 allowed patent applications and over 30 patent applications currently pending in Australia, Canada, China, the European Patent Office, India, Israel, Japan and the United States.

Strategy

Our goal is to become a leading specialty pharmaceutical company by developing, manufacturing and commercializing products based on our proprietary PLEX platform in the field of extended release, local drug delivery. These products are intended to address some of modern medicine's main challenges, where current local or systemic administration has limited effect, is too toxic, or both. Our primary focus is on the field of infection management.

Our commercial strategy has two elements: internal product development and collaboration and licensing. We intend to discover, develop and commercialize novel therapeutic products either on our own or in collaboration with partners. In orthopedics, we are in late stage clinical development. We plan to establish an independent sales force in the United States, Germany, and later in France, to commercialize our products, starting with BonyPid-1000. In geographies where we do not intend to market our products ourselves, we plan to team up with commercial partners for certain applications to benefit from their existing sales force and market reach.

We expect to collaborate with pharmaceutical companies through licensing and collaboration agreements for the encapsulation of their drugs (generic or proprietary) using our PLEX platform to enable administration of drugs in a localized, targeted manner. The purpose of these collaborations is to enhance our PLEX platform into a partnered product pipeline and to generate revenues through licensing of PLEX for certain applications. As a first step in this strategy, we have recently entered into a preliminary technology evaluation agreement with a large U.S. pharmaceutical company. We envision that this technology evaluation agreement may lead to discussions on a license and collaboration contract.

Competitive Strengths

Our PLEX-based product candidates offer three distinct potential advantages that together can overcome the limitations of other local delivery solutions:

- We can improve therapeutic effect by pre-determining the duration that a drug or a drug combination is most effectively released inside the body. We are capable of enabling drug delivery up to several months. For example, we have designed BonyPid-1000 with a drug release period of three to four weeks and PLEX with a drug release period of several months.
- We enhance safety and efficacy when we pre-define the rate and quantity of drugs released. As a result, our PLEX-based product candidates release a small but effective drug dose with the benefit of reducing potential adverse side effects, toxicity and costs. One vial of BonyPid-1000 for example, utilizes slightly more than 1% of the accepted 30-day systemic antibiotic regimen.
- We ensure that the drugs, encapsulated by PLEX technology, are fully active upon release by protecting them in a dry, secure, physical reservoir located at the area of the treated site. We are also able to encapsulate sensitive or unstable drugs over significant periods.

In the field addressed by BonyPid-1000, there are a number of companies that have regulatory approval to market products, incorporating anti-bacterial agents, outside the United States that are designed to assist in bone healing. These products include:

- PMMA beads/Septopal (Biomet Manufacturing Corp)
- Osteoset T (Wright Medical Group)
- Targobone (Ossacur AG)
- PerOssal (AAP implante AG)
- Certamet G (BoneSupport AB)

We believe that these products can be evaluated by five different criteria, namely:

- whether the product is biodegradable;
- the ability to support bone growth;

- the ability to pre-determine the release profile of the active drug;
- the ability to provide long-term release of up to weeks; and
- the stability of the drug reservoir in a hydrated environment.

We believe that BonyPid-1000 satisfactorily achieves each of these performance measures, and that the others meet one or two of the five criteria. We believe that meeting all five criteria is essential for successful treatment. Additional detail on competition can be found below under "BonyPid-1000 — *Existing approaches to support bone growth by the prevention of bone infection.*"

More generally, with regard to localized, prolonged drug delivery systems, there are drug delivery solutions in the market, such as those offered by Pacira Pharmaceuticals. Pacira's lead products, based on their DepoFoam technology, is a multivesicular liposome technology that encapsulates drugs and releases them over a period of several days. Similarly, Tyrx Inc. (acquired by Medtronic) markets a polymer-based local release solution called AIGISRx that elutes drugs over several days. We believe, however, that the technological solutions offered by these companies are less suited for the markets we are addressing and that our PLEX technology and related product candidates offer more flexible, long-term solutions.

Risks Associated with Our Business

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled "Risk Factors" immediately following this prospectus summary. These are not the only risks we face. These risks include, among others:

- We are an emerging specialty pharmaceutical company and have a limited operating history on which to assess our business, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future.
- Since inception, we have financed our operations almost entirely by the private placement of our preferred stock. Since inception, gross proceeds from the sale of our preferred stock were approximately $12.7 million in the aggregate. In addition, we received grants from (i) the Israeli Chief Scientist in the aggregate amount of $1.2 million and (ii) the European 7^{th} Framework Programme in the aggregate amount of $618,000. We believe that our current capital resources, without additional financing, may not be sufficient to support our operations beyond June 30, 2015.
- Even if this offering is successful, we expect that we will need to raise additional capital to complete our clinical trials, and such capital may not be available to us or available only on unfavorable terms. We currently estimate that we shall require approximately $7.5 million for clinical studies and regulatory approvals for our product candidates.
- To date, we have not generated revenue from the sale of any product, and we do not expect to generate revenue unless and until we obtain marketing approval of, and commercialize, our BonyPid-1000 and BonyPid-500. We are unable to predict the extent of future losses or when we will become profitable based on the sale of any product, if at all. Even if we succeed in developing and commercializing our product candidates, we may never generate sufficient revenue to sustain profitability. As of June 30, 2014 we had an accumulated deficit of $11.0 million.
- All of our product candidates are in pre-clinical or clinical development, and we cannot provide any assurance that any of our product candidates will receive any regulatory approvals.
- If we are unable to obtain and maintain effective intellectual property rights for our technologies, product candidates, or any future product candidates, we may not be able to compete effectively in our markets.
- Our future success depends in part upon our ability to retain our executive team and key consultants, and to attract, retain and motivate other qualified personnel.

- As a public company following the conclusion of this offering, we will need to comply with extensive additional governmental regulations, which will be expensive and which will require significant management attention.

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 4917002 Israel. Our telephone number is +972-74-7195700. 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

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not "emerging growth companies" including, but not limited to:

- the ability to provide only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure; and
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We intend to take advantage of these and other exemptions available to "emerging growth companies." We could remain an "emerging growth company" for up to five years following the completion of this offering.

Implications of being a Foreign Private Issuer

Our status as a foreign private issuer also exempts us from compliance with certain laws and regulations of the Securities and Exchange Commission, or the SEC, and certain regulations of the NASDAQ Stock Market, or NASDAQ, including the proxy rules, the short-swing profits recapture rules, the composition of various board committees and certain governance requirements such as independent director oversight of the nomination of directors and executive compensation. In addition, we will not be required to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as registered United States companies. These exemptions will be available to us as long as we qualify as a foreign private issuer. Thus, even if we no longer qualify as an emerging growth company but remain a foreign private issuer, we will be exempt from the more stringent compensation disclosures required of companies that are not either an emerging growth company or a foreign private issuer.

THE OFFERING

Ordinary shares offered by us	ordinary shares.
Ordinary shares to be outstanding after this offering	ordinary shares.
Over-allotment option	The underwriters have an option for a period of 45 days to purchase up to additional ordinary shares to cover over-allotments, if any.
Use of proceeds	We expect to receive approximately $ million in net proceeds from the sale of ordinary shares offered by us in this offering (approximately $ million if the underwriters exercise their over-allotment option in full), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming the shares are offered at $ per share, the midpoint of the estimated price range set forth on the cover of this prospectus. We currently expect to use the net proceeds from this offering in the following approximate amounts: • $2.5 million to advance our research and development activities of our product candidates; • Based on our current regulatory expectations, $7.5 million for clinical studies and regulatory approvals for our product candidates; and • $2 million to establish manufacturing facilities for some of our product candidates. The remainder will be used for working capital and general corporate purposes.
Risk factors	You should read the “Risk Factors” section starting on page 9 of this prospectus for a discussion of factors to consider carefully before deciding to invest in ordinary shares.
Proposed NASDAQ Capital Market Symbol	“PLPD”

The number of our ordinary shares to be outstanding immediately after this offering is based on ordinary shares outstanding as of June 30, 2014, and assumes or gives effect to:

- the conversion of all outstanding preferred shares into ordinary shares;
- the exercise immediately prior to the closing of this offering of warrants to purchase convertible series A preferred shares which will immediately convert into ordinary shares;
- the exercise immediately prior to the closing of this offering of warrants to purchase convertible series B-1 preferred shares which will immediately convert into ordinary shares;
- the issuance, in , 2014, of series B-1 preferred shares at a price of $ per share which will immediately convert into ordinary shares; and
- no exercise of outstanding options under our equity incentive plans.

All information in this prospectus assumes or gives effect to:

- the filing of our amended and restated articles of association, which will occur immediately prior to the effectiveness of the registration statement of which this prospectus is a part; and
- no exercise of the underwriters’ over-allotment option.

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, 2013 and 2012 and the balance sheet data as of December 31, 2013 from our audited financial statements included elsewhere in this prospectus. We have derived the following statements of operations data for the six month periods ended June 30, 2014 and 2013 and the balance sheet data as of June 30, 2014 from our unaudited interim financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The following summary financial data should be read in conjunction with "Selected Consolidated 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.

	Years Ended December 31,		Six months Ended June 30,	
	2013	2012	2014	2013
	(in thousands of U.S. dollars, except share and per share amounts)		*(in thousands of U.S. dollars, except share and per share amounts)*	
Statements of Operations Data:				
Research and development expenses, net	$ 2,641	$ 1,377	$ 1,499	$ 1,752
General and administrative expenses	938	410	874	463
Operating loss	3,579	1,787	2,373	2,215
Financial expenses, net	305	3	235	73
Net loss	3,884	1,790	2,608	2,288
Basic and diluted net loss per Ordinary share	$ 1.04	$ 0.48	$ 0.82	$ 0.63
Weighted average number of ordinary shares used in computing basic and diluted loss per share	4,500,000	4,500,000	4,500,000	4,500,000
Pro forma basic and diluted net loss per Ordinary share (unaudited)	$ 0.14		$ 0.07	
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share – pro forma (unaudited)	27,372,630		35,080,686	

	As of December 31, 2013			As of June 30, 2014		
	Actual	Pro Forma[1]	Pro Forma, As Adjusted (unaudited)[2]	Actual	Pro Forma[1]	Pro Forma, As Adjusted (unaudited)[2]
	(in thousands of U.S. dollars)			*(in thousands of U.S. dollars)*		
Balance Sheet data:						
Cash and cash equivalents	$ 1,263	$		$ 4,029	$ 4,092	
Total current assets	$ 1,604	$		$ 4,350	$ 4,413	
Total long-term assets	355			562	562	
Total current liabilities	502			984	984	
Total long-term liabilities	832			1,194	542	
Preferred shares warrant liability	332			652	—	
Convertible preferred shares	8,685			13,134	—	
Shareholders' equity (deficiency)	$ (8,060)	$		$(10,400)	$ 3,449	

(1) Pro forma gives effect to: (i) the conversion of all outstanding preferred shares into 30,048,123 ordinary shares; (ii) the exercise immediately prior to the closing of this offering of warrants to purchase convertible series A preferred shares which will immediately convert into 532,563 ordinary shares;

(2) Pro forma, as adjusted, gives additional effect to the sale of ordinary shares in this offering at the initial public offering price of $ per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, as if the sale had occurred on June 30, 2014.

RISK FACTORS

An investment in our ordinary shares involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this prospectus, including our financial statements and related notes thereto, before deciding to invest in our ordinary shares. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our ordinary shares could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Condition and Capital Requirements

We are a clinical-stage company and have a limited operating history on which to assess our business. We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We are an emerging specialty pharmaceutical company with a limited operating history focused on the discovery and development of advanced drug delivery systems. We have incurred net losses each year since our inception in 2008 including net losses of $3.9 million for the year ended December 31, 2013 and $2.6 million for the six-month period ended June 30, 2014. As of June 30, 2014 we have an accumulated deficit of $11 million.

We have devoted substantially all of our financial resources to design and develop our product candidates, including conducting preclinical and clinical studies and providing general and administrative support for these operations. To date, we have financed our operations primarily through the sale of equity securities, through royalty-bearing and non-royalty bearing grants that we received from Israel's Office of the Chief Scientist of the Ministry of Economy, or the OCS, non-royalty bearing grants under the European Commission's Seventh Framework Programme for Research (FP7) and advances from a potential collaborator. 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. Biopharmaceutical and drug-device combination product development is a highly speculative undertaking and involves a substantial degree of risk. We are still in research and development, preclinical development and clinical development stages for our product candidates, we have not yet commenced pivotal clinical studies for any product candidate and it may be a significant period of time, if ever, before we complete pivotal clinical studies and have a product candidate approved for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidates in those markets.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue and expand our research of our product candidates;
- initiate additional preclinical development, including toxicology, or other studies for our product candidates;
- further expand our clinical trial program for our product candidates;
- continue to improve our quality standards;
- secure second-source manufacturing of our product candidates and initiate limited in-house manufacturing capabilities;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify, assess, acquire, license, and/or develop other product candidates;

- enter into license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- invest in additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with 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.

Further, the net losses 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.

Our recurring operating losses have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring operating losses raise substantial doubt about our ability to continue as a going concern. Our financial statements include a note describing the conditions which raise this substantial doubt. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2013 and for the six-month period ended June 30, 2014, with respect to this uncertainty. We have no current source of revenue to sustain our present activities, and we do not expect to generate revenue until, and unless, the FDA or other regulatory authorities approve our product candidates and we successfully commercialize our product candidates. Accordingly, our ability to continue as a going concern will require us to obtain additional financing to fund our operations. The perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

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

We have no products approved for commercialization and have never generated any revenue. 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 before the first half of 2017. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and preclinical and toxicology and clinical development of our product candidates;
- obtaining regulatory and marketing approvals for our product candidates, if and when we complete clinical studies;
- developing and obtaining regulatory approval for a sustainable and scalable third-party manufacturing process and in-house manufacturing capabilities, meeting all regulatory standards for our approved product candidates, and in some instances, establishing and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate (in amount and quality) products to support clinical development and the market demand for our product candidates, if approved;
- launching and commercializing our product candidates, if and when we obtain regulatory and marketing approval, either directly or with collaborators or distributors;
- exposing, educating and training physicians to use our products;
- obtaining market acceptance of our product candidates as viable treatment options;

- ensuring our product candidates are approved for reimbursement from governmental agencies, health care providers and insurers;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patent applications, trade secrets, and know-how;
- attracting, hiring, and retaining qualified personnel; and
- locating and leasing or acquiring suitable facilities to support our growth.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency (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. In cases where we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. We may not generate significant revenue from sales of such products, even if approved. Further, if we are not able to generate revenue from the sale of any approved products, we may be forced to cease operations.

Even if this offering is successful, we expect that we will need to raise substantial additional funding before we can expect to become profitable from product sales. This additional financing may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit, or terminate our product development efforts or other operations.

We are currently advancing our product candidates through preclinical and clinical development and regulatory approval. 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.

If our product candidates enter and advance through research, preclinical studies and clinical trials, either pre- or post-marketing study or studies, and regulatory approval, and ultimately commercialization, we will need substantial additional funds to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with other organizations to provide these capabilities for us. We have used substantial funds to develop our product candidates and will require significant funds to conduct further research and development and preclinical testing and clinical trials of our product candidates, to seek regulatory approvals for our product candidates and to manufacture and market products, if any, which are approved for commercial sale.

As of June 30, 2014, our cash and cash equivalents were $4 million. Our existing cash resources, and together with anticipated grants from OCS as well as participations in our research and development programs, may not be sufficient to fund our projected cash requirements through June 30, 2015. Therefore, we will require significant additional financing in the future to fund our operations. If we do not generate sufficient cash through this offering or otherwise, however, our cash on hand may not be sufficient to meet our anticipated cash needs. For this reason, Note 1b to our interim financial statements for the six months ended June 30, 2014 and to our audited financial statements for the year ended December 31, 2013 include references to substantial doubt about our ability to continue as a going concern. In addition, the independent public accountants' report for the year ended December 31, 2013 includes an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern. We currently anticipate that, assuming consummation of the current offering, we will advance current and planned research programs, complete the clinical development of our three lead product candidates, file the appropriate submissions of

such product candidates for regulatory approval, establish a manufacturing facility for the production of some of our product candidates and use the remainder for working capital and general corporate purposes.

In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including but not limited to:

- the scope, rate of progress, results and cost of our clinical studies, post marketing studies if needed, preclinical testing, toxicology studies, and other related activities of our product candidates;
- the cost of manufacturing clinical supplies, and establishing commercial supply of our product candidates and any future products;
- the number and characteristics of product candidates that we pursue;
- the cost, timing, and outcomes of regulatory approvals for our product candidates;
- the cost and timing of establishing sales, marketing, and distribution capabilities; and
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish.

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. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and 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. The incurrence of indebtedness could result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable, and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results, and prospects. Even if we believe 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.

If we are unable to obtain funding 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 product candidates, 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.

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

We may seek additional capital through a combination of private and public equity offerings, 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 may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt or making capital expenditures. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that are not favorable to us.

Risks Related to the Discovery and Development of Our Product Candidates.

The approach we are taking to discover and develop novel drug delivery solutions and drug-device combination products is novel and may never lead to marketable products.

We have concentrated our efforts and product research on drug delivery technology and drug-device combination products, 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.

We are heavily dependent on the success of our product candidates, including BonyPid-1000 and BonyPid-500, which are still in research, preclinical or clinical development. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

To date, we have invested all of our efforts and financial resources to: (i) research and develop our product candidates, including BonyPid-1000 and BonyPid-500, 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 then successfully commercialize one or more of our product candidates. We currently generate no revenue from sales of any drugs or drug-devices combination or technology platforms, nor from any technology licensing agreements (even though we have received certain cash advances) and we may never be able to develop or commercialize a marketable drug or drug-device combination.

Our first product candidate is in clinical development and will require additional clinical development (and in some cases additional preclinical development), managing of nonclinical, clinical and manufacturing activities, regulatory approval, obtaining adequate manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenue from product sales. None of our product candidates have advanced into a pivotal study. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

Other than in connection with BonyPid-1000, we have never submitted marketing applications to the FDA or comparable foreign regulatory authorities. We cannot be certain that any of our product candidates will be successful in clinical studies or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical studies. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

We plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union, or the EU, and in additional foreign countries. To obtain regulatory approval, we must comply with numerous and varying regulatory requirements regarding safety, efficacy, chemistry, manufacturing and controls, clinical studies, commercial sales, pricing, and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions, or will pass any post-approval tests. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical studies, and depends upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve a marketing application.

We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's safety-benefit ratio for its proposed indication is acceptable;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical studies;
- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of a new drug application, or NDA, or a biologics license application, or BLA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA and/or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical studies, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct additional clinical studies to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process.

Clinical trials can be delayed, prevented or terminated for a number of reasons, including, but not limited to:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on the design of clinical studies;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;
- failure to recruit a Principal Investigator of suitable caliber to manage the clinical studies;
- imposition of a clinical hold by regulatory agencies, after review of an investigational new drug, or IND, application, or equivalent application, or an inspection of our clinical study operations or study sites;
- difficulties collaborating with patient groups and investigators;

- challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including size and nature of subject population, proximity of subjects to clinical sites, eligibility criteria for the trial, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- failure by our CROs, other third parties, or us to adhere to current Good Clinical Practices, or cGCP, and the requirements of the clinical study protocols;
- failure to perform in accordance with the FDA's cGCP requirements or applicable regulatory guidelines in other countries;
- unforeseen safety issues, including the occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding, or regulators requiring us, to conduct additional clinical studies or abandon drug development programs;
- failures associated with data interpretation, data management and data storage of such studies;
- government or regulatory delays and changes in regulatory requirements, policies and guidelines;
- failures associated with data interpretation, data management and data storage of such studies; and
- lack of adequate funding to continue the clinical trial.

If we ultimately are unable to successfully complete clinical development of our product candidates, we would be forced to cease operations. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, and to successfully commercialize our product candidates.

Positive results in previous pre-clinical and clinical trials of our product candidates may not be replicated in future clinical trials of our product candidates, which could result in development delays or a failure to obtain marketing approval.

Positive results in previous pre-clinical and clinical studies of product candidates may not be predictive of similar results in future clinical trials. Also, interim results during a clinical trial do not necessarily predict final results. In general, even product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent registration clinical studies. There is a high failure rate for drugs, biologics and medical devices proceeding through clinical studies, and product candidates in later stages of clinical studies may fail to show the desired safety and efficacy profiles, data or results, despite having progressed through preclinical studies and initial clinical studies. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain FDA approval for their products.

We may find it difficult to enroll patients in our clinical studies. Difficulty in enrolling patients could delay or prevent clinical studies of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies 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 studies if we encounter difficulties in enrollment.

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 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 or other comparable foreign authorities. 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 or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications.

The 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 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 withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, 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 could be sued and held liable for harm caused to patients; 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 obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

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. 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. We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs devices, and drug-device combinations 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 approval. The holder of an approved NDA or BLA 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. If we obtain initial marketing approval via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical study to confirm clinical benefit for our product candidates. 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;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us; or
- seize or detain products, or require a product recall.

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.

We and our collaborators are subject to significant regulation with respect to manufacturing our product candidates. Our contract manufacturing organization may not meet regulatory requirements and have limited capacity.

All entities involved in the preparation and manufacturing of therapeutics for clinical studies or commercial sale are subject to extensive regulation. A finished therapeutic product, including all components thereof, approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with current good manufacturing practices, or cGMP. In addition, manufacturers of medical devices are subject to Quality System Regulation, or QSR. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of product candidates and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaborators, or any contract manufacturers must supply all necessary documentation in support of an NDA, BLA, or Marketing Authorization Application, or MAA, on a timely basis and must adhere to Good Laboratory Practices, or GLP, cGMP and QSR regulations enforced by the FDA and other regulatory agencies through their facilities inspection programs. We have never produced a commercially approved pharmaceutical product or medical device and therefore have not obtained the requisite regulatory authority approvals to do so. The manufacturing facilities of our collaborators and any third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, regulatory approval

of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit a manufacturing facility. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we, our collaborators, or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or medical device, withdrawal of an approval, or suspension of production. As a result, our business, financial condition, and results of operations may be materially harmed.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical studies, regulatory submissions, required approvals, or commercialization of our product candidates.

Risks Related to our Reliance on Third Parties

We rely on third parties to conduct our preclinical and clinical studies 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, and our business could be substantially harmed.

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 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 cGMP, QSR, 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 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, 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. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical studies comply with cGCP regulations. In addition, our clinical studies must be conducted with products produced under cGMP regulations. 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 on-going 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. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

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, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

We rely on third parties to manufacture the raw materials and products that we use to create our product candidates and to supply us with the medical devices used to administer such products. Our business could be harmed if those 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 do not currently have the infrastructure or capability internally to manufacture the raw materials and other products that we use to manufacture our product candidates, and we lack the resources and the capability to manufacture the medical devices which we use to administer our products. There are a limited number of suppliers for these raw materials, products and devices, and there may be a need to identify alternate suppliers to prevent a possible disruption to our clinical studies, 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.

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.

Risks Related to Commercialization of 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. In addition, medical advances may reduce our target markets. For example, new processes and advances in oral antibiotic medications may limit the need for localized delivery systems such as BonyPid-1000 in some of our product candidates. Also, advances in treatments in the fields in which we are conducting research programs (such as, among others, the ones disclosed in this document) that reduce side effects and have better deliverability to target organs may limit the market for our future product candidates.

We do not have experience producing our product candidates at commercial levels 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 have not entered into binding agreements with 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 such manufacturers. We may be unable to negotiate binding agreements with the manufacturers to support our commercialization activities at commercially reasonable terms. Additionally, these third party manufacturers may not be able to supply us with the necessary quantities of these raw materials and products to support our own manufacturing process, or in compliance with cGMP or other pertinent regulatory requirements, and within our planned timeframe and estimated cost parameters, and the development and sales of our products, if approved, may be materially harmed.

Some of our products are more suitable for emerging countries, and in these countries there may be less availability of adequate funds or healthcare insurance to successfully adopt wide use of our products.

The potentially addressable patient population for each of our product candidates may be limited. In addition, some of our products are more suitable for emerging countries. For example, the demand for our BonyPid-1000 product candidate for open fracture markets is expected to be higher in emerging countries where there may be a higher incidence of open fractures. In these countries there may be less availability of adequate funds or healthcare insurance to successfully adopt wide use of our products.

We face intense competition and 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 commercialize our product candidates.

The biotechnology and pharmaceutical industries are 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. Other approaches may also emerge for the treatment of any of the disease areas in which we focus.

We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, specialty pharmaceutical companies, and biotechnology 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.

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 revenue.

We as a company have no experience selling and marketing our product candidates, and we currently have no marketing or sales organization. To successfully commercialize any products 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 the commercialization of our products.

Further, given our lack of prior experience in marketing and selling biopharmaceutical 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 as a result of hiring 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. If our future collaborators do not commit sufficient resources to 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 be competing 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.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid for by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government authorities, private health insurers, and other third-party payors. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about coverage and reimbursement are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products such as ours. Currently, there are no separate, distinct Current Procedural Terminology, or CPT, codes that accurately describe the application or insertion of synthetic bone void fillers. The insertion of our product candidates is likely to be performed in conjunction with another more significant procedure, for which there may be existing codes. Some of these codes may include the insertion of bone void filler and for some procedures, it is likely that there is no inclusion of the insertion of a bone void filler as part of the procedure described by that code. Currently, it is not expected that Medicare will reimburse for our product candidates. It is our further understanding that several companies have attempted obtaining separate reimbursement codes that would directly cover the insertion of different bone void fillers, but have been unsuccessful.

As a result of these factors, there are no assurances that adequate third-party coverage will be available for us to establish and maintain price levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Current cost containment and health care reform initiatives add additional uncertainty.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has, and will continue to, put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicinal products and devices, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product

candidates. Accordingly, in markets outside the United States, the reimbursement for our products candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved, and, as a result, they may not cover or provide adequate payment for our product candidates. 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 entry of new products.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Health Care Reform Law, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. On March 1, 2013, the President signed an executive order implementing sequestration, and on April 1, 2013, the 2% Medicare payment reductions went into effect. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

If we receive marketing approval for our product candidates, sales will be limited unless the product achieves broad market acceptance.

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

- demonstration of clinical safety and efficacy compared to other products;
- the prevalence and severity of any adverse side effects;
- limitations or warnings contained in the 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;
- availability of alternative treatments;
- pricing and cost effectiveness;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- the willingness of patients to pay for drugs out of pocket in the absence of third-party coverage.

If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, 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.

Risks Related to Competition

The markets for pharmaceutical and drug-device combination products are intensely competitive. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we may be unable to commercialize successfully any products that we develop.

The markets for pharmaceutical and medical device are intensely competitive and rapidly changing. Many large companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs and medical devices. Many of our competitors have:

- much greater financial, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization of products;
- more extensive experience in pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufacturing, marketing and selling pharmaceutical and medical device products;
- product candidates that are based on previously tested or accepted technologies;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

We will face intense competition from drugs and drug device combination products that have already been, or may in the future become approved and accepted by the medical community. We also expect to face competition from new drugs and medical devices that enter the market. We believe a significant number of these products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may try to develop drugs and therapies. These drugs may be more effective, safer, less expensive, or marketed and sold more effectively, than any product candidate we develop.

Our competitors may develop or commercialize products with significant advantages over any products we develop. Our competitors may therefore be more successful in commercializing their products than us, which could adversely affect our competitive position and business. Competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses of developing and commercializing our product candidates.

We face competition from other companies that are working to develop novel drugs and technology platforms using technology in the same field as ours. If these companies develop products more rapidly than we do or their technologies, including delivery technologies, are more effective, our ability to successfully commercialize drugs may be adversely affected.

We face competition from other companies working to develop novel products using technology that competes more directly with our own. We are aware of multiple companies that are working in the field of drug delivery systems, including major pharmaceutical companies. Also, we compete with companies commercializing and/or working to develop drug delivery systems, including drug delivery systems for local (or regional) release.

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 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 will 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 1, 2014, our portfolio of owned patents and patent applications consists of five patent families protecting various aspects of our technology, that collectively, contain two issued patents (in the United States and China), two allowed patent applications and over 30 patent applications currently pending in Australia, Canada, China, the European Patent Office, India, Israel, Japan and the United States. 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 and medical device 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 it is filed. Although various extensions may be available, 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, in the United States prior to March 15, 2013, the first to make the 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 Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be 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 act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act 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 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 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 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 for 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 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 and medical device industries expand 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 Leahy-Smith Act, 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 and medical device industries 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 can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States.

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, 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 and medical device 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.

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 our existing product candidates, 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.

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

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and NASDAQ has imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and pay parity. Recent legislation permits smaller "emerging growth companies" to implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of this

new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we will be required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report, commencing in our annual report on Form 20-F for the year ending December 31, 2015, on the effectiveness of our internal controls over financial reporting, if then required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner or if we identify, or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline, and we could be subject to sanctions or investigations by NASDAQ, the SEC, or other regulatory authorities, which would require additional financial and management resources.

New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act and rules adopted by the SEC and by NASDAQ, would likely result in increased costs to us as we respond to their requirements.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims 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 customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. 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 federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Health Care Reform Laws requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, 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, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and
- 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 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.

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, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends 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, the Health Care Reform Law 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.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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 and patient association outreach activities, as well as clinical trials, outside of the United States 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 products 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, 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 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.

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees 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, 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 misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, 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. 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.

Risks Related to this Offering and Ownership of Our Ordinary Shares

We may be a "passive foreign investment company", or PFIC, for U.S. federal income tax purposes in the current taxable year or may become one in any subsequent taxable year. There generally would be negative tax consequences for U.S. taxpayers that are holders of our ordinary shares if we are or were to become a PFIC.

We will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (1) at least 75% of our gross income is "passive income" or (2) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. 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 cannot rule out that we will not be a PFIC for our current taxable year or in the future. The tests for determining PFIC status are applied annually, and it is difficult to make accurate projections of future income and assets which are relevant to this determination. In addition, our PFIC status may depend in part on the market value of our ordinary shares. Accordingly, there can be no assurance that we currently are not or will not become a PFIC in the future. If we are a PFIC in any taxable year during which a U.S. taxpayer holds our ordinary shares, such U.S. taxpayer would be subject to certain adverse U.S. federal income tax rules. In particular, if the U.S. taxpayer did not make an election to treat us as a "qualified electing fund," or QEF, or make a "mark-to-market" election, then "excess distributions" to the U.S. taxpayer, and any gain realized on the sale or other disposition of our ordinary shares by the U.S. taxpayer: (1) would be allocated ratably over the U.S. taxpayer's holding period for the ordinary shares; (2) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (3) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the IRS determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. taxpayer to make a timely QEF or mark-to-market election. U.S. taxpayers that

have held our ordinary shares during a period when we were a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. taxpayer who made a timely QEF or mark-to-market election. A U.S. taxpayer can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. We do not intend to notify U.S. taxpayers that hold our ordinary shares if we believe we will be treated as a PFIC for any taxable year in order to enable U.S. taxpayers to consider whether to make a QEF election. In addition, we do not intend to furnish such U.S. taxpayers annually with information needed in order to complete IRS Form 8621 and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC. U.S. taxpayers that hold our ordinary shares are strongly urged to consult their tax advisors about the PFIC rules, including tax return filing requirements and the eligibility, manner, and consequences to them of making a QEF or mark-to-market election with respect to our ordinary shares in the event that we are a PFIC. See "Taxation — U.S. Federal Income Tax Consequences — Passive Foreign Investment Company Rules" for additional information.

The market price of our ordinary shares may be highly volatile, and you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, there has not been a public market for our shares. If an active trading market for our ordinary shares does not develop following this offering, you may not be able to sell your shares quickly or at the market price. The initial public offering price for the shares will be determined by negotiations between us and representatives of the underwriters and may not be indicative of prices that will prevail in the trading market.

The trading price of our ordinary shares is likely to be volatile. 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 and medical devices.

In addition, the stock market in general, and NASDAQ in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of small companies. Broad market and industry factors may negatively affect the market price of our ordinary shares, regardless of our actual operating performance. Further, a systemic decline in the financial markets and related factors beyond our control may cause our share price to decline rapidly and unexpectedly.

We may be subject to securities litigation, which is expensive and could divert management attention.

In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could seriously hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

Our principal shareholders, chief executive officer and directors currently own over 74% of our outstanding ordinary shares and will own approximately % of our ordinary shares upon the closing of this offering. They will therefore be able to exert significant control over matters submitted to our shareholders for approval.

After this offering, our chief executive officer and directors, and shareholders who own more than 5% of our outstanding ordinary shares before this offering will, in the aggregate, beneficially own approximately % of our ordinary shares (assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options). This significant concentration of share ownership may adversely affect the trading price for our ordinary shares because investors often perceive disadvantages in owning stock in companies with controlling shareholders. As a result, these shareholders, if they acted together, could significantly influence or even unilaterally approve matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these shareholders may not always coincide with our interests or the interests of other shareholders.

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 is substantially higher than the net tangible book value per share of our ordinary shares. Investors purchasing ordinary shares in this offering will pay a price per share that substantially exceeds the net tangible book value of our ordinary shares. As a result, investors purchasing ordinary shares in this offering will incur immediate dilution of $ per share, based on the initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus) and our pro forma net tangible book value as of June 30, 2014. In addition, as of the date of this prospectus, options and warrants to purchase 6,858,815 of our ordinary shares at a weighted average exercise price of $0.34 per share were outstanding. The exercise of these options and warrants would result in additional dilution. As a result of this dilution, investors purchasing shares in this offering may receive significantly less than the purchase price paid in this offering in the event of liquidation. For more information, please refer to the section of this prospectus entitled "Dilution."

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 section of this prospectus entitled "Shares Eligible for Future Sale." 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.

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

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.

Because we do not intend to declare cash dividends on our ordinary shares in the foreseeable future, shareholders must rely on appreciation of the value of our ordinary shares for any return on their investment.

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, only appreciation of the price of our ordinary shares, if any, will provide a return to investors in this offering.

The JOBS Act and our status as a foreign private issuer will allow us to postpone the date by which we must comply with some of the laws and regulations intended to protect investors and to reduce the amount of information we provide in our reports filed with the SEC, which could undermine investor confidence in our company and adversely affect the market price of our ordinary shares.

For so long as we remain an “emerging growth company” as defined in the JOBS Act, we intend to take advantage of certain exemptions from various requirements that are applicable to public companies that are not “emerging growth companies” including:

- the provisions of the Sarbanes-Oxley Act requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- the “say on pay” provisions requiring a non-binding shareholder vote to approve compensation of certain executive officers and the “say on golden parachute” provisions requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations of the Dodd-Frank Act and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer;
- Section 107 of the JOBS Act, which 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. This means that an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are electing to delay such adoption of new or revised accounting standards. As a result of this adoption, our financial statements may not be comparable to companies that comply with the public company effective date;
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Securities Exchange Act of 1934, or the Exchange Act, and instead provide a reduced level of disclosure concerning executive compensation;

- our ability not to comply with new accounting principles that do not apply to public companies until such accounting principles become applicable to private companies;
- any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements; and
- our ability to furnish two rather than three years of income statements and statements of cash flows in various required filings.

We intend to take advantage of these exemptions until we are no longer an "emerging growth company." We will remain an emerging growth company until the earlier 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 revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our ordinary shares that is held by non-affiliates exceeds $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Our status as a foreign private issuer also exempts us from compliance with certain SEC laws and regulations and certain regulations of NASDAQ, including the proxy rules, the short-swing profits recapture rules, and certain governance requirements such as independent director oversight of the nomination of directors and executive compensation. Furthermore, as a foreign private issuer, we are also not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act.

We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares, and our share price may be more volatile and may decline.

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 officers and directors are residents of Israel. Accordingly, 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. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. During the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party and since March 2011, there has been a civil war in Syria, Israel's neighboring country to the north. Occasionally, violence from Syria has spilled over into Israel, and Israel has responded militarily several times since the onset of the civil war. During November 2012 and July 2014, Israel was engaged in an armed conflict with a militia group and political party which controls the Gaza Strip. These conflicts involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees and some of our consultants are located, and negatively affected business conditions in Israel. Any potential future conflict could also include such missile strikes against other parts of Israel, including the Company's offices and laboratories. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions, could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business may sometimes decline to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government has in the past covered the reinstatement value of certain damages that were 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. Any armed conflicts or political instability in the region would likely negatively affect business conditions generally and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial conditions or the expansion of our business.

Our operations may be disrupted as a result of the obligation of management or key personnel to perform military service.

Our male employees and consultants in Israel, including members of our senior management, may be obligated to perform one month, and in some cases longer periods, of annual military reserve duty until they reach the age of 40 (or older, for citizens who hold certain positions in the Israeli armed forces reserves) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be similar large-scale military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of our officers, directors, employees and consultants. Such disruption could materially adversely affect our business and operations.

Our operations are subject to currency and interest rate fluctuations.

We incur expenses in U.S. dollars, Euros and New Israeli Shekels, but our functional currency is the U.S. dollar. As a result, we are affected by foreign currency exchange fluctuations through both translation risk and transaction risk. In particular, strengthening of the New Israeli Shekel against the U.S. dollar may have a material adverse effect on our operating results.

We received Israeli government grants for certain of our research and development activities. The terms of those grants may require us to pay royalties and to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. We may be required to pay penalties in addition to repayment of the grants.

Our research and development efforts have been financed in part through royalty-bearing and non-royalty-bearing grants in an aggregate amount of approximately $1.2 million that we received from the OCS as of June 30, 2014. The current OCS approved research and development grants end on December 31, 2014. With respect to the royalty-bearing grants we are committed to pay royalties at a rate of 3% to 5% on sales proceeds from our products that were developed under OCS 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. Regardless of any royalty payment, we are further required to comply with the requirements of the Israeli Encouragement of Industrial Research and Development 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 OCS grants, the terms of these grants and the Research Law restrict the transfer 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 OCS. Therefore, the discretionary approval of an OCS committee would be required for any transfer to third parties inside or outside of Israel of know how or manufacturing or manufacturing rights related to those aspects of such technologies. We may not receive those approvals. Furthermore, the OCS may impose certain conditions on any arrangement under which it permits us to transfer technology or development out of Israel.

The transfer of OCS-supported technology or know-how outside of Israel may involve the payment of significant amounts, depending upon the value of the transferred technology or know-how, our research and development expenses, the amount of OCS support, the time of completion of the OCS-supported research project and other factors. These restrictions and requirements for payment may impair our ability to sell 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 OCS funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the OCS.

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, our company, 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. See "Taxation — Israeli Tax Considerations" for additional information.

Our amended and restated articles of association that will be in effect immediately prior to the consummation of this offering will also contain provisions that could delay or prevent changes in control or changes in our management without the consent of our Board of Directors. These provisions will include the following:

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; and
- the exclusive right of our Board of Directors to elect a director to fill a vacancy created by the expansion of the Board of Directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our Board of Directors.

It may be difficult to enforce a judgment of a United States court against us and our officers and directors and the Israeli experts named in this prospectus in Israel or the United States, to assert United States securities laws claims in Israel or to serve process on our 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 necessarily be enforced by an Israeli court. It also may be difficult for you to affect 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 United States securities laws in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of United States 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 United States law is applicable to the claim. If United States law is found to be applicable, the content of applicable United States 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 United States 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 typical U.S.-based corporations. In particular, a shareholder of an Israeli company has certain duties to act in good faith and fairness toward the Company and other shareholders and to refrain from abusing its power in the Company. See “Management — Shareholder Duties” for additional information. There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements made under "Prospectus Summary," "Risk Factors," "Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and elsewhere in this prospectus constitute forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" "intends" or "continue," or the negative of these terms or other comparable terminology.

Forward-looking statements include, but are not limited to, statements about:

- our timeline for our product candidate development path, including the anticipated starting and ending dates of our anticipated clinical trials;
- anticipated actions of the FDA or other regulatory bodies, including approval to conduct clinical trials, the scope of those trials and the prospects for regulatory approval of, or other regulatory action with respect to our product candidates;
- the commercial launch and future sales of our existing product candidates or any other future potential product candidates;
- our ability to achieve favorable pricing;
- our expectations regarding the commercial supply of our products;
- third-party payor reimbursement for our products;
- our estimates regarding anticipated capital requirements and our needs for additional financing;
- the patient market size and market adoption of our product candidates by physicians and patients;
- the timing, cost or other aspects of the commercial launch of our product candidates;
- completion and receiving favorable results of our anticipated clinical trials; and
- our expectations regarding licensing, acquisitions and strategic partnering.

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

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this prospectus.

USE OF PROCEEDS

We expect to receive approximately $ million in net proceeds from the sale of ordinary shares offered by us in this offering (approximately $ million if the underwriters exercise their over-allotment option in full), after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds from this offering in the following approximate amounts:

- $2.5 million to advance our research and development activities of our product candidates;
- Based on our current regulatory expectations, $7.5 million for clinical studies and regulatory approvals for our product candidates; and
- $2 million to establish manufacturing facilities for some of our product candidates.

The remainder will be used for working capital and general corporate purposes.

The amounts and timing of our actual expenditures will depend upon numerous factors, including the progress of our development and commercialization efforts, the status of and results from our clinical trials, whether or not we enter into strategic collaborations or partnerships, and our operating costs and expenditures. Accordingly, our management will have significant flexibility in applying the net proceeds of this offering.

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

DIVIDEND POLICY

We have never declared or paid any cash dividends on our ordinary shares and do not anticipate paying any 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 and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors 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 — Israeli Tax Considerations" for additional information.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2014:

- on an actual basis;
- on a pro forma basis to reflect as of June 30, 2014: (i) the conversion of all outstanding preferred shares into ordinary shares; (ii) the exercise immediately prior to the closing of this offering of warrants to purchase convertible series A preferred shares which will immediately convert into ordinary shares; and
- on a pro forma as adjusted basis to also give effect to the sale of ordinary shares in this offering at the initial public offering price of $ per share (the midpoint of the range set forth on the cover page of this prospectus), after deducting underwriting discounts and commissions and estimated offering expenses payable by us, at the closing of the offering, as if the sale of the shares in each case had occurred on June 30, 2014.

You should read this table in conjunction with the sections titled “Selected Financial Data” and “Management's Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this prospectus.

	June 30, 2014		
	Actual	Pro Forma	Pro Forma. As Adjusted (unaudited)
	(in thousands, except share and per share data)		
Preferred A, A-1, B and B-1 shares of NIS 0.1 par value	13,134	—	
Shareholders' equity (deficiency):			
Ordinary shares of NIS 0.10 par value	125	1,015	
Additional paid-in capital	516	13,475	
Accumulated deficit	(11,041)	(11,041)	
Total shareholders' equity (deficiency)	(10,400)	3,449	
Total capitalization	$ 2,734	$ 3,449	

DILUTION

If you invest in our ordinary shares, you will experience immediate and substantial dilution to the extent of the difference between the initial public offering price of our ordinary shares and the pro forma as adjusted net tangible book value (deficit) per share of our ordinary shares immediately after the offering.

- Our pro forma net tangible book value (deficit) per share is determined by dividing our total tangible assets, less total liabilities, by the actual number of outstanding ordinary shares as of June 30, 2014, after giving retroactive effect on a pro forma basis to reflect as of June 30, 2014: (i) the conversion of all outstanding preferred shares into 30,048,123 ordinary shares; (ii) the exercise immediately prior to the closing of this offering of warrants to purchase convertible series A preferred shares and of warrants to purchase convertible series B-1 preferred shares which will immediately convert into 532,563 ordinary shares; and
- on a pro forma as adjusted basis also gives effect to the sale of ordinary shares in this offering at the initial public offering price of $ per share (the midpoint of the range set forth on the cover page of this prospectus), after deducting underwriting discounts and commissions and estimated offering expenses payable by us, at the closing of the offering, as if the sale of the shares in each case had occurred on June 30, 2014: (i) the conversion of all outstanding preferred shares into ordinary shares; (ii) the exercise immediately prior to the closing of this offering of warrants to purchase convertible series A preferred shares which will convert into ordinary shares; (iii) the exercise immediately prior to the closing of this offering of warrants to purchase convertible series B-1 preferred shares which will convert into 82,563 ordinary shares; and (iv) the issuance, in , 2014, of series B-1 preferred shares at a price of $ per share, which will immediately convert into ordinary shares; The pro forma net tangible book value (deficit) of our ordinary shares as of June 30, 2014 was $3.4 million or $0.1 per share.

The pro forma as adjusted net tangible book value (deficit) of our ordinary shares as of June 30, 2014 was $, or $ per share. The pro forma as adjusted net tangible book value (deficit) gives additional effect to the sale of ordinary shares in this offering at the initial public offering price of $ per share (the midpoint of the range set forth on the cover page of this prospectus), after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The difference between the initial public offering price and the pro forma as adjusted net tangible book value (deficit) per share represents an immediate dilution of $ per share to new investors purchasing ordinary shares in this offering.

The following table illustrates this dilution on a per share basis to new investors:

Assumed initial public offering price per share	$
Pro forma net tangible book value per share before this offering, as of June 30, 2014	
Increase in pro forma net tangible book value per share attributable to new investors in this offering	
Pro forma net tangible book value per share after offering	
Dilution in pro forma tangible book value per share to new investors	$

If the underwriters' over-allotment option to purchase additional shares from us is exercised in full, and based on the initial public offering price of $ per share, the pro forma as adjusted net tangible book value (deficit) per share after this offering would be approximately $ per share, the increase in the pro forma net tangible book value (deficit) per share attributable to new investors would be approximately $ per share, and the dilution to new investors purchasing shares in this offering would be approximately $ per share.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per ordinary share would increase (decrease) our pro forma net tangible book value per share by $ and the dilution per ordinary share to new investors by $, 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.

The table below summarizes as of June 30, 2014, on the pro forma as adjusted basis described above, the number of ordinary shares we issued and sold, the total consideration we received and the average price per share (1) paid by our existing shareholders and (2) to be paid by new investors purchasing our ordinary shares in this offering at the initial public offering price of $ per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing shareholders		%	$	%	$
New investors		%			
Total		100%	$	100%	$

To the extent that new options, not mentioned above, are granted under our equity benefit plans, there will be further dilution to investors purchasing ordinary shares in this offering.

SELECTED FINANCIAL DATA

The following tables summarize our financial data. We have derived the following statements of operations data for the years ended December 31, 2013 and 2012 and the balance sheet data as of December 31, 2013 from our audited financial statements included elsewhere in this prospectus. We have derived the following statements of operations data for the six month periods ended June 30, 2014 and 2013 and the balance sheet data as of June 30, 2014 from our unaudited interim financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The following summary 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. The tables have been prepared on an actual historical basis, and do not give effect to the pro forma adjustments referred to in the immediately preceding section called "Dilution."

	Years ended December 31,		Six months ended June 30,	
	2013	2012	2014	2013
	(in thousands of U.S. dollars, except share and per share amounts)			
Statements of Operations Data:				
Research and development expenses, net	$ 2,641	$ 1,377	$ 1,499	$ 1,752
General and administrative expenses	938	410	874	463
Operating loss	3,579	1,787	2,373	2,215
Financial expenses, net	305	3	235	73
Net Loss	3,884	1,790	2,608	2,288
Basic and diluted net loss per Ordinary share	$ 1.04	$ 0.48	$ 0.82	$ 0.63
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	4,500,000	4,500,000	4,500,000	4,500,000
Pro forma basic and diluted net loss per Ordinary share (unaudited)	$ 0.14		$ 0.07	
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share – pro forma (unaudited)	27,372,630		35,080,686	

	Years ended December 31,		Six months ended June 30,
(in thousands of U.S. dollars)	2013	2012	2014
Balance Sheet Data:			
Cash and cash equivalents	$ 1,263	$ 977	$ 4,029
Total current assets	1,604	1,184	4,350
Total long-term assets	355	365	562
Total current liabilities	502	212	984
Total long-term liabilities	832	118	1,194
Preferred shares warrant liability	332	46	652
Convertible preferred shares	8,685	5,768	13,134
Shareholders' equity (deficiency)	(8,060)	(4,549)	(10,400)

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

The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of the prospectus contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this prospectus.

Introduction

We are an emerging specialty pharmaceutical company engaged in research and development of our product candidates based on PLEX, our proprietary drug delivery technology. PLEX (abbreviation for Polymer-Lipid Encapsulation MatriX) is able to encapsulate many types of drugs to enable targeted, localized drug delivery into the body over periods of time ranging from days to several months. The application of our PLEX technology in our product candidates enables us to optimize drug treatment regimens with release rates and durations that are pre-determined by us, a combination of attributes not currently available. We are a clinical stage company, meaning that our product candidates are yet to be approved for sale by any regulatory agency.

To date, we have not generated revenue from the sale of any product, and we do not expect to generate significant revenue unless and until we obtain marketing approval of, and commercialize our product candidates. As of December 31, 2013, we had an accumulated deficit of $8.4 million and as of June 30, 2014, we had an accumulated deficit of $11 million. Our financing activities are described below under "Liquidity and Capital Resources."

In February, 2013, we signed a memorandum of understanding (the "MOU"), with MIS Implants Technologies Ltd. ("MIS"). Under the terms of the MOU, and subject to continued collaboration, the Company has agreed to grant MIS an exclusive right to market a specific dental application of our technology for a certain period starting after receipt of either EMA marketing approval or FDA approval and beginning of commercialized sales in the applicable market, accordingly. Under the terms of the MOU, we are entitled to receive certain milestone-based and sales-based compensation payments. Prior to commercialization of the product, MIS may terminate the MOU, in which case we would be obligated to return all milestone payments received until such notification. In addition, under the terms of the MOU, in the event that the FDA imposes certain additional requirements with respect to a clinical trial, MIS may choose to decline to undertake the expenses related to such additional requirements, in which case the license to MIS granted by us shall exclude the U.S. territory and MIS shall not be obligated to make certain milestone payments, and we will be obligated to return any such milestone payment, to the extent received. Upon termination of the MOU, we shall retain all rights to the existing intellectual property and all intellectual property developed during the term of the MOU. Through June 30, 2014, payments totaling $367,000 were received by us as participation in R&D development from MIS. These amounts were recorded as an advance on account of the said MIS collaboration arrangement. To date, no amounts were recognized in the Statements of Operation with respect to the said MIS collaboration arrangement, as all the amounts are refundable.

Financial Overview

Operating Expenses

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

Research and Development Expenses

Our research and development expenses consist primarily of salaries and related personnel expenses, share-based compensation relating to employees and consultants, cost of third party consultants, subcontractors and materials expenses related to early research and development programs and pre-clinical studies, cost of completing chemical, manufacturing and control activities (CMC), costs of conducting clinical trials, costs of regulatory consultants and regulatory submissions, intellectual property maintenance, and other research and

development expenses. The research and development expenses are net of research and development grants received from the Office of the Chief Scientist of the Ministry of Economy of the State of Israel (OCS) and participations received from the European Commission's Seventh Framework Programme for Research (FP7).

We expect that our research and development expenses will materially increase due to new research programs requiring additional employees, further CMC development activities, and significant regulatory expense. In addition, we plan to conduct additional clinical trials in the near future, for both our lead product candidates, BonyPid-1000 and BonyPid-500.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related personnel expenses, professional service and consulting fees, including legal, accounting, audit and tax fees, facilities expenses, and other general and administrative expenses.

We expect our general and administrative expenses to increase in order to support the growth in research and development projects. In addition, we expect, professional service and consulting fees, including accounting and legal fees to increase significantly after we become a U.S. public company, and we expect increases in the number of our executive, accounting and administrative personnel due to our anticipated growth.

Financial Expense and Income

Financial expense and income consist of bank fees, exchange rate differences and revaluation of warrants.

Critical Accounting Policies and Estimate

We describe our significant accounting policies more fully in Note 2 to our financial statements for the year ended December 31, 2013. We believe that the accounting policies below are critical in order to fully understand and evaluate our financial condition and results of operations.

We prepare our financial statements in accordance with accounting principles generally accepted in the United States (U.S. GAAP).

The preparation of the financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions. Our management believes that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent 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.

The critical accounting policies that were impacted by the estimates, judgments and assumptions used in the preparation of our consolidated financial statements are discussed below.

Convertible Preferred Shares and Warrants to Purchase Convertible Preferred Shares

The terms of the Preferred A, A-1, B and B-1 shares allow the holders to redeem shares, under certain circumstances, outside of our control. Therefore, the shares are classified as mezzanine equity on the balance sheet and 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 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 operation. We 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.

The fair value of the warrants on the issuance date and on subsequent reporting dates was determined using the OPM model. The fair value of the underlying 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 various equity classes, deriving a fully marketable value per share for the preferred shares.

Grants and Participation

Royalty-bearing grants from the Office of the Chief Scientist of the Ministry of Economy in Israel ("OCS") 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. Non-royalty-bearing grants from the OCS 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 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 OCS until the related revenues are recognized. In the event of failure of a project that was partly financed by the OCS, we will not be obligated to pay any royalties or repay the amounts received.

Consideration earned from participations from third parties in R&D development is recognized as 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, 2013, we received payments totaling $367, as participation in R&D development from MIS. These amounts were capitalized and recorded as an advance on account of collaboration arrangement. For the six month period ended June 30, 2014, no additional amounts were received from MIS. To date, no amounts were recognized in the Statement of Operation with respect to collaboration arrangement, as all the amounts are refundable.

JOBS Act

On April 5, 2012, the U.S. Congress enacted the Jumpstart Our Business Startups Act of 2012, or the JOBS Act.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company", we intend to rely on certain exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404 and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). These exemptions will apply for a period of five years following the completion of our initial public offering or until we are no longer an "emerging growth company."

Share-Based Compensation and Fair Value of Ordinary Shares

We account for share-based compensation granted to employees, non-employee directors and service providers in accordance with ASC 718-10, "Compensation — Stock Compensation" (ASC 718) and ASC 505-50, "Equity-Based Payments to Non-Employees" (ASC 505-50), which requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model (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. 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.

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 the Company's Ordinary shares, the board of directors has determined fair value of an Ordinary share at the time of grant of the option by considering a number of objective and subjective factors including data from other comparable companies, sales of convertible Preferred shares to unrelated third parties, operating and financial performance, the lack of liquidity of share capital and general and industry specific economic outlook, amongst other factors. The fair value of the underlying Ordinary shares will be determined by the board of directors until such time as 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 valuations performed using the OPM method for the year ended December 31, 2013 and for the six months ended June 30, 2014.

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, as discussed in the "Ordinary shares valuations" section below. 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.
- *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.
- *Dividend yield.* We have never declared or paid cash dividends and we do not have plans to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

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

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

	Year Ended December 31, 2013	Six Months Ended June 30, 2014
Expected term (in years)	5 – 10	6 – 10
Expected volatility	116% – 122	111%
Risk-free rate	0.85% – 2.54%	1.1% – 2.1%
Dividend yield	0.0%	0.0%

We incurred non-cash share-based compensation expense of $0.4 million during the year ended December 31, 2013 and non-cash share-based compensation expense of $0.3 million for the six month period ended June 30, 2014. We expect to continue to grant share options in the future, and to the extent that we do, our actual share-based compensation expenses recognized are likely to increase.

Ordinary shares valuations

The following table presents the share option grants made between January 1, 2013 and June 30, 2014 and the related exercise price and estimated fair value per ordinary share at the grant date:

Option Grant Date	Number of Options Granted	Ordinary Shares Fair Value Per Share of Ordinary shares at Grant Date	Exercise Price	Aggregate Grant Date Fair Value[(1)]
March 19, 2013	3,999,980	$ 0.12	$0 – $0.43	$ 438,538
October 30, 2013	157,858	$ 0.11	$0.61	$ 28,041
December 24, 2013	470,748	$ 0.40	$0.43 – $0.61	$ 158,695
May 5, 2014	2,167,843	$ 0.95	$ 0.61	$ 787,072
June 22, 2014	154,500	$ 0.97	$ 0.61	$ 133,262

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

Based upon the assumed midpoint of the initial public offering price range set forth on the cover page of this prospectus ($ per share), the aggregate intrinsic value of options outstanding as of June 30, 2014 was approximately $ million, of which approximately $ million related to vested options and approximately $ million related to unvested options.

The fair value of the ordinary shares underlying our share-options 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;
- 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 our Company's value in an exit scenario due to a liquidity event, such as an initial public offering ("IPO") using the market approach and based on preliminary discussions with investment banks. In this scenario, all preferred shares, warrants to purchase 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 Company's value using a market approach (based on the backsolve method). The backsolve method involves making 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 our Series B-1 preferred share price determined in recent financing rounds of our Series B-1 preferred shares, 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 option pricing model ("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. Because the Series B-1 Preferred shares financing rounds were led by unrelated investors and was an arms-length transaction, we determined it was 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.

We believe we applied a reasonable valuation method to determine the share option exercise prices on the respective share option grant dates. A combination of factors led to changes in the fair value of our ordinary shares. Certain of the significant factors considered by our board of directors to determine the fair value per share of our ordinary shares for purposes of calculating share-based compensation costs during this period included:

March 2013 grant. Our board determined the fair value of our ordinary shares as of March 19, 2013 to be $0.12 per share. As part of this determination, our board considered an independent third party valuation conducted for this date. We based this price using the backsolve method using the OPM and according to the value derived from a third-party sale of shares in an arms' length transaction (preferred share B-1) which was carried out on February 4, 2013. We considered the overall probability of a sale transaction to be 100%. We then applied a 49% discount due to lack of marketability to arrive at a final value of $0.12 per share for our ordinary shares.

October 2013 grant. Our board determined the fair value of our ordinary shares as of October 30, 2013 to be $0.12 per share. As part of this determination, our board considered an independent third party valuation conducted for this date. We based this price using the backsolve method using the OPM and according to the value derived from a third-party sale of shares in an arms' length transaction (preferred share B-1) which was concluded on October 7, 2013. We considered the overall probability of a sale transaction to be 100%. We then applied a 43% discount due to lack of marketability to arrive at a final value of $0.12 per share for our ordinary shares.

December 2013 grant. Our board determined the fair value of our ordinary shares to be $0.40 per share as of Dec 24, 2013. As part of this determination, our board considered an independent third party valuation conducted for this date. For the purpose of the exit scenario, we considered preliminary valuation discussions that we held with underwriters, assuming an IPO in the fourth quarter of 2015. This resulted in an estimated fair value per ordinary share of $1.62 after discounting to present value the preliminary estimated IPO valuation, at a discount rate of 25%. For the purpose of the liquidity scenario, we used the enterprise value derived by the backsolve method from the purchase at arms' length of our Series B-1 preferred shares pursuant to an agreement entered into in December 2013. The resulting enterprise value was allocated among the elements of our capital structure using the OPM assuming a liquidity event in two years. This resulted in a value per ordinary share of $0.19. Using the Hybrid method, we then estimated that the probability of the exit scenario was 35%, while the probability of the liquidity scenario was 65%. Applying these weightings, we arrived at a value of $0.69 per ordinary share, to which we applied a 42% discount due to lack of marketability, to arrive at a final value of $0.40 per share for our ordinary shares.

May 5, 2014 grant. Our board determined the fair value of our ordinary shares to be $0.95 per share as of May 14, 2014. As part of this determination, our board considered an independent third party valuation conducted for this date. For the purpose of the exit scenario, we considered preliminary valuation discussions that we held with underwriters, assuming an IPO in the fourth quarter of 2014. This resulted in an estimated fair value per ordinary share of $1.78 after discounting to present value the preliminary estimated IPO valuation, at a discount rate of 25%. For the purpose of the liquidity scenario, we used the enterprise value derived by the backsolve method from the purchase at arms' length of our Series B-1 preferred shares pursuant to an agreement entered into in May 2014. The resulting enterprise value was allocated among the elements of our capital structure using the OPM assuming a liquidity event in seven month. This resulted in a value per ordinary share of $0.24. Using the Hybrid method, we then estimated that the probability of the exit scenario was 65%, while the probability of the liquidity scenario was 35%. Applying these weightings, we arrived at a value of $1.25 per ordinary share, to which we applied a 24% discount due to lack of marketability, to arrive at a final value of $0.95 per share for our ordinary shares.

June 22, 2014 grant. Our board determined the fair value of our ordinary shares to be $0.97 per share as of June 22, 2014. As part of this determination, our board considered an independent third party valuation conducted for this date. For the purpose of the exit scenario, we considered preliminary valuation discussions that we held with underwriters, assuming an IPO in the fourth quarter of 2014. This resulted in an estimated fair value per ordinary share of $1.70 after discounting to present value the preliminary estimated IPO valuation, at a discount rate of 25%. For the purpose of the liquidity scenario, we used the enterprise value derived by the backsolve method from the purchase at arms' length of our Series B-1 preferred shares pursuant to an agreement entered into in June 2014. The resulting enterprise value was allocated among the elements of our capital structure using the OPM assuming a liquidity event in six month. This resulted in a value per ordinary share of $0.23. Using the Hybrid method, we then estimated that the probability of the exit scenario was 65%, while the probability of the liquidity scenario was 35%. Applying these weightings, we arrived at a value of $1.19 per ordinary share, to which we applied a 19% discount due to lack of marketability, to arrive at a final value of $0.97 per share for our ordinary shares.

Recently Adopted Accounting Pronouncements

In June 2014, the FASB issued ASU 2014-10, "Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities" (ASU 2014-10). The amendment removes the definition of a development stage entity from ASC 915, "Development Stage Entities" (ASC 915), thereby removing the distinction between development stage entities and other reporting entities under US-GAAP. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information on the statements of income, cash flows, and shareholder's equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. These amendments are effective for annual reporting periods beginning after December 15, 2014, with early application permitted. The Company has elected to early adopt ASU No. 2014-10, and removed the inception to date information and all references to development stage.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported while also improving comparability in the financial statements of companies reporting using IFRS and US GAAP. The core principle of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration (that is, payment) to which the company expects to be entitled in exchange for those goods or services. The new standard also will result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively (for example, service revenue and contract modifications) and improve guidance for multiple-element arrangements. ASU 2014-09 will be effective for the Company in the first quarter of fiscal 2017 and may be applied on a full retrospective or modified retrospective approach. The Company is evaluating the impact of implementation of this standard on its financial statements.

Results of Operations

	Year Ended December 31,	
	2013	2012
	(in thousands US$)	
Research and development expenses, net	$ 2,641	$ 1,377
General and administrative expenses	938	410
Operating loss	3,579	1,787
Financial expenses, net	305	3
Net loss	$ 3,884	$ 1,790

	Six Months Ended June 30,	
	2014	2013
	(in thousands US$)	
Research and development expenses, net	$ 1,499	$ 1,752
General and administrative expenses	874	463
Operating loss	2,373	2,215
Financial expenses, net	235	73
Net loss	$ 2,608	$ 2,288

Comparison of the Year Ended December 31, 2013 to the Year Ended December 31, 2012

Research and Development Expenses

Our research and development expenses, net, for the year ended December 31, 2013 amounted to $2,641 representing an increase of $1,264, or 92%, compared to $1,377 for the year ended December 31, 2012. The increase was primarily attributable to an increase of salaries and related personnel expenses in an amount of $355 reflecting an increase in the number of employees engaged in research and development related activities from nine to fifteen, an increase in share-based compensation to employees and consultants in an amount of $298, an increase of $348 in cost to third-party consultants, an increase of $438 in chemical, manufacturing and control expenses for the manufacture of BonyPid for clinical trial and regulatory purposes, an increase in $76 in clinical trial expenses as we expanded our clinical trial program for BonyPid, an increase of $25 in costs associated with maintenance and prosecution of our intellectual property, and an increase of $152 in other research and developments costs and overhead costs related to the growth in our activities. An increase of $428 in grants received from OCS and European Commission's Seventh Framework Programme for Research reduced our research and development costs.

Substantially all of our research and development costs in 2013 and 2012 were in connection with the development of our two lead product candidates, and for our research programs.

General and administrative expenses

Our general and administrative expenses for the year ended December 31, 2013 amounted to $938 representing an increase of $528, or 129%, compared to $410 for the year ended December 31, 2012. The

increase was primarily attributable to an increase of salaries and related personnel expenses in an amount of $172 reflecting an increase in the number of employees required to support research and development activities as well as new employees in business development, an increase in share-based compensation to consultants in an amount of $74, an increase of $88 in costs for third-party consultants, an increase of $92 in legal and professional costs, an increase of $32 in facility and maintenance cost as we expanded our facilities related to additional employees and new activities and as an increase of $71 in other overhead costs.

Operating loss

As a result of the foregoing, our operating loss for the year ended December 31, 2013 was $3,579, as compared to $1,787 for the year ended December 31, 2012, an increase of 100%.

Financial expense and income

We recognized financial expenses of $305, including $286 related to the reevaluation of the preferred share warrant liability, for the year ended December 31, 2013, as compared to $3 for the year ended December 31, 2012.

Net loss

As a result of the foregoing, our loss for the year ended December 31, 2013 was $3,884, as compared to $1,790 for the year ended December 31, 2012, an increase of 117%.

Comparison of the Six Month Period Ended June 30, 2014 to the Six Month Period Ended June 30, 2013

Research and Development Expenses

Our research and development expenses, net, for the six month period ended June 30, 2014 amounted to $1,499 representing a decrease of $253 or 14%, compared to $1,752 for the six month period ended June 30, 2013. Our gross research and development expenses for the six month period ended June 30, 2014 amounted to $1,970 representing a decrease of $30 or 2%, compared to $2,000 for the six month period ended June 30, 2013. For the six month period ended June 30, 2014, salaries and related personnel expenses increased by an amount of $231 reflecting an increase in the number of employees engaged in research and development related activities from twelve to nineteen, share-based compensation to employees and consultants decreased by an amount of $56, costs of third-party consultants decreased by an amount of $83, chemical, manufacturing and control expenses for the manufacture of BonyPid for clinical trial and regulatory purposes decreased by an amount of $482. Clinical trial expenses increased by an amount of $153 as we expanded our clinical trial program for BonyPid, costs associated with maintenance and prosecution of our intellectual property decreased by an amount of $21, whilst other research and developments costs and overhead costs related to the growth in our activities increased by $228. An increase of $223 in grants received from OCS and European Commission's Seventh Framework Programme for Research reduced our research and development costs.

Substantially all our research and development costs in 2014 and 2013 were in connection with the development of our lead product candidates, and our research programs.

General and administrative expenses

Our general and administrative expenses for the six month period ended June 30, 2014 amounted to $874 representing an increase of $411 or 89%, compared to $463 for the six month period ended June 30, 2013. The increase was primarily attributable to an increase of salaries and related personnel expenses in an amount of $208 reflecting an increase in the number of employees required to support research and development activities as well as new employees in business development, an increase in share-based compensation to employees in an amount of $36, an increase of $121 in costs for third-party consultants, an increase of $11 in legal and professional costs, an increase of $38 in facility and maintenance cost as we expanded our facilities related to additional employees and new activities.

Operating loss

As a result of the foregoing, our operating loss for the six month period ended June 30, 2014 was $2,373, as compared to $2,215 for the six month period ended June 30, 2013, an increase of 7%.

Financial expense and income

For the six month period ended June 30, 2014, we recognized financial expenses of $235, including $211 related to the reevaluation of the preferred share warrant liability, as compared to $73 for the six month period ended June 30, 2013 including $74 related to the reevaluation of the preferred share warrant liability,

Net loss

As a result of the foregoing, our loss for the six month period ended June 30, 2014 was $2,608, as compared to $2,288 for the six month period ended June 30, 2013, an increase of 14%.

Liquidity and Capital Resources

As of June 30, 2014, we had $4,029 in cash and cash equivalents, an increase of $2,766 compared to December 31, 2013. During the six months ending June 30, 2014 we issued 7,625,493 preferred B-1 shares for a total consideration of $4.4 million (net of issuance costs of $170). The Company believes that its current capital resources are not sufficient to support its operations beyond June 30, 2015. For this reason, Note 1b to our interim financial statements for the six months ended June 30, 2014 and to our audited financial statements for the year ended December 31, 2013 include reference to substantial doubt about our ability to continue as a going concern. In addition the independent registered public accountants' report for the year ended December 31, 2013 includes an explanatory paragraph that expresses substantial doubt about our ability to continue as a "going concern".

We believe that our existing cash resources and the net proceeds from the current anticipated offering, together with anticipated grants from OCS as well as participations in R&D development, will be sufficient to fund our projected cash requirements at least through June 30, 2015. We currently anticipate that, assuming consummation of the current offering, we will advance current and planned research programs, complete the clinical development of our two lead product candidates, file the appropriate submissions of such product candidates for regulatory approval, establish a manufacturing facility for the production of some of our product candidates and use the remainder for working capital and general corporate purposes.

We will require significant additional financing in the future to fund our operations. However, if we do not generate sufficient cash through this offering or otherwise, our cash on hand may not be sufficient to meet our anticipated cash needs.

The table below presents our cash flows for 2013 and 2012:

	Years Ended December 31,	
	2013	2012
	(in thousands US$)	
Operating activities	$ (2,518)	$ (1,857)
Investing activities	(113)	(145)
Financing activities	2,917	2,578
Net increase (decrease) in cash and cash equivalents	$ 286	$ 576

The table below presents our cash flows for the six months ended June 30, 2014 and June 30, 2013:

	Six Months Ended June 30,	
	2014	2013
	(in thousands US$)	
Operating activities	$ (1,579)	(1,440)
Investing activities	(72)	(14)
Financing activities	4,417	1,536
Net increase (decrease) in cash and cash equivalents	$ 2,766	82

Operating Activities

The use of cash in operating activities resulted primarily from our net losses adjusted for non-cash charges and measurements and changes in components of working capital. Adjustments for non-cash items include depreciation, re-evaluation of preferred share warrants and share-based compensation.

Net cash used in operating activities in 2013 was $2,518, an increase of $661 as compared to $1,857 used in 2012. The increase was attributable primarily to the increased research and developments costs as well increased general and administrative costs.

In the six month period ended June 30, 2014, net cash used in operating activities was $1,579, an increase of $139 as compared to $1,440 used in the six month period ended June 30, 2013. The increase was attributable primarily to the increased general and administrative costs, offset by decrease in research and development costs.

Investing Activities

Net cash used in investing activities is primarily related to the purchase of laboratory equipment, office equipment and furniture and leasehold improvements. Net cash used in investing activities was $113 in 2013, a decrease of $32 as compared to 2012. A decrease of $97 in the purchase of equipment in 2013 as compared to 2012 was off-set by an increase of $65 in restricted cash in the same period.

In the six month period ended June 30, 2014, net cash used in investing activities was $72 related to purchase of equipment, an increase of $58, as compared to the six month period ended June 30, 2013.

Financing Activities

Net cash provided by financing activities of $2,917 in the year ended December 31, 2013 consisted of net proceeds from the issuance of preferred shares. Net cash provided by financing activities of $2,578 in the year ended December 31, 2012 consisted of net proceeds from the issuance of preferred shares and from the exercise of warrants on preferred shares.

Net cash provided by financing activities of $4,029 in the six month period ended June 30, 2014 consisted of net proceeds of $4,558 from the issuance of preferred shares, offset by $141 related to payment of deferred offering costs. Net cash provided by financing activities of $1,059 in the six month period ended June 30, 2013 consisted of net proceeds of $1,206 from the issuance of preferred shares and $330 repayment of receivables on account of shares.

Current Outlook

We have financed our operations to date primarily through proceeds from sales of our shares, and grants from OCS and FP7. We have incurred losses and generated negative cash flows from operations since inception. To date, we have not generated any revenue from the sale of products and we do not expect to generate revenues from sale of our products in the next few years.

As of June 30, 2014, we had $4,029 in cash and cash equivalents, an increase of $2,766 compared to December 31, 2013. During the six months ending June 30, 2014 we issued 7,625,493 preferred B-1 shares for a total consideration of $4.4 million (net of issuance costs of $170). The Company believes that its current capital resources are not sufficient to support its operations beyond June 30, 2015. For this reason, Note 1b to our interim financial statements for the six months ended June 30, 2014 and to our audited financial statements for the year ended December 31, 2013 include reference to substantial doubt about our ability to

continue as a going concern. In addition the independent registered public accountants' report for the year ended December 31, 2013 includes an explanatory paragraph that expresses substantial doubt about our ability to continue as a "going concern".

We believe that our existing cash resources and the net proceeds from the current offering will be sufficient to fund our projected cash requirements at least through June 30, 2015. Nevertheless, we will require significant additional financing in the future to fund our operations if and when we obtain regulatory approval and commercialize our products. We currently anticipate that, assuming consummation of the current offering, we will advance current and planned research programs, complete the clinical development of product candidates, file the appropriate submissions for such product candidates for regulatory approval, establish a manufacturing facility for the production of some of our product candidates and use the remainder for working capital and general corporate purposes. Our future capital requirements will depend on many factors, including:

- the progress and costs of our research programs, preclinical studies, clinical trials, chemical, manufacturing and control activities, regulatory submission costs and other development activities;
- the scope, prioritization and number of our clinical trials;
- the costs and timing of obtaining regulatory approval for our product candidates;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of, and timing for, strengthening our manufacturing agreements for production of sufficient clinical and commercial quantities of our product candidates;
- the potential costs of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally; and
- the costs of acquiring or undertaking the development and commercialization efforts for additional, future therapeutic applications of our product candidates.

Until we can generate significant recurring revenues, we expect to satisfy our future cash needs through the net proceeds from the current offering, debt or equity financings, or by out-licensing applications of our product candidates. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans for, or commercialization efforts with respect to, one or more applications of our product candidates. This may raise substantial doubts about our ability to continue as a going concern.

Contractual Obligations

The following table summarizes our significant contractual obligations at December 31, 2013:

	Total	Less than 1 year	1 – 3 years	4 – 5 years	More than 5 years
			(in thousands US$)		
Operating leases:					
Facility	422	199	223	—	—
Motor Vehicles	160	77	83	—	—

The following table summarizes our significant contractual obligations at June 30, 2014:

	Total	Less than 1 year	1 – 3 years	4 – 5 years	More than 5 years
			(in thousands US$)		
Operating leases:					
Facility	4,756	453	1,357	894	2,052
Motor Vehicles	231	100	131	—	—

Off-Balance Sheet Arrangements

We currently do not have any off-balance sheet arrangements.

Quantitative and Qualitative Disclosure about Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of foreign currency exchange rates.

Foreign Currency Exchange Risk

Our results of operations and cash flow are subject to fluctuations due to changes in foreign currency exchange rates. Certain of our expenses are denominated in New Israeli Shekels. Our results of operations and cash flow are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. Approximately 40% of our expenses are denominated in New Israeli Shekels. Changes of 5% and 10% in the USD/NIS exchange rate will increase/decrease the operation expenses by 2% and 4%, respectively. We do not hedge our foreign currency exchange 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.

Inflation-related Risks

We do not believe that the rate of inflation in Israel has had a material impact on our business to date. However, our costs in Israel will increase if inflation in Israel exceeds the devaluation of the New Israeli Shekel against the U.S. Dollar or if the timing of such devaluation lags behind inflation in Israel.

BUSINESS

Overview

We are an emerging specialty pharmaceutical company engaged in research and development of our product candidates based on PLEX, our proprietary drug delivery technology. PLEX (abbreviation for **P**olymer-**L**ipid **E**ncapsulation Matri**X**) is able to encapsulate many types of drugs to enable targeted, localized drug delivery into the body over extended periods of time, including periods not previously thought possible. The application of our PLEX technology in our product candidates enables us to optimize drug treatment regimens with release rates and durations that are pre-determined by us, spanning from days, to weeks and several months. We are a clinical stage company, meaning that our product candidates are yet to be approved for sale by any regulatory agencies.

The localized (as opposed to systemic), controlled and constant release of drugs over extended periods is essential in many treatment regimens, such as the treatment of infections, inflammation and pain. Our PLEX technology platform is a matrix of several thousand alternating layers of polymers (plastics) and lipids (fatty substances) that entrap a therapeutic drug between them. Our preliminary studies show that our product candidates are effective using a very small fraction of the active pharmaceutical ingredients required in systemic administration. One vial of BonyPid-1000, one of our lead product candidates, utilizes slightly more than 1% of the accepted 30-day systemic antibiotic regimen. One vial of BonyPid-500, one of our other lead product candidates, utilizes approximately 1.5% of the normal 10-day antibiotic regimen used in dental applications.

Our most advanced product candidates, BonyPid-1000 and BonyPid-500, address current treatment problems in orthopedics and dental implants that are not adequately addressed by current treatments (either local or systemic). Our additional product candidate D-PLEX addresses the prevention and treatment of surgical site infections generally. BonyPid-1000 and BonyPid-500 are specifically directed at combatting bacterial colonization on implanted bone substitutes and resulting complications, as well as supporting bone recovery around dental implants, in each case by releasing a broad-spectrum antibiotic at the site to enhance healing. We expect to begin a confirmatory clinical trial for BonyPid-1000 in the second half of 2015 for a CE Mark authorizing marketing in Europe. We expect to begin a pilot clinical trial for BonyPid-500 in the second half of 2015. Both studies are expected to serve as a safety and preliminary effectiveness study as part of the FDA approval process. We expect, assuming continued favorable clinical results, that both BonyPid-1000 and BonyPid-500 will be ready for commercial release in Europe during the first half of 2017. We are also planning to begin a pilot clinical trial for D-PLEX shortly after our BonyPid-1000 and BonyPid-500 trials. Our estimates of the funds required to achieve these goals are set forth under “Use of Proceeds.”

The attributes of our PLEX platform can be used in a wide variety of products and indications in addition to orthopedics and dental implants, including infection treatment and prevention more generally. Based on our current clinical data, we believe that our product candidates have the capability to reduce the number of surgical procedures, side effects, hospitalizations and recovery times while improving clinical and patient outcomes, thus significantly impacting health economics.

Background and Market Focus

Infection resulting from surgery remains a major health problem despite the intensive use of systemically administered antibiotics both pre- and post-surgery. Infection causes medical complications that can even be fatal, and creates a significant public health burden. Furthermore, according to the Food and Drug Administration (FDA)FDA) and its international counterparts, the increasing resistance of bacteria to antibiotics and similar drugs — called antimicrobials — is a major public health threat. Additionally, systemic administration of antimicrobials frequently involves high dosing that causes safety concerns and potential side effects, in addition to increasing the likelihood of the development of antibacterial resistance. Existing localized treatments are limited by one or several or the following factors that can affect safety or effectiveness: short maximum release periods; controllability of the drug release; no mechanism to prevent drug degradation; applicability to a limited number of drugs; and difficulties in bonding between the drug and the delivery mechanism.

Our current market focus is to create a range of effective, extended release pharmaceutical products for medicating tissues locally with antibiotics for infection treatment and prevention in surgical procedures. Our studies suggest that our product candidates are effective in a number of cases where systemic administration or other localized solutions have either little or no effect, are too toxic, or both. Based on our clinical and pre-clinical experience, we believe that use of our product candidates will reduce overall surgical infection rates and reduce bacterial resistance, thus benefiting patients, hospitals and healthcare organizations.

Lead Product Candidates

Our three lead product candidates are as follows:

- BonyPid-1000 is a conventional bone substitute used in orthopedic surgery that has been coated with our PLEX technology and contains antibiotics. Bone substitutes are inserted into severe open bone fractures to promote bone healing, and the antibiotics protect the implants from bacterial adhesion by releasing a broad-spectrum antibiotic. This combination has also been designed for use in other orthopedic surgical procedures, such as spine surgeries and joint replacements that require the filling of bone voids and that are also prone to infection.

  Penetration of antibiotics and other drugs from the blood stream into bone can be ineffective due to limited blood supply which results in inadequate delivery of sufficient dosages. The most severe open bone fracture cases frequently become infected and may require amputation of the limb despite the best available treatment and medications, both local and systemic. The antibiotics that are encapsulated by BonyPid-1000 are directly applied to the surgical site instead of being delivered through the blood supply. The entrapped antibiotics are released at an effective rate over a period of three to four weeks. In our clinical trials to date with BonyPid-1000, there have been no bone infection complications and no amputations despite the severity of the treated cases, suggesting a substantial improvement over current success rates. Additionally, the ability of BonyPid-1000 to permit immediate or early closure of the wound is an advance over current procedures and promotes earlier healing and reduces the risk for hospital-related bacterial contaminations. As a result, BonyPid-1000 has the potential to significantly reduce treatment costs because it can reduce the number of required recurring surgical procedures and the number, length and cost of hospitalizations. BonyPid-1000 also has the potential to be used in dental applications.

- BonyPid-500 allows bone regrowth in bacterially-infected dental sites surrounding dental implants. Current treatments of bone resorption around these dental implants are largely ineffective and often require implant removal. BonyPid-500 acts as a scaffold to support bone recovery and delivers antibiotics locally over a prolonged period to prevent local development of device-related microbial colonization, which subsequently result in infections and bone resorption. We expect BonyPid-500 to reduce implant procedure costs and prevent prolonged and painful follow-on dental procedures. We are currently collaborating with MIS Implants Ltd. for the development and future commercialization of BonyPid-500 in the field of peri-implantitis — one of the potential applications of BonyPid-500 in the maxiofacial market. BonyPid-500 may also potentially be used in other dental applications.

- D-PLEX is in active development to treat infection and is directed at preventing and treating surgical site infections (known as SSI) addressing medical needs that are currently lacking effective solutions and that are of great concern to the medical community. D-PLEX is designed to provide localized infection treatment and prevention of soft tissues that will be administered locally during surgical procedures. SSI occur in varying percentages of surgical procedures despite administration of systemic antibiotics, depending on the procedure type. D-PLEX is expected to reduce the overall infection rate and overcome or reduce existing infections, including hospital-acquired resistant bacteria. D-PLEX is planned to be applied into a variety of tissues and solid organs to treat and prevent infections that may exist prior to, or appear after, surgery. Some possible examples include abdominal surgeries such as colectomy, appendectomy and chronic bone infection (osteomyelitis). We are currently evaluating our regulatory alternatives with regard to this product candidate. We expect, in 2015, to begin a limited clinical trial in Asia and to enter discussions with the FDA as to our clinical path in the United States.

Target Markets

Orthopedics. According to multiple published Millennium Research Group reports, in 2013 approximately one million annual orthopedic surgical procedures on open fractures requiring bone grafts were performed worldwide, with over 335,000 procedures in the United States. In a 2007 article in The Internet Journal of Orthopedic Surgery, it was reported that, depending on severity, up to 50% of these procedures result in bone infections. It was also reported that approximately 1,550,000 thoracolumbar and cervical spine procedures take place globally, of which around 720,000 were conducted in the United States. Two studies published in 2012 by the European Spine Journal show that between 2 – 10% of these shall incur infection, despite systemic antibiotic administration. According to the Millennium reports, approximately 328,500 hip and knee replacement revision surgeries took place, of which a total of 136,200 occurred in the US. Almost all of these revision treatments, which are complications of primary hip and knee replacement surgeries, are expected to benefit from our product candidates.

Dental. According to multiple Millennium Research Group reports, there were over 12 million dental implants worldwide in 2013, and approximately 10 – 20% of dental implants become infected up to five years after implantation. Millennium also reports that approximately 4.2 million dental procedures such as sinus lifts, ridge augmentation and expansion surgeries and socket extractions took place in 2013 with the US accounting for approximately 1,4500,000 of them.

SSI. According to the a datasheet published by the U.S. Centers for Disease Control and Prevention (CDC) in 2010 and several Millennium reports, of the 100 million interventional procedures conduced in the United States, approximately 30 million carry a risk of incurring surgical site infections (SSI) despite systemic antibiotic administration. In a 2001 report prepared for the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, 80 – 90% of surgeries use systemic antibiotic administration. As an example, according to numerous Millennium reports, there were approximately 1,500,000 primary hip replacements conducted globally during 2013, of which approximately 300,000 took place in the United States. Although almost all of these procedures are accompanied by antibiotic administration, around 11% of these procedures will still incur infections according to the American Journal of Health-System Pharmacy published in February 2013. Similarly, according to the above CDC report, approximately 305,000 colectomy procedures are performed annually in the United States. According to a 2014 Journal of Hospital Infection review, 14 – 18% of colectomy procedures result in infections despite systemic antibiotic treatment. These are just a few of many examples of the need for an effective, localized and prolonged antibiotic treatment that our product candidates are intended to address.

Research Programs

The following programs, based on our PLEX platform, are in the early research phase:

- Anti-Inflammatory Research Program. Systemic treatments are very effective for the treatment of inflamed conditions. However, wide use of anti-inflammatory agents is limited due to serious systemic side effects that include liver damage, heart disease, addiction and pain. We are developing a localized and controlled delivery of a very small, yet effective dose with minimal systemic side effects.
- Anti-Cancer Research Program. Systemic anti-cancer treatments have serious side effects. Our program is designed to treat cancer by extended localized release of common chemotherapeutic agents. The program is aimed at reducing the overall dose of toxic agents for a prolonged, local delivery while achieving effectiveness that is at least comparable to systemic administration.

Intellectual Property

Various aspects of our technology are protected by five patent families, including two issued patents (U.S. and China), 2 allowed patent applications and over 30 patent applications currently pending in Australia, Canada, China, the European Patent Office, India, Israel, Japan and the United States.

Strategy

Our goal is to become a leading specialty pharmaceutical company by developing, manufacturing and commercializing products based on our proprietary PLEX platform in the field of extended release, local drug delivery. These products are intended to address some of modern medicine's main challenges, where current local or systemic administration has limited effect, is too toxic, or both. Our primary focus is on the field of infection management.

Our commercial strategy has two elements: internal product development and collaboration and licensing. We intend to discover, develop and commercialize novel therapeutic products either on our own or in collaboration with partners. In orthopedics, we are in late stage clinical development. We plan to establish an independent sales force in the United States, Germany, and later in France, to commercialize our products, starting with BonyPid-1000. In geographies where we do not intend to market our products ourselves we plan to team up with commercial partners for certain applications to benefit from their existing sales force and market reach.

We expect to collaborate with pharmaceutical companies through licensing and collaboration agreements for the encapsulation of their drugs (generic or proprietary) using our PLEX platform to enable administration of drugs in a localized, targeted manner. The purpose of these collaborations is to enhance our PLEX platform into a partnered product pipeline and to generate revenues through licensing of PLEX for certain applications. As a first step in this strategy, we have recently entered into a preliminary technology evaluation agreement with a large U.S. pharmaceutical company. We envision that this technology evaluation agreement may lead to discussions on a license and collaboration contract.

Competitive Strengths

Our PLEX-based product candidates offer three distinct potential advantages that together can overcome the limitations of other local delivery solutions:

- We can improve therapeutic effect by pre-determining the duration that a drug or a drug combination is most effectively released inside the body. We are capable of enabling drug delivery up to several months. For example, we have designed BonyPid-1000 with a drug release period of three to four weeks and PLEX with a drug release period of several months.
- We enhance safety and efficacy when we pre-define the rate and quantity of drugs released. As a result, our PLEX-based product candidates release a small but effective drug dose with the benefit of reducing potential adverse side effects, toxicity and costs. One vial of BonyPid-1000 for example, utilizes slightly more than 1% of the accepted 30-day systemic antibiotic regimen.
- We ensure that the drugs, encapsulated by PLEX technology, are fully active upon release by protecting them in a dry, secure, physical reservoir located at the area of the treated site. We are also able to encapsulate sensitive or unstable drugs over significant periods.

In the field addressed by BonyPid-1000, a number of companies have regulatory approval to market products, incorporating anti-bacterial agents, outside the United States that are designed to assist in bone healing. These products include:

- PMMA beads/Septopal (Biomet Manufacturing Corp)
- Osteoset T (Wright Medical Group)
- Targobone (Ossacur AG)
- PerOssal (AAP implante AG)
- Certamet G (BoneSupport AB)

We believe that these products can be evaluated by five different criteria, namely:

- whether the product is biodegradable;
- the ability to support bone growth;

- the ability to pre-determine the release profile of the active drug;
- the ability to provide long-term release of up to weeks; and
- the stability of the drug reservoir in a hydrated environment.

We believe that BonyPid-1000 satisfactorily achieves each of these performance measures, and that the others meet one or two of the five criteria. We believe that meeting all five criteria is essential for successful treatment. Additional detail on competition can be found below under "*BonyPid 1000–Existing approaches to support bone growth by the prevention of bone infection.*

More generally, with regard to localized, prolonged drug delivery systems, there are drug delivery solutions in the market, such as those offered by Pacira Pharmaceuticals. Pacira's lead products, based on their DepoFoam technology, is a multivesicular liposome technology that encapsulates drugs and releases them over a period of several days. Similarly, Tyrx Inc. (acquired by Medtronic) markets a polymer-based local release solution called AIGISRx that elutes drugs over several days. We believe, however, that the technological solutions offered by these companies are less suited for the markets we are addressing and that our PLEX technology and related product candidates offer more flexible, long-term solutions.

Background

Localized drug delivery systems — concept and benefits

The ideal local drug delivery system has been a pursuit of scientists and physicians for the past five decades. Delivering drugs locally to the diseased area rather than through systemic circulation can eliminate or reduce the concomitant secondary systemic complications. An effective local drug delivery system is designed to place the appropriate drug at the right location, for the desired duration and in the appropriate concentration. In many cases, a successful drug delivery system can overcome challenging medical situations where no effective and safe medication alternatives are available. Drug delivery systems are often approached via a drug's chemical formulation, but may also involve medical devices or drug-device combination products.

The major advantages of local delivery of drugs over systemic treatments are:

- Delivering the drug into a particular location where systemic administration has limited efficacy due to poor penetration from the blood stream into the needed organ or compartment;
- Delivering drugs that cannot be used effectively via systemic administration due to various limitations such as solubility, sensitivity to blood factors or toxicity; and
- Delivering extended effective dosing where prolonged systemic exposure may be too toxic.

Faced with increasing research and development costs, impending patent expirations, competitive pressures and increasing consumer demands for improved medications, pharmaceutical companies are relying more heavily on advanced drug delivery system technologies to help sustain their historical high growth and profit margins. Pharmaceutical companies are recognizing that these technologies can differentiate products and extend product life cycles. Use of advanced drug delivery systems by pharmaceutical companies is a valuable, cost-effective lifecycle management resource. Patients benefit from reduced adverse effects and new indications, as well as improved therapy, safety, efficacy, convenience and compliance. Drug delivery systems may also reduce the development time for new active substances. Each year, more companies assess and abandon thousands of active substances for reasons such as insolubility or unacceptable toxicity. Other drugs are abandoned because of adverse effects or high dosing frequency.

Advanced delivery systems are important for medications that are needed to reach the brain, the skeletal system and abdominal organs, which are often limited due to the low penetration of drugs from the circulatory system. To overcome the low accessibility, systemic methods have limited alternatives beside the administration of higher drug doses for significant periods in order to achieve a more effective local drug concentration. This systemic exposure may prove to be toxic and/or too expensive. Moreover, in certain instances, even systemic administration of high, unsafe doses over prolonged periods are still ineffective and may continue to run the risk of developing immune responses.

Infection resulting from surgery remains a major health problem despite the intensive use of systemically administered antibiotics both pre- and post-surgery. Infection causes medical complications that can even be

fatal, and creates a significant public health burden. Furthermore, according to the FDA and its international counterparts, the increasing resistance of bacteria to antibiotics and similar drugs — called antimicrobials — is a major public health threat. Additionally, systemic administration of antimicrobials frequently involves high dosing that causes safety concerns and potential side effects, in addition to increasing the likelihood of the development of antibacterial resistance. Existing localized treatments are limited by one or several or the following factors that can affect safety or effectiveness: short maximum release periods; controllability of the drug release; no mechanism to prevent drug degradation; applicability to a limited number of drugs; and difficulties in bonding between the drug and the delivery mechanism.

Our Solution

Our PLEX localized delivery system (i) encapsulates a drug in a mechanism that is designed to be implanted exactly where it is needed, (ii) contains a drug that is protected even inside the body from pre-mature exposure and early degradation, and (iii) allows effective doses of drug to be released constantly over a sufficient period to accomplish its therapeutic purpose. Our system can customize release rates to be optimally effective as well as safe. Our PLEX system is unique in that it remains effective and safe at the treated site over the needed time period of up to several months while dispensing minimal yet locally effective drug quantities into the surrounding tissues with minimal or no systemic exposure.

Our ability to deliver a small but effective dose allows us to take advantage of the relatively small volume available in the vicinity of some of the treated organs and tissue area and to bypass the kidney activity and other body mechanisms that reduce plasma drug concentrations. The low overall dose further supports the safety of our PLEX system and opens new opportunities for therapeutic treatments that use potentially harmful drugs such as antibiotics, cytotoxic chemotherapy and growth factors. Another inherent advantage is the ability to minimize treatment costs associated with expensive drugs such as peptides and proteins. Many of these drugs, as well as nucleic-acid based drugs, are highly sensitive to the body's systemic degradation mechanisms and therefore the local delivery as we are offering is potentially one of the most practical solution for the use of such drugs.

Our PLEX technology platform overcomes the major deficiencies that other local delivery systems typically encounter. Systems designed to localize administration are often unable to avoid an excessively large burst release upon administration and lack a sufficiently prolonged and controlled drug release that is highly beneficial to optimize therapeutic efficacy and to reduce potential toxicity. We achieve our superior results through a unique combination of technologies in which we create a matrix of alternating layers of polymers and lipids that entrap the drug between them. This "sandwich" approach can be repeated thousands of times and creates a highly organized super-molecular structure. Our proprietary PLEX matrix which is created by the assembly of the right type of lipids with the right type of polymers under specific mild physical conditions achieves unmatched performance. Our ability to create these combinations is based on the self-assembly of known polymeric and lipid components into highly organized super-molecular structures.

The advantages of our PLEX drug delivery system lie in its unique combined characteristics, namely:

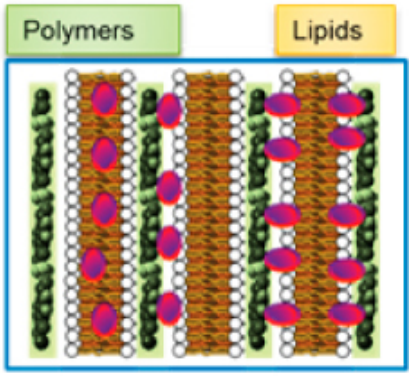
- *Flexible entrapment*, which is the ability to incorporate many types of drugs, with a large range of drug molecule size or physical characteristics. Examples of molecules we have tested successfully range from small drugs (antibiotics, steroids and others), to larger therapeutic molecules, including peptides and proteins to very large molecules such as nucleic acid-based drugs. If required, depending on the release parameters needed and the nature of the drugs, more than one drug may be entrapped; synergism and multi-factorial effects are feasible in some combinations. Other delivery systems tend to be limited to certain types of drugs only, and are not able to create the range of solutions that our platform can offer.
- *Formulations that accommodate unstable drugs*, certain drugs are heat-sensitive, and as a result cannot be used in certain competing drug delivery solutions. Other drugs are sensitive to some organic solvents, $_{p}$H levels or enzymes that are used in other products. Our technology differs from such other solutions in that it can effectively encapsulate and release drugs with these characteristics.
- *Flexible design*, which permits local drug delivery as a coating of medical devices or other substrates.

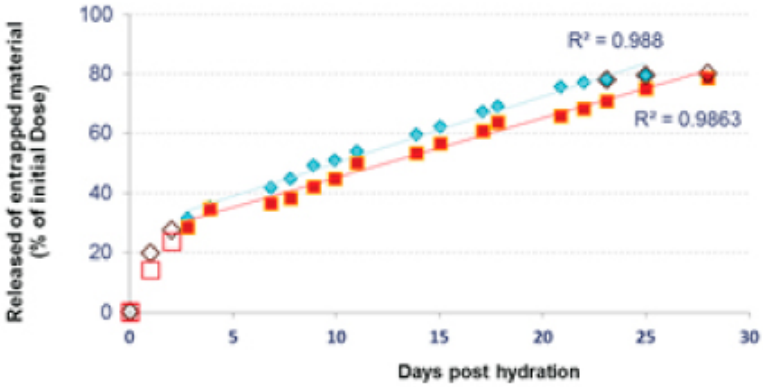
- *Ability to protect drugs from degradation*, which we accomplish by incorporating the drug in an internal reservoir that protects it from biological and water-related destruction. This characteristic is particularly important when long-lasting activity of unstable drugs is needed, for example, to protect water sensitive drugs over weeks of delivery.
- *Extended long release cycles*, which enable to predetermine the release of drugs in the range of several days to several months.
- *Pre-determined constant release rate*, which can be pre-set differently for each drug according to the desired medical application. The release rate can be programmed to be a constant rate, or, in technical terms, a zero order kinetic release rate, for most of the drug reservoir.
- *Compatibility*, using compounds that are biocompatible and often biodegradable and which isolate the drug and the formulation compounds without creating any new chemical entities and without changing the drug's chemistry.
- *Conventional components*, we often use components that are well-known and extensively used in the pharmaceutical industry, and can be commercially purchased in pharmaceutical grade.
- *Simple production techniques*, under which production of complex matrices are performed under cost effective, self-assembly conditions. No covalent bonds are necessary during the assembly of the PLEX matrix, either with the drugs or between the formulating materials. This significantly simplifies the production and scale up as well as the regulatory burden.

PolyPid's technology platform can incorporate a large variety of either a single drug or combinations of drugs and to release them at a pre-programmed constant rate for the desired, pre-set time ranging from several days to several months.

The figure below on the left illustrates the multilayer structure that encapsulates the drug. The depiction shows alternating, thin layers of lipids (shown in brown) and polymers (shown in green), with the drug molecules (shown in purple) captured between them. Depending on drug characteristics, and as suggested by the model, we can place the drug molecules in different functional and defined areas within this multilayer structure. The drug that is entrapped deep inside the internal layers is protected not only against biological destruction but also against hydration. This is particularly important when long lasting activity of unstable drugs is required. The suggested underlying release mechanism is surface degradation of the layers over time so that only the entrapped drug that is located within the outer layer is released.

The figure below on the right demonstrates that, as expected from surface degradation and the suggested release mechanism, the release of the drug (red symbols) correlates to the release of the coating compound (blue symbol). In short, this figure, which is from an actual in-vitro study by us, shows that we are able to release drugs at a constant rate over prolonged periods.





Market for Lead Product Candidates

Orthopedics. According to multiple published Millennium Research Group reports, in 2013, approximately one million annual orthopedic surgical procedures on open (through the skin) bone fractures requiring bone grafts were performed worldwide, with over 335,000 procedures in the United States. It was also reported that approximately 1,550,000 thoracolumbar and cervical spine procedures take place globally, of which around 720,000 were conducted in the United States. In addition, a significant proportion of medical implants (such as in joint reconstruction surgeries) develop infections that are impossible or difficult to eradicate because the bacteria live in biofilms where the penetration of antibiotic using systemic administration is poor and the sensitivity to antibiotics is low. In 2013, close to 3,300,000 of such joint reconstruction surgeries took place, of which approximately 1,000,000 were in the United States. Approximately 328,500 hip and knee replacement revision surgeries took place in 2013, of which a total of 136,200 occurred in the United States. These surgeries are recurring joint surgeries that usually result from joint replacement complications. Depending on venue, between 6 – 10% of such surgeries incur infection that may require the localized treatment that can be offered by BonyPid-1000.

A significant percentage of severe open bone fracture cases (up to 50% in the most severe cases) become infected requiring amputation of the limb despite the best available treatment and medications (both local and systemic). Similarly, approximately 6 – 12% of joint reconstruction surgeries may develop infections that can lead to the removal of implants and costly treatment of chronic, hard-to-treat infections. Two studies published in 2012 by the European Spine Journal show that between 2 – 10% of cervical spine procedures shall incur infection, despite systemic antibiotic administration. The prevention as well as the treatment of bacterial-related infections in open orthopedic fractures, spinal-surgeries, joint replacements and implants is primitive by modern medical standards. Limited penetration of drugs, including antibiotics, from the blood stream into bone tissue poses a formidable obstacle. Furthermore, often the lengthy healing process demands long systemic treatment of high drug doses, which significantly elevates side effects and potential toxicity risks.

Treatment of open fractures generally requires multiple surgical procedures. Commonly, the wound is allowed to remain open both before and after the initial procedure in order to determine whether or not there is an infection. Closure takes place only after it is determined that there is no significant risk of infection, and keeping the wound open only increases the probability that nosocomial infections will occur. At best, where there is no infection, a second procedure is necessary to close the wound.

We are also able to coat medical devices with our technology to prevent the growth of bacteria on the device surface, which is becoming critically important given increasing antibacterial resistance. This enables us to micro-coat the BonyPid-1000 bone void filler with a fine matrix layer that entraps a broad spectrum antibiotic. Upon local implantation into bone voids such as the fracture site, spinal treatment area or the joint reconstruction site, the coating releases the antibacterial drug (Doxycycline) at a constant rate for a predetermined period of approximately three to four weeks. This prolonged drug release period provides an extended protective environment for the graft that is needed for an effective bone-healing process.

Dental. In 2013, over 12 million dental implant procedures were performed worldwide. Of these implants, up to 10 – 20% develop peri-implantitis during the first five years after implantation, and therefore will suffer from significant bone loss that may lead to implant removal and additional prolonged recovery of the missing bone. Reports also show that approximately 4.2 million dental procedures such as sinus lifts, ridge augmentation and expansion surgeries and socket extractions took place in 2013 with the US accounting for approximately 1,4500,000 of them. Our BonyPid line is designed to recover significant bone loss around dental implants to prevent the removal of such implants. In the other dental applications, our BonyPid line acts as a scaffold to support bone recovery and delivers antibiotics locally over a prolonged period. Current treatments of bone loss around dental implants and other maxillofacial bone loss are largely ineffective, and these morbidities often require implant removal and prolonged reconstruction of the bone prior to the implantation of a new implant. BonyPid-500 acts as a scaffold to support bone recovery and delivers a local and prolonged delivery of an antibiotic to prevent local development microbial colonization, which subsequently may result in infections and bone resorption. Expected outcomes are to reduce implant procedure costs and to prevent prolonged and painful dental procedures.

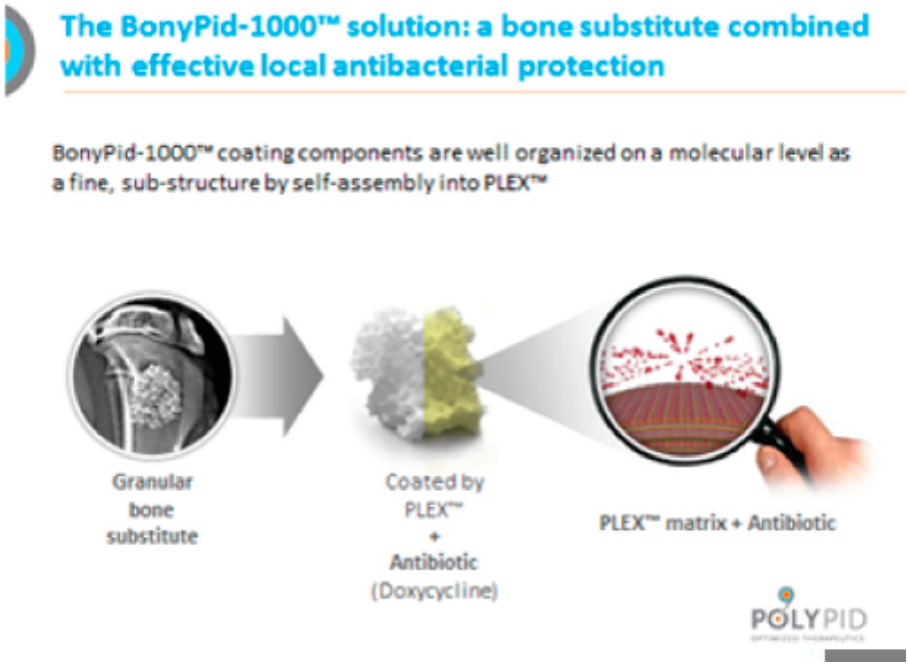
We have entered into commercial understandings with MIS Dental Implants Ltd. (MIS) for the distribution and sale of BonyPid-500 for the indication of peri-implantitis. MIS, which is reported to hold approximately 6% of the global implant market, has undertaken to pay PolyPid a milestone-based license fee, as well as an ongoing revenue stream based on future sales.

SSI. According to the a datasheet published by the U.S. Centers for Disease Control and Prevention (CDC) in 2010 and several Millennium reports, of the 100 million interventional procedures conduced in the United States, approximately 30 million carry a risk of incurring surgical site infections (SSI) despite systemic antibiotic administration. In a 2001 report prepared for the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, 80 – 90% of surgeries use systemic antibiotic administration. As an example, according to numerous Millennium reports, there were approximately 1,500,000 primary hip replacements conducted globally during 2013, of which approximately 300,000 took place in the United States. Although almost all of these procedures are accompanied by antibiotic administration, around 11% of these procedures will still incur infections according to the American Journal of Health-System Pharmacy published in February 2013. Similarly, according to the above CDC report, approximately 305,000 colectomy procedures are performed annually in the United States. According to a 2014 Journal of Hospital Infection review, 14 – 18% of colectomy procedures result in infections despite systemic antibiotic treatment. These are just a few of many examples of the need for an effective, localized and prolonged antibiotic treatment that our product candidates are intended to address.

Lead Product Candidates — BonyPid-1000, BonyPid-500 and D-PLEX

Osteoconductive-Drug Combination (ODC) family of products.

Two of our three lead product candidates (BonyPid-1000 and BonyPid-500) address the orthopedic and dental markets for treatment of bones, and the third (D-PLEX), for infection management in various soft tissues. The following graphic illustrates how BonyPid-1000 is combined with a conventional granular bone substitute to improve the healing of severe fractures.



Bones are difficult to medicate due to poor access by systemically-administrated drugs to the skeletal system. This major obstacle in orthopedic practice can be overcome by direct release of medications into damaged bones. Our osteoconductive PLEX-based line of products (BonyPid-1000 and BonyPid-500) in

development are commercially available medical devices that have been coated with our PLEX matrix. These products support bone recovery by loading a PLEX-coated biodegradable bone graft substitute to the affected site, and medicate the bone locally over prolonged periods of time to create a supportive environment for bone recovery and growth. Our proprietary PLEX micro-coating is a proprietary matrix that demonstrates a stably medicated local bone environment over prolonged periods of weeks and months. The suggested mechanism of gradual surface degradation of the PLEX-matrix layers PLEX releases the drug that is encapsulated between them, and in this way the drug is released in a programmed continuous, constant and controlled manner. Our PLEX-based line of products encapsulates broad spectrum antibiotics, but the PLEX technology underlying them is versatile enough to encapsulate multiple different types of drugs, or combination of drugs.

The PLEX matrix is a formulation that can also be used to coat other medical devices such as orthopedic implants. The advantages of the PLEX-based family are achieved using a combination of known and commonly used osteoconductive bone void fillers plus the PLEX matrix components. All these components are pharmaceutically-approved that do not create new chemical bonds and do not adversely affect the active drugs. The combination of these elements in our product candidates is currently in the clinical trial stage.

BonyPid-1000

BonyPid-1000 is the first product we are developing based on the osteoconductive PLEX-based technology and concept. BonyPid-1000 is an osteoconductive device that is comprised of a bone void filler, micro-coated by a fine matrix layer that entraps a broad spectrum antibiotic. Upon local implantation into bone voids such as the fractured site, the coating releases an initial dose of the antibacterial drug (Doxycycline) followed by a constant release rate for a predetermined period of approximately three to four weeks. The initial dose is designed to provide initial anti-microbial protection and that may be critical in many trauma cases, followed by a prolonged drug release period that provides an extended protective environment for the graft that is needed for an effective bone-healing process.

Bone Infections. Contamination of bones by bacteria can lead to bone infections and subsequently to bone loss, non-union of fractures and overall poor bone recovery from traumatic events and bone surgeries that in severe, acute cases may lead to sepsis and amputations. Other chronic bone infections by pathogenic microorganisms may result in a severe prolonged inflammatory disease, followed by bone resorption (such a condition is known as osteomyelitis). These bacterial infections (acute or chronic) are difficult to cure due to poor blood supply and a resulting poor accessibility of systemically-administrated antibiotics to the infected bone and biofilm resistance to antibiotics. Biofilm tends to develop on dead tissue and on the surface of medical devices commonly used to support bone recovery. As a result, physicians are required to prescribe large amounts of the therapeutic drug to reach sufficiently high drug concentrations in the blood over prolonged periods. These regimens may be associated with toxic effects such as ototoxicity and nephrotoxicity, or can cause adverse gastrointestinal side effects. Furthermore, surgery does not ensure that the infected tissue was completely excised or that infection will not relapse. These major drawbacks led to the development of local antibiotic treatments. Local antibiotic administration is often used together with systemic antibiotics in order to overcome poor antibiotic bone penetration that has been administered systemically (intravenously or orally).

In current medical practice, open fractures are assumed to be contaminated by bacteria in the development of a treatment plan. The Gustilo-grade (known also as Gustilo-Anderson classification — seen in the opposite diagram) is a common way to classify the severity of open fractures. Regardless of the standard of care used (systemic antibiotic or even the currently available local administration of antibiotics), infection and amputation rates increase in direct correlation to the Gustilo grading. As shown in the diagram, the infection rate of a Gustilo grade II is much lower than the infection rate of the more severe, Gustilo grade IIIA, IIIB or IIIC. In Gustilo grade IIIC, the amputation rate can reach 50%.

Existing approaches to support bone growth by the prevention of bone infection. The only product that is approved for sale in the United States for local treatment of contaminated or infected bone is based on antibiotics loaded in a polymethylmethacrylate (PMMA) bone cement. PMMA loaded with antibiotics are sometimes used off-label in a similar way as the commercially available antibiotic beads (such as Septopal®). The clinical effect of using this method is hampered by the fact that over 90% of the drug remains entrapped

inside the cement beads and is not released into the body. Furthermore, bone cement is not biodegradable and is not osteoconductive, and therefore the PMMA beads have to be removed in a second surgical procedure. Biodegradable polymers such as polylactic/polyglycolide (PLGA), chitosan or collagen have also been used as antibiotic-loaded implants in bone lesions. There is doubt, however, whether such polymeric drug delivery systems can maintain a constant and sufficient release rate of antibiotics over the prolonged period of time needed to fully eradicate the invading bacteria. To overcome these major limitations, attempts were made to add antibiotics to osteoconductive bone fillers such as calcium sulfate hemihydrate pellets, and to calcium hydroxyapatite ceramics. The release of antibiotics in these bone fillers is characterized by a rapid discharge of the drug during the first few hours and days, followed by a sharp decline in the released amounts thereafter. Others have tried to combine an antibiotic biodegradable polymer scaffold, together with a scaffold for bone formation. We believe that these combinations do not appear to have overcome the drawbacks associated with using polymers as a drug delivery system, where most of the antibiotic content is discharged in a few days.

An alternative approach that was tried, used a liposomal drug delivery system to deliver antibiotics into the needed bone site. Liposomes offer a safe and convenient way to control the location of the delivered drug. The drawback, however, is that this treatment requires prolonged and repeated systemic administration of the encapsulated drugs in order to achieve complete eradication of bacteria from bone and soft tissues. When liposomal antibiotics were combined with osteoconductive elements, most of the drug was released in the first 24 hours, followed by sharply decreasing amounts in the following days. Liposomes are also limited in their ability to penetrate deeply into the contaminated voids.

The composition of BonyPid-1000. BonyPid-1000 is a synthetic bone substitute comprising resorbable beta tricalcium phosphate (β-TCP) granules. A portion of these granules is coated with a broad-spectrum antibiotic, Doxycycline-hyclate (Doxycycline, or Doxy). Upon hydration in the body, the bone filler acts as a scaffold to support osteoconductive bone recovery, while the Doxy is released from the coating. The antibacterial activity of the released antibiotic is ancillary to the osteoconductive activity of the bone substitute, and prevents its potential rejection or early absorption by bacteria-related local bone infection. BonyPid-1000 is designed as a sterile, biocompatible and biodegradable product. As a result, there is no need to remove it by a second surgery.

BonyPid-1000 has been designed to meet the following set of requirements: safety, biocompatibility, biodegradability, having osteoconductive properties and having antibacterial activity together with allowing constant and prolonged antibiotic release at the implantation site.

Indications for BonyPid-1000. Similar to the indication for other granular bone fillers, BonyPid-1000 is intended for filling and reconstruction of bone voids, defects or gaps within the skeletal system. These osseous defects may be surgically created, caused by traumatic injuries or caused by bone infections. BonyPid-1000 is resorbed and replaced with bone during the healing process and, ancillary to this activity, continuously releases its antibiotic load. Doxy is an established antibiotic that has been shown to be effectively used for treating infections caused by many strains of both gram positive and gram negative bacteria, due to its broad spectrum activity.

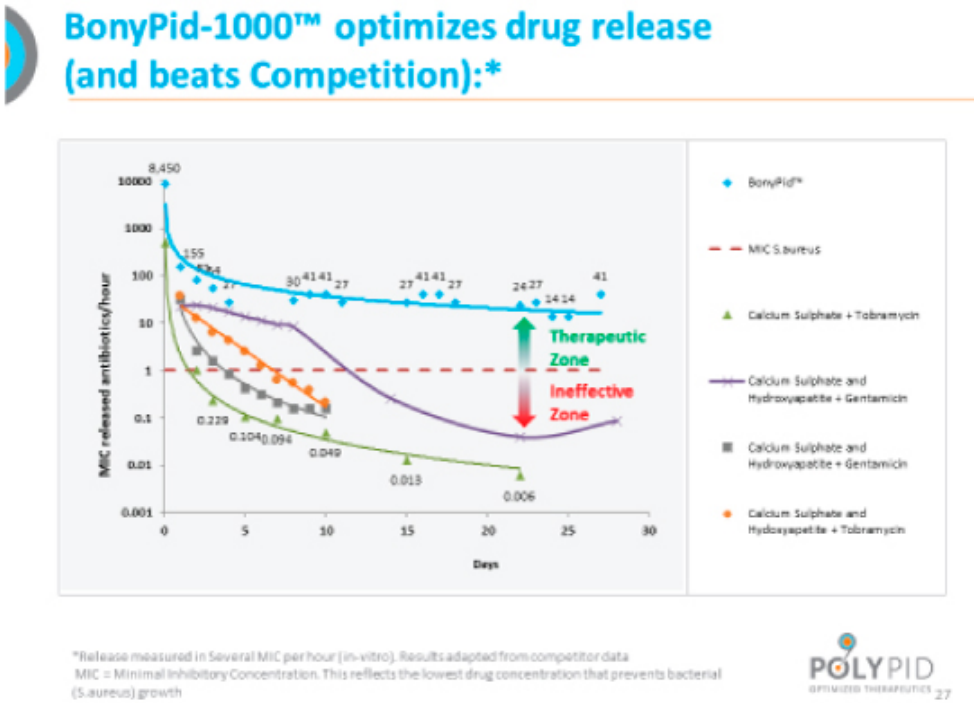
The standard of care for severe open fractures with significant bone loss may include the implantation of about 10g of bone filler into the void. Depending on the severity of the bone fracture, lower or higher bone filler doses may be used. A BonyPid-1000 vial contains 10g of coated TCP bone void filler. Doxy composes 0.65% in weight of a BonyPid-1000 vial; therefore the expected applied dose for the entire three to four week period in which one BonyPid-1000 vial is used, the release of Doxy will be as low as 65mg of Doxy which is only about 1.1% of a 30-day oral regimen and only 33% of a standard daily oral dose.

BonyPid-1000 is designed to have a two-phased release profile: The first phase provides a high initial release of Doxy from BonyPid-1000 during the first 24 hours after administration. This important characteristic allows a very effective initial anti-bacterial preventive environment. The second phase has a prolonged release of the remaining dose of Doxy up to four weeks thereafter creates complementary support in the effective eradication of the bacteria by the immune system, and the prevention of the formation of biofilm on the bone filler implant.

Due to the very low overall dose per vial, BonyPid-1000 has a large safety zone that allows surgeons to use BonyPid-1000 with minimal concerns regarding the safety of using multiple vials, even when exceptionally large voids need to be filled, such as in Gustilo III grade open fractures.

Release Profile. Upon hydration in the body, the formulation gradually degrades, layer by layer, from the outer layers through to the inner layers. This degradation allows the entrapped antibiotic in the layers to be released constantly into its surroundings, aimed to protect the surface of the graft from the development of biofilm.

The following diagram details the BonyPid-1000 release profile, as well as the release profile of other products and compares the activity of the released anti-bacterial drugs of various competitors over up to a 30-day period. Only BonyPid-1000 (marked in blue) demonstrates a prolonged release of highly effective concentration between 1 to 4 weeks post hydration. The numbers beside the blue line indicate the calculated multiples of Minimum Inhibitory Concentration (or MIC) for S.aureus bacteria of the antibiotic generated by BonyPid-1000 per hour around the implant, over a period of 30 days. S.aureus is the most common bacteria infecting bones. In comparison, the diagram indicates that competing products may fail to deliver sufficient concentrations to combat bacteria after a few days, which may prove to be insufficient to protect the implant over the prolonged bone recovery period. The BonyPid-1000 data was generated by the Company's own in-vitro studies. The competitive data was derived from commercially available publications and public domain data made available by the competitors.



BonyPid-1000 — Safety

The currently available bio-compatibility package data support the safety and tolerability of BonyPid-1000. Moreover the safety and the osteoconductivity of BonyPid-1000 at the skeletal tissue has been proven in testing to date and is comparable to the non-coated portion of the BonyPid-1000 TCP granules.

BonyPid-1000 — Clinical data

There have been two clinical trials using BonyPid-1000 in orthopedic indications: Pilot (First in Man) study BonyPid-1000-101 and study BonyPid-1000-102 (both are pilot studies). Both studies assessed the safety and effectiveness of BonyPid-1000 when implanted in highly traumatic patients experiencing severe contaminated or infected open long fractures classified as Gustilo IIIA and IIIB. The severe open fracture indication was selected as one of the most sensitive disease model in order to demonstrate the efficacy of immediate implantation of BonyPid-1000 into the open fracture void during the first surgical intervention. We are currently planning BonyPid-1000-103, our confirmatory clinical study which is designed to support CE mark submission which study is expected to also serve as a safety and preliminary effectiveness study as part of the FDA approval process. The study is planned to be a multinational, multicenter, prospective, open-label, dual arm study to demonstrate the safety and efficacy of BonyPid-1000.

The BonyPid-1000-101 clinical study, conducted in the Philippines, had all the patients enrolled and complete their follow-up as required in the study. The BonyPid-1000-102 clinical study is in the same status and demonstrated similar results. Both studies for orthopedic indications are open label, non-randomized, single arm clinical studies using BonyPid-1000 concomitantly with the best available standard of care: intravenous antibiotics (systemic treatment), irrigation and debridement followed by fracture stabilization by fixation.

BonyPid-1000-101 clinical study

This study was a pilot (First in Man) clinical trial assessing the safety and effectiveness of a BonyPid-1000 medical device implanted in highly traumatic patients experiencing contaminated or infected open long fractures with high severity grades of Gustilo IIIA and IIIB. Most patients were injured by traumatic motorbike accidents, and most of the remaining patients were either injured pedestrians or fall victims. The study was designed to demonstrate both the safety and the efficacy of BonyPid-1000 upon immediate implantation into the open fracture void during the first surgical intervention in severe and contaminated open fractures. BonyPid-1000 was used concomitantly with the standard of care (SOC) used in the trial hospital, which represents the most common standard of care used worldwide in this indication. For this study, 16 patients were enrolled. Their mean age was 31 (ages 21 – 55 years), and all of them had open tibial fractures. Eleven patients had Gustilo IIIA and five patients had Gustilo IIIB.

Primary BonyPid-1000 implantation was performed following target fracture irrigation and debridement. In case additional irrigation of the soft tissue was needed prior to soleus flap and or skin graft, a second BonyPid-1000 implantation was performed at the discretion of the investigator. All fractures were fixated by external fixators. Soft tissue closure and X-Ray images of the bone healing process demonstrated the healing of the fractures.

Immediate wound closure on the first surgery including BonyPid-1000 implantation (day 0) was done in eight patients. In eight other patients, the treatment was much more complicated; five patients needed skin grafts and three patients needed a soleus flap followed by skin graft procedures.

From a safety perspective, results at the time of reporting (six-month follow up) have shown no serious adverse events (AEs) nor have any deaths been reported. All AEs reported were mild or moderate. No amputation events were recorded. No target bone infection was reported in any of the patients during the 12 months following treatment (namely, no target bone infections in any of the 16 patients). In contrast, the historical control group with a similar severity of open fracture from the same hospital demonstrated a 27% bone infection rate.

Callus, which represents the initiation of bone healing process, was seen in 14 patients within few weeks post BonyPid-1000 implantation, initiating at as early as eight weeks after bone implantation in 50% of the patients.

BonyPid-1000-102 clinical study — ongoing

This study is a multicenter study to confirm the safety and the effectiveness of BonyPid-1000 in contaminated or infected open fractures. It’s an open-label single arm clinical study, using BonyPid-1000 in contaminated or infected open fractures. It is being conducted at clinical sites in Europe. In this study to date, three patients have been enrolled, and all patients underwent a six-month follow-up. The patients enrolled and

complete their follow-up as required in the study. Study 102 is materially similar to Study 101 and is in effect an extension to Europe of Study 101 that was conducted in the Far East.

Clinical development plan — next steps for market approval

We are currently planning to perform clinical study BonyPid-1000-103 which is our confirmatory study designed to support CE mark submission which study is expected to also serve as a safety and preliminary effectiveness study as part of the FDA approval process. The study is planned to be a multinational, multicenter, prospective, open-label, dual arm study to demonstrate the safety and efficacy of BonyPid-1000. The study population includes patients with a diagnosis of Gustilo IIIA or IIIB long-bone open fractures and that are suitable for intra-medullary fixation or intramedullary nailing in accordance with the standard of treatment of the medical centers.

We estimate that the confirmatory clinical trial for BonyPid-1000 will start during the second half of 2015. We are in the process of preparation for submission of BonyPid-1000 for CE certification in the EU. We expect to submit BonyPid-1000 for regulatory approval in Europe as early as the second half of 2016.

BonyPid-500

BonyPid-500 is a synthetic bone graft substitute which is made of Beta Tricalcium Phosphate (β-TCP) granules. BonyPid-500 is composed of bare granules and of similar granules that are coated by doxycycline-hyclate (Doxy) using our PLEX proprietary coating technology. The total percentage by weight of Doxy incorporated into BonyPid-500 in each vial is 0.65%. BonyPid-500 is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects, such as filling of periodontal/infrabony defects; ridge augmentation; filling of extraction sites (implant preparation/placement); sinus lifts, and filling of cystic cavities. BonyPid-500 gradually resorbs and is replaced with bone during the healing process. Doxy incorporated into BonyPid-500 reduces microbial colonization of the grafting material by Doxy sensitive bacteria.

Clinical study BonyPid-500-201

We are currently planning clinical study BonyPid-500-201, as a pilot (First in Man) trial. We are currently preparing to initiate this clinical study, and expect it to be conducted during 2015. The study is planned to demonstrate healing of defects associated with dental implant complications by combination of a process of manual surface decontamination procedures in combination with implantation of BonyPid-500. The primary objective of this study is to radiographically evaluate surgical treatment outcomes with or without adjuvant implantation of BonyPid-500 in peri-implant intrabony defects.

D-PLEX

D-PLEX is designed to provide localized infection treatment and prevention that shall be administered locally during surgical procedures. Surgical Site Infections, also known as SSI, occur in varying percentages of surgical procedures despite administration of systemic antibiotics, depending on the procedure type. D-PLEX is expected to reduce the overall infections and overcome or reduce existing infections, including hospital-acquired resistant bacteria. D-PLEX is planned to be applied into a variety of tissues and solid organs to treat and prevent infections that may exist prior to, or appear after, surgery. Some possible examples include abdominal surgeries such as colectomy and appendectomy and chronic bone infection (osteomyelitis). We are currently evaluating our regulatory alternatives with regard to this product candidate. We expect, in 2015, to begin a limited clinical trial in Asia and to enter discussions with the FDA as to our clinical path in the United States.

Research Programs

The following programs, based on our PLEX platform, are in the early research phase:

- Anti-Inflammatory Research Program. Systemic treatments are very effective for the treatment of inflamed conditions. However, wide use of anti-inflammatory agents is limited due to serious systemic side effects that include liver damage, heart disease, addiction and pain. We are developing a localized and controlled delivery of a very small, yet effective dose with minimal systemic side effects.

- Anti-Cancer Research Program. Systemic anti-cancer treatments have serious side effects. Our program is designed to treat cancer by extended localized release of common chemotherapeutic agents. The program is aimed at reducing the overall dose of toxic agents for a prolonged, local delivery while achieving effectiveness that is at least comparable to systemic administration.

Intellectual Property

Patent and trade secret protection is critical to our business. Our success will depend in large part on our ability to obtain, maintain, defend and enforce patents and other intellectual property for PolyPid technology and our product candidates, to preserve trade secrets and proprietary know-how, and to operate without infringing the patents and proprietary rights of third parties. We have sought and continue to actively seek patent protection through the filing of Patent Cooperation Treaty patent applications as well as national patent filing in various countries, including the United States, Europe, Australia, Canada, China, India, Israel, Japan, and Hong Kong.

Patents. PolyPid has five published Patent Cooperation Treaty, or PCT, applications, of which four have been nationalized in most or all of the countries listed above, and national stage filings of the fifth are planned for early 2015. These and other patent applications in preparation are designed to provide several layers of protection for PolyPid's unique controlled and prolonged drug delivery technology, including protection of the composition per se, methods of producing those compositions and their use in different medical applications. Among other things, these patents applications are intended to protect the use of PolyPid's unique technology for the delivery of different types of drugs from small molecules through peptides, and up to nucleic acid-based drugs such as siRNA and DNA.

Examination of several of PolyPid's patent applications is underway in the United States, Europe, China, Japan and Israel (requests for examinations of PolyPid's patent application were also filed in Australia, Canada and India, to date, examination of the applications in these jurisdictions has not started).

With respect to PolyPid's first product, BonyPid-1000 (for local treatment of bone voids, bone defects and bone fractures), patent applications of this family have been issued in China and allowed in the United States and Israel. Patent applications of this family are currently pending (as of September 15, 2014) in Europe and Japan and are awaiting examination in Australia, Canada and India.

Additionally, a patent covering compositions for sustained release of nucleic acid agents has been issued in the US. One of PolyPid's applications are in the PCT stage.

Trade Secrets. In certain circumstances, we rely on trade secrets to protect our technology. Trade secrets are difficult to protect. Generally we protect our proprietary processes and manufacturing this way and we secure confidentiality agreements from all of our employees, contractors, consultants and advisors. We cannot assure that the agreements will not be breached or that we will be able to remedy such a breach or that our trade secrets will not become known in the public domain and be discovered by our competitors. Disputes may also arise with respect to know-how and inventions created by our employees, contractors and consultants. See the section entitled "Risk Factors — Risks Related to Our Intellectual Property."

Other products

Our intention is to expand our product line based on our platform technology to treat other poorly accessible organs, and treating the brain in particular. Additionally we plan to develop different administration techniques for our existing line of product candidates so as to enable more effective localized antibiotic protection of organs and tissues.

Collaborations

Our goal is to become a leading specialty pharmaceutical company in the field of extended release, local drug delivery. Based on our proprietary PLEX platform, we aspire to address some of modern medicine's main challenges, where current local or systemic administration has limited effect, is too toxic, or both. Our primary focus is on the field of infection treatment and prevention.

Our commercial strategy has two elements: our product development activities, and our collaboration and licensing activities.

Within the scope of our product development activities, we intend to discover, develop and commercialize novel solutions either on our own or in collaboration with partners.

Within the scope of our collaborations and licensing activities, we are aiming to collaborate with pharmaceutical companies for the encapsulation of their drugs (generic or proprietary) using our PLEX platform to enable administration of drugs in a localized, targeted manner. The purpose of these collaborations is to enhance our PLEX platform into a partnered product pipeline and to generate revenues through licensing of PLEX for certain applications. As a first step in this strategy, we have recently entered into a preliminary technology evaluation agreement with a large U.S. pharmaceutical company. We envision that this technology evaluation agreement may lead to discussions on a license and collaboration contract.

The Company is also engaged in several research and scientific collaborations and consortia with several third parties, as follows:

- *Development and commercial collaboration with MIS Implants Technologies Ltd*. for the dental implant market (BonyPid-500). Subject to continued collaboration, we have agreed to grant MIS worldwide marketing rights for peri-implantitis indications, which are indications involving deep oral bone infections and consequent bone loss around dental implants. MIS is partially funding our development program and has agreed to participate in the financing of the clinical studies necessary for sales approvals in the United States and Europe. In addition, we have received certain milestone payments from MIS that are refundable, or subject to cancellation, under certain conditions. See Note 1 to the audited financial statements included herein.
- *European consortium: Biofilm Alliance*. This is a consortium comprised of European universities and companies. It was established to develop a unique treatment of biofilm-associated infections, and is funded by the European Union’s Seventh Framework Program. We have executed the formal consortium documents governing this activity as required by all the consortium members that among other matters, govern the members' rights with respect to intellectual property developed as a result of the consortium activities. Our consortium activities have not generated rights in other parties to any of our intellectual property. We have received non-royalty bearing grants from this consortium. See Note 2(g) and (i) to the financial statements included herein.
- *Israeli consortium: Rimonim*. This consortium is comprised of Israeli biotechnology companies and major universities under the auspices of the Israeli Office of the Chief Scientist. It was established to promote siRNA-based therapeutics and is focused on the chemistry and delivery of RNA-based drugs for cancer treatment. We have executed the formal consortium documents governing this activity as required by all the consortium members that among other matters, govern the members' rights with respect to intellectual property developed as a result of the consortium activities. Our consortium activities have not generated rights in other parties to any of our intellectual property. We have received non-royalty bearing grants from this consortium. See Note 2(g) and (i) to the financial statements included herein.

Competition

A wide variety of local-delivery solutions have been offered and are currently being developed in order to bypass the shortcomings of systemic administration of drugs. However, currently existing solutions are often very limited, either in the duration in which drugs can administered, or the controllability of drug release: Most competitive local delivery solutions rely on lipid-based matrices and cease to be effective after a mere few days. Such a short duration is often not sufficient to have a lasting substantial therapeutic effect. Other solutions that are based on various polymers can extend drug release duration over a few weeks. However, these solutions have difficulties in controlling the amount of drug that is released at any given time and it is doubtful whether they can ensure that potentially harmful drug bursts are not released in the body. Another common disadvantage is the poor capability to secure the drug reservoir over the desired extended therapeutic period.

BonyPid-1000 is our first product candidate that utilizes the benefits of the PLEX platform technology. To our knowledge, to date, the only product that is approved for sale in the United States for local treatment of contaminated or infected bone is based on antibiotics loaded in a polymethylmethacrylate (PMMA) bone

cement, in the form of antibiotic beads (such as Septopal®). The clinical effect of using this method is hampered by the fact that over 90% of the drug remains trapped inside the cement beads and is not released into the body. Furthermore, bone cement is not biodegradable and is not osteoconductive, and therefore has to be removed by a second surgical procedure. Biodegradable polymers such as polylactic/polyglycolide (PLGA), chitosan or collagen have also been used as antibiotic-saturated implants in bone lesions. There is doubt however, whether such polymeric drug delivery systems can maintain a constant and sufficient release rate of antibiotics over the prolonged period of time needed to fully eradicate the invading bacteria. Moreover, the polymeric systems are often unable to sufficiently support osteoconductive bone growth into the void. To overcome these major limitations, antibiotics were added to osteoconductive bone fillers such as calcium sulfate hemihydrate pellets and tricalcium phosphate, and to calcium hydroxyapatite ceramics. The release of antibiotics in these bone fillers is characterized by a rapid release of the drug during the first few days, followed by a sharp decline in the released amounts thereafter. Others have tried to combine these two methods by providing an antibiotic biodegradable polymer scaffold, together with a scaffold for bone formation. Unfortunately, these combinations do not appear to have overcome the drawbacks associated with using polymers as a drug delivery system, where most of the antibiotic content is expended in a few days.

In the specific field of BonyPid-1000, there are a number of companies that have regulatory approval to market products outside the United States only that are designed to assist in bone healing. These products include:

- PMMA beads/Septopal (Biomet Manufacturing Corp)
- Osteoset T (Wright Medical Group)
- Targobone (Ossacur AG)
- PerOssal (AAP implante AG)
- Certamet G (BoneSupport AB)

We believe that these products can be evaluated by five different criteria, namely:

- whether the product is biodegradable;
- the ability to support bone growth;
- the ability to pre-determine the release profile of the active drug;
- the ability to provide long-term release of up to weeks; and
- the stability of the drug reservoir in a hydrated environment.

We believe that BonyPid-1000 satisfactorily achieves each of these performance measures, that one of the listed competitive products meets none of the criteria, and the others meet one or two of the five criteria.

More generally with regard to localized, prolonged drug delivery systems, there are certain drug delivery solutions in the market, such as those offered by Pacira Pharmaceuticals. Pacira’s lead product, DepoFoam, is a multivesicular liposome technology that encapsulates drugs and releases them over a period of several days. Similarly, Tyrx Inc. (acquired by Medtronic) provide a polymer-based local release solution called AIGISRx that elutes drugs over several days. We believe, however, that the technological solutions offered by these companies are less suited for the markets we are addressing and that our PLEX technology and related product candidates offer more flexible, long-term solutions.

Government Regulation

We are subject to extensive regulation by the FDA, under the Federal Food, Drug, and Cosmetic Act, as well as by other federal, state, and local regulatory agencies. Our product candidates must be approved by the FDA before we can commence clinical trials and/or market those products.

The process of obtaining regulatory marketing approvals and/or clearance, and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Regulatory Strategy

We have submitted documentation to the relevant regulatory authorities for BonyPid-1000 in the EU as a device-drug combination product and plan to submit BonyPid-500 as a device-drug combination product in the United States as well. We currently estimate that the authorities will regulate these products as such. We plan to submit D-PLEX, under the drug pathway. However, until the registration process is completed, and marketing approvals are obtained, there is no assurance that relevant regulatory authorities will accept our regulatory strategy. The regulatory authorities may request that we change the regulatory pathways leading to marketing approvals in their various jurisdictions. To date, the regulatory authorities in the EU have provided their official response confirming our regulatory strategy for BonyPid-1000 as a Class III medical device incorporating an ancillary medicinal substance. In the United States, our discussions with the FDA are still ongoing, and we estimate that the U.S. authorities will direct us to follow a similar regulatory pathway, with some variations, due to its different regulatory environment. In the United States, we expect the orthopedic and dental indications to be submitted separately. In the EU, BonyPid-1000 will be jointly submitted for both orthopedic and dental indications.

To date, we have made the following regulatory submissions and have received the following responses:

United States — FDA

- A pre-submission package was submitted to Center for Devices and Radiological Health (CDRH) on March 28, 2014.
- We received from CDRH on June 27, 2014 a non-formal response with a recommendation to submit a pre-submission amendment, while pursuing a PMA pathway. We are currently preparing the clinical development plan and clinical synopsis to support the pre-submission amendment. We anticipate that we will submit this amendment by the end of September 2014. We also anticipate that a meeting with the FDA will be held within the next four to eight weeks, although there can be no assurance that this schedule will be met.
- A pre-submission amendment was submitted on August 15, 2014. We anticipate that a meeting with the FDA will be held by November 2014, although there can be no assurance that this schedule will be met.

CE Mark for the EU — British Standards Institute (BSI), Notified Body

- A Clinical and Regulatory Strategy document was submitted to BSI on December 12, 2013.
- An official response was given by BSI on February 21, 2014, following a review by clinical and medicinal substance reviewers.
- BSI has confirmed that BonyPid-1000 is classified as a Class III implantable medical device with the following applicable rules:
    - Rule 8 — Implantable devices and long-term surgically invasive devices (>30 days);
    - Rule 13 — Devices incorporating, as an integral part, a medicinal product or a human blood derivative.
- BSI has also confirmed that a clinical trial will be required to demonstrate the safety and performance of BonyPid-1000 to support a CE MARK Certification.
- We have also submitted to the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) a scientific advice meeting request. A scientific advice meeting has been scheduled in September 2014.

FDA Regulation

The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and its implementing regulations govern and set forth, among other things, requirements, which we and our contract manufacturers, contract testing laboratories and suppliers are involved. These activities include, but are not limited to, product research, development, testing, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, sales, distribution, import, export, advertising and promotion.

Failure to comply with the law could result in, among other things, warning letters, civil penalties, delays in approving or refusal to approve a product candidate, product recall, product seizure, interruption of production, operating restrictions, suspension on withdrawal of product approval, injunctions, or criminal prosecution.

For combination products, the FDA, Office of Combination Products (OCP), determines which center or centers within the FDA will review the product and under what legal authority the product will be reviewed.

FDA Clearance of Medical Devices

In the US, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the extent of controls the FDA determines are necessary to reasonably ensure their safety and efficacy:

- Class I: general controls, such as labeling and adherence to quality system regulations;
- Class II: general controls, premarket notification (510(k)), and specific controls such as performance standards, patient registries, and post-market surveillance; and
- Class III: general controls and Premarket Approval (PMA).

To request a marketing authorization by means of a 510(k) clearance, we must submit a premarket notification demonstrating that the proposed device is substantially equivalent to another legally marketed medical device; that is, it has the same intended use, and is as safe and effective as a legally marketed device and does not raise different concerns of safety and effectiveness than does a legally marketed device.

510(k) submissions generally include, among other things, a description of the device and its manufacturing, device design, device labeling, medical devices to which the device is substantially equivalent, safety and biocompatibility information, and the results of performance testing. In some cases, a 510(k) submission must include data from human clinical studies. Marketing may commence only when the FDA issues a clearance letter finding substantial equivalence. After a device receives 510(k) clearance, any product modification that could significantly affect the safety or effectiveness of the product, or that would constitute a significant change in intended use, requires a new 510(k) clearance or, if the device would no longer be substantially equivalent, would require a PMA.

If the FDA determines that the product does not qualify for 510(k) clearance, then the company can submit a De Novo petition arguing that the relative risk of the product is of a class II device. Alternatively, the company must submit and the FDA must approve a PMA before marketing can begin.

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive pre-clinical data and a well-controlled clinical trial. Information about the device and its components, device design, manufacturing and labeling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. During the review period, an FDA advisory committee, typically a panel of clinicians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. The FDA is not bound by the advisory panel decision, but the FDA often follows the panel's recommendation. The PMA can include post-approval conditions including, among other things, restrictions on labeling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

During the review of either a 510(k) or PMA, the FDA may request more information or additional studies and may decide that the indications for which we seek approval or clearance should be limited. We cannot be sure that our product candidates will be cleared or approved in a timely fashion or at all. The review of combination products is often more complex and may require more time than the review of a product under the jurisdiction of only one center within the FDA.

Our device-drug combination products (BonyPid-1000 and BonyPid-500) are beta-Tri-Calcium Phosphate (β-TCP), doxycycline coated Bone Void Fillers. BonyPid-500 and BonyPid-1000 are expected to be regulated in the US as class III medical devices, and require FDA authorization prior to marketing, by means of a PMA. Based on 21 CFR 888.3045, we anticipate that BonyPid-1000 (primarily for orthopedic indication) will be classified as a resorbable calcium salt bone void filler, antibiotic containing (Product code: to be assigned, analogous to MQV) whereas, based on 21 CFR 872.3930, BonyPid-500 (primarily for dental indication) will be classified as a bone grafting material antibiotic containing (Product code: to be assigned, analogous to LPK).

With respect to our drug product candidates, such as D-PLEX, we anticipate that the FDA will select different centers and/or legal authorities for review, depending on the incorporated active pharmaceutical ingredient, or API (such as, but not limited to, drug, siRNA and biologics respectively). In these cases, the governmental review requirements would substantially vary. If a product candidate was reviewed under drug or biologic legal authorities and/or reviewed by the Center for Drug Evaluation and Research (CDER), or Center for Biologics Evaluation and Research (CBER), the path to regulatory approval would be different and could be more costly and lengthy.

FDA Approval of Pharmaceutical products

In general, the regulatory steps required before a new pharmaceutical drug-device combination product may be marketed in the United States generally include:

- Completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practices regulations;
- Submission to the FDA of an IND, which must become effective before human clinical studies may begin;
- Approval by an IRB at each clinical site before each trial may be initiated;
- Performance of adequate and well-controlled clinical trials in accordance with federal regulations and with current good clinical practices, or GCPs, to establish the safety and efficacy of the investigational drug product for each targeted indication;
- Submission of an NDA or a BLA to the FDA;
- Satisfactory completion of an FDA Advisory Committee review, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facilities at which the investigational product is produced to assess compliance with cGMP, and to assure that the facilities, methods and controls are adequate; and
- FDA review and approval of the NDA or BLA.

Section 505 of the FFDC Act describes three types of NDAs 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 effectiveness. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, created two additional marketing pathways under Sections 505(b)(2) and 505(j) of the FFDC Act. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. This regulatory pathway enables the applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for 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 effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to (i.e., performs in the same manner as) the innovator drug.

The generic version generally must deliver approximately the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) 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. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor 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 an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) 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 an ANDA or 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.

Hatch-Waxman Act

This statute establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For example, the holder of an NDA may obtain five years of exclusivity upon approval of a new drug containing a new chemical entity, or NCE, that has not been previously approved by the FDA. The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDA for drugs that include the innovation that required the new clinical data. Potentially, some of our pharmaceutical products' candidates may utilize the section 505(b)(2) regulatory pathway. Even though our pharmaceutical products' candidates will utilize active drug (or biologic) ingredients that are commercially marketed in the United States in other dosage forms, we need to establish safety and effectiveness of those active ingredients in the formulation and dosage forms that we are developing.

Expedited review and approval

The FDA has various programs, including Fast Track, priority review and accelerated approval, which are intended to expedite or simplify the process for reviewing product candidates, or provide for the approval of a product candidate on the basis of a surrogate endpoint. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, product candidates that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of product candidates to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Priority review is designed to give product candidates that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months.

Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated product candidate and expedite review of the application for a product candidate designated for priority review. Accelerated approval, which is described in Subpart H of 21 CFR Part 314, provides for an earlier approval for a new product candidate that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a laboratory measurement or physical

sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a product candidate receiving accelerated approval perform post-marketing clinical trials.

In the Food and Drug Administration Safety and Innovation Act, which was signed into law in July 2012, the U.S. Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of product candidates under accelerated approval. The law required the FDA to issue related draft guidance within a year after the law's enactment and also promulgate confirming regulatory changes. In June 2013, the FDA published a draft Guidance for Industry titled "Expedited Programs for Serious Conditions — Drugs and Biologics," which provides guidance on FDA programs that are intended to facilitate and expedite development and review of new product candidates as well as threshold criteria generally applicable to concluding that a product candidate is a candidate for these expedited development and review programs.

In addition to the Fast Track, accelerated approval and priority review programs discussed above, the FDA also provided guidance on a new program for Breakthrough Therapy designation. The FDA defines a Breakthrough Therapy as a drug that 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. A drug designated as a Breakthrough Therapy is eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a Breakthrough Therapy. 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. A request for Breakthrough Therapy designation should be submitted concurrently with, or as an amendment to an IND. FDA has already granted this designation to approximately 30 new product candidates and recently approved the first Breakthrough Therapy designated drug.

Medical devices Clinical Trials

One or more clinical trials are always required to support a PMA application and are also sometimes required to support a 510(k) submission. Clinical studies of unapproved or uncleared medical devices or devices being studied for uses for which they are not approved or cleared (investigational devices) must be conducted in compliance with FDA requirements. The sponsor company must submit an Investigational Device Exemption, or IDE, application to the FDA prior to initiation of the clinical study. An IDE application must be supported by appropriate data, such as, but not limited to, laboratory and animal test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. Clinical studies of investigational devices may not begin until an IRB has approved the study.

During the study, the sponsor must comply with the FDA's IDE requirements including, for example, for investigator selection, trial monitoring, adverse event reporting, and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. We, the FDA and the IRB at each site at which a clinical trial will be conducted may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable risk.

During the approval or clearance process, the FDA typically inspects the records relating to the conduct of one or more studies supporting the application.

Pharmaceutical products Clinical Trials

An IND is a request for authorization from the FDA to administer an investigational drug and/or biological product to humans. This authorization is required before interstate shipping and administration of any new drug product to humans that is not the subject of an approved NDA. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational drug to patients under the

supervision of qualified investigators following GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors. Clinical trials are conducted under protocols that detail the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. The informed written consent of each participating subject is required. The clinical investigation of an investigational drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are generally described as follows:

Phase 1 — Phase 1 includes the initial introduction of an investigational drug into humans. Phase 1 clinical trials may be conducted in patients with the target disease or condition or healthy volunteers. These studies are designed to evaluate the safety, metabolism, pharmacokinetics and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational product's pharmacokinetics and pharmacological effects may be obtained to permit the design of Phase 2 clinical trials. The total number of participants included in Phase 1 clinical trials varies, but is generally in the range of 20 to 80.

Phase 2 — Phase 2 includes the controlled clinical trials conducted to evaluate the preliminary effectiveness of the investigational product for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.

Phase 3 — Phase 3 clinical trials are controlled clinical trials conducted in an expanded patient population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the investigational product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product, and to provide an adequate basis for product approval. Phase 3 clinical trials usually involve several hundred to several thousand participants. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The decision to terminate development of an investigational drug product may be made by either a health authority body, such as the FDA or IRB/ethics committees, or by a company for various reasons. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, or the clinical monitoring board. This group provides authorization for whether or not a trial may move forward at designated check points. These decisions are based on the limited access to data from the ongoing trial. The suspension or termination of development can occur during any phase of clinical trials if it is determined that the participants or patients are being exposed to an unacceptable health risk. In addition, there are requirements for the registration of ongoing clinical trials of drugs on public registries and the disclosure of certain information pertaining to the trials as well as clinical trial results after completion.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and 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, the manufacturer 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.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of a NDA or a BLA to request market approval for the product in specified indications.

New Drug and Biologic License Applications

In order to obtain approval to market a drug in the United States, a marketing application must be submitted to the FDA that provides data establishing the safety and effectiveness of the drug product for the proposed indication. The application includes all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

In most cases, the NDA must be accompanied by a substantial user fee; there may be some instances in which the user fee is waived. The FDA will initially review the NDA/BLA for completeness before it accepts the NDA/BLA for filing. The FDA has 60 days from its receipt of an NDA/BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. After the NDA/BLA submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDA/BLAs. Most such applications for standard review drug products are reviewed within ten to 12 months of filing. The FDA can extend this review by three months to consider certain late-submitted information or information intended to clarify information already provided in the submission. The FDA does not always achieve its performance goal and its review of NDA/BLAs can take significantly longer. The FDA reviews the NDA/BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP. The FDA may refer applications for novel drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and 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.

Before approving an NDA/BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA/BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. After the FDA evaluates the NDA/BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA/BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. The approval process is lengthy and difficult and notwithstanding the submission of any requested additional information, the FDA ultimately may refuse to approve an NDA/BLA if applicable regulatory criteria are not satisfied or if the FDA believes additional clinical data or other data and information

are required. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than a company interprets the same data.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. FDA's approval of a product may be significantly limited to specific disease and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. In addition, as a condition of NDA/BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA/BLA or NDA/BLA supplement before the change can be implemented. An NDA/BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA/BLA supplements as it does in reviewing NDA/BLAs.

Post-Approval or Clearance Regulation

After a medical device is cleared or approved for marketing, extensive regulatory requirements continue to apply. These include, but not limited to:

- The QSR regulation, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over, and document manufacturing of their products;
- Labeling and claims regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and
- The Medical Device Reporting regulation, which requires reporting to the FDA in the case of certain adverse experiences associated with use of the product.

After regulatory approval of a drug is obtained, a company is required to comply with a number of post-approval requirements. For example, as a condition of approval of an NDA/BLA, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, as a holder of an approved NDA/BLA, a company would be required to report adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to assure and preserve the long term stability of the drug or biological product. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural and substantive record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA/BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical studies, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Compliance

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the FDA's imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention or refusal to permit the import or export of products, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

Advertising and Promotion

The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses — that is, uses not approved by the FDA and therefore not described in the drug's labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but may engage in non-promotional, balanced communication regarding off-label use under specified conditions. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

International Regulation

Although the discussion above focuses on regulation in the United States, we are also seeking approval for, and marketing of, our products in other countries and regions, such as Europe, Latin America, Asia and Australia. Generally, our activities in other countries will be subjected to regulation that is similar in nature and scope as that imposed in the United States, although specific-country regulations may be potentially required.

The time required to obtain clearance by foreign countries may be longer or shorter than that required for FDA approval or clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements. The primary regulatory environment in Europe is that of the EU, which consists of 27 countries encompassing most of the major countries in Europe.

In the EU, the British Standards Institute, or BSI, the Notified Body, issued an official response (February 2014) that BonyPid-1000 has been classified as a Class III implantable medical device.

The applicable rules are rule 8 (Implantable devices and long-term surgically invasive devices (>30 days)) and rule 13 (Devices incorporating, as an integral part, a medicinal product or a human blood derivative). It was also confirmed that BonyPid-1000 will be regulated as a medical device incorporating, as an integral part, an ancillary medicinal substance (based on MEDDEV 2.1/3 rev. 3) and will be approved via a CE mark process. BSI has also confirmed that a clinical trial will be required to demonstrate the safety and performance of BonyPid-1000. We have submitted to the UK, Medicines and Healthcare Products Regulatory Agency (MHRA) a scientific advice meeting request to discuss our clinical evaluation strategy. We plan to file the CE mark documentation, during the second half of 2016.

In addition to FDA regulations in the United States, we will be subject to a variety of comparable regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries.

Some countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed. To obtain regulatory approval to commercialize a new drug under European Union regulatory systems, we must submit a marketing authorization application, or MAA. The MAA is similar to the NDA/BLA, with the exception of, among other things, country-specific document requirements.

In Canada, pharmaceutical product candidates are regulated by the Food and Drugs Act and the rules and regulations promulgated thereunder, which are enforced by the Therapeutic Products Directorate of Health Canada, or TPD. Before commencing clinical trials in Canada, an applicant must complete preclinical studies and file a CTA with the TPD. After filing a CTA, the applicant must receive different clearance authorizations to proceed with Phase 1 clinical trials, which can then lead to Phase 2 and Phase 3 clinical trials. To obtain regulatory approval to commercialize a new drug in Canada, a new drug submission, or NDS, must be filed with the TPD. If the NDS demonstrates that the product was developed in accordance with the regulatory authorities' rules, regulations and guidelines and demonstrates favorable safety and efficacy and receives a favorable risk/benefit analysis, the TPD issues a notice of compliance which allows the applicant to market the product.

For other countries outside of the European Union and Canada, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Reimbursement

Reimbursement is an important factor in the success of any medical device. Reimbursement in the United States depends, in part, upon our ability to obtain FDA clearances and approvals to market our product candidates, as well as obtain coverage and payment for our products. Reimbursement for medical care in the United States is provided by federal and state governments, private health insurers and other third-party payors. There are three critical components to obtaining reimbursement from these sources — coverage, coding and payment. First, the particular procedure or device must be covered by the applicable plan. Reimbursement is governed by reimbursement codes, such as Medicare's CPT codes, that dictate if there is reimbursement and the amount of it. Private insurers generally follow, to a certain extent, the government reimbursement codes. Outside the United States, pricing and reimbursement can vary significantly.

The distinct nature of inserting bone void filler, and the wide variety of places in which it can be inserted, has created challenges from a coding and billing standpoint. Currently, there are no separate, distinct so-called CPT codes that accurately describe the application or insertion of synthetic bone void fillers. The insertion of our product candidates is likely to be performed in conjunction with another more significant procedure, for which there may be existing codes. Some of these codes may include the insertion of bone void

filler and for some procedures, it is likely that there is no inclusion of the insertion of a bone void filler as part of the procedure described by that code. Currently, it is not expected that Medicare will reimburse for our product candidates. It is our further understanding that several companies have attempted obtaining separate reimbursement codes that would directly cover the insertion of different bone void fillers, but have been unsuccessful.

As a result of these factors, there are no assurances that adequate third-party coverage will be available for us to establish and maintain price levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Current cost containment and health care reform initiatives add additional uncertainty.

Manufacturing and Supply

Production of BonyPid-1000 is conducted by a third-party contract manufacturer in a GMP-approved facility located in the Netherlands. We expect that existing production capabilities are sufficient to supply our currently forecasted demands for BonyPid-1000 for the next few years. In parallel, we are planning to establish a pilot plant in our own facilities in Israel as a manufacturing site for the initial demand of our other proposed product candidates, and as a contingency backup to our current third-party contract manufacturer. BonyPid-1000 is formulated using an auto-assembly process of its components. As a result, scale-up activities are relatively easier to perform, in comparison with other polymer or lipid based manufacturing processes.

Employees

As of June 30, 2014, we had 27 employees, of whom nine hold Ph.D. degrees. 25 of our employees work on a full-time basis and 2 of our employees work on a part-time basis. We also rely on our Advisory Board that are very engaged in our business. We have no collective bargaining agreements with our employees and have not experienced any work stoppages. We believe that relations with our employees are good.

Facilities

Our corporate headquarters are located in Petach Tikva, Israel and consists of approximately 18,000 square feet of leased office and laboratory space under a lease that expires in January 2020, with an optional renew of additional 5 years.

Legal Proceedings

We are not currently subject to any material legal proceedings.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors as of June 30, 2014:

Name	Age	Position
Anat Segal	51	Chairman of the Board of Directors
Amir Weisberg	58	Chief Executive Officer and Director
Shaun Marcus	64	Chief Financial Officer
Noam Emanuel	55	Chief Technology Officer and Director
Jack Eitan Kyiet	45	Chief Operating Officer and Director
Asaf Bar	40	Chief Business Officer
Dikla Czaczkes Axelbrad	41	Chief Strategy Officer
Yechezkel Barenholz	73	Director
Rami Lerner	60	Director
Arik Lukach(1)	70	Director
Moshe Neuman(1)	46	Director
Yafit Stark	61	Director

(1) The named persons will resign from our Board of Directors immediately prior to the declaration of effectiveness of the registration statement of which this prospectus forms a part.

The Company intends to add additional members to its Board of Directors prior to the closing of this offering. These directors will be “independent directors” and nominees for the purposes of election as “external directors” as contemplated by the Listing Rules of the NASDAQ Stock Market and Israeli law. The Company will also establish an Audit Committee and a Compensation Committee.

Anat Segal has served on our Board of Directors since April 2008. Since April 2003 she has served as the chief executive officer of Xenia Venture Capital, a high-tech investment company traded on the Tel Aviv Stock Exchange, and has over 18 years of experience in corporate finance and strategic business development. Ms. Segal holds a B.A. in Economics and Management, an MBA in Finance and an LL.B. from the Tel Aviv University.

Amir Weisberg has been our Chief Executive Officer and a director since October 2010. Since 2007, he has also served as chairman of Vibrant Ltd., a private company. 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. Mr. Weisberg led companies in all stages, including two financial exits.

Noam Emanuel, Ph.D., is our co-founder and has served as a director since our organization in April 2008. He is also our Chief Technology Officer. 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.

Shaun Marcus joined us as our Chief Financial Officer in May 2011. Since October 2010, Mr. Marcus has also served as part-time Chief Financial Officer and director of Aspireo Pharmaceuticals Ltd., a biopharmaceutical company. Mr. Marcus has over 20 years of diversified senior managerial experience and has held senior financial positions with public and private biotechnology and medical device companies in Israel and the United States. Most recently, from 2008 to 2010 Mr. Marcus served as a chief financial officer of BSP Ltd., a public company traded in Israel. He holds a B.A. in accounting and economics from Tel Aviv University.

Jack Eitan Kyiet has been 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. Most recently from 2011 to 2013, he held a senior operations and

business planning position in Biosense Webster, a Johnson & Johnson medical device company and from 2006 to 2011 in Lumenis Ltd. Prior to that, he pursued a legal career as a partner in the law firm of Amit, Pollak Matalon & Co. in Tel Aviv. He holds an LL.B. and an MBA from the Haifa University.

Asaf Bar joined us as our Chief Business Officer in April 2014. Mr. Bar has over 13 years of experience in finance, business development and marketing positions and has held senior positions in public and private companies in Israel and the United States including Omrix Biopharmaceuticals Ltd., Johnson & Johnson and Lumenis Ltd. He holds a B.A. in finance and business administration from Haifa University.

Dikla Czaczkes Akselbrad joined us as our Chief Strategy Officer in July, 2014. For the past 12 years she has served as an executive of Compugen Ltd. She has served as Compugen Ltd.'s chief financial officer since 2008, and had a leading role in numerous capital transactions raising over $130 million. Prior to joining Compugen Ltd., Ms. Czaczkes Akselbrad was the chief financial officer of Packet Technologies Ltd., mobile internet security hardware and software Startup Company, and an audit manager at Ernst & Young Israel. Ms. Czaczkes Akselbrad holds an MBA in finance and a BA in accounting and economics, both from Tel Aviv University, and is a certified public accountant in Israel.

Prof. Yechezkel Barenholz, Ph.D., has served on our Board of Directors since April 2008. For more than five years, Prof. Barenholz has served as head of the Laboratory of Membrane and Liposome Research at the Department of Biochemistry of the Hadassah Medical School at the Hebrew University of Jerusalem. 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.

Rami Lerner has served on our Board of Directors since December 2012**.** Since 2005 he has managed privately held family companies investing in real estate both in Israel and abroad. From 2003 – 2005, he was Chief Executive Officer of the Israel Society for Protection of Nature. Previously, he held senior positions in Israel's Prime Minister's Office. Mr. Lerner holds an EMBA from Tel Aviv University.

Arik Lukach has served on our Board of Directors since October 2010. For the past 30 years, Mr. Lukach served as the manager of the IT department at the Israeli prime minister offices. He serves as a director of several private companies, including Fruitura Bioscience Ltd., Vibrant Ltd. and Fricso Ltd. Mr. Lukach holds a B.A. in statistics and economics and an M.A. in business administration from the Hebrew University of Jerusalem.

Moshe Neuman, MD, has served on our Board of Directors since April 2008. For the past 11 years he has been a periodontist specializing, among other things, in dental implants. Dr. Neuman is a graduate of the University of Rochester (NY) Eastman Dental Center, Rochester, has a D.M.D. and M.Sc. in Bone Biology from the Hebrew University of Jerusalem and is a Diplomat of the American Board of Periodontology and member of the American Academy of Periodontology.

Dr. Yafit Stark, Ph.D., has served on our Board of Directors since April 2008. For the past 20 years she has been Vice President and Chief Clinical Officer at Teva Pharmaceutical Industries, Ltd. Dr. Stark holds a Ph.D. in Pathology from the Sackler School of Medicine, Tel Aviv University, and a post-doctorate in Immuno-Histopathology from Tel Aviv University and the Weizmann Institute of Science.

Arrangements Concerning Election of Director; Family Relationships

There are no arrangements or understandings with customers, suppliers or others pursuant to which any of our directors or members of senior management were selected as such. In addition, other than as set forth below, there are no family relationships among our executive officers and directors.

Pursuant to our articles of association in effect prior to this offering, certain of our shareholders had rights to appoint members of our Board of Directors. These provisions will no longer be applicable upon consummation of this offering.

Corporate Governance Practices

As an Israeli company issuing shares to the public, we are subject to various corporate governance requirements under Israeli law relating to such matters as the election of external directors, the appointment of the audit committee, the compensation committee and an internal auditor. These requirements are in addition

to the corporate governance requirements imposed by the Listing Rules of NASDAQ and other applicable provisions of U.S. securities laws as applicable to foreign private issuers to which we will become subject upon consummation of this offering and the listing of our ordinary shares on the NASDAQ Capital Market. Under the Listing Rules of NASDAQ, a foreign private issuer may generally follow its home country rules of corporate governance in lieu of the comparable requirements of the Listing Rules of NASDAQ, except for certain matters, including (among others) the composition and responsibilities of the audit committee and the independence of its members within the meaning of the rules and regulations of the SEC. For further information, see "Risk factors" and "NASDAQ Listing Rules and Home Country Practices."

Board Practices

Board of Directors

Under the Israeli Companies Law, the responsibility for setting up the Company's policy and oversight over our business is vested in our Board of Directors. Our Board of Directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our Board of Directors. Our Chief Executive Officer is appointed by, and serves at the discretion of, our Board of Directors, subject to the employment and service agreements that we have entered into with him and the management company controlled by him. All other executive officers are appointed by our Chief Executive Officer, 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, which will be effective immediately prior to the consummation of this offering, our Board of Directors must consist of at least and not more than directors, including at least two external directors required to be appointed under the Israeli Companies Law. Accordingly, at any time, the minimum number of directors (other than the external directors) may not fall below . Our Board of Directors will consist of directors immediately prior to the consummation of this offering, which will include new directors and two nominees as external directors whose service as directors will commence immediately prior to the consummation of this offering and, in the case of the external directors, their appointment as external directors shall be subject to ratification at a meeting of our shareholders to be held no later than three months following the completion of this offering. We have only one class of directors.

Other than external directors, for whom special election requirements apply under the Israeli Companies Law as detailed below, our directors are each elected at a general meeting of our shareholders and serve for a term of one year. Directors (other than external directors) shall nevertheless be removed prior to the end of their term by the majority of our shareholders at a general meeting of our shareholders or upon the occurrence of certain events, all in accordance with the Israeli Companies Law and our amended and restated articles of association.

In addition, our amended and restated articles of association allow our Board of Directors to appoint directors (who satisfy the eligibility requirements under the Companies Law), other than external directors, to fill vacancies on our Board of Directors, for a term of office equal to the remaining period of the term of office of the director(s) whose office(s) have been vacated, also known as Alternate Directors. Alternate Directors have the same rights and obligations as the other directors. External directors are elected for an initial term of three years and may be elected for additional three-year terms under the circumstances described below. External directors may be removed from office only under the limited circumstances set forth in the Israeli Companies Law. See "— External directors."

In accordance with the exemption available to foreign private issuers under the Listing Rules of the NASDAQ Stock Market, we do not intend to follow the requirements of the Listing Rules of the NASDAQ Stock Market with regard to the process of nominating directors, and instead, will follow Israeli law and practice, in accordance with which our Board of Directors (or a committee thereof, or a certain number of directors serving thereon) is authorized to recommend to our shareholders director nominees for election. Under the Israeli Companies Law and our amended and restated articles of association, nominations for directors may also be added to the agenda of future general meetings, which has yet to have been summoned, upon the request of any one or more shareholders holding at least 1% of our outstanding voting power.

Furthermore, under the Israeli Companies Law, either (a) (i) two directors; or (ii) no less than one quarter of the directors in office; or (b) one or more shareholders holding, in the aggregate, either (i) 5% of our outstanding shares and 1% of our outstanding voting power; or (ii) 5% of our outstanding voting power, may request the Board of Directors to summon a general meeting in order to nominate one or more persons for election as directors at a special meeting. However, any such shareholders may make such a nomination only if a written notice of such shareholder's intent to make such nomination has been given to our chairman of the board (or, if we have no chairman of the board, our chief executive officer). Any such notice must include certain information we are required under the Israeli Companies Law to provide to our shareholders, the consent of the proposed director nominee(s) to serve as our director(s) if elected and a declaration signed by the nominee(s) declaring that there is no limitation under the Israeli Companies Law preventing their election and that all of the information that is required under the Israeli Companies Law to be provided to us in connection with such election has been provided.

In addition to its role in making director nominations, under the Israeli Companies Law, our Board of Directors must determine the minimum number of directors who are required to have accounting and financial expertise. Under applicable regulations, a director with accounting and financial expertise is a director who, by reason of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements, sufficient to be able to thoroughly comprehend the financial statements of the Company and initiate debate regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, our Board of Directors must consider, among other things, the type and size of our company, the scope and complexity of its operations and the number of directors if prescribed in our articles of association. Our Board of Directors has determined that our company requires one director with such expertise.

External Directors

Under the Israeli Companies Law, the boards of directors of companies whose shares are publicly traded, including companies with shares listed on the NASDAQ Capital Market, are required to include at least two members elected to serve as external directors. and have agreed to serve as our external directors following the consummation of this offering, subject to ratification at a meeting of our shareholders to be held no later than three months following the completion of this offering.

The definitions of an external director under the Israeli Companies Law and independent director under the Listing Rules of the NASDAQ Stock Market are similar to such an extent that it would be generally expected that our two external directors will also comply with the independence requirement under the Listing Rules of the NASDAQ Stock Market. The definition of an external director includes a set of statutory criteria that must be satisfied, while the definition of an independent director also requires the board to consider any factor which would impair the ability of a director to exercise independent judgment. In addition, while external directors serve for an initial period of three years and may be elected to serve for two additional periods of three years each, as further elaborated below, pursuant to the requirements of Israeli law, independent directors serve for one year pursuant to the provisions of our amended and restated articles of association. However, external directors must be elected by a special majority of shareholders while independent directors are elected by an ordinary majority.

The Israeli Companies Law provides that external directors must be elected by a majority vote of the shares present and voting at a shareholders meeting, provided that either:

- the majority voted in favor of election includes a majority of the shares held by non-controlling shareholders who do not have a personal interest in the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) that are voted at the meeting, excluding for such purpose any abstentions, which we refer to as a disinterested majority; or
- the total number of shares held by non-controlling disinterested shareholders (as described in the previous bullet-point) that voted against the election of the director does not exceed 2% of the aggregate voting rights in the Company.

The term controlling shareholder is defined in the Israeli Companies Law as a shareholder with the ability to direct the activities of the Company, other than by virtue of being an office holder. A shareholder is in any case deemed to be a controlling shareholder if the shareholder holds 50% or more of the means of control, which include the right to vote at a shareholders meeting and the right to appoint the directors of the Company or its general manager. In connection with approval by shareholders of: (i) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, (ii) certain private placements in which the controlling shareholder has a personal interest, (iii) certain transactions with a controlling shareholder or relative with respect to services provided to or employment by the company, (iv) the terms of employment and compensation of the general manager, and (v) the terms of employment and compensation of office holders of the company when such terms deviate from the compensation policy previously approved by the company's shareholders, any shareholder (or group of shareholders having interest in the same matter being brought for approval) who hold(s) in the aggregate 25% or more of the means of control if no other shareholder holds more than 50% of the voting rights, would also be deemed a controlling shareholder.

After an initial term of three years, external directors may be reelected to serve in that capacity for up to two additional three year terms, provided that either (i) (1) his or her service for each such additional term is recommended by one or more shareholders holding in aggregate at least 1% of the Company's voting rights and is approved at a shareholders meeting by a majority of the shares held by non-controlling shareholders who do not have a personal interest in the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) that are voted at the meeting, excluding for such purpose any abstentions, where the total number of shares held by non-controlling, disinterested shareholders voting for such reelection exceeds 2% of the aggregate voting rights in the Company, and (2) the external director who has been nominated in such fashion by the shareholders is not a linked or competing shareholder, and does not have or has not had, on or within the two years preceding the date of such person's appointment to serve as another term as external director, any affiliation with a linked or competing shareholder. The term "linked or competing shareholder" means the shareholder(s) who nominated the external director for reappointment or a material shareholder of the company holding more than 5% of the shares in the company, provided that at the time of the reappointment, such shareholder(s) of the company, the controlling shareholder of such shareholder(s) of the company, or a company under such shareholder(s) of the company's control, has a business relationship with the company or are competitors of the company; the Israeli Minister of Justice, in consultation with the Israeli Securities Authority, may determine that certain matters will not constitute a business relationship or competition with the company; or (ii) his or her service for each such additional term is recommended by the board of directors and is approved at a shareholders meeting by the same disinterested majority required for the initial election of an external director (as described above). The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the NASDAQ Capital Market, may be further extended, indefinitely, in increments of additional three-year terms, in each case provided that, in addition to reelection in such manner described above, (i) the audit committee and subsequently the board of directors of the Company confirm that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the reelection for such additional period is beneficial to the Company, and (ii) prior to the approval of the reelection of the external director, the Company's shareholders have been informed of the term previously served by such nominee and of the reasons why the board of directors and audit committee recommended the extension of such nominee's term.

If an external director no longer complies with the applicable requirements, the external director must notify the Company, and his term shall terminate upon such notification. Furthermore, where concerns regarding an external director's compliance with any requirements under the Israeli Companies Law, or regarding an external director's breach of any fiduciary duty, have been brought to the Board of Directors' attention, the Board of Directors is required to discuss such concerns in its following meeting.

If the Board of Directors resolves that an external director no longer complies with any requirement for qualification as an external director, or that such external director has breached any fiduciary duty, a special general meeting shall be convened at which the termination of such external director's service shall be included in the agenda.

If an external directorship becomes vacant and there are less than two external directors on the board of directors at the time, then the board of directors is required under the Israeli Companies Law to call a shareholders' meeting as soon as possible to appoint a replacement external director.

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

The Israeli Companies Law provides that a person is not qualified to serve as an external director if (i) the person is a relative of the controlling shareholder of the Company, or (ii) if that person or his or her relative, partner, employer, another person to whom he or she was directly or indirectly subject, or any entity under the person's control, has or had, during the two years preceding the date of appointment as an external director: (a) any affiliation or other prohibited relationship with the Company, with any person or entity who is a controlling shareholder of the Company at the date of appointment or a relative of such person, or with any entity controlled, during the two years preceding the date of appointment as an external director, by the Company or a controlling shareholder of the Company; or (b) in the case of a company with no controlling shareholder, any affiliation or other prohibited relationship with a person serving, at the date of appointment as external director, as chairman of the board, chief executive officer, a substantial shareholder who holds at least 5% of the issued and outstanding shares of the company or voting rights which entitle him to vote at least 5% of the votes in a shareholders meeting or the most senior office holder in the Company's finance department.

The term relative is defined as a spouse, sibling, parent, grandparent or descendant; spouse's sibling, parent or descendant; and the spouse of each of the foregoing persons. The term affiliation and the similar types of prohibited relationships include (subject to certain exemptions):

- an employment relationship;
- a business or professional relationship even if not maintained on a regular basis (excluding insignificant relationships);
- control; and
- service as an office holder, excluding service as a director in a private company prior to the first offering of its shares to the public if such director was appointed as a director of the private company in order to be nominated to serve as an external director following the initial public offering.

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

In addition, no person may serve as an external director if that person's position or professional or other activities create, or may create, a conflict of interest with that person's responsibilities as a director or otherwise interfere with that person's ability to serve as an external director or if the person is an employee of the Israel Securities Authority or of an Israeli stock exchange. A person may furthermore not continue to serve as an external director if he or she received direct or indirect compensation for his or her role as a director, other than compensation paid or given in accordance with Israeli Companies Law regulations or amounts paid pursuant to indemnification and/or exculpation contracts or commitments and insurance coverage. Following the termination of an external director's service on a board of directors, such former external director and his or her spouse and children may not be provided with direct or indirect benefit by the Company, its controlling shareholder or any entity under its controlling shareholder's control. This includes appointment as an office

holder of the Company or a company controlled by its controlling shareholder, employment as an employee, or receipt of professional services for consideration, either directly or indirectly, including through a corporation in his or her control. These restrictions extend for a period of two years with regard to the former external director and his or her spouse or child, and for one year with respect to other relatives of the former external director.

If at the time at which an external director is appointed all members of the board of directors, who are not controlling shareholders or relatives thereof, are of the same gender, the external director must be of the other gender. A director of one company may not be appointed as an external director of another company if a director of the other company is acting as an external director of the first company at such time.

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

A director with accounting and financial expertise is a director who, due to his or her education, experience and skills, possesses an expertise in, and an understanding of, financial and accounting matters and financial statements, in such a manner which allows him or her to understand the financial statements of the Company and initiate a discussion about the presentation of financial data. A director is deemed to have professional qualifications if he or she has any of (i) an academic degree in economics, business management, accounting, law or public service, (ii) an academic degree or has completed other higher education, in the main field of business of the Company or a field relevant for the position, or (iii) at least five years of experience as one of the following, or at least five years accumulated experience as two or more of the following — (a) a senior officer in the business management of a company with a significant volume of business, (b) a senior public officer or senior position in the public service, and (c) a senior position in the Company's main line of business.

Our Board of Directors has determined that , one of our nominees to serve as an external director, has accounting and financial expertise and possesses professional qualifications as required under the Israeli Companies Law.

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 Anat Segal to serve as Chairman of the Board of Directors.

Role of Board in Risk Oversight Process

Risk assessment and oversight are an integral part of our governance and management processes. Our Board of Directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings, and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Board Committees

Audit Committee

Under the Israeli Companies Law, the board of directors of a public company must appoint an audit committee. The audit committee must be comprised of at least three directors, including all of the external directors, one of whom must serve as chairman of the committee. The audit committee may not include the

chairman of the board, any director employed by, or otherwise providing services on a regular basis to the Company, to a controlling shareholder or to any entity controlled by a controlling shareholder, any director whose main livelihood is dependent on a controlling shareholder, nor a controlling shareholder or a relative thereof.

Under the Israeli Companies Law, the audit committee of a publicly traded company must consist of a majority of unaffiliated directors. An "unaffiliated director" is defined as either an external director or as a director, classified as an "unaffiliated director" by the Company, who meets the following criteria:

- he or she meets the qualifications for being appointed as an external director (and such appointment was approved by the audit committee), except for (i) the requirement that the director be an Israeli resident (which requirement does not, in any event, apply to external directors at public companies such as ours whose securities have been offered outside of Israel or are listed outside of Israel) and (ii) the requirement for accounting and financial expertise or professional qualifications with respect to the proposed unaffiliated director; and
- he or she has not served as a director of the Company for a period exceeding nine consecutive years. For this purpose, a break of less than two years in the service shall not be deemed to interrupt the continuation of the service.

Our Board of Directors intends to adopt an audit committee charter that will set forth the responsibilities of the Audit Committee consistent with the rules of the SEC and the Listing Rules of the NASDAQ Stock Market, as well as subjecting the audit committee charter to the requirements under the Israeli Companies Law, as described below.

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

Under the Israeli Companies Law, our Audit Committee is responsible for (i) determining whether there are deficiencies in the business management practices of our company, including in consultation with our internal auditor or the independent auditor, and making recommendations to the Board of Directors to improve such practices and amend such deficiencies (where material deficiencies have been revealed, at least one meeting of the Audit Committee is required to be convened, with the presence of our internal auditor or the independent auditor, and without the presence of any members of the Board of Directors who are not members of the Audit Committee (unless their presence is required for the purpose of presenting their position to matters under their responsibility)), (ii) determining whether certain related party transactions (including transactions in which an office holder has a personal interest) should be deemed as material or extraordinary, and to approve such transactions (which may be approved according to certain criteria set out by our Audit Committee on an annual basis) (see "— Approval of related party transactions under Israeli Law"), (iii) to establish procedures to be followed in respect of related party transactions with a controlling shareholder (where such are not extraordinary transactions), which may include, where applicable, the establishment of a competitive process for such transaction, under the supervision of the audit committee, or individual, or other committee or body selected by the audit committee, in accordance with criteria determined by the audit committee; (iv) to determine procedures for approving certain related party transactions with a controlling shareholder, which having been determined by the audit committee not to be extraordinary transactions, were also determined by the audit committee not to be negligible transactions; (v) where the Board of Directors approves the working plan of the internal auditor, to examine such working plan before its submission to the Board and propose amendments thereto, (vi) examining our internal controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of its responsibilities, considering, among other things, the Company's specific needs and size, (vii) examining the scope of our auditor's work and compensation and submitting a recommendation with respect thereto to our Board of Directors or shareholders, depending on which of them is considering the appointment of our auditor, and (viii) establishing procedures for the handling of employees' complaints as to the management of

our business and the protection to be provided to such employees. Our Audit Committee may not approve an action or a related party transaction, or take any other action required under the Israeli Companies Law, unless at the time of approval a majority of the committee's members are present, which majority consists of unaffiliated directors including at least one external director, and it further complies with the committee composition set forth above.

NASDAQ requirements

Under the NASDAQ Marketplace Rules, we are required to maintain an audit committee consisting of at least three independent directors, all of whom are financially literate and one of whom has accounting or related financial management expertise.

Compensation Committee

We intend to rely upon the exemption available to foreign private issuers under the Listing Rules of the NASDAQ Stock Market with respect to the determination of the compensation of our Chief Executive Officer and other executive officers in lieu of forming a compensation committee consisting entirely of independent directors (or the determination of such compensation solely by the independent members of our Board of Directors) and instead will form a compensation committee in compliance with the Israeli Companies Law. See "— NASDAQ Listing Rules and home country practices."

Under the Israeli Companies Law, the board of directors of a public company must appoint a compensation committee. The compensation committee must be comprised of at least three directors, including all of the external directors, which shall be a majority of the members of the compensation committee and one of whom must serve as chairman of the committee. However, subject to certain exceptions, Israeli companies whose securities are traded on stock exchanges such as NASDAQ, and who do not have a controlling party, do not have to meet this majority requirement; provided, however, that the compensation committee meets other Israeli Companies Law composition requirements, as well as the requirements of the non-Israeli jurisdiction where the company's securities are traded. Other than the external directors, the rest of the members of the compensation committee shall be directors who will receive compensation for their role as directors only in accordance with Israeli Companies Law regulations which are applicable to compensation of external directors, and/or the provision of or amounts paid pursuant to indemnification and/or exculpation contracts or commitments and insurance coverage.

The compensation committee may not include the chairman of the board, any director employed by or otherwise providing services on a regular basis to the Company, to a controlling shareholder or to any entity controlled by a controlling shareholder, any director whose main livelihood is dependent on a controlling shareholder, nor a controlling shareholder or a relative thereof.

The members of our compensation committee, which will be formed prior to the consummation of this offering, will be , along with our two external director nominees, Messrs. and .

Under the Israeli Companies Law, our compensation committee is responsible for (i) proposing an office holder compensation policy to the Board of Directors, (ii) propose necessary revisions to the compensation policy and examine its implementation, (iii) determining whether to approve transactions with respect to the terms of office and employment of office holders, and (iv) determining, in accordance with our office holder compensation policy, whether to exempt an engagement with an unaffiliated nominee for the position of chief executive officer from requiring shareholders' approval.

Under the Israeli Companies Law, our compensation policy must generally serve as the basis for corporate approvals with respect to the financial terms of employment or engagement of office holders, including exemption, 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 objective, the company's business plan and its long term strategy, and creation of appropriate incentives for office holders. It must also consider, among other things, the company's risk management, size and nature of its operations. The compensation policy must furthermore consider the following additional factors:

- the knowledge, skills, expertise, and accomplishments of the relevant office holder;

- the office holder's roles and responsibilities and prior compensation agreements with him or her;
- the relationship between the terms offered and the average and median compensation of the other employees of the company, including those employed through manpower companies;
- 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 contributions to 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 the long term performance and measurable criteria;
- the relationship between variable and fixed compensation, and the ceiling for the value of variable compensation;
- the conditions under which an office holder would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements;
- the minimum holding or vesting period for variable, equity-based compensation, with reference to long-term incentives; and
- maximum limits for severance compensation.

Under the amendment to the Israeli Companies Law, we are required to adopt an office holder compensation policy no later than nine months after the date of this initial public offering, i.e. by no later than , 2015.

Compensation Committee — Charter

Our Board of Directors intends to adopt a compensation committee charter setting forth the responsibilities of the committee, subjecting the compensation committee charter to the requirements under the Israeli Companies Law, as described above.

Compensation Committee — NASDAQ Requirements

and are independent under the Listing Rules of the NASDAQ Stock Market.

Nominating Committee

Our Board of Directors does not currently have a nominating committee, as director nominees are presented by our Board of Directors to our shareholders based upon the nominations made by the Board of Directors itself. We intend to rely upon the exemption available to foreign private issuers under the Listing Rules of the NASDAQ Stock Market from the requirements related to independent director oversight of nominations to our Board of Directors and the adoption of a formal written charter or board resolution addressing the nominations process. See "— NASDAQ Listing Rules and home country practices."

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 and nominated by the board of directors. An internal auditor may not be:

- a person (or a relative of a person) who holds more than 5% of the Company's outstanding shares or voting rights;

- a person (or a relative of a person) who has the power to appoint a director or the general manager of the Company;
- an office holder (including a director) of the Company (or a relative thereof); or
- a member of the Company's independent accounting firm, or anyone on his or her behalf.

The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures.

NASDAQ Listing Rules and Home Country Practices

The Sarbanes-Oxley Act, as well as related rules subsequently implemented by the SEC, requires foreign private issuers, such as us, to comply with various corporate governance practices. In addition, upon the contemplated listing of our ordinary shares on the NASDAQ Capital Market, we will need to comply with the Listing Rules of the NASDAQ Stock Market. Under those Listing Rules, we may elect to follow certain corporate governance practices permitted under the Israeli Companies Law in lieu of compliance with corresponding corporate governance requirements otherwise imposed by the Listing Rules of the NASDAQ Stock Market for U.S. domestic issuers.

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

- *Distribution of periodic reports to shareholders; proxy solicitation.* As opposed to the Listing Rules of the NASDAQ Stock Market, which require listed issuers to make such reports available to shareholders in one of a number of specific manners, Israeli law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports available through a public website. In addition to making such reports available on a public website, we plan to make our audited financial statements available to our shareholders at our offices and will only mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.
- *Nomination of our directors.* With the exception of our external directors and directors elected by our Board of Directors due to vacancy or our CEO who will serve as a director ex-officio, our directors are elected by an annual meeting of our shareholders to hold office until the next annual meeting following one year from his or her election. See "Management — Board Practices — Board of Directors." The nominations for directors, which are presented to our shareholders by our Board of Directors, are generally made by the Board of Directors itself, in accordance with the provisions of our amended and restated articles of association and the Israeli Companies Law. Nominations need not be made by a nominating committee of our Board of Directors consisting solely of independent directors, as required under the Listing Rules of the NASDAQ Stock Market. Nominations may also be made by one or more of our shareholders, as provided in our Articles of Association, or under the Israeli Companies Law.
- *Compensation of officers.* Israeli law and our amended and restated articles of association do not require that the independent members of our Board of Directors (or a compensation committee composed solely of independent members of our Board of Directors) determine an executive officer's compensation, as is generally required under the Listing Rules of the NASDAQ Stock Market with respect to the Chief Executive Officer and all other executive officers.

Instead, compensation of executive officers is determined and approved by our Board of Directors and our Compensation Committee, either in consistency with our office holder compensation policy or, in special circumstances, taking into account certain considerations stated in the Israeli Companies Law.

Shareholder approval shall be further required in the event (i) approval by our Board of Directors and our Compensation Committee is not consistent with our office holders compensation policy, or (ii) compensation required to be approved is that of our chief executive officer or an executive officer who is also the controlling

shareholder of our company (including an affiliate thereof). Such shareholder approval shall require a majority vote of the shares present and voting at a shareholders meeting, provided either (i) such majority includes a majority of the shares held by non-controlling shareholders who do not have a personal interest in the compensation arrangement that are voted at the meeting, excluding for such purpose any abstentions disinterested majority, or (ii) the total shares held by non-controlling disinterested shareholders voted against the arrangement does not exceed two percent (2%) of the voting rights in our company.

Additionally, approval of the compensation of an executive officer, who is also a director, shall require a simple majority vote of the shares present and voting at a shareholders meeting, if consistent with our office holders compensation policy or a special majority as set forth above if the proposed compensation for the director is not consistent with our office holders compensation policy. Our Compensation Committee may, in special circumstances, approve the compensation of an executive officer (other than a director or a controlling shareholder) despite shareholders objection, based on specified arguments and taking shareholders' objection into account. Our Compensation Committee may exempt an engagement with a nominee for the position of chief executive officer, who meets the non-affiliation requirements set forth for an external director, from requiring shareholders' approval, if such engagement is consistent with our office holders compensation policy and our Compensation Committee determines based on specified arguments that presentation of such engagement to shareholders' approval is likely to prevent such engagement. To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years, approval is required once every three years.

A director or executive officer may not be present when the compensation committee or board of directors of a company discusses or votes upon the terms of his or her compensation, unless the chairman of the compensation committee or board of directors (as applicable) determines that he or she should be present to present the transaction that is subject to approval.

- *Independent directors.* Israeli law does not require that a majority of the directors serving on our Board of Directors be "independent," as defined under NASDAQ Listing Rule 5605(a)(2), and rather requires we have at least two external directors who meet the requirements of the Israeli Companies Law, as described above under "Management — Board Practices — External Directors." We are required, however, to ensure that all members of our Audit Committee are "independent" under the applicable NASDAQ and SEC criteria for independence (as we cannot exempt ourselves from compliance with that SEC independence requirement, despite our status as a foreign private issuer), and we must also ensure that a majority of the members of our Audit Committee are "unaffiliated directors" as defined in the Israeli Companies Law. Furthermore, Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only they are present, which the Listing Rules of the NASDAQ Stock Market otherwise require.
- *Shareholder approval.* We will seek shareholder approval for all corporate actions requiring such approval under the requirements of the Israeli Companies Law, rather than seeking approval for corporation actions in accordance with NASDAQ Listing Rule 5635. In particular, under this NASDAQ rule, shareholder approval is generally required for: (i) an acquisition of shares/assets of another company that involves the issuance of 20% or more of the acquirer's shares or voting rights or if a director, officer or 5% shareholder has greater than a 5% interest in the target company or the consideration to be received; (ii) the issuance of shares leading to a change of control; (iii) adoption/amendment of equity compensation arrangements; and (iv) issuances of 20% or more of the shares or voting rights (including securities convertible into, or exercisable for, equity) of a listed company via a private placement (and/or via sales by directors/officers/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, shareholder approval is required for, among other things: (i) transactions with directors concerning the terms of their service or indemnification, exemption and insurance for their service (or for any other position that they may hold at a company), for which approvals of the compensation committee, board of directors and shareholders are all required, (ii) extraordinary transactions with controlling shareholders of publicly held companies, which require the special approval described below under "Approval of related party transactions under Israeli Law — Disclosure of personal interests of controlling shareholders", and (iii) terms of

employment or other engagement of the controlling shareholder of the Company or such controlling shareholder's relative, which require the special approval described below under "Approval of related party transactions under Israeli Law — Disclosure of personal interests of controlling shareholders". In addition, under the Israeli Companies Law, a merger requires approval of the shareholders of each of the merging companies.

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 "Management — 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 requires that an office holder act in good faith and in the best interests of the Company. The duty of care includes a duty to use reasonable means to obtain:

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

The duty of loyalty requires an office holder to act in good faith and for the benefit of the Company, and 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

The Israeli Companies Law requires that an office holder promptly disclose to the board of directors any personal interest that he or she may have concerning any existing or proposed transaction with the Company, as well as any substantial information or document with respect thereof. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. A personal interest includes an interest of any person in an act or transaction of a company, including a personal interest of one's relative or of a corporate body in which such person or a relative of such person is a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, but excluding a personal interest stemming from one's ownership of shares in the Company. A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the interest of the office holder with respect to his or her vote on behalf of the shareholder for whom he or she holds a proxy even if such shareholder itself has no personal interest in the approval of the matter. An office holder is not, however, obliged to disclose a personal interest if it derives solely from the personal interest of a relative of such office holder 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 duty of loyalty. However, a company may not approve a transaction or action that is adverse to the Company's interest or that is not performed by the office holder in good faith. Approval first by the Company's audit committee and subsequently by the board of directors is required for an extraordinary transaction in which an office holder has a personal interest. Arrangements regarding the compensation, indemnification or insurance of an office holder require the approval of the compensation committee, board of directors and, in certain circumstances, the shareholders, in that order, as described above under "— NASDAQ Listing Rules and home country practices — Compensation of officers" and "— NASDAQ Listing Rules and home country practices — Shareholder approval."

Generally, except with respect to non-extraordinary transactions, 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 a majority of the directors or members of the audit committee have a personal interest in the matter, or 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. Generally, if a majority of the members of the audit committee and/or the board of directors has a personal interest in the approval of a transaction, then all directors may participate in discussions of the audit committee and/or the board of directors on such transaction and the voting on approval thereof, but shareholder approval is also required for such transaction.

Disclosure of a personal interest is also required of a person who is an interested party with respect to (i) a private placement submitted for approval whereby 20% or more of the company's outstanding share capital prior to the placement is offered, and the payment for which is not only in cash or in tradable securities registered in a stock exchange, or that is not at market terms, and which will result in an increase of the holdings of a shareholder that already holds 5% or more of the company's outstanding share capital or voting rights or will cause any person to become, as a result of the issuance, a holder of more than 5% of the company's outstanding share capital or voting rights, or (ii) that as a result of a private placement submitted for approval will become a controlling shareholder. Such personal interest disclosure requirements also apply to certain shareholders of a public company who have a personal interest in the adoption by the shareholders of certain proposals with respect to (i) certain special tender offers or forced bring along share purchase transactions, (ii) election of external directors, (iii) approval of a compensation policy governing the terms of employment and compensation of office holders, (iv) approval of the terms of employment and compensation of the general manager, (v) approval of the terms of employment and compensation of office holders of the company when such terms deviate from the compensation policy previously approved by the company's shareholders, and (vi) approving the appointment of either (1) the chairman of the board or his/her relative as the chief executive officer of the company, or (2) the chief executive officer or his/her relative as the chairman of the board of directors of the company. If any shareholder casting a vote at a shareholders meeting in connection with such proposals as aforesaid does not notify the company if he, she or it has a personal interest with respect to such proposal, his, her or its vote with respect to the proposal will be disqualified.

Disclosure of Personal Interests of Controlling Shareholders

The disclosure requirements regarding personal interests that apply to directors and executive officers also apply to controlling shareholders, as defined below. The Israeli Companies Law requires a special approval procedure for (1) extraordinary transactions with controlling shareholders, (2) extraordinary transactions with a third party where a controlling shareholder has a personal interest in the transaction, and (3) any transaction with the controlling shareholder or the controlling shareholder's relative regarding terms of service provided directly or indirectly (including through a company controlled by the controlling shareholder) and terms of employment (for a controlling shareholder who is not an office holder). A "relative" is defined in the Israeli Companies Law as spouse, sibling, parent, grandparent, descendant, spouse's descendant, sibling, parent, or the spouse of any of the foregoing.

Such extraordinary transactions with controlling shareholders require the approval of the audit committee or the compensation committee, as applicable, the board of directors and the majority of the voting power of the shareholders present and voting at the general meeting of the company (not including abstentions), provided that either:

- the majority of the shares of shareholders who have no personal interest in the transaction and who are present and voting, vote in favor; or
- shareholders who have no personal interest in the transaction who vote against the transaction do not represent more than two percent of the aggregate voting rights in the company.

Any shareholder participating in the vote on approval of an extraordinary transaction with a controlling shareholder must inform the company prior to the voting whether or not he or she has a personal interest in the approval of the transaction, and if he or she fails to do so, his or her vote will be disregarded.

Further, extraordinary transactions with controlling shareholders, extraordinary transactions with a third party where a controlling shareholder has a personal interest in the transaction, or transactions with a controlling shareholder or his or her relative concerning terms of service or employment need to be re-approved once every three years, provided, however, that with respect to extraordinary transactions with controlling shareholders or extraordinary transaction with a third party where a controlling shareholder has a personal interest in the transaction, the audit committee may determine that the duration of the transaction in excess of three years is reasonable given the circumstances related thereto.

In accordance with regulations promulgated under the Israeli Companies Law, certain defined types of extraordinary transactions between a public company and its controlling shareholder or controlling shareholders are exempt from the shareholder approval requirements. Pursuant to regulations adopted under the Israeli Companies Law, a transaction with a controlling shareholder that would otherwise require approval of the shareholders is generally exempt from shareholders' approval if the audit committee and the board of directors determine that the transaction is in market terms and in the ordinary course of business and does not otherwise harm the company. Examples to such transactions are stipulated in the regulations and include transactions which terms were concluded as a framework transaction and approved as such; transactions which are solely extensions to ongoing transactions which terms remained largely the same; transactions that can only benefit the company, without imposing any charges. However, such exemptions will not apply if one or more shareholders holding at least 1% of the issued and outstanding shares or voting rights, objects to the use of these exemptions in writing not later than 14 days from the date the company notifies its shareholders of the adoption by the relevant corporate bodies of the resolution regarding the transaction without shareholder approval in reliance upon such exemption.

In addition, the approval of the audit committee, followed by the approval of the board of directors and the shareholders, is required in order to effect a private placement of securities, in which either (i) 20% or more of the company's outstanding share capital prior to the placement is offered, and the payment for which is not only in cash or in tradable securities registered in a stock exchange, or that is not at market terms, and which will result in an increase of the holdings of a shareholder that already holds 5% or more of the company's outstanding share capital or voting rights or will cause any person to become, as a result of the issuance, a holder of more than 5% of the company's outstanding share capital or voting rights or (ii) a person will become a controlling party in the company.

A "controlling shareholder" is defined in the Israeli Companies Law for purposes of the provisions governing related party transactions and office holder compensation as a person with the ability to direct the actions of a company, or a person who holds 25% or more of the voting power in a public company if no other shareholder owns more than 50% of the voting power in the company, but excluding a person whose power derives solely from his or her position as a director of the company or any other position with the company. Any two or more persons holding voting rights in the company, who each have a personal interest in the approval of the same such transaction, shall be deemed to be one holder with respect thereto.

Arrangements regarding the terms of engagement and compensation of a controlling shareholder who is an office holder, and the terms of employment of a controlling shareholder who is an employee of the Company, require the approval of the compensation committee, board of directors and, generally, the

shareholders, in that order, as described above under "NASDAQ Listing Rules and home country practices — Compensation of officers".

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 the general meeting of shareholders and at class shareholder 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;
- approval of interested party transactions and acts of office holders that require shareholder approval; or
- approval of the compensation policy.

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

Certain shareholders have a further duty of fairness toward the Company. These shareholders include any controlling shareholder, any shareholder who knows that it has the power to determine the outcome of a shareholder vote or a shareholder class vote and any shareholder who has the power to appoint or to prevent the appointment of an office holder of the Company or other power toward the Company. The Israeli Companies Law does not define the substance of this 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 include such a provision. The company may not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Israeli Companies Law and the Israeli Securities Law, a company may indemnify, or undertake in advance to indemnify, an office holder for the following liabilities and expenses, imposed on office holder or incurred by office holder due to acts performed by him or her as an office holder, provided its articles of association include a provision authorizing such indemnification:

- financial liability incurred by or 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 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 or as a monetary sanction (the items (i) and (ii) above shall have the meanings ascribed to them in section 260(a)(1a) of the Israeli Companies Law);

- 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; and
- expenses, including reasonable litigation expenses and legal fees, incurred by an office holder in relation to an administrative proceeding instituted against such office holder, or certain compensation payments required to be made to an injured party, pursuant to certain provisions of the Israeli Securities Law.

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 duty of care to the Company or to a third party; and
- a financial liability imposed on the office holder in favor of a third party.

Without derogating from the aforementioned, subject to the provisions of the Israeli Companies Law and the Israeli Securities Law, we may also enter into a contract to insure an office holder, in respect of expenses, including reasonable litigation expenses and legal fees, incurred by an office holder in relation to an administrative proceeding instituted against such office holder or payment required to be made to an injured party, pursuant to certain provisions of the Securities Law.

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

- a breach of fiduciary duty, except for indemnification and insurance for a breach of the duty of loyalty to the Company in the event office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the Company;
- a breach of 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 unlawful personal benefit; or
- a fine, monetary sanction, penalty or forfeit levied against the office holder.

Under the Israeli Companies Law, exculpation, indemnification and insurance of office holders require the approval of the compensation committee, board of directors and, in certain circumstances, the shareholders, as described above under "— NASDAQ Listing Rules and home country practices — Compensation of officers".

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

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

Code of Business Conduct and Ethics

We have adopted, effective upon the consummation of this offering, a Code of Business Conduct and Ethics applicable to all of our directors and employees, including our Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer, or other persons performing similar functions, which is a "code of ethics" as defined in Item 16B of Form 20-F promulgated by the SEC. Upon the effectiveness of the registration statement of which this prospectus forms a part, the full text of the Code of Business Conduct and Ethics will be posted on our website at *www.polypid.com*. 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 to the extent required by the rules and regulations of the SEC. Under Item 16B of the SEC's Form 20-F, if a waiver or amendment of the Code of 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 such Form 20-F, we will disclose such waiver or amendment in accordance with the requirements of Instruction 4 to such Item 16B.

Compensation of Executive Officers and Directors

The aggregate compensation, including share-based compensation, paid by us to our directors and executive officers with respect to the six months ended June 30, 2014 was approximately $682,000. This includes amounts paid for pension, severance or similar benefits, but does not include business travel, relocation, professional and business association due and expenses reimbursed to office holders, and other benefits commonly reimbursed or paid by companies in our industry. As of June 30, 2014, options to purchase 5,247,669 ordinary shares granted to our directors and executive officers were outstanding under our share option plans at a weighted average exercise price of $0.33 per share.

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. Pursuant to those agreements, in the event that the Company terminates their employment without giving effect to the applicable notice period, and without justifiable cause, then the Company shall pay Mr. Weisberg, Mr. Emanuel and Mr. Kyiet an amount equal to the salary and benefits to which he would have otherwise been entitled during the remainder of such notice period.

Employment or Service Agreements with Executive Officers; Consulting and Directorship Services Provided by Directors

We have entered into written employment agreements with Mr. Amir Weisberg, our chief executive officer, Dr. Noam Emanuel, our chief technology officer, Mr. Jack Eitan Kyiet, our chief operating officer, Mr. Shaun Marcus, our chief financial officer and Ms. Dikla Czaczkes Axelbrad, our chief strategy officer. We have entered into a written service agreement with Mr. Asaf Bar, our chief business officer. These agreements contain provisions standard for a company in our industry regarding non-competition, confidentiality of information and assignment of inventions. See "Agreements and Arrangements with, and Compensation of, Directors and Executive Officers" below.

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. Please see "Risk factors — Risks Relating to Competition." for a further description of the enforceability of non-competition clauses. See "Agreements and Arrangements with, and Compensation of, Directors and Executive Officers" below.

PolyPid Ltd. — 2012 Share Option Plan

We maintain one equity incentive plan — our 2012 Share Option Plan, or the Option Plan, which was adopted by our Board of Directors on August 29, 2012. The Option 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 141,185 shares are reserved but unissued under our Option Plan.

The Option 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 Option 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% 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, 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 Option 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 Option 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.

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.

Financing Transactions

In December 2012, we entered into a Share Purchase Agreement with certain investors, including some of our directors and officers, pursuant to which we issued a total of 4,128,137 series B-1 shares at a price of $0.61 per share.

In February 2013, we closed the Joinder to Series B-1 Preferred Share Purchase Agreement, pursuant to which we sold an aggregate of 371,937 series B-1 preferred shares at a price of $0.61 per share.

In October 2013, we entered into a Share Purchase Agreement with certain investors, including some of our directors and officers, pursuant to which we issued a total of 3,467,630 series B-1 shares at a price of $0.61 per share.

In June 2014, we entered into a Share Purchase Agreement with certain investors, including some of our directors and officers, pursuant to which we issued a total of 6,605,020 series B-1 shares at a price of $0.61 per share.

Services Agreement for Authorized Representation

On August 20, 2013, we entered into an authorized representation services agreement with PolyPid Pharm SRL, or PolyPid Pharm, a company organized under the laws of Romania, and wholly owned by our shareholder and Chief Executive Officer, Mr. Amir Weisberg. Under the terms of the agreement, effective as of September 1, 2012, PolyPid Pharm is entitled to reimbursement of any costs and expenses. The agreement is terminable by either party upon 30 days' prior written notice, and contains provisions regarding confidentiality of information and assignment of inventions.

Registration Rights Agreement

On , 2014, we entered into a registration rights agreement, pursuant to which certain of the holders of our ordinary shares are parties. We intend to enter into waivers of these registration rights with respect to this offering.

Rights of Appointment

Our current Board of Directors consists of 9 directors. Pursuant to our articles of association in effect prior to this offering, certain of our shareholders had rights to appoint members of our Board of Directors. See “Management.”

All rights to appoint directors will terminate upon the closing of this offering, although some of the currently-serving directors that were appointed prior to this offering will continue to serve pursuant to their appointment until the annual meeting of shareholders at which the term of their class of director expires.

Employment Agreements with Immediate Family Members of Our Executive Officers and Directors

Hili Emanuel, the daughter of Dr. Noam Emanuel, our Chief Technology Officer and director, is employed by us as a part-time data mining expert. This engagement is non-material in market terms.

Moran Cohen, the daughter of Mr. Amir Weisberg, our chief executive officer and directors, is employed by us as office manager and administrator. This engagement is non-material in market terms.

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

Certain of our officers have consulting agreements with the Company. These agreements will terminate at the closing of this offering and be replaced by employment agreements. In addition, and subject to the completion of this offering, our Board of Directors and shareholders have agreed to pay a one-time bonus of approximately in the aggregate to certain of our executive officers for their contribution to completing this offering. These agreements will contain provisions standard for a company in our industry regarding non-competition, confidentiality of information and assignment of inventions. 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. Please see “Risk factors — Risks Relating to Competition.” for a further description of the enforceability of non-competition clauses.

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. For further information, see “Management — Exculpation, insurance and indemnification of directors and officers.”

PRINCIPAL SHAREHOLDERS

The following table sets forth information regarding beneficial ownership of our ordinary shares as of the date of this prospectus by:

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

Beneficial ownership is determined in accordance with the rules of the SEC, and includes voting or investment power with respect to ordinary shares. Ordinary shares issuable under share options or warrants that are exercisable within 60 days after the date of this prospectus are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options or warrants but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. Percentage of shares beneficially owned before this offering is based on 34,548,122 shares outstanding on the date of this prospectus. The number of ordinary shares deemed outstanding after this offering includes the ordinary shares being offered for sale in this offering but assumes no exercise of the underwriter's over-allotment option.

As of the date of this prospectus, there were 36 record holders of our ordinary shares. None of our shareholders has different voting rights from other shareholders. To the best of our knowledge, we are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Except as indicated in footnotes to this table, we believe that the shareholders named in this table have sole voting and investment power with respect to all shares shown to be beneficially owned by them, based on information provided to us by such shareholders. Unless otherwise noted below, each shareholder's address is: c/o PolyPid Ltd., 18 Hasivim Street, P.O. Box 7126 Petach Tikva, 4917002 Israel.

	No. of Shares Beneficially Owned Prior to this Offering	Percentage Owned Before this Offering	Percentage Owned After this Offering
Holders of 5% or more of our voting securities			
Dr. Noam Emanuel*[1]	2,761,230	7.1%	
Yehuda Nir	2,654,595	6.9%	
Prof. David Segal[2]	2,275,583	5.9%	
Amir Weisberg*[3]	2,061,319	5.3%	
Anat Segal*[4]	6,187,682	16.0%	
Jack Eitan Kyiet*[5]	4,805,286	12.4%	
Arik Lukach*	2,045,828	5.3%	
Directors and executive officers who are not 5% holders			
Rami Lerner*	1,803,594	4.7%	
Yechezkel Barenholz*[6]	1,142,832	3.0%	
Dr. Moshe Neuman*	1,300,000	3.4%	
Yafit Stark*[7]	534,408	1.4%	
Shaun Marcus[8]	36,826	0.1%	
Asaf Bar	—		
Dikla Czaczkes Axelbrad	—		
All directors and executive officers as a group (12 persons):	22,679,005	58.6%	

* Indicates Director.

(1) Includes vested options as of August 30, 2014, to purchase 1,061,230 ordinary shares, of which 832,220 options at an exercise price of par value per share and 229,010 options at an exercise price of $.43 per share. Of such options, 1,008,206 options expire on March 2023 and 53,024 options expire on December 2023.

(2) Includes vested options as of August 30, 2014, to purchase 229,560 ordinary shares at an exercise price of par value per share. The options expire on March 2023.

(3) Includes vested options as of August 30, 2014, to purchase 701,047 ordinary shares at an exercise price of $.21 per share. The options expire on March 2023.

(4) All shares and convertible securities have been issued to Xenia Venture Capital Ltd. Ms. Anat Segal, the Chairman of our Board of Directors, is the Chief Executive Officer of Xenia Venture Capital Ltd. Includes 450,000 series A preferred shares issuable upon the exercise of a warrant, at an exercise price of NIS 0.1 per share. The warrant shall expire upon the consummation of this offering.

(5) Includes: (i) 4,722,923 shares issued to Friendly Angels Club (the “Club”), an entity affiliated with Mr. Kyiet, who serves as one of its principals. Pursuant to an arrangement between the Club and Mr. Kyiet, Mr. Kyiet is entitled to receive warrants to purchase up to 4% of the aggregate shares purchased by the Club. In addition, Mr. Kyiet will be entitled to receive a portion of 10% of any profits derived from the investment made by the Club; and (ii) vested options granted to Mr. Kyiet as of August 30, 2014, to purchase 82,363 ordinary shares at an exercise price of $.61 per share. The options expire on October 2023.

(6) Includes vested options as of August 30, 2014, to purchase 450,000 ordinary shares at an exercise price of par value per share. The options expire on March 2023.

(7) Includes vested options as of August 30, 2014, to purchase 450,000 ordinary shares at an exercise price of par value per share. The options expire on March 2023.

(8) Includes vested options as of August 30, 2014, to purchase 36,826 ordinary shares, at an exercise price of $.43 per share. The options expire on March 2023.

Record Holders

As of the date of this prospectus, there were 36 holders of record of our Ordinary Shares, of which 2 record holders holding approximately 0.62% of our outstanding shares had registered addresses in the United States.

DESCRIPTION OF SHARE CAPITAL

The following description of our share capital and provisions of our amended and restated articles of association which will be adopted immediately prior to the consummation of this offering are summaries and do not purport to be complete.

General

Ordinary Shares

Immediately prior to the consummation of this offering, effective upon the adoption of our amended and restated articles of association, our authorized share capital will consist of ordinary shares, par value NIS 0.01 per share, of which shares will be issued and outstanding.

All of our outstanding ordinary shares are validly issued, fully paid and non-assessable. They are not redeemable and do not have any preemptive rights.

Our Board of Directors may determine the issue prices and terms for such shares or other securities, and may further determine any other provision relating to such issue of shares or securities. We may also issue and redeem redeemable securities on such terms and in such manner as our Board of Directors shall determine. Our Board of Directors may not make calls or assessments on our issued ordinary shares.

Warrants

In connection with the March 2008 Founders and Share Purchase Agreement, we issued warrants to purchase up to 450,000 series A preferred Shares at an exercise price equal to par value per share. These warrants will expire upon the consummation of this offering assuming said offering constitutes a "qualified IPO" under such warrant terms.

Options

As of June 30, 2014, our option pool, pursuant to the Company's Option Plan, consists of 7,000,000 ordinary shares, of which options to purchase 6,858,815 ordinary shares have been granted. We describe our option plans under "Management — PolyPid Ltd. — 2012 Share Option Plan."

Share History

The following is a summary of the history of our share capital for the last three years.

Series B Preferred Share Purchase Agreement. In December 2011, we closed the Series B Preferred Share Purchase Agreement, pursuant to which we sold an aggregate of 4,390,387 series B preferred shares at a price of $0.43 per share.

Joinder to Series B Preferred Share Purchase Agreement. In March 2012, we closed the Joinder to Series B Preferred Share Purchase Agreement, pursuant to which we sold an aggregate of 349,243 series B preferred shares at a price of $0.43 per share.

Series B-1 Preferred Share Purchase Agreement. In December 2012, we closed the Series B-1 Preferred Share Purchase Agreement, pursuant to which we sold an aggregate of 4,128,137 series B-1 preferred shares at a price of $0.61per share.

Joinder to Series B-1 Preferred Share Purchase Agreement. In February 2013, we closed the Joinder to Series B-1 Preferred Share Purchase Agreement, pursuant to which we sold an aggregate of 371,937 series B-1 preferred shares at a price of $0.61per share.

Series B-1 Preferred Share Purchase Agreement. In April 2013, we closed the Series B-1 Preferred Share Purchase Agreement, pursuant to which we sold an aggregate of 165,125 series B-1 preferred shares at a price of $0.61per share.

Series B-1 Preferred Share Purchase Agreement. In October 2013, we closed the Series B-1 Preferred Share Purchase Agreement, pursuant to which we sold an aggregate of 3,302,505 series B-1 preferred shares at a price of $0.61per share.

Series B-1 Preferred Share Purchase Agreement. In June 2014, we closed the Series B-1 Preferred Share Purchase Agreement, pursuant to which we sold an aggregate of 6,605,019 series B-1 preferred shares at a price of $0.61 per share.

Immediately prior to the consummation of this offering, effective upon the adoption of our amended and restated articles of association, all outstanding preferred shares will convert into ordinary shares.

Voting Rights

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.

Transfer of Shares

Our ordinary shares that are fully paid for 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 applicable law or the rules of a stock exchange on which the shares are traded. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our amended and restated articles of association or the laws of the State of Israel, except under certain circumstances 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 in the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, subject to the special approval requirements for external directors in accordance with Israeli Companies Law which are described under “Management — External directors.”

Our directors hold office for their scheduled term unless they are removed from office upon the occurrence of certain events, in accordance with the Israeli Companies Law and our amended and restated articles of association. 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 to serve for a term of office equal to the remaining period of the term of office of the directors(s) whose office(s) have been vacated. External directors are elected for an initial term of three years, may be elected for additional terms of three years each under certain circumstances, and may be removed from office pursuant to the terms of the Israeli Companies Law. See “Management — Board practices — External 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, subject to certain restrictions. 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, as such are defined in the Israeli Companies Law, according to our then last reviewed or audited financial reports, provided that the date of the financial reports is not more than six months prior to the date of distribution, or we may distribute dividends that do not meet such criteria only with court approval. Where court approval is required, we will only be permitted to pay a dividend if the court 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 under certain circumstances 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 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 as special meetings. Our Board of Directors may call special 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 a special meeting upon the written request of (i) any two of our directors or one-quarter of our Board of Directors, or (ii) one or more shareholders holding, in the aggregate, either (a) 5% of our outstanding issued shares and 1% of our outstanding voting power, or (b) 5% 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 generally 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 amended and restated articles of association;
- 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;
- appointment or termination of our auditors;
- appointment of external directors;
- approval of acts and transactions involving related parties, as defined by the Israeli Companies Law;
- increases or reductions of our authorized share capital; and
- a merger.

The Israeli Companies Law and our amended and restated articles of association require that a notice of any annual general meeting or special shareholders meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes matters upon which shareholders may vote by means of a voting deed, including the appointment or removal of directors, the approval of a compensation policy with respect to office holders, 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 the Israeli Companies Law and our amended and restated articles of association, shareholders are not permitted to take action via written consent in lieu of a meeting.

Voting Rights

Quorum Requirements

The quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy or written ballot who hold or represent between them at least one-third 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/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.

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 certain actions require a special majority, which may include (i) appointment of external directors, requiring the approval of certain transactions described above under "Management — Board Practices — External Directors", (ii) approval of an extraordinary transaction with a controlling shareholder and the terms of employment or other engagement of the controlling shareholder of the Company or such controlling shareholder's relative (even if not extraordinary), requiring the approval described above under "Approval of Related Party Transactions under Israeli Law — Disclosure of Personal Interests of Controlling Shareholders.", (iii) approval of executive officer' compensation inconsistent with our office holder compensation policy, compensation of our chief executive officer, or the compensation of an executive officer who is also the controlling shareholder of our company (including an affiliate thereof), all of which require the special majority approval described above under "Management — NASDAQ Listing Rules and Home Country Practices — Compensation of Officers."; (iv) approving the authorization of the chairman of the board or a relative thereof to assume the role or responsibilities of the chief executive officer, or the authorization of the chief executive officer or a relative thereof to assume the role or responsibilities of the chairman of the board, for periods of no longer than three years each and subject to receipt of the approval of a majority of the shares voting on the matter, providing that either (1) included in such majority are at least two-thirds of the shares of shareholders who are non-controlling parties and do not have a personal interest in the said resolution (excluding for such purpose any abstentions); or (2) the total number of shares of shareholders specified in clause (3) who voted against the resolution does not exceed two percent (2%) of the voting rights in the company; and (v) mergers, certain private placements that will increase certain types of shareholders' relative holdings in the company, or certain special tender offers or forced bring along share purchase transactions, all of which require the approval described below under "Acquisitions under Israeli Law".

Under our amended and restated articles of association, the alteration of the rights, privileges, preferences or obligations of any class of our share capital 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, which requires the approval of the majority of the shareholders in each class of shareholders present at the meeting and who are together the holders of 75% of the voting rights represented at the meeting, in person, by proxy or by voting deed and voting on the resolution.

Israeli law provides that a shareholder of a public company may vote in a meeting and in a class meeting by means of a voting deed in which the shareholder indicates how he or she votes on resolutions relating to the following matters:

- appointment or removal of directors;
- approval of transactions with office holders or interested or related parties;
- approval of a merger;
- authorization of the chairman of the board or a relative thereof to assume the role or responsibilities of our chief executive officer, and authorization of our chief executive officer or a relative thereof to assume the role or responsibilities of the chairman of the board;
- approval of an arrangement or reorganization of the Company pursuant to Section 350 of the Israeli Companies Law;

- approval of the compensation policy with respect to the terms of office and employment of office holders; and
- other matters in respect of which there is a provision in the articles of association providing that decisions of the general meeting may also be passed by voting deed or which may be prescribed by Israel's Minister of Justice.

The provision allowing the vote by voting deed does not apply if, to the best knowledge of the Company at the time of calling the general shareholders meeting, a controlling shareholder will hold on the record date for such shareholders meeting, voting power sufficient to determine the outcome of the vote.

The Israeli Companies Law provides that a shareholder, in exercising his or her rights and performing his or her obligations toward the Company and its other shareholders, including voting at general meetings, must act in good faith and in a customary manner, and avoid abusing his or her power. See "Approval of Related Party Transactions under Israeli Law — Shareholder Duties" above for further detail.

Access to Corporate Records

Under the Israeli Companies Law and our amended and restated articles of association, shareholders are provided access to the following corporate records: minutes of our general meetings; our shareholders register and principal shareholders register, articles of association and 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 submit a reasoned request to be provided with any document related to an action or transaction requiring shareholder approval under the approval of related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been submitted in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

Modification of Class Rights

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 (or a special majority, as may be applicable to the particular matter) 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.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of a public Israeli company and who could as a result hold over 90% of the target company's issued and outstanding share capital or voting rights 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 could as a result hold over 90% of the issued and outstanding share capital or voting rights 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 and voting rights of the company or of the applicable class, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved it, which condition shall not apply if, following consummation of the tender offer, the acquirer would hold at least 98% of all of the company's outstanding shares and voting rights (or shares and voting rights of the relevant class)). However, shareholders may, at any time within six months following the completion of the tender offer, petition the court to alter the consideration for the acquisition. Even shareholders who indicated their acceptance of the tender offer may so petition the court, unless the acquirer stipulated that a shareholder that accepts the offer may not seek appraisal rights. If the shareholders who did not accept the tender offer hold 5% or more of the issued and outstanding share capital or voting rights of the company or of the applicable class, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or voting rights or 90% of the shares or voting rights of the applicable class, from shareholders who accepted the tender offer.

Special Tender Offer

The Israeli Companies Law provides that an acquisition of a control bloc of shares in a public Israeli company must be made by means of a special tender offer if as a result of the transaction the shareholder could become a holder of 25% or more of the voting rights in the company, unless one of the exemptions in the Israeli Companies Law (as described below) is met. This rule 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 an acquisition of shares in a public company must be made by means of a tender offer if as a result of the acquisition the purchaser could 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, unless one of the exemptions in the Israeli Companies Law is met. Such exemptions include (a) acquisition of shares issued in the course of a private placement approved by the general meeting of the company as a private placement intended to provide purchaser with holdings of 25% or more of the voting rights in the company, if there is no other shareholder of the company who holds more than 25% of the voting rights in the company, or as a private placement intended to provide purchaser with holdings 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, (b) acquisition of shares from a holder of 25% or more of the voting rights in the company following which purchaser shall hold 25% or more of the voting rights in the company, or (c) acquisition of shares from a holder of 45% or more of the voting rights in the company following which purchaser shall hold 45% or more of the voting rights in the company.

A special tender offer must be extended to all shareholders of a company but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (disregarding holders who control the offeror and who have a personal interest in the acceptance of the offer or the holder of 25% or more of the voting rights of the company, any of their relatives, or corporations controlled by any of the above).

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.

Merger

The Israeli Companies Law permits merger transactions between Israeli companies 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 shares, and, in the case of the target company, a majority vote of each class of its shares, voted on the proposed merger at a shareholders meeting called with at least 35 days' prior notice.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of shares represented at the shareholders meeting (disregarding abstentions) 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, or anyone on such parties' behalf, including relatives of such parties and corporations controlled them, 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 above in this prospectus under "Management — NASDAQ Listing Rules and Home Country Practices — Shareholder Approval.")

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 request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value of the parties to the merger and the consideration offered to the shareholders of the company that have petitioned the court to approve the merger.

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

In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger was filed by each party 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 allow us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights, distributions or other matters and shares having preemptive rights. As of the 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 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 or other corporate bodies, 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 and, in certain circumstances, an issuance of shares for less than their nominal value, require the approval of both our Board of Directors and an Israeli court.

Transfer Agent

Our transfer agent in the United States will be.

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 their over-allotment option with respect to this offering and assuming no exercise of options outstanding following the offering, we will have an aggregate of ordinary shares outstanding upon completion 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. Because substantially all of these shares were sold outside the United States to persons residing outside the United States at the time, they also will be freely tradable without restriction or further registration, except that shares held by affiliates must be sold under Rule 144, and except for the lock-up restrictions described below. Further, substantially all of our outstanding shares are subject to the lock-up agreements.

Lock-up agreements

We, all of our directors and executive officers and holders of substantially all of our outstanding ordinary shares have signed lock-up agreements pursuant to which, subject to certain exceptions, we and they have agreed not to sell or otherwise dispose of their 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 Aegis Capital Corp. In addition, certain holders of options to purchase our shares have entered into similar lock-up agreements.

Rule 144

In general, under Rule 144, beginning 90 days after the date of this prospectus, any person who is not our affiliate and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, provided that we have filed all reports required by the Exchange Act during the previous 12 months (or such shorter period that were required to file such reports), may sell shares without restriction. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

Beginning 90 days after the date of this prospectus, a person who is our affiliate or who was our affiliate at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, provided that we have filed all reports required by the Exchange Act during the previous 12 months (or such shorter period that were required to file such reports), is entitled to sell a number of shares within any three-month period that does not exceed the greater of:

- one percent of the number of ordinary shares then outstanding, which will equal shares; or
- the average weekly trading volume of our ordinary shares on the NASDAQ Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

If an affiliate acquires "restricted securities," those securities will also be subject to holding period requirements.

Upon expiration of the 180-day lock-up period described above, substantially all of our outstanding ordinary shares will either be unrestricted or will be eligible for sale under Rule 144. We cannot estimate the number of our ordinary shares that our existing stockholders will elect to sell.

Form S-8 Registration Statements

Following the completion of this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act to register up the ordinary shares issued or reserved for issuance under our Option Plan. The registration statement on Form S-8 will become effective automatically upon filing. Ordinary shares issued to individuals upon exercise of a share option and registered under the Form S-8 registration statement will, subject to vesting and lock-up 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 or, if subject to the lock-up, immediately after the 180-day lock-up period expires.

TAXATION

The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership or disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign, including Israeli, or other taxing jurisdiction.

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 consequences concerning the ownership and disposition of our ordinary shares. 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

Israeli resident companies, such as the Company, are generally subject to corporate tax at the rate of 26.5% as of 2014.

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%, or 30% 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, 2013, an additional income tax at a rate of 2% is imposed on high earners whose annual income or gain exceeds NIS 811,560.

A “substantial Shareholder” is generally a person who alone, or together with his relative or another person who collaborates with him on a regular basis, holds, directly or indirectly, at least 10% of any of the “means of control” of the corporation. “Means of control” generally include the right to vote, 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 all regardless of the source of such right.

The term "Israeli Resident" is generally defined under Israeli tax legislation with respect to individuals as a person whose center of life is in Israel. The Israeli Tax Ordinance New Version, 1961 (the "Israeli Tax Ordinance") provides that 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) place of permanent home; (b) place of residential dwelling of the individual and the individual's immediate family; (c) place of the individual's regular or permanent occupation or the place of his 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 as long as the profits from which the dividends were distributed were derived in Israel.

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%. 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%. As of January 1, 2013, an additional tax at a rate of 2% is imposed on high earners whose annual income or gains exceed NIS 811,560.

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 (26.5 as of 2014 for corporations and up to 50% for individuals).

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% (or 30% for individuals, if such person 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 lower tax rate is provided in a tax treaty between Israel and the shareholder's country of residence.

A non-Israeli resident who receives dividends from which tax was withheld is generally exempt from the duty to file returns in Israel in respect of such income; provided such income was not derived from a business conducted in Israel by the taxpayer, and the 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 (the "U.S.-Israel Tax Treaty"), Israeli withholding tax on dividends paid to a U.S. resident for treaty purposes may not, in general, exceed 25%, or 15% in the case of dividends paid out of the profits of a Benefited Enterprise, subject to certain conditions. Where the recipient is a U.S. corporation owning 10% or more of the 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 the dividend is not paid from the profits of a Benefited Enterprise, the Israeli tax withheld may not exceed 12.5%, subject to certain conditions.

Capital gains income taxes applicable to non-Israeli shareholders.

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 will not be entitled to the foregoing exemptions if an Israeli resident (i) has a controlling interest

of more than 25% in such non-Israeli corporation or (ii) is the beneficiary of or is entitled to 25% 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.

Estate and gift tax

Israeli law presently does not impose estate or gift taxes.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR ISRAELI TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR ORDINARY SHARES, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

U.S. FEDERAL INCOME TAX CONSEQUENCES

General

The following are the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our ordinary shares covered by this prospectus.

The discussion below of the U.S. federal income tax consequences to "U.S. Holders" will apply to a beneficial owner of our ordinary shares that is for U.S. federal income tax purposes:

- an individual citizen or resident of the United States;
- a corporation (or other entity treated as a corporation) that is created or organized (or treated as created or organized) in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate whose income is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (i) a U.S. court can exercise primary supervision over the trust's administration and one or more U.S. persons are authorized to control all substantial decisions of the trust or (ii) it has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

A beneficial owner of our ordinary shares that is described above is referred to herein as a "U.S. Holder." If a beneficial owner of our ordinary shares is not described as a U.S. Holder and is not an entity treated as a partnership or other pass-through entity for U.S. federal income tax purposes, such owner will be considered a "Non-U.S. Holder." The material U.S. federal income tax consequences applicable specifically to Non-U.S. Holders are described below under the heading "Non-U.S. Holders."

This discussion is based on the Code, its legislative history, Treasury regulations promulgated thereunder, published rulings and court decisions, all as currently in effect. These authorities are subject to change or differing interpretations, possibly on a retroactive basis.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to any particular holder based on such holder's individual circumstances. In particular, this discussion considers only holders that purchase our ordinary shares pursuant to this offering and own and hold the ordinary shares as capital assets within the meaning of Section 1221 of the Code, and does not address the potential application of the alternative minimum tax or the U.S. federal income tax consequences to holders that are subject to special rules, including:

- financial institutions or financial services entities;
- broker-dealers;
- persons that are subject to the mark-to-market accounting rules under Section 475 of the Code;
- tax-exempt entities;

- governments or agencies or instrumentalities thereof;
- insurance companies;
- regulated investment companies;
- real estate investment trusts;
- certain expatriates or former long term residents of the United States;
- persons that actually or constructively own 5% or more of our voting shares;
- persons that acquired the ordinary shares pursuant to an exercise of employee options, in connection with employee incentive plans or otherwise as compensation;
- persons that hold the ordinary shares as part of a straddle, constructive sale, hedging, conversion or other integrated transaction;
- persons whose functional currency is not the U.S. dollar;
- passive foreign investment companies; or
- controlled foreign corporations.

This discussion does not address any aspect of U.S. federal non-income tax laws, such as gift or estate tax laws, or state, local or non-U.S. tax laws or, except as discussed herein, any tax reporting obligations applicable to a holder of our ordinary shares. Additionally, this discussion does not consider the tax treatment of partnerships or other pass-through entities or persons who hold our ordinary shares through such entities. If a partnership (or other entity classified as a partnership for U.S. federal income tax purposes) is the beneficial owner of our ordinary shares, the U.S. federal income tax treatment of a partner in the partnership generally will depend on the status of the partner and the activities of the partnership. This discussion also assumes that any distribution made (or deemed made) to a holder in respect of our ordinary shares and any consideration received (or deemed received) by a holder in connection with the sale or other disposition of our ordinary shares will be in U.S. dollars.

We have not sought, and will not seek, a ruling from the IRS, or an opinion of counsel as to any U.S. federal income tax consequence described herein. The IRS may disagree with the description herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion.

EACH PROSPECTIVE INVESTOR IN OUR ORDINARY SHARES IS URGED TO CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES, INCLUDING THE APPLICABILITY AND EFFECT OF ANY STATE, LOCAL AND NON-U.S. TAX LAWS, AS WELL AS U.S. FEDERAL TAX LAWS AND ANY APPLICABLE TAX TREATIES.

U.S. Holders

Taxation of Cash Distributions

Subject to the “Passive Foreign Investment Company Rules” discussed below, a U.S. Holder generally will be required to include in gross income as ordinary income the amount of any cash dividend paid in respect of our ordinary shares. A cash distribution on our ordinary shares generally will be treated as a dividend for U.S. federal income tax purposes to the extent the distribution is paid out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes). Such dividend generally will not be eligible for the dividends-received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations. The portion of such cash distribution, if any, in excess of such earnings and profits will be applied against and reduce (but not below zero) the U.S. Holder’s adjusted tax basis in the ordinary shares. Any remaining excess generally will be treated as gain from the sale or other taxable disposition of such ordinary shares.

With respect to non-corporate U.S. Holders, any such cash dividends may be subject to U.S. federal income tax at the lower applicable regular long term capital gains tax rate (see "— *Taxation on the Disposition of Ordinary Shares*" below) provided that (a) the ordinary shares are readily tradable on an established securities market in the United States or we are eligible for the benefits of the U.S.-Israeli Tax Treaty, (b) we are not a PFIC, as discussed below, for either the taxable year in which the dividend was paid or the preceding taxable year and (c) certain holding period requirements are met. Therefore, if our ordinary shares are not readily tradable on an established securities market, and we are not eligible for the benefits of the U.S.-Israel Tax Treaty, then cash dividends paid by us to non-corporate U.S. Holders will not be subject to U.S. federal income tax at the lower regular long term capital gains tax rate. Under published IRS authority, shares are considered for purposes of clause (a) above to be readily tradable on an established securities market in the United States only if they are listed on certain exchanges, which presently include the NASDAQ Capital Market. Although we intend to apply to have our ordinary shares listed and traded on the NASDAQ Capital Market, we cannot guarantee that our application will be approved or, if approved, that our ordinary shares will continue to be listed and traded on the NASDAQ Capital Market. U.S. Holders should consult their own tax advisors regarding the availability of the lower rate for any cash dividends paid with respect to our ordinary shares.

If an Israeli income tax applies to cash dividends paid to a U.S. Holder on our ordinary shares, as discussed in "Taxation — Israeli Tax Considerations" above, such tax may be treated as a foreign tax eligible for a deduction from such holder's U.S. federal taxable income or a foreign tax credit against such holder's U.S. federal income tax liability (subject to applicable conditions and limitations). In addition, if such Israeli tax applies to any such dividends, a U.S. Holder may be entitled to certain benefits under the U.S.-Israeli Tax Treaty, if such holder is considered a resident of the United States for purposes of, and otherwise meets the requirements of, the U.S.-Israeli Tax Treaty. U.S. Holders should consult their own tax advisors regarding the deduction or credit for any such Israeli tax and their eligibility for the benefits of the U.S.-Israeli Tax Treaty.

Taxation on the Disposition of Ordinary Shares

Upon a sale or other taxable disposition of our ordinary shares, and subject to the PFIC rules discussed below, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the ordinary shares.

The regular U.S. federal income tax rate on capital gains recognized by U.S. Holders generally is the same as the regular U.S. federal income tax rate on ordinary income, except that long term capital gains recognized by non-corporate U.S. Holders generally are subject to U.S. federal income tax at a maximum regular rate of 20%. Capital gain or loss will constitute long term capital gain or loss if the U.S. Holder's holding period for the ordinary shares exceeds one year. The deductibility of capital losses is subject to various limitations.

If an Israeli income tax applies to any gain from the disposition of our ordinary shares by a U.S. Holder, as discussed in "Taxation — Israeli Tax Considerations" above, such tax may be treated as a foreign tax eligible for a deduction from such holder's U.S. federal taxable income or a foreign tax credit against such holder's U.S. federal income tax liability (subject to applicable conditions and limitations). In addition, if such Israeli tax applies to any such gain, a U.S. Holder may be entitled to certain benefits under the U.S.-Israeli Tax Treaty, if such holder is considered a resident of the United States for purposes of, and otherwise meets the requirements of, the U.S.-Israeli Tax Treaty.

U.S. Holders should consult their own tax advisors regarding the deduction or credit for any such Israeli tax and their eligibility for the benefits of the U.S.-Israeli Tax Treaty.

Additional Taxes

U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally will be subject to a 3.8% Medicare contribution tax on unearned income, including, without limitation, dividends on, and gains from the sale or other taxable disposition of, our ordinary shares, subject to certain limitations and exceptions. U.S. Holders should consult their own tax advisors regarding the effect, if any, of such tax on their ownership and disposition of our ordinary shares.

Passive Foreign Investment Company Rules

A foreign (i.e., non-U.S.) corporation will be a PFIC if either (a) at least 75% of its gross income in a taxable year of the foreign corporation, including its pro rata share of the gross income of any corporation in which it is considered to own at least 25% of the shares by value, is passive income or (b) at least 50% of its assets in a taxable year of the foreign corporation, ordinarily determined based on fair market value and averaged quarterly over the year, including its pro rata share of the assets of any corporation in which it is considered to own at least 25% of the shares by value, are held for the production of, or produce, passive income. Passive income generally includes dividends, interest, rents and royalties (other than certain rents or royalties derived from the active conduct of a trade or business) and gains from the disposition of passive assets.

Based on the anticipated composition (and estimated values) of our assets and the nature of our expected income and operations, we do not expect to be treated as a PFIC for our current taxable year. Nevertheless, because this determination is made annually after the close of each taxable year, because we expect to hold following this offering a substantial amount of cash and cash equivalents, and because the calculation of the value of our assets may be based in part on the value of our ordinary shares, which may fluctuate after this offering and may fluctuate considerably given that market prices of emerging biopharmaceutical companies, such as us, historically often have been volatile, it is difficult to predict whether we will be a PFIC in any taxable year. Even if we determine that we are not a PFIC after the close of our taxable year, there can be no assurance that the IRS will agree with our conclusion. Accordingly, there can be no assurance with respect to our status as a PFIC for our current taxable year or any subsequent taxable year.

If we are determined to be a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U.S. Holder of the ordinary shares, and the U.S. Holder did not make either a timely QEF election for our first taxable year as a PFIC in which the U.S. Holder held (or was deemed to hold) the ordinary shares, a QEF election along with a purging election or a mark-to-market election, each as described below, such holder generally will be subject to special rules for regular U.S. federal income tax purposes with respect to:

- any gain recognized by the U.S. Holder on the sale or other disposition of its ordinary shares; and
- any “excess distribution” made to the U.S. Holder (generally, any distributions to such U.S. Holder during a taxable year of the U.S. Holder that are greater than 125% of the average annual distributions received by such U.S. Holder in respect of the ordinary shares during the three preceding taxable years of such U.S. Holder or, if shorter, such U.S. Holder’s holding period for the ordinary shares).

Under these rules:

- the U.S. Holder’s gain or excess distribution will be allocated ratably over the U.S. Holder’s holding period for the ordinary shares;
- the amount allocated to the U.S. Holder’s taxable year in which the U.S. Holder recognized the gain or received the excess distribution or to the period in the U.S. Holder’s holding period before the first day of our first taxable year in which we qualified as a PFIC will be taxed as ordinary income;
- the amount allocated to other taxable years (or portions thereof) of the U.S. Holder and included in its holding period will be taxed at the highest tax rate in effect for that year and applicable to the U.S. Holder; and
- the interest charge generally applicable to underpayments of tax will be imposed in respect of the tax attributable to each such other taxable year of the U.S. Holder.

In general, if we are determined to be a PFIC, a U.S. Holder may avoid the PFIC tax consequences described above with respect to the ordinary shares by making a timely QEF election (or a QEF election along with a purging election). Pursuant to the QEF election, a U.S. Holder will be required to include in income its pro rata share of our net capital gains (as long term capital gain) and other earnings and profits (as ordinary income), on a current basis, in each case whether or not distributed, in the taxable year of the U.S. Holder in which or with which our taxable year ends. However, a U.S. Holder may make a QEF election

only if we agree to provide certain tax information to such holder annually. At this time, we do not intend to provide U.S. Holders with such information as may be required to make a QEF election effective.

Alternatively, if a U.S. Holder, at the close of its taxable year, owns ordinary shares in a PFIC that are treated as marketable stock, the U.S. Holder may make a mark-to-market election with respect to such ordinary shares for such taxable year. If the U.S. Holder makes a valid mark-to-market election for the first taxable year of the U.S. Holder in which the U.S. Holder holds (or is deemed to hold) the ordinary shares and for which we are determined to be a PFIC, such holder generally will not be subject to the PFIC rules described above with respect to its ordinary shares. Instead, in general, the U.S. Holder will include as ordinary income for each year that we are a PFIC the excess, if any, of the fair market value of its ordinary shares at the end of its taxable year over the adjusted tax basis in its ordinary shares. The U.S. Holder also will be allowed to take an ordinary loss in respect of the excess, if any, of the adjusted tax basis of its ordinary shares over the fair market value of its ordinary shares at the end of its taxable year (but only to the extent of the net amount of previously included income as a result of the mark-to-market election). The U.S. Holder's adjusted tax basis in its ordinary shares will be adjusted to reflect any such income or loss amounts, and any further gain recognized on a sale or other taxable disposition of the ordinary shares will be treated as ordinary income.

The mark-to-market election is available only for stock that is regularly traded on a national securities exchange that is registered with the SEC, including the NASDAQ Capital Market, or on a foreign exchange or market that the IRS determines has rules sufficient to ensure that the market price represents a legitimate and sound fair market value. Although we intend to apply to have our ordinary shares listed and traded on the NASDAQ Capital Market, we cannot guarantee that our application will be approved or, if approved, that our ordinary shares will continue to be listed and traded on the NASDAQ Capital Market. U.S. Holders should consult their own tax advisors regarding the availability and tax consequences of a mark-to-market election with respect to our ordinary shares under their particular circumstances.

If we are a PFIC and, at any time, have a foreign subsidiary that is classified as a PFIC, a U.S. Holder of our ordinary shares generally should be deemed to own a portion of the shares of such lower-tier PFIC, and generally could incur liability for the deferred tax and interest charge described above if we receive a distribution from, or dispose of all or part of our interest in, or the U.S. Holder were otherwise deemed to have disposed of an interest in, the lower-tier PFIC. A mark-to-market election generally would not be available with respect to such a lower-tier PFIC. U.S. Holders are urged to consult their own tax advisors regarding the tax issues raised by lower-tier PFICs.

A U.S. Holder that owns (or is deemed to own) ordinary shares in a PFIC during any taxable year of the U.S. Holder may have to file an IRS Form 8621 (whether or not a mark-to-market election is or has been made) with such U.S. Holder's U.S. federal income tax return and provide such other information as may be required by the U.S. Treasury Department.

The rules dealing with PFICs and mark-to-market elections are very complex and are affected by various factors in addition to those described above. Accordingly, U.S. Holders of our ordinary shares should consult their own tax advisors concerning the application of the PFIC rules to our ordinary shares under their particular circumstances.

Non-U.S. Holders

Cash dividends paid or deemed paid to a Non-U.S. Holder with respect to our ordinary shares generally will not be subject to U.S. federal income tax unless such dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that such holder maintains or maintained in the United States).

In addition, a Non-U.S. Holder generally will not be subject to U.S. federal income tax on any gain attributable to a sale or other taxable disposition of the ordinary shares unless such gain is effectively connected with its conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base that such holder maintains or maintained in the United States) or the Non-U.S. Holder is an individual who is present in the United States

for 183 days or more in the taxable year of such sale or other disposition and certain other conditions are met (in which case, such gain from U.S. sources generally is subject to U.S. federal income tax at a 30% rate or a lower applicable tax treaty rate).

Cash dividends and gains that are effectively connected with the Non-U.S. Holder's conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that such holder maintains or maintained in the United States) generally will be subject to regular U.S. federal income tax at the same regular U.S. federal income tax rates as applicable to a comparable U.S. Holder and, in the case of a Non-U.S. Holder that is a corporation for U.S. federal income tax purposes, may also be subject to an additional branch profits tax at a 30% rate or a lower applicable tax treaty rate.

Backup Withholding and Information Reporting

In general, information reporting for U.S. federal income tax purposes should apply to cash distributions made on our ordinary shares within the United States to a U.S. Holder (other than an exempt recipient) and to the proceeds from sales and other dispositions of the ordinary shares by a U.S. Holder (other than an exempt recipient) to or through a U.S. office of a broker. Payments made (and sales and other dispositions effected at an office) outside the United States will be subject to information reporting in limited circumstances. In addition, certain information concerning a U.S. Holder's adjusted tax basis in its ordinary shares and adjustments to that tax basis and whether any gain or loss with respect to such ordinary shares is long term or short term also may be required to be reported to the IRS, and certain holders may be required to file an IRS Form 8938 (Statement of Specified Foreign Financial Assets) to report their interest in our ordinary shares.

Moreover, backup withholding of U.S. federal income tax at a rate of 28% generally will apply to cash dividends paid on the ordinary shares to a U.S. Holder (other than an exempt recipient) and the proceeds from sales and other dispositions of the ordinary shares by a U.S. Holder (other than an exempt recipient), in each case who:

- fails to provide an accurate taxpayer identification number;
- is notified by the IRS that backup withholding is required; or
- in certain circumstances, fails to comply with applicable certification requirements.

A Non-U.S. Holder generally may eliminate the requirement for information reporting and backup withholding by providing certification of its foreign status, under penalties of perjury, on a duly executed applicable IRS Form W-8 or by otherwise establishing an exemption.

Backup withholding is not an additional tax. Rather, the amount of any backup withholding will be allowed as a credit against a U.S. Holder's or a Non-U.S. Holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that certain required information is timely furnished to the IRS.

Holders are urged to consult their own tax advisors regarding the application of backup withholding and the availability of and procedures for obtaining an exemption from backup withholding in their particular circumstances.

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

UNDERWRITING

Aegis Capital Corp is acting as the representative of the underwriters of this offering (the "Representative"). We have entered into an underwriting agreement dated the date of this prospectus with the Representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of our ordinary shares next to its name in the following table:

Underwriter	Number of Shares
Aegis Capital Corp	
Total	

The underwriters are committed to purchase all the shares offered by us if any shares are purchased, other than those covered by the option to purchase additional shares described below. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may be increased or the offering may be terminated.

The underwriters propose to offer the shares offered by us to the public at the public offering price set forth on the cover of this prospectus. In addition, the underwriters may offer some of the shares to other securities dealers at such price less a concession of $ per share. If all of the shares offered by us are not sold at the public offering price, the underwriters may change the offering price and other selling terms by means of a supplement to this prospectus.

The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase a maximum of additional shares from us to cover over-allotments. If the underwriters exercise all or part of this option, they will purchase shares covered by the option at the public offering price less the underwriting discounts and commissions that appear on the cover page of this prospectus. If this option is exercised in full, the total price to the public will be approximately $, and the total proceeds to us, before expenses, will be $.

Underwriting Discounts and Commissions. We have agreed to pay underwriting discounts and commissions of 6.5% of the gross proceeds of the offering (equivalent to 6.5% of the per share public offering price of $. The following table shows the public offering price, underwriting discounts and commissions and expenses to be paid by us to the underwriters and the proceeds of the public offering, before expenses, to us.

	Without over-allotment exercise	With full over-allotment exercise
Public offering price	$	$
Underwriting discounts and commissions paid by us (per ordinary share)		
Underwriting discounts and commissions paid by us (total)		
Proceeds before other expenses[(1)]		

(1) We have agreed to pay the underwriters a non-accountable expense allowance in the amount of 1% of the total public offering price of the shares sold (excluding the over-allotment option). We have paid a $25,000 advance to the underwriters, such amount to be applied against the underwriters' out-of-pocket accountable expenses actually incurred by the underwriters in connection with this offering. We will also pay or reimburse the underwriters over and above the underwriting discount up to a maximum of $120,000, to cover certain out of pocket items of expenses they incur in connection with this offering, including (i) expenses relating to background checks of our officers and directors not to exceed an aggregate of $15,000, (ii) $21,775 for costs associated with the use of Ipreo's book-building, prospectus tracking and compliance software; and (iii) up to $20,000 for the underwriters' actual accountable "road show" expenses.

Right of First Refusal. We have agreed to grant to the Representative the right of first refusal to act as sole investment banker, sole book-runner and/or sole placement agent for each and every future public and private equity and debt offerings, including all equity linked financings, by us or by any successor to or any subsidiary of us that takes place within a period of 10 months from the closing of this offering.

Representative's Warrants. We have also agreed to issue to the Representative or its designees, at the closing of this offering, warrants (the "Representative's Warrants") to purchase that number of our ordinary shares equal to 5% of the aggregate number of shares sold in the offering (excluding the over-allotment option). The Representative's Warrants will be exercisable at any time and from time to time, in whole or in part, for four years commencing one year from the date of effectiveness of this registration statement, at a price per share equal to 125.0% of the public offering price per share of ordinary shares at the offering. The Representative's Warrants and the ordinary shares underlying the Representative's Warrants have been deemed compensation by FINRA and are, therefore, subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The Representative (or permitted assignees under such rule) will not sell, transfer, assign, pledge or hypothecate the Representative's Warrants or the ordinary share underlying the Representative's Warrants, nor will it engage in any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the Representative's Warrants or the ordinary shares underlying the Representative's Warrants for a period of 180 days after the effective date of the registration statement. The Representative's Warrants will provide for one demand registration right with a duration of not more than five years from the date of effectiveness of this registration statement) and customary anti-dilution provisions (for share dividends and splits and recapitalizations) and customary anti-dilution provisions (for share dividends and splits and recapitalizations) consistent with FINRA Rule 5110, and further, the number of shares underlying the Representative's Warrants shall be reduced if necessary to comply with FINRA rules or regulations.

Discretionary Accounts. The underwriters do not intend to confirm sales of the shares offered hereby to any accounts over which they have discretionary authority.

Lock-Up Agreements. We, our officers and directors and holders of all of our outstanding ordinary shares have entered into lock-up agreements with the underwriters. Under these agreements, we and these other individuals have agreed, subject to specified exceptions, not to sell or transfer any ordinary shares or securities convertible into, or exchangeable or exercisable for, our ordinary shares, during a period ending

180 days after the date of this prospectus, without first obtaining the written consent of the Representative. Specifically, we and these other individuals have agreed not to:

- offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of any ordinary shares, or any options or warrants to purchase any shares of our ordinary shares, or any securities convertible into, exchangeable for or that represent the right to receive ordinary shares; or
- engage in any hedging or other transactions, including, without limitation, any short sale or any purchase, sale or grant of any right (including without limitation any put or call option) with respect to any of the ordinary shares or with respect to any security that includes, relates to, or derives any significant part of its value from the individual's ordinary shares,

whether any such transaction described above is to be settled by delivery of ordinary shares or other securities, in cash or otherwise.

The restrictions described above, applicable to us, do not apply to:

- the sale of shares of ordinary shares to the underwriters pursuant to the underwriting agreement;
- the issuance by us of shares of our ordinary shares upon the exercise of an option or warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing or that is described in this prospectus;
- the grant by us of stock options or other stock-based awards, or the issuance of shares of our ordinary shares upon exercise thereof, to eligible participants pursuant to employee benefit or equity incentive plans described in this prospectus, provided that, prior to the grant of any such stock options or other stock-based awards that vest within the restricted period, each recipient of such grant shall sign and deliver a lock-up agreement agreeing to be subject to the restrictions on transfer described above; and
- the filing by us of a registration statement on Form S-8 or any successor form thereto with respect to the registration of securities to be offered under any employee benefit or equity incentive plans described in this prospectus.

If the Representative agrees to release any party from the restrictions set forth in the lock-up agreement with such party prior to the expiration of the restricted period, all other parties subject to the lock-up agreement shall be entitled to a proportionate release of their ordinary shares from the lock-up agreement restrictions.

Electronic Offer, Sale and Distribution of Shares. A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The Representative may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Other Relationships. Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fee; however, except as disclosed in this prospectus, we have no present arrangements with any of the underwriters for any further services.

Stabilization. In connection with this offering, the underwriters may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while the offering is in progress.
- Overallotment transactions involve sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the overallotment option. In a naked short position, the number of shares involved is greater than the number of shares in the overallotment option. The underwriters may close out any short position by exercising their overallotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the overallotment option. If the underwriters sell more shares than could be covered by exercise of the overallotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.
- Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our ordinary shares or preventing or retarding a decline in the market price of our ordinary shares. As a result, the price of our ordinary shares in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our ordinary shares. These transactions may be effected on NASDAQ, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Initial public offering of ordinary shares

Prior to this offering, there has been no public market for our ordinary shares. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representative;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded ordinary shares of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our ordinary shares, or that the shares will trade in the public market at or above the initial public offering price.

Offering restrictions outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the ordinary shares offered by this prospectus in any jurisdiction where action for that purpose is required. The ordinary shares offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such ordinary shares be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any ordinary shares offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

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 any ordinary shares which are the subject of the offering contemplated by this Prospectus, or the Shares, may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any Shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representative for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of Shares shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any 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 any Shares to be offered so as to enable an investor to decide to purchase any 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 (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

United Kingdom

Each underwriter has represented and agreed that:

- it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) received by it in connection with the issue or sale of the Shares in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the Shares in, from or otherwise involving the United Kingdom.

Israel

In the State of Israel, the securities offered hereby may not be offered to any person or entity other than the following:

- a fund for joint investments in trust (i.e., mutual fund), as such term is defined in the Law for Joint Investments in Trust, 5754 1994, or a management company of such a fund;
- a provident fund as defined in the Control of the Financial Services (Provident Funds) Law 5765-2005, or a management company of such a fund;
- an insurer, as defined in the Law for Oversight of Insurance Transactions, 5741 1981;
- a banking entity or satellite entity, as such terms are defined in the Banking Law (Licensing), 5741 1981, other than a joint services company, acting for its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law, 1968;
- a company that is licensed as a portfolio manager, as such term is defined in Section 8(b) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law, 1968;
- an investment advisor or investment distributer, as such term is defined in Section 7(c) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account;
- a member of the Tel Aviv Stock Exchange, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law, 1968;
- an underwriter fulfilling the conditions of Section 56(c) of the Securities Law, 5728-1968, acting on its own account;
- a venture capital fund (defined as an entity primarily involved in investments in companies which, at the time of investment, (i) are primarily engaged in research and development or manufacture of new technological products or processes and (ii) involve above-average risk);
- an entity fully owned by investors of the type listed in Section 15A(b) of the Securities Law, 1968;
- an entity, other than an entity formed for the purpose of purchasing securities in this offering, in which the shareholders' equity is in excess of NIS 50 million; and
- an individual fulfilling the conditions of Section 9 to the supplement to the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account (for this matter, Section 9 to the supplement shall be referred to as "as an investor for the meaning of Section 15A(b)(1) of the Securities Law 1968" instead of "as an eligible client for the meaning of this law").

Offerees of the securities offered hereby, or the Investors, in the State of Israel shall be required to submit written confirmation that they fall within the scope of one of the above criteria, that they are fully aware of the significance of being an Investor pursuant to such criteria and that they have given their consent, or the Consent. An appeal to an Investor for the Consent shall not be considered a public offering. This prospectus supplement will not be distributed or directed to investors in the State of Israel who do not fall within one of the above criteria.

In addition, if a purchase of securities is made within an institutional trading system, as that term is defined in the Tel Aviv Stock Exchange regulations, a person giving a stock exchange member his prior Consent before submitting a purchase order to the institutional trading system for the first time will be seen as acting within the provisions the above criteria with respect to the Consent, provided that if such person is an investor pursuant to the sixth, tenth, eleventh or twelfth bullet points specified above, such person committed in advance that, until the last business day of the third month in each year, he will renew his Consent, and that if he withdraws his Consent, he will notify the stock exchange member immediately and will cease to give purchase orders in such institutional trading institution.

Canada

The Shares sold in this offering have not been and will not be qualified for distribution under applicable Canadian securities laws. Shares may be offered to residents of Canada pursuant to exemptions from the prospectus requirements of such laws.

* * *

The address of Aegis Capital Corp. is 810 Seventh Avenue, 18th Floor, New York, New York 10019.

EXPENSES

We estimate that the total expenses of this offering payable by us, excluding the underwriting discounts and commissions and expenses, will be approximately $ as follows:

SEC filing fee	$
FINRA filing fee	
Transfer agent fees and expenses	
Printer fees and expenses	
Legal fees and expenses	
Accounting fees and expenses	
Miscellaneous	
Total	$

LEGAL MATTERS

Certain legal matters concerning this offering will be passed upon for us by Zysman, Aharoni, Gayer and Sullivan & Worcester LLP, New York, New York. Certain legal matters with respect to the legality of the issuance of the securities offered by this prospectus will be passed upon for us by Zysman, Aharoni, Gayer & Co., Tel Aviv, Israel. Certain legal matters related to the offering will be passed upon for the underwriters by Troutman Sanders LLP, New York, New York and Yigal Arnon & Co., Tel Aviv, Israel.

EXPERTS

The financial statements of PolyPid Ltd. for its fiscal years ended December 31, 2013 and December 31, 2012, included herein have been audited by Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, independent registered public accounting firm, as set forth in their report thereon. Such financial statements are included herein in reliance upon such report given on the authority of such firm as experts in accounting and auditing. As set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1b to the consolidated financial statements) appearing elsewhere herein. The address of Kost Forer Gabbay & Kasierer is Aminadav 3, Tel Aviv, Israel.

ENFORCEABILITY 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, substantially all 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 a violation of U.S. securities laws because 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.

Subject to specified time limitations and legal procedures, Israeli courts may enforce a United States judgment in a civil matter which, subject to certain exceptions, is non-appealable, including judgments 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 is obtained after due process before a court of competent jurisdiction, according to the laws of the state in which the judgment is given and the rules of private international law currently prevailing in Israel;
- the judgment is final and is not subject to any right of appeal;
- 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 liabilities under the judgment are enforceable according to the laws of the State of Israel and the judgment and the enforcement of the civil liabilities set forth in the judgment is not contrary to the law or public policy in Israel nor 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 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 ADDITIONAL 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, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains an Internet website that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through the SEC's website at *http://www.sec.gov*.

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. Those 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 annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. However, we will file with the SEC, within 120 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and will submit to the SEC, on Form 6-K, unaudited quarterly financial information.

We expect to maintain a corporate website at *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. We will post on our website any materials required to be so posted on such website under applicable corporate or securities laws and regulations, including, posting any XBRL interactive financial data required to be filed with the SEC, and any notices of general meetings of our shareholders.

POLYPID LTD.

FINANCIAL STATEMENTS

INDEX

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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, 2012 and December 31, 2013 and the related statements of operations, changes in convertible preferred shares and shareholders' equity (deficiency) and cash flows for each of the two years in the period ended December 31, 2013. 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 and as of December 31, 2012 and December 31, 2013, and the related results of its operations and its cash flows for each of the two years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1b to the financial statements, the Company has not yet generated revenues from its operations and is dependent on external sources for financing its operations. These factors, among others discussed in Note 1b, raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Tel-Aviv, Israel
July 8, 2014

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

POLYPID LTD.

BALANCE SHEETS
U.S. dollars in thousands

	December 31,		Pro forma Shareholders' equity as of December 31, 2013
	2013	2012	
			Unaudited
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	$ 1,263	$ 977	$ 1,276
Prepaid expenses and other receivables	276	207	276
Restricted deposit	65	—	65
Total current assets	1,604	1,184	1,617
LONG-TERM ASSETS:			
Property and equipment, net	328	351	328
Other long-term assets	27	14	27
Total long-term assets	355	365	355
TOTAL ASSETS	$ 1,959	$ 1,549	$ 1,972

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

POLYPID LTD.

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

	December 31,		Pro forma shareholders' equity as of December 31, 2013
	2013	2012	
			Unaudited
LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' DEFICIENCY			
CURRENT LIABILITIES:			
Trade payables	$ 234	$ 59	$ 234
Other payables and accrued expenses	268	153	268
Total current liabilities	502	212	502
LONG-TERM LIABILITIES:			
Advances on account of collaboration arrangement	367	—	367
Other liabilities	133	72	133
Preferred shares warrant liability	332	46	—
Total long-term liabilities	832	118	500
COMMITMENTS AND CONTINGENCIES			
CONVERTIBLE PREFERRED SHARES			
Preferred A, A-1, B and B-1 shares of NIS 0.1 par value – Authorized: 25,623,137 and 21,500,000 shares at December 31, 2013 and 2012, respectively; Issued and outstanding: 22,422,630 and 18,148,882 shares at December 31, 2013 and 2012, respectively; Aggregate liquidation preference of $9,187 at December 31, 2013; No shares issued and outstanding pro forma at December 31, 2013 (unaudited)	8,685	5,768	—
SHAREHOLDERS' EQUITY (DEFICIENCY):			
Share capital –			
Ordinary shares of NIS 0.1 par value – Authorized: 74,371,863 and 78,500,000 shares December 31, 2013 and 2012, respectively; Issued and outstanding: 4,500,000 shares at December 31, 2013 and 2012. 27,372,630 shares issued and outstanding pro forma at December 31, 2013 (unaudited)	125	125	784
Additional paid-in capital	248	(125)	8,619
Accumulated deficit	(8,433)	(4,549)	(8,433)
Total shareholders' equity (deficiency)	(8,060)	(4,549)	970
Total liabilities, convertible preferred shares and Shareholders' equity (deficiency)	$ 1,959	$ 1,549	$ 1,972

July 8, 2014	/s/ Amir Weisberg	/s/ Shaun Marcus
Date of approval of the financial statements	Amir Weisberg Chief Executive Officer and Director	Shaun Marcus Chief Financial Officer

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,	
	2013	2012
Operating expenses:		
Research and development, net	$ 2,641	$ 1,377
General and administrative	938	410
Total operating expenses	3,579	1,787
Operating loss	3,579	1,787
Financial expenses, net	305	3
Net loss	$ 3,884	$ 1,790
Basic and diluted net loss per Ordinary share	$ 1.04	$ 0.48
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	4,500,000	4,500,000
Pro forma basic and diluted net loss per Ordinary share (unaudited)	$ 0.14	
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share – pro forma (unaudited)	27,372,630	

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

POLYPID LTD.

STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
U.S. dollars in thousands (except share data)

	Convertible Preferred Shares				Shareholders' Deficiency				
	Number of Preferred Shares	Amount	Unpaid Share Capital	Total	Number of Ordinary Shares	Amount	Additional Paid-in Capital	Accumulated deficit	Total Shareholders' Deficiency
Balance as of January 1, 2012	12,442,890	3,212	(22)	3,190	4,500,000	125	(125)	(2,759)	(2,759)
Issuance of Series B Preferred shares, net of issuance costs of $18	3,032,510	1,284	(130)	1,154	—	—	—	—	—
Issuance of Series B-1 Preferred shares, net of issuance costs of $17	2,673,482	1,602	(200)	1,402	—	—	—	—	—
Repayment of receivable on account of shares	—	—	22	22	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(1,790)	(1,790)
Balance as of December 31, 2012	18,148,882	6,098	(330)	5,768	4,500,000	125	(125)	(4,549)	(4,549)
Issuance of Series B-1 Preferred shares	4,273,748	2,587	—	2,587	—	—	—	—	—
Repayment of receivable on account of shares	—	—	330	330	—	—	—	—	—
Share-based compensation	—	—	—	—	—	—	373	—	373
Net loss	—	—	—	—	—	—	—	(3,884)	(3,884)
Balances as of December 31, 2013	22,422,630	8,685	—	8,685	4,500,000	125	248	(8,433)	(8,060)

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,	
	2013	2012
Cash flows from operating activities:		
Net loss	$ (3,884)	$ (1,790)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	71	60
Reevaluation of warrants	286	(26)
Share-based compensation	373	—
Changes in assets and liabilities:		
Increase in receivables and prepaid expenses	(69)	(26)
Decrease in other long-term assets	(13)	(11)
Increase in advances from on account of R&D reimbursement	367	—
Increase (decrease) in trade payables	175	(71)
Increase in other payables and accrued expenses and other liabilities	176	7
Net cash used in operating activities	(2,518)	(1,857)
Cash flows from investing activities:		
Purchase of property and equipment	(48)	(145)
Increase in restricted cash	(65)	—
Net cash used in investing activities	(113)	(145)
Cash flows from financing activities:		
Proceeds from issuance of Preferred shares, net	2,587	2,556
Repayment of receivable on account of shares	330	22
Net cash provided by financing activities	2,917	2,578
Increase in cash and cash equivalents	286	576
Cash and cash equivalents at the beginning of the period	977	401
Cash and cash equivalents at the end of the period	$ 1,263	$ 977
Non cash activity:		
Unpaid share capital issued to shareholders’	$ —	$ 330

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

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 specialty pharmaceutical company engaged in research and development of products based on PLEX (Polymer-Lipid Encapsulation MatriX), the Company's proprietary drug delivery technology. PLEX is capable of encapsulating many types of drugs to enable targeted, localized drug delivery into the body over extended periods of time with pre-determined release rates thus optimizing drug treatment regimens.

The Company's most advanced product candidates address current treatment problems in orthopedics and dental implants. An additional product candidate addresses the prevention and treatment of surgical site infections generally.

Through December 31, 2013, the Company has been primarily engaged in research and development and in raising capital to fund its operations.

b. Going concern

The Company's activities since inception have consisted principally of raising capital and performing research and development activities. The Company is considered to be in the development stage as of December 31, 2013, as its principal commercial operations have not commenced. 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 and access potential markets; secure financing, develop a customer base; attract, retain and motivate qualified personnel; and develop strategic alliances. 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. The Company plans to meet its capital requirements primarily through raising capital and, in the longer term, by generating revenues from product sales.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP), which contemplate continuation of the Company as a going concern. As of December 31, 2013, the Company had cash and cash equivalents of $1,263. During the year ended December 31, 2013, the Company incurred a net loss of $3,884 and had negative cash flows from operating activities of $2,518. In addition, the Company had an accumulated deficit of $8,433 at December 31, 2013. The Company believes its current capital resources are not sufficient to support its operations beyond December 31, 2014. 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 or public offerings or strategic partnerships.

There can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all. These matters raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 1:- GENERAL - (continued)

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 follows: (1) $150 upon signing the MOU; (2) $450 upon the initiation of a clinical study and supply of clinical material to MIS; (3) $650 upon marketing approval from EMA (4) $150 upon initiation of regulatory process with FDA; (5) $450 upon the initiation of a FDA approved clinical study and supply of clinical material to MIS. (6) $650 upon receipt of the FDA approval. 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 and MIS shall not be obligated to make payments pursuant to milestones (4), (5) and (6) above and the Company will be obligated to return any such milestone payment, to the extent received. See Note 2i.

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 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.

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

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES - (continued)

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. 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 and software 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

f. 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, 2012 and 2013, no impairment losses have been identified.

g. 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 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, to expense when incurred. Grants from the OCS 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.

h. 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

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES - (continued)

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 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 year ended December 31, 2013.

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 and directors during 2013 is estimated at the date of grant using a Black-Scholes-Merton Option Pricing Model with the following assumptions: expected volatility of 116 – 121%, risk free interest rates of 0.85% – 2.54%, dividend yield of 0%, and an expected term of 5 – 6 years. The Company's board of directors deemed the fair value of the Company's Ordinary shares to be $0.11 – 0.40 per share as of the grant date of the options. There were no options grants during 2012.

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 a 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 year ended December 31, 2013, amounted to $373 (out of which $31 were related to non-employees).

i. Grants and participation:

Royalty-bearing grants from the Office of the Chief Scientist of the Ministry of Economy in Israel ("OCS") 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. Non-royalty-bearing grants from the OCS 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 the OCS until the related revenues are recognized. In the event of failure of a project that was partly financed by the OCS, the Company will not be obligated to pay any royalties or repay the amounts received.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES - (continued)

The Company recognizes consideration earned from participations in R&D development, as 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, 2013, payments totaling $367 were received by the Company as participation in R&D development from MIS (see Note 1c). These amounts were capitalized and recorded as an advance on account of collaboration arrangement. To date, no amounts were recognized in the statements of operations with respect to collaboration arrangement, as all the amounts are refundable.

j. Convertible preferred shares and preferred shares warrant liability:

The terms of the Preferred A, A-1, B and B-1 shares allow the holders to redeem shares, under certain circumstances, outside of the Company's control. Therefore, the 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 preferred shares is equal to cost. The Company has not adjusted the carrying value to redemption value since it is not probable that the 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 9).

k. Fair value of financial instruments:

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 financial instruments carried at fair value on the Company's balance sheet as of December 31, 2012 and 2013 are preferred shares warrants classified as a liability. See Note 7.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES - (continued)

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, advance 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.

l. Basic and diluted net loss per share:

Basic loss per share is computed based on the weighted average number of shares of ordinary shares outstanding during each year. Diluted loss per share is computed based on the weighted average number of ordinary shares outstanding during each year, plus the dilutive effect of options considered to be outstanding during each year, in accordance with ASC 260, “Earnings Per Share” (“ASC 260”).

For the years ended December 31, 2012 and 2013, all outstanding options and 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.

m. Unaudited pro forma balance sheet and pro forma net loss per ordinary share:

The Company’s board of directors has authorized the filing of a Registration Statement with the U.S. Securities and Exchange Commission of which this prospectus is a part, to register certain of the Company’s Ordinary shares in connection with the Company’s planned initial qualified public offering (“Qualified IPO”). 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 $15,000, which yields an imputed pre-money valuation of at least $75,000 on a fully diluted basis.

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 preferred shares warrants would automatically expire if not exercised immediately prior to the Qualified IPO. The unaudited pro forma balance sheet as of December 31, 2013, has been prepared assuming the automatic conversion of all outstanding preferred shares and warrants into 22,872,630 ordinary shares. 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 and warrants as described above.

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 clarifies the accounting for uncertainty in income taxes by prescribing a minimum recognition threshold for a tax position taken or expected to be taken in a tax return that is required to be met before being recognized in the financial statements.

The Company’s policy is to accrue interest and penalties related to unrecognized tax benefits in its taxes on income.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES - (continued)

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 and cash equivalents are invested in major banks or financial institutions in Israel. Such investments in Israel may be in excess of insured limits and are not insured in other jurisdictions. Generally, these investments may be redeemed upon demand and, therefore, bear minimal risk.

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. Neither severance pay liability nor severance pay fund under Section 14 for such employees is recorded on the Company's balance sheet.

Severance pay expense for the years ended December 31, 2012 and 2013 amounted to $71 and $113, 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. As of December 31, 2012 and 2013, the Company is not a party to any ligation that could have a material adverse effect on the Company's business, financial position, results of operations or cash flows.

r. Recently Adopted Accounting Pronouncements:

In June 2014, the FASB issued ASU 2014-10, "Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities" (ASU 2014-10). The amendment removes the definition of a development stage entity from ASC 915, "Development Stage Entities" (ASC 915), thereby removing the distinction between development stage entities and other reporting entities from GAAP. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information on the statements of income, cash flows, and shareholder's equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. These amendments are effective for annual reporting periods beginning after December 15, 2014, with early application permitted. The Company has elected to early adopt ASU No. 2014-10, and removed the inception to date information and all references to development stage.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 3:- RECEIVABLES AND PREPAID EXPENSES

	December 31,	
	2013	2012
Government authorities	$ 76	$ 102
Prepaid expenses	45	18
Grants receivable from the OCS	76	67
Others	79	20
	$ 276	$ 207

NOTE 4:- PROPERTY AND EQUIPMENT, NET

	December 31,	
	2013	2012
Cost:		
Computers and software	$ 61	$ 40
Laboratory equipment	248	234
Furniture and office equipment	71	58
Leasehold improvements	104	104
	484	436
Accumulated depreciation	(156)	(85)
Depreciated cost	$ 328	$ 351

Depreciation expenses amounted to $60 and $71 for the years ended December 31, 2012 and 2013, respectively.

NOTE 5:- OTHER PAYABLES AND ACCRUED EXPENSES

	December 31,	
	2013	2012
Employees and payroll accruals	$ 159	$ 71
Accrued expenses	83	73
Others	26	9
	$ 268	$ 153

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 2016. The Company also leases motor vehicles under various operating leases, which expire on various dates, the latest of which is in 2016.

Future minimum lease payments under non-cancelable operating leases as of December 31, 2013, are as follows:

As of December 31, 2013	
2014	$ 276
2015	219
2016	87
	$ 582

As of December 31, 2013, the Company made advance payments on account of installments on car leases in the amount of $87.

Lease and rental expenses for the years ended December 31, 2012 and 2013 were $158 and $223, respectively.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 6:- COMMITMENTS AND CONTINGENT LIABILITIES - (continued)

b. In connection with its research and development programs, the Company received and accrued participation payments from the Office of the Chief Scientist of the Ministry of Economy in Israel ("OCS") and from FP7 in the aggregate amount of $1,610. In return for the OCS'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. During the years 2012 and 2013, no royalties have been paid or accrued.

NOTE 7:- FAIR VALUE MEASUREMENTS

Financial instruments measured at fair value on a recurring basis include preferred shares warrants. The warrants are classified as a liability in accordance with ASC 480-10-25 (see Note 9). These warrants were classified as level 3 in the fair value hierarchy since some of the inputs used in the valuation (the share price) were determined based on management's assumptions. The fair value of the warrants on the issuance date and on subsequent reporting dates was determined using the OPM model. The fair value of the underlying 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 preferred shares. The underlying preferred share price as of December 31, 2013 was $0.28.

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

	December 31,	
	2013	2012
Beginning of year	$ 46	$ 73
Change in fair value	286	(27)
End of year	$ 332	$ 46

NOTE 8:- INCOME TAXES

a. Corporate tax rates:

The Israeli corporate tax rate was 25% in 2012 and 2013.

On July 30, 2013, the Israeli Parliament (the Knesset) approved the second and third readings of the Economic Plan for 2013 – 2014 ("Amended Budget Law") which consists, among others, of fiscal changes whose main aim is to enhance long-term collection of taxes.

These changes include, among others, raising the Israeli corporate tax rate from 25% to 26.5%, cancelling the lowering of the tax rates applicable to Preferred Enterprises (9% in development area A and 16% in other areas), taxing revaluation gains and increasing the tax rates on dividends within the scope of the Law for the Encouragement of Capital Investments to 20% effective from January 1, 2014.

b. Net operating losses carry forward:

The Company has accumulated losses for tax purposes as of December 31, 2013, in the amount of approximately $6,411, which may be carried forward and offset against taxable income in the future for an indefinite period.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
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,	
	2013	2012
Reserves and allowances	$ —	$ —
Loss carryforward	2,206	1,120
Deferred tax assets before valuation allowance	2,206	1,120
Less – valuation allowance	(2,206)	(1,120)
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 2012 and 2013, the main reconciling item of the statutory tax rate of the Company (25%) in 2012 and 2013) to the effective tax rate (0%) is tax loss carryforwards and other deferred tax assets for which a full valuation allowance was provided.

d. Tax assessment:

The Company had not received final tax assessments since its incorporation.

NOTE 9:- CONVERTIBLE PREFERRED SHARES AND WARRANTS

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

	December 31, 2013		December 31, 2012	
	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	4,739,630	5,000,000	4,739,630
Series B-1 convertible Preferred shares of NIS 0.1 par value	8,628,137	6,947,230	4,500,000	2,673,482
Total	25,628,137	22,422,630	21,500,000	18,148,882

The Company issued Series A, A-1, B and B-1 preferred shares between the years 2008 and 2013. 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 preferred shares are entitled to liquidation preferences which may trigger a distribution of cash or assets that is not solely within the Company's control. Pursuant to the Company's Amended and Restated Articles of Incorporation (the "AOA"), a deemed liquidation event would occur, inter alia, upon the closing of the transfer of the Company's securities to a person or a group of affiliated persons, in one or a series of related transactions, if immediately after such transaction, such person

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 9:- CONVERTIBLE PREFERRED SHARES AND WARRANTS - (continued)

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, 2012 and 2013, 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 and B-1 preferred shares confer upon their holders all the rights conferred by Ordinary shares, in addition to certain rights mentioned in the Company's AOA, inter alia, the following:

Dividend rights — the holders of Series A, A-1, B and B-1 preferred shares shall be entitled to receive on a paripassu 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 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 paripassu, 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 Preferred share, 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. The liquidation order is such that 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 and B-1 Preferred shares is $0.18, $0.21, $0.43 and $0.61, per share, respectively.

Voting rights — each holder of Series A, A-1, B and B-1 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, and B-1will convert to ordinary shares on a 1-for-1 ratio. The current conversion price per preferred share will be adjusted for certain recapitalizations, splits, ordinary share dividends and standard anti-dilution events.

c. Investment rounds:

On December, 2011, the Company entered into Share Purchase Agreements (the "2011 SPAs") with new and existing investors. According to the 2011 SPAs, the Company shall issue to the investors up to 5,005,820 Series B preferred shares for an aggregate amount of up to $2,150, at a price per shares of $0.43.

As of December 31, 2011, the Company issued to the investors 1,707,120 Series B preferred shares, for an aggregate amount of $733. Issuance costs were $4.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 9:- CONVERTIBLE PREFERRED SHARES AND WARRANTS - (continued)

During 2012, the Company issued to new and existing investors 3,032,510 Series B preferred shares, based on the terms of the 2011 SPA, for an aggregate amount of $1,302. Issuance costs were $18. As of December 31, 2012 the Company received an aggregate amount of $1,172, and $130 was received during 2013.

On December, 2012, the Company entered into Share Purchase Agreement (the "2012 SPA") with new and existing investors. According to the 2012 SPA, the Company shall issue to the investors up to 4,500,074 Series B-1 preferred shares, in two installments, for an aggregate amount of up to $2,725, at a price per shares of $0.61. As of December 31, 2012, the Company issued to the investors 2,673,482 Series B preferred shares, for an aggregate consideration of $1,619. Issuance costs amounted to $17. Out of the total amount, an amount of $1,419 was received as of December 31, 2012, and an additional amount of $200 was received during 2013.

During 2013, the Company entered into Share Purchase Agreements (the "2013 SPA") with new and existing investors. According to the 2013 SPA, the Company shall issue to the investors up to 3,467,630 Series B-1 preferred shares, for an aggregate amount of up to $2,099, at a price per share of $0.61.

During 2013, the Company issued to new and existing investors 4,273,748 Series B-1 preferred shares, in accordance with the terms of the 2012 and 2013 SPA, for an aggregate consideration of $2,587.

d. Warrants to purchase preferred shares:

As of December 31, 2012 and 2013, the Company has outstanding warrants to purchase 450,000 preferred A shares, with an exercise price of NIS 0.1.

The warrants may be converted any time upon the earlier of (1) consummation of an initial public offering on certain stock exchanges as set forth in the Warrant with net proceeds to the Company of at least $15,000 (and pre-money valuation of at least $75,000), (2) merger or consolidation of the Company with another company, and (3) the sale of substantially all of the Company's properties or substantially all of the shares to another party.

The warrants are classified as a 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.

NOTE 10:- SHAREHOLDERS' EQUITY (DEFICIENCY)

a. Ordinary share capital is composed as follows:

	December 31, 2013		December 31, 2012	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Ordinary shares of NIS 0.01 par value	74,371,863	4,500,000	78,500,000	4,500,000

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.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 10:- SHAREHOLDERS' EQUITY (DEFICIENCY) - (continued)

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 4,996,624 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, 2013, 460,152 of the Company's options were available for future grants.

A summary of the status of the Company's option plan as of December 31, 2013 and changes during the relevant period ended on that date is presented below:

	Year ended December 31, 2013		
	Number of options	Weighted average exercise price	Aggregate intrinsic value
Outstanding at beginning of period	—	$ —	$ —
Granted	4,394,420	$ 0.22	
Exercised	—	—	
Forfeited and cancelled	(92,064)	$ 0.43	
Outstanding at end of period	4,302,356	$ 0.21	$ 925
Exercisable options	2,909,720	$ 0.11	$ 840
Vested and expected to vest	4,302,356	$ 0.21	$ 925

The total equity-based compensation expense related to all of the Company's equity-based awards recognized for the year ended December 31, 2013, was comprised as follows:

	Year ended December 31, 2013
Research and development	$ 299
General and administrative	74
Total share-based compensation expense	$ 373

As of December 31, 2013, there were unrecognized compensation costs of $246, which are expected to be recognized over a weighted average period of approximately 2.1 years.

The weighted average grant date fair value of the Company's options granted during the year ended December 31, 2013 was $0.14. No options were granted in 2012.

No options were exercised during the year ended December 31, 2013 and December 31, 2012. The Company's board of directors deemed the fair value of the Company's Ordinary shares to be $0.39 per share as of December 31, 2013.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 10:- SHAREHOLDERS' EQUITY (DEFICIENCY) - (continued)

The options outstanding as of December 31, 2013 have been separated into ranges of exercise prices, as follows:

Exercise price	Options outstanding as of December 31, 2013	Weighted average exercise price	Weighted average remaining contractual term (years)	Options exercisable as of December 31, 2013	Weighted average exercise price	Weighted average remaining contractual term (years)
0.03*)	2,088,368	0.03*)	9.22	2,003,974	0.03*)	9.22
0.21	902,960	0.21	9.22	601,898	0.21	9.22
0.43	795,280	0.43	9.28	232,094	0.43	9.22
0.61	515,748	0.61	9.95	71,753	0.61	9.87
	4,302,356	0.21	9.32	2,909,720	0.11	9.24

*) The exercise price as per the option terms was denominated in NIS and translated to USD in the table above using the exchange rate as of December 31, 2013. The options were granted at the ordinary share par value.

d. Options issued to consultants:

The Company's outstanding options granted to consultants as of December 31, 2013 were as follows:

	Options outstanding as of December 31, 2013	Exercise price per share	Options exercisable as of December 31, 2013	Exercisable through
March 2013	186,258	$ 0.21	155,991	March 2023
October 2013	47,858	$ 0.61	—	October 2023
	234,116		155,991	

NOTE 11:- FINANCIAL EXPENSES, NET

	Year ended December 31,	
	2013	2012
Financial expenses:		
Foreign currency transaction losses, net	$ 18	$ 29
Revaluation of warrants	286	—
Others	2	1
Total financial expenses, net	306	30
Financial income:		
Foreign currency transaction gains, net	—	—
Revaluation of warrants	—	(27)
Others	(1)	—
	(1)	(27)
	$ 305	$ 3

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 12:- BASIC AND DILUTED NET LOSS PER SHARE

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

	Year ended December 31,	
	2013	2012
Numerator:		
Net loss attributable to ordinary shares as reported	$ (3,884)	$ (1,790)
Preferred share dividend	(784)	(365)
Net loss applicable to ordinary shareholders	(4,668)	(2,155)
Denominator:		
Weighted average shares used in computing net loss per ordinary share, basic and diluted:		
Ordinary share – basic	4,500,000	4,500,000
Ordinary share equivalents	—	—
Ordinary share – dilutive	4,500,000	4,500,000
Net loss per ordinary share, basic and diluted	(1.04)	(0.48)

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 2012 and 2013.

NOTE 13:- 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):

	Year ended December 31, 2013
Net loss attributable to ordinary shares as reported	$ (3,884)
Shares used in computing net loss per ordinary share, basic and diluted	4,500,000
Pro forma adjustments to reflect assumed conversion of convertible preferred shares and exercise of warrants	22,872,630
Shares used in computing pro forma net loss per ordinary share, basic and diluted	27,372,553
Pro forma net loss per ordinary share, basic and diluted	$ (0.14)

NOTE 14:- SUBSEQUENT EVENTS

a. In connection with the preparation of the financial statements and in accordance with authoritative guidance for subsequent events, the Company evaluated subsequent events after the balance sheet date of December 31, 2013 through July 7, 2014, the date on which the financial statements were issued.

b. Grant of options to employees and consultants:

On May 2014, the Company's Board of directors approved the grant of 1,921,514 options exercisable into ordinary shares, under the Company's 2012 option plan, to officers, employees and consultants. The options are with an exercise price of $0.61 and a vesting period of between 3 to 4 years. In addition, the number of shares reserved under the option plan was increased by 2,003,376 ordinary shares, following which, the aggregate number of shares reserved under the option plan, is 7,000,000.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 14:- SUBSEQUENT EVENTS - (continued)

c. On June, 2014, the Company entered into a Share Purchase Agreement (the "2014 SPA") with new and existing investors. According to the 2014 SPA, the Company shall issue to the investors up to 6,605,020 Series B-1 preferred shares for an aggregate amount of up to $4,000, at a price per shares of $0.61. As of the issuance date of the financial statements, aggregate proceeds of $4,000 were received by the Company.

In addition, the Company issued a warrant to purchase 82,563 preferred B-1 shares, as a brokerage fee, to an individual whom introduced the Company to a significant new investor in the 2014 SPA, as a commission fee for introducing the new investors to the Company.

POLYPID LTD.

INTERIM FINANCIAL STATEMENTS
AS OF JUNE 30, 2014
U.S. DOLLARS IN THOUSANDS

INDEX

POLYPID LTD.

BALANCE SHEETS
U.S. dollars in thousands

	June 30, 2014	December 31, 2013	Pro forma Shareholders' equity as of June 30, 2014
	Unaudited		Unaudited
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	$ 4,029	$ 1,263	$ 4,092
Prepaid expenses and other receivables	256	276	256
Restricted deposit	65	65	65
Total current assets	4,350	1,604	4,413
LONG-TERM ASSETS			
Property and equipment, net	315	328	315
Other long-term assets	36	27	36
Deferred equity offering costs	211	—	211
Total long-term assets	562	355	562
TOTAL ASSETS	$ 4,912	$ 1,959	$ 4,975

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

POLYPID LTD.

BALANCE SHEETS
U.S. dollars in thousands, except share and per share data

	June 30, 2014	December 31, 2013	Pro forma shareholders' equity as of June 30, 2014
	Unaudited		Unaudited
LIABILITIES, CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIENCY)			
CURRENT LIABILITIES			
Trade payables	$ 544	$ 234	$ 544
Other payables and accrued expenses	440	268	440
Total current liabilities	984	502	984
LONG-TERM LIABILITIES:			
Advances on account of collaboration arrangement	367	367	367
Other liabilities	175	133	175
Preferred shares warrant liability	652	332	—
Total long-term liabilities	1,194	832	542
COMMITMENTS AND CONTINGENCIES			
CONVERTIBLE PREFERRED SHARES			
Preferred A, A-1, B and B-1 shares of NIS 0.1 par value – Authorized: 32,628,137 and 25,628,137 shares at June 30, 2014 (unaudited) and December 31, 2013, respectively; Issued and outstanding: 30,048,123 and 22,422,630 shares at June 30, 2014 (unaudited) and December 31, 2013, respectively; Aggregate liquidation preference of $14,111 at June 30, 2014 (unaudited); No shares issued and outstanding pro forma at June 30, 2014 (unaudited)	13,134	8,685	—
SHAREHOLDERS' EQUITY (DEFICIENCY)			
Share capital –			
Ordinary shares of NIS 0.1 par value – Authorized: 67,371,863 and 74,371,863 shares at June 30, 2014 (unaudited) and December 31, 2013, respectively; Issued and outstanding: 4,500,000 shares at June 30, 2014 (unaudited) and December 31, 2013. 35,080,686 and 27,372,630 shares issued and outstanding pro forma at June 30, 2014 (unaudited), and December 31, 2013, respectively	125	125	1,015
Additional paid-in capital	516	248	13,475
Accumulated deficit	(11,041)	(8,433)	(11,041)
Total shareholders' equity (deficiency)	(10,400)	(8,060)	3,449
Total liabilities, convertible preferred shares and shareholders' equity (deficiency)	$ 4,912	$ 1,959	$ 4,975

September 23, 2014	/s/ Amir Weisberg	/s/ Shaun Marcus
Date of approval of the financial statements	Amir Weisberg Chief Executive Officer and Director	Shaun Marcus Chief Financial Officer

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

POLYPID LTD.

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

	Six months ended June 30,	
	2014	2013
	Unaudited	Unaudited
Operating expenses:		
Research and development, net of $471 and $248 participation grants as of June 30, 2014 and June 30, 2013, respectively	$ 1,499	$ 1,752
General and administrative	874	463
Total operating expenses	2,373	2,215
Operating loss	2,373	2,215
Financial expenses, net	235	73
Net loss	$ 2,608	$ 2,288
Basic and diluted net loss per Ordinary share	$ 0.82	$ 0.63
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share	4,500,000	4,500,000
Pro forma basic and diluted net loss per Ordinary share	$ 0.07	
Weighted average number of Ordinary shares used in computing basic and diluted net loss per share – pro forma	35,080,686	

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

POLYPID LTD.

STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIENCY)
U.S. dollars in thousands (except share data)

	Convertible Preferred Shares				Shareholders' Equity (Deficiency)				
	Number of Preferred Shares	Amount	Unpaid Share Capital	Total	Number of Ordinary Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Shareholder' Deficiency
Balance as of January 1, 2013	18,148,882	6,098	(330)	5,768	4,500,000	125	(125)	(4,549)	(4,549)
Issuance of Series B-1 preferred shares	4,273,748	2,587	—	2,587	—	—	—	—	—
Repayment of receivable on account of shares	—	—	330	330	—	—	—	—	—
Share-based compensation	—	—	—	—	—	—	373	—	373
Net loss	—	—	—	—	—	—	—	(3,884)	(3,884)
Balances as of December 31, 2013	22,422,630	8,685	—	8,685	4,500,000	125	248	(8,433)	(8,060)
Issuance of Series B-1 preferred shares, net of issuance costs of $170*)	7,625,493	4,449	—	4,449	—	—	—	—	—
Share-based compensation	—	—	—	—	—	—	268	—	268
Net loss	—	—	—	—	—	—	—	(2,608)	(2,608)
Balances as of June 30, 2014 (unaudited)	30,048,123	13,134	—	13,134	4,500,000	125	516	(11,041)	(10,400)

*) $61 paid in cash and $109 fair value of warrant liability.

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

POLYPID LTD.

STATEMENTS OF CASH FLOWS
U.S. dollars in thousands

	Six months ended June 30,	
	2014	2013
	Unaudited	Unaudited
Cash flows from operating activities:		
Net loss	$ (2,608)	$ (2,288)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	85	35
Revaluation of warrants	211	74
Share-based compensation	268	288
Changes in assets and liabilities:		
Decrease (increase) in receivables and prepaid expenses	20	(109)
Decrease (increase) in other long-term assets	(9)	6
Increase in advances from on account of R&D reimbursement		152
Increase in trade payables	310	355
Increase in other payables and accrued expenses and other liabilities	144	47
Net cash used in operating activities	(1,579)	(1,440)
Cash flows from investing activities:		
Purchase of property and equipment	(72)	(14)
Net cash used in investing activities	(72)	(14)
Cash flows from financing activities:		
Proceeds from issuance of preferred shares, net	4,558	1,206
Repayment of receivable on account of shares	—	330
Payment of deferred equity offering costs	(141)	—
Net cash provided by financing activities	4,417	1,536
Increase in cash and cash equivalents	2,766	82
Cash and cash equivalents at the beginning of the period	1,263	977
Cash and cash equivalents at the end of the period	$ 4,029	$ 1,059
Non cash activity:		
Issuance of warrants to purchase preferred shares	$ 109	$ —
Unpaid deferred equity offering costs	$ 70	$ —

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

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 1:– GENERAL

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 specialty pharmaceutical company engaged in research and development of products based on PLEX (Polymer-Lipid Encapsulation MatriX), the Company's proprietary drug delivery technology. PLEX is capable of encapsulating many types of drugs to enable targeted, localized drug delivery into the body over extended periods of time with pre-determined release rates thus optimizing drug treatment regimens.

The Company's most advanced product candidates address current treatment problems in orthopedics and dental implants. An additional product candidate addresses the prevention and treatment of surgical site infections generally.

Through December 31, 2013, the Company has been primarily engaged in research and development and in raising capital to fund its operations.

b. Going concern

The Company's activities since inception have consisted principally of raising capital and performing research and development activities. The Company is considered to be in the development stage as of June 30, 2014, as its principal commercial operations have not commenced. 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 and access potential markets; secure financing, develop a customer base; attract, retain and motivate qualified personnel; and develop strategic alliances. 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. The Company plans to meet its capital requirements primarily through raising capital and, in the longer term, by generating revenues from product sales.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP), which contemplate continuation of the Company as a going concern. As of June 30, 2014 (unaudited), the Company had cash and cash equivalents of $4,029. During the six months ended June 30, 2014 (unaudited), the Company incurred a net loss of $2,608 and had negative cash flows from operating activities of $1,579. In addition, the Company had an accumulated deficit of $11,041 and total shareholders deficiency of $10,400 at June 30, 2014 (unaudited). The Company believes its current capital resources are not sufficient to support its operations beyond June 30, 2015. 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 or public offerings or strategic partnerships.

There can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all. These matters raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 2:– SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation:

The unaudited Interim Consolidated Financial Statements should be read in conjunction with the audited consolidated financial statements and notes for the year ended December 31, 2013.

These unaudited interim consolidated financial statements of the Company, as of June 30, 2014 and for the six month then ended, have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP").

The unaudited interim consolidated 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 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's board of directors has authorized the filing of a Registration Statement, of which this prospectus forms a part, with the U.S. Securities and Exchange Commission to register certain of the Company's ordinary shares in connection with the Company's planned initial qualified public offering ("Qualified IPO"). 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, with gross offering proceeds of not less than $15,000, which yields an imputed pre-money valuation of at least $75,000 on a fully diluted basis.

Immediately prior to the closing of the Qualified IPO, all of the issued and outstanding preferred shares will be automatically converted into ordinary shares on a 1:1 ratio. The preferred shares warrants would automatically expire if not exercised immediately prior to the Qualified IPO. The unaudited pro forma balance sheet as of June 30, 2014, has been prepared assuming the automatic conversion of all outstanding preferred shares and warrants into 30,580,686 ordinary shares. 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 and warrants as described above.

e. Recent accounting pronouncements:

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported while also improving comparability in the financial statements of companies reporting using IFRS and US GAAP. The core principle of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration (that is, payment) to which the company expects to be entitled in exchange for those goods or services. The new standard also will result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively (for example, service revenue and contract modifications) and improve guidance for multiple-element arrangements.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 2:– SIGNIFICANT ACCOUNTING POLICIES - (continued)

ASU 2014-09 will be effective for the Company in the first quarter of fiscal 2017 and may be applied on a full retrospective or modified retrospective approach. The Company is evaluating the impact of implementation of this standard on its 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 2017.

As of June 31, 2014 (unaudited), an amount of $36 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 June 30, 2014 (unaudited) are as follows:

	As of June 30, 2014
	Unaudited
2014	$ 263
2015	580
2016	518
2017	458
2018	444
Thereafter	2,484
Total	$ 4,987

As of June 30, 2014 (unaudited), the Company made advance payments on account of installments on car leases in the amount of $114.

Lease and rental expenses for the six months ended June 30, 2013 (unaudited) and June 30, 2014 (unaudited) were $101 and $150, respectively.

b. In connection with its research and development programs, the Company received participation payments from the Office of the Chief Scientist of the Ministry of Economy in Israel (“OCS”) of $959 for industrial research and development projects as of June 30, 2014 (unaudited). In return for the OCS’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 six months ended June 30, 2014 (unaudited) and June 30, 2013 (unaudited), no royalties have been paid or accrued.

NOTE 4:– FAIR VALUE MEASUREMENTS

Financial instruments measured at fair value on a recurring basis include warrants to purchase preferred A and B-1 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 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 and price indications from an investment banker. 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 preferred share prices were $1.32 for the preferred B-1 shares and

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 4:– FAIR VALUE MEASUREMENTS - (continued)

$1.207 for the preferred A shares as of June 30, 2014 (unaudited) and $0.26 for the preferred A shares as of June 30, 2013 (unaudited). There were no issued warrants to purchase preferred B-1shares as of June 30, 2013.

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

	June 30, 2014	December 31, 2013
	Unaudited	
Beginning of period	$ 332	$ 46
Change in fair value	211	286
Issuance of warrants	109	—
End of period	$ 652	$ 332

NOTE 5:– CONVERTIBLE PREFERRED SHARES

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

	June 30, 2014		December 31, 2013	
	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	4,739,630	5,000,000	4,739,630
Series B-1 convertible Preferred shares of NIS 0.1 par value	15,628,137	14,473,223	8,628,137	6,947,230
Total	32,628,137	30,048,123	25,628,137	22,422,630

The Company issued Series A, A-1, B and B-1 preferred shares between February 2008 and June 30, 2014. 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 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. Investment rounds:

During the six months ended June 30, 2014 (unaudited), the Company issued to new and existing investors 1,020,473 Series B-1 preferred shares, based on the terms of the 2013 SPA, for an aggregate consideration of $618.

In June, 2014 (unaudited), the Company entered into a Share Purchase Agreement (the "2014 SPA") with new and existing investors. According to the 2014 SPA, the Company shall issue to the investors up to 6,605,020 Series B-1 preferred shares for an aggregate amount of up to $4,000, at a price per shares of $0.61. As of June 30, 2014, the entire consideration was received. Issuance costs amounted to $170, which consisted of cash fees of $61 and fair value of $109, related to the issuance of 82,563 warrants to purchase preferred B-1 shares. The 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.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 5:– CONVERTIBLE PREFERRED SHARES - (continued)

The warrants automatically convert upon the earlier of (1) consummation of an initial public offering on certain stock exchanges as set forth in the warrant terms, with net proceeds to the Company of at least $15,000 (and pre-money valuation of at least $75,000), (2) merger or consolidation of the Company with another company, and (3) the sale of substantially all of the Company's assets or substantially all of the shares to another party.

NOTE 6:– SHAREHOLDERS' EQUITY (DEFICIENCY)

a. Ordinary share capital is composed as follows:

	June 30, 2014 (Unaudited)		December 31, 2013	
	Authorized	Issued and outstanding	Authorized	Issued and outstanding
	Number of shares			
Ordinary shares of NIS 0.01 par value	67,371,863	4,500,000	74,371,863	4,500,000

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 7,000,000 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 June 30, 2014 (unaudited), 141,185 of the Company's options were available for future grants.

The fair value for options granted to employees and directors during the six months ending June 30, 2014 (unaudited), is estimated at the date of grant using a Black-Scholes-Merton Option Pricing Model with the following assumptions: expected volatility of 111%, risk free interest rates of 1.1%%, 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 $0.95 – 0.97 per share as of the grant date of the options.

The fair value for options granted to employees and directors during the six months ending June 30, 2013 (unaudited), was estimated at the date of grant using a Black-Scholes-Merton Option Pricing Model with the following assumptions: expected volatility of 116%, risk free interest rates of 10.84%, dividend yield of 0%, and an expected term of 5 – 6 years. The Company's board of directors deemed the fair value of the Company's ordinary shares to be $0.12 per share as of the grant date of the options.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 6:– SHAREHOLDERS' EQUITY (DEFICIENCY) - (continued)

A summary of the status of the Company's option plan as of June 30, 2014 (unaudited), and changes during the period then ended is presented below:

	Six months ended June 30, 2014		
	Number of options	Weighted average exercise price	Aggregate intrinsic value
		Unaudited	
Outstanding at beginning of period	4,302,356	$ 0.21	$
Granted	2,191,514	$ 0.61	
Exercised	—		
Forfeited and cancelled	—	$	
Outstanding at end of period	6,493,870	$ 0.34	$ 4,037
Exercisable options	3,366,053	$ 0.15	$ 2,742
Vested and expected to vest	6,493,870	$ 0.34	$ 4,037

The total equity-based compensation expense related to all of the Company's equity-based awards recognized for the six months ended June 30, 2014 (unaudited), was comprised as follows:

	Six months ended June 30, 2014
	Unaudited
Research and development	$ 178
General and administrative	90
Total share-based compensation expense	$ 268

As of June 30, 2014 (unaudited), there were unrecognized compensation costs of $1,941, which are expected to be recognized over a weighted average period of approximately 2.79 years.

The weighted average grant date fair value of the Company's options granted during the six months ended June 30, 2014 (unaudited) was $0.83 ($0.09 during the six months ended June 30, 2013 (unaudited)).

No options were exercised during the six months ended June 30, 2014 (unaudited) and June 30, 2014 (unaudited).

The Company's board of directors deemed the fair value of the Company's ordinary shares to be $0.97 and $0.12 per share as of June 30, 2014 (unaudited) and June 30, 2013 (unaudited), respectively.

The options outstanding as of June 30, 2014 (unaudited) have been separated into ranges of exercise prices, as follows:

Exercise price	Options outstanding as of June 30, 2014	Weighted average exercise price	Weighted average remaining contractual term (years)	Options exercisable as of June 30, 2014	Weighted average exercise price	Weighted average remaining contractual term (years)
0.03*)	2,088,368	0.03*)	8.72	2,038,893	0.03*)	8.72
0.21	902,960	0.21	8.72	701,047	0.21	8.72
0.43	795,280	0.43	8.79	440,323	0.43	8.72
0.61	2,707,262	0.61	9.80	185,789	0.61	9.43
	6,493,870	0.34	9.18	3,366,053	0.15	8.76

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

NOTE 6:– SHAREHOLDERS' EQUITY (DEFICIENCY) - (continued)

*) 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 June 30, 2014. The options were granted at ordinary share par value.

c. Options issued to consultants:

The outstanding options granted to consultants as of June 30, 2014 (unaudited) were as follows:

	Options outstanding as of June 30, 2014	Exercise price per share	Options exercisable as of June 30, 2014	Exercisable through
March 2013	186,258	$ 0.211	186,258	March 2023
October 2013	47,858	$ 0.611	—	October 2023
May 2014	83,829	$ 0.611	—	May 2024
June 2014	47,000	$ 0.611	—	June 2024
	364,945		186,258	

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:

	Six months ended	
	June 30, 2014	June 30, 2013
	Unaudited	Unaudited
Numerator:		
Net loss attributable to ordinary shares as reported	$ (2,608)	$ (2,288)
Preferred share dividend	(1,090)	(563)
Net loss applicable to ordinary shareholders	(3,698)	(2,851)
Denominator:		
Weighted average shares used in computing net loss per ordinary share, basic and diluted:		
Ordinary share – basic	4,500,000	4,500,000
Ordinary share equivalents	—	—
Ordinary share – dilutive	4,500,000	4,500,000
Net loss per ordinary share, basic and diluted	(0.82)	(0.63)

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 during the six months ended June 30, 2014 and June 30, 2013.

POLYPID LTD.

NOTES TO FINANCIAL STATEMENTS
U.S. dollars in thousands (except share and per share data)

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):

	Six months ended June 30, 2014
	Unaudited
Net loss attributable to ordinary shares as reported	$ (2,608)
Shares used in computing net loss per ordinary share, basic and diluted	4,500,000
Pro forma adjustments to reflect assumed conversion of convertible preferred shares and exercise of warrants	30,580,186
Shares used in computing pro forma net loss per ordinary share, basic and diluted	35,080,186
Pro forma net loss per ordinary share, basic and diluted	$ (0.07)

NOTE 9:– SUBSEQUENT EVENTS

a. In connection with the preparation of the financial statements and in accordance with authoritative guidance for subsequent events, the Company evaluated subsequent events after the balance sheet date of June 30, 2014 through September 23, 2014, the date on which the financial statements were issued.

b. In August 2014 (unaudited), the Company's Board of Directors approved the grant of bonuses to employees and executives of the Company, upon the conclusion of an IPO in the amount of 2% of the net proceeds of the IPO and an additional amount not to exceed $176.

TABLE OF CONTENTS

Ordinary Shares

PROSPECTUS

Aegis Capital Corp

, 2014

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 6. Indemnification of Directors, Officers and Employees

An Israeli company may indemnify an office holder in respect of certain liabilities either in advance of an event or following an event provided that a provision authorizing such indemnification is inserted in its articles of association. Our amended and restated articles of association contain such a provision. An undertaking provided in advance by an Israeli company to indemnify an office holder with respect to a financial liability imposed on him or her in favor of another person pursuant to a judgment, settlement or arbitrator's award approved by a court 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 must detail the abovementioned events and amount or criteria.

In addition, a company may indemnify an office holder against the following liabilities incurred for acts performed as an office holder:

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder 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, such as a criminal penalty, was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent or as 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 a crime that does not require proof of criminal intent.

An Israeli company may insure a director or officer against the following liabilities incurred for acts performed as a director or officer:

- a breach of duty of care to the Company or to a third party, including a breach arising out of the negligent conduct of an office holder;
- a breach of duty of loyalty to the Company, provided the director or officer acted in good faith and had a reasonable basis to believe that the act would not prejudice the interests of the Company; and
- Financial liabilities imposed on the office holder for the benefit of a third party.

An Israeli company may not, however, indemnify or insure an office holder against any of the following:

- a breach of duty of loyalty, except to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the Company;
- a breach of 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 unlawful personal benefit; or
- a fine, monetary sanction, penalty or forfeit levied against the office holder.

The Israeli Securities Law, provides that a company cannot obtain insurance against or indemnify a third party (including its officers and/or employees) for any administrative procedure conducted by the Israeli Securities Authority and/or monetary fine (other than for certain legal expenses and payments of damages to an injured party). The Israeli Securities Law permits insurance coverage and/or indemnification for certain liabilities incurred in connection with an administrative procedure, such as reasonable legal fees and certain

compensation payable to injured parties for damages suffered by them, provided that such insurance and/or indemnification is permitted under the company's articles of association. Our articles of association contain such a provision.

Under the Israeli Companies Law, indemnification and insurance of office holders must be approved by our compensation committee, our Board of Directors and, in certain circumstances, by our shareholders. We have obtained directors' and officers' liability insurance for the benefit of our office holders and intend to continue to maintain such coverage and pay all premiums thereunder to the fullest extent permitted by the Israeli Companies Law, and our articles of association. In addition, we have entered into indemnification agreements with each of our directors and officers providing them with indemnification for liabilities or expenses incurred as a result of acts performed by them in their capacity as our, or our subsidiaries', directors and officers. This indemnification is limited both in terms of amount and coverage. 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.

It is our intention to include in our office holders compensation policy to be brought for approval of the shareholders following the initial issuance of the securities hereunder (and as required under the Companies Law) applicable provisions with respect to directors’ and officers’ liability insurance for the benefit of our office holders, as well as with respect to indemnification of office holders.

Item 7. Recent Sales of Unregistered Securities

Set forth below are the sales of all securities by the Company since January 1, 2011.

- On December 28, 2011, we issued an aggregate of 4,390,387 series B preferred shares pursuant to a private placement, at a price per share of $.43.
- On March 20, 2012, we issued an aggregate of 349,243 series B preferred shares pursuant to a private placement, at a price per share of $.43.
- On December 30, 2012 we issued an aggregate of 4,128,137 series B-1 preferred shares pursuant to a private placement, at a price per share of $0.61.
- On February 12, 2013, we issued an aggregate of 371,937 series B-1 preferred shares pursuant to a private placement, at a price per share of $0.61.
- In April 2013, we issued an aggregate of 165,125 series B-1 preferred shares pursuant to a private placement, at a price per share of $0.61.
- On October 30, 2013, we issued an aggregate of 3,302,505 series B-1 preferred shares pursuant to a private placement, at a price per share of $0.61.
- 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.

We claimed exemption from registration under the Securities Act for the foregoing transactions under Regulation S under the Securities Act and/or Regulation D under the Securities Act and/or Section 4(a)(2) under the Securities Act. No underwriters were employed in connection with the securities issuances set forth in this Item 7.

Item 8. Exhibits and Financial Statement Schedules

Exhibits:

Exhibit Number	Exhibit Description
1.1*	Form of Underwriting Agreement by and among the Company and the underwriters named therein.
3.1*	Articles of Association of the Company, as currently in effect.
3.2*	Amended and Restated Articles of Association of the Company, to be in effect upon completion of this offering.
4.1*	Form of Representative's Warrant.
4.2*	Registration Rights Agreement between the Company and the holders of Ordinary Shares that are parties thereto.
5.1*	Opinion of Zysman, Aharoni, Gayer & Co., Israeli counsel to the Company, as to the validity of the ordinary shares being offered (including consent).
10.1*	PolyPid Ltd. Plan.
10.2*	Employment Agreement between the Company and , effective December 1, 2008.
10.3*	English Translation of Binding Memorandum of Understanding between the Company and MIS Implants Technologies Ltd.(Confidential Treatment Requested).
23.1*	Consent of Kost Forer Gabbay & Kasierer (a member of Ernst & Young Global).
23.2*	Consent of Zysman, Aharoni, Gayer & Co. (included in Exhibit 5.1).
24.1	Power of Attorney (included on the signature page of the Registration Statement).

* To be filed by amendment.

Financial Statement Schedules:

All financial statement schedules have been omitted because either they are not required, are not applicable or the information required therein is otherwise set forth in the Company's financial statements and related notes thereto.

Item 9. Undertakings

(a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the provisions described in Item 6 hereof, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the 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 whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) That for purposes of determining any liability under the Securities Act of 1933, 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.

(2) That for the purpose of determining any liability under the Securities Act of 1933, 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.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 has duly caused this registration statement on Form F-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Tel Aviv, Israel on , 2014.

POLYPID LTD.

By: _____
Amir Weisberg,
Chief Executive Officer

POWER OF ATTORNEY

The undersigned officers and directors of PolyPid Ltd. hereby constitute and appoint and with full power of substitution, our true and lawful attorney-in-fact and agent to take any actions to enable the Company to comply with the Securities Act, and any rules, regulations and requirements of the SEC, in connection with this registration statement on Form F-1, including the power and authority to sign for us in our names in the capacities indicated below any and all further amendments to this registration statement and any other registration statement filed pursuant to the provisions of Rule 462 under the Securities Act.

Pursuant to the requirements of the Securities Act of 1933, this registration statement on Form F-1 has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Anat Segal	Chairman of the Board of Directors	
Amir Weisberg	Chief Executive Officer and Director (Principal Executive Officer)	
Shaun Marcus	Chief Financial Officer (Principal Financial and Accounting Officer)	
Noam Emmanuel	Director	
Yechezkel Barenholz	Director	
Rami Lerner	Director	
Yafit Stark	Director	
Arik Lukach	Director	
Moshe Neuman	Director	

SIGNATURE OF AUTHORIZED REPRESENTATIVE IN THE UNITED STATES

Pursuant to the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of PolyPid Ltd., has signed this registration statement on , 2014.

ZYSMAN, AHARONI, GAYER AND
SULLIVAN & WORCESTER LLP