As confidentially submitted to the Securities and Exchange Commission on July 14, 2017.
This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-_____

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

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

ENTERA BIO LTD.
(Exact Name of Registrant as Specified in its Charter)

State of Israel	**2836**	**Not Applicable**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

Entera Bio Ltd.
Kiryat Hadassah
Minrav Building - Fifth Floor
Jerusalem 9112002
Israel
+972.2. 532.7151
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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

Copies to:

Michael P. Kaplan, Esq.	**Ron Ben Menachem, Adv.**
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(212) 450-4000	**+972 (3) 6922020**

Approximate date of commencement of proposed sale to the public: As soon as practicable after effectiveness of this registration statement.
If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐
If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐
If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐
If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

Emerging growth company ☒

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

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Proposed Maximum Aggregate Offering Price[(1)]**	**Amount of Registration Fee[(2)]**
Ordinary shares, par value NIS 0.01	$	$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933.

(2) This registration statement is being submitted in accordance with the procedures described in the announcement of the Division of Corporate Finance of the Securities and Exchange Commission regarding submission of draft registration statements by emerging growth companies pursuant to the Jumpstart Our Business Startups Act of 2012. Accordingly, a registration fee is not required for this confidential draft registration statement submission.

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 Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This registration statement contains two forms of prospectus, as set forth below.

- *Public Offering Prospectus*. A prospectus to be used for the initial public offering by Entera Bio Ltd. of $ of ordinary shares (and an additional $ of shares of ordinary shares which may be sold upon exercise of the underwriters' over-allotment option) through the underwriters named on the cover page of the Public Offering Prospectus; and

- *Selling Stockholder Resale Prospectus*. A prospectus to be used in connection with the potential resale by certain selling stockholders of our ordinary shares previously issued.

The Public Offering Prospectus and the Selling Stockholder Resale Prospectus will be substantively identical in all respects except for the following principal points:

- they contain different front covers;

- all references in the Public Offering Prospectus to “this offering” or “this initial public offering” will be changed to “the IPO,” defined as the underwritten initial public offering of our ordinary shares, in the Selling Stockholders Resale Prospectus;

- all references in the Public Offering Prospectus to “underwriters” will be changed to “underwriters of the IPO” in the Selling Stockholders Resale Prospectus;

- they contain different Use of Proceeds sections;

- a “Shares Registered for Resale” section is included in the Selling Stockholder Resale Prospectus;

- a “Selling Stockholders” section is included in the Selling Stockholder Resale Prospectus;

- the section “Summary—The Offering” from the Public Offering Prospectus is deleted from the Selling Stockholder Resale Prospectus;

- the section “Shares Eligible For Future Sale—Selling Stockholder Resale Prospectus” from the Public Offering Prospectus is deleted from the Selling Stockholder Resale Prospectus;

- the Underwriting section from the Public Offering Prospectus is deleted from the Selling Stockholder Resale Prospectus and a Plan of Distribution section is inserted in its place;

- the Legal Matters section in the Selling Stockholder Resale Prospectus deletes the reference to counsel for the underwriters; and

- they contain different back covers.

We have included in this registration statement, after the financial statements, a set of alternate pages to reflect the foregoing differences between the Public Offering Prospectus and the Selling Stockholder Resale Prospectus.

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 we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS (Subject to Completion)
Issued , 2017

ORDINARY SHARES

Entera Bio Ltd. is offering ordinary shares. This is our initial public offering and no public market exists for our shares. We anticipate that the initial public offering price will be between $ and $ per ordinary share.

We expect to apply to list our ordinary shares on the under the symbol " ".

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act and will therefore be subject to reduced reporting requirements.

Investing in our ordinary shares involves risks. See "Risk Factors" beginning on page 15.

PRICE $ **A SHARE**

	Price to Public	Underwriting Discounts and Commissions	Proceeds to Company(1)
Per share	$	$	$
Total	$	$	$

(1) We have agreed to reimburse the underwriter for certain FINRA-related expenses. See "Underwriters."

Entera Bio Ltd. has granted the underwriters the right to purchase up to an additional ordinary shares to cover over-allotments at the initial public offering price less the underwriting discount.

The Securities and Exchange Commission and state securities regulators have not approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the ordinary shares to purchasers on , 2017.

, 2017

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Neither we nor the underwriters have authorized anyone to provide information other than that contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus prepared by us or on our behalf. Neither we nor the underwriters take any responsibility for, and can provide no assurance as to the reliability of, any information other than the information in this prospectus, any amendment or supplement to this prospectus and any free writing prospectus prepared by us or on our behalf. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of our ordinary shares. This prospectus is not an offer to sell or the solicitation of an offer to buy these ordinary shares in any circumstances under which such offer or solicitation is unlawful.

We have not taken any action to permit a public offering of the ordinary shares outside the United States or to permit the possession or distribution of this prospectus outside the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about and observe any restrictions relating to the offering of the ordinary shares and the distribution of this prospectus outside of the United States.

PRESENTATION OF FINANCIAL INFORMATION

We report under International Financial Reporting Standards as issued by the International Accounting Standards Board (the "IFRS" and the "IASB"). None of the financial statements were prepared in accordance with generally accepted accounting principles in the United States. We present our financial statements in U.S. dollars. We have made rounding adjustments to some of the figures included in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

Items included in our financial statements are measured using the currency of the primary economic environment in which we operate, the U.S. dollar ("the functional currency"). Our financial statements and other financial information included in this prospectus are presented in U.S. dollars unless otherwise noted. See Note 2 to our financial statements included elsewhere in this prospectus.

Unless otherwise indicated or the context otherwise requires, references in this prospectus to "NIS" are to the legal currency of Israel, "U.S. dollars," "$" or "dollars" are to United States dollars, "euro" or "€" are to the Euro, the legal currency of certain countries of the European Union.

MARKET AND INDUSTRY DATA

This prospectus includes market and industry data and forecasts that we obtained from publicly available information and independent industry publications and reports that we believe to be reliable sources. These publicly available industry publications and reports generally state that they obtain their information from sources that they believe to be reliable, but they do not guarantee the accuracy or completeness of the information. Certain estimates and forecasts involve uncertainties and risks and are subject to change based on various factors, including those discussed under the headings "Special Note Regarding Forward-Looking Statements" and "Risk Factors" in this prospectus.

SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our ordinary shares. You should read this entire prospectus carefully, including the "Risk Factors" section and the financial statements and the notes to those financial statements, before making an investment decision. In this prospectus, the terms "Entera," "we," "us," "our" and "our company" refer to Entera Bio Ltd.

Our Business

We are a biopharmaceutical company focused on the development and commercialization of orally delivered large molecule therapeutics for use in orphan indications and other areas with significant unmet medical need. We are initially applying our technology to develop an oral formulation of parathyroid hormone, or PTH, which has been approved in the United States in injectable form for over a decade. Our lead oral PTH product candidate, EB612, has successfully completed a Phase 2a trial for hypoparathyroidism, a rare condition in which the body fails to produce sufficient amounts of PTH. The U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, have granted EB612 orphan drug designation for the treatment of hypoparathyroidism. We expect to initiate a Phase 2b/3 clinical trial of EB612 in the first quarter of 2018, and we plan to submit applications for regulatory approval of EB612 in the first half of 2020.

Hypoparathyroidism is a rare condition in which the body does not produce sufficient amounts of PTH, or the PTH produced lacks biologic activity. Individuals with a deficiency of PTH typically exhibit abnormally low levels of calcium in the blood, or hypocalcemia, and high levels of phosphorus, or hyperphosphatemia. Hypoparathyroidism is estimated to affect approximately 58,700 individuals in the United States. Historically, the treatments for hypoparathyroidism have been calcium supplements, vitamin D supplements and phosphate binders, the chronic use of which results in serious side effects with significant costs to the healthcare system. Natpara®, a once-daily injectable form of PTH ("Natpara"), has been approved for the treatment of hypoparathyroidism. Our lead product candidate, EB612, is delivered orally and can be administered in customized doses several times a day. Multiple dosing per day has been shown to more effectively treat the symptoms of hypoparathyroidism than a once-daily injection, thus reducing the serious side effects of supplement treatment and improving patient outcomes. We believe patients generally prefer oral drugs. For these reasons, we believe EB612 is clinically superior to existing therapies and has the potential to become the standard of care for hypoparathyroidism.

In the third quarter of 2015 we successfully completed our Phase 2a trial for EB612. The end points in the trial were met, and 17 subjects completed the four-month trial and reported no related adverse events. Although our trial Phase 2a trial involved a smaller number of patients, was conducted for a shorter duration and did not include an initial optimization period in comparison to the design of the pivotal trial used for regulatory approval of Natpara, the REPLACE study, our Phase 2a trial still showed similar efficacy. We believe that EB612 will have inherent advantages compared to injectable forms, including convenience of application, the fact that no special preparations are required and the fact that no restrictive storage conditions are necessary. Additionally, we believe that EB612 will have an enhanced clinical profile as compared to Natpara, with an additional positive effect on elevated urinary calcium, as well as reduced side effects. We believe this combination of advantages and long term clinical benefits will be very compelling to both patients and physicians.

Based on consultations with key opinion leaders in the hypoparathyroidism field who have reviewed our Phase 2a results and are familiar with the REPLACE study we are planning for a Phase 2b/3 trial, designed to possibly be a pivotal study for registration. This Phase 2b/3 study will be designed to repeat the REPLACE study in virtually every aspect, as well as to achieve a reduction in urinary calcium.

We are also developing a distinct oral PTH product candidate, EB613, for the treatment of osteoporosis. Osteoporosis is a systemic skeletal disease characterized by low bone mass, deterioration of bone tissue and increased bone fragility and susceptibility to fracture. An estimated 10 million people in the United States already have osteoporosis, and another approximately 43 million have low bone mass placing them at increased risk for

osteoporosis. PTH plays a key role in the ongoing process of formation and degradation of bones. Forteo®, a once-daily injectable form of PTH ("Forteo"), has been approved for the treatment of osteoporosis in the United States for over 10 years and is widely considered one of the most effective treatments due to its ability to build bone. Because our product candidate EB613 is oral, we believe it will reduce the treatment burden on patients and lead to significantly higher patient and physician acceptance compared to an injectable form of PTH. We intend to commence a Phase 2a clinical trial of EB613 in the fourth quarter of 2017. After completing this trial we intend to collaborate with a strategic partner to further develop and commercialize EB613. We are also preparing to conduct a clinical trial of our oral PTH in non-union fractures, one indication within the field of bone healing.

Our product candidates utilize our proprietary technology for the oral delivery of large molecules. Drug development has shifted towards the use of peptides, proteins and other large molecules for the treatment of various diseases. Between 1993 and 2004, large-molecule clinical approval success rates have outpaced small molecules by about two-to-one. Large molecules have been particularly widely used in orphan indications. Oral drug delivery reduces the treatment burden on patients relative to injectable drugs and provides significantly more flexibility, both in size of dose and number of doses per day, than injectable drugs, which are frequently administered once per day by preset injection pen. However, peptides, proteins and other large molecule therapeutics can currently only be delivered via injections and other non-oral pathways because oral administration leads to poor absorption into the blood stream as well as enzymatic degradation within the gastrointestinal tract. Our proprietary oral drug delivery technology is designed to address both of these issues by utilizing a combination of a synthetic absorption enhancer to facilitate the enhanced absorption of large molecules and protease inhibitors to prevent enzymatic degradation.

We also intend to use our technology as a platform for the oral delivery of other protein and large molecule therapeutics. We initially intend to focus on the development of products based on previously approved therapeutic agents. We believe this will allow us to more efficiently and predictably advance product candidates through the development cycle based on well-defined clinical and regulatory approval pathways. We have conducted initial feasibility studies with a number of candidates and intend to commence clinical development for our next, non-PTH, product candidate by the end of 2018.

The following chart summarizes important information about each of our current product candidates, including their indications, and their current stage of development. We have not out-licensed any intellectual property rights to our PTH product candidates listed below, and, therefore, have retained the ability to pursue their worldwide commercialization.

Program	Indication	Pre-Clinical	Phase I	Phase II	Phase III	Status
EB612 PTH 1-34	Hypoparathyroidism	Phase 2a complete				• Phase 2a complete • Pivotal Phase 2b/3 initiation expected 1Q18 • Topline Data expected 1H19
EB613 PTH 1-34	Osteoporosis	Phase 1 complete				• Phase 2a initiation expected 4Q17
	Non-union fractures	Phase 1 complete				• Phase 2a initiation expected 1H18

We commenced operations in August 2010 after receiving startup financing in the form of $0.6 million in cash from D.N.A Biomedical Solutions Ltd. and a license from Oramed Ltd., a subsidiary of Oramed Pharmaceuticals, Inc., to certain patent rights relating to the oral administration of proteins. These previously licensed patent rights were assigned to us in 2011, subject to an exclusive, royalty-free license in specified fields under such patent rights that we granted to Oramed Ltd.

We subsequently advanced our oral PTH product candidates from preclinical studies in animals to a Phase 2a clinical trial of EB612 in hypoparathyroidism in less than five years.

While our operations are currently focused in our offices in Israel, we intend eventually to build a substantial U.S. presence to execute on our later stage development of our products, including clinical operations, regulatory operations, and commercialization.

Our Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of orally delivered large molecule therapeutics in indications with significant unmet medical need. The key elements of our strategy to achieve this goal are to:

- Advance our lead product candidate, EB612, through clinical development and into commercialization for the treatment of hypoparathyroidism;
- Produce supportive clinical data for our second product candidate, EB613, for the treatment of osteoporosis, before advancing into late-stage clinical trials;
- Leverage our expertise in the oral delivery of PTH to develop product candidates in additional indications;
- Improve the efficacy profile of large molecule therapeutics through the application of our proprietary oral delivery technology;
- Focus our development and commercialization efforts on indications with significant unmet medical need; and
- Initially develop products based on FDA-approved large molecule therapeutics.

Our Technology

Currently, peptides, proteins and other large molecule therapeutics can only be delivered via injections and other non-oral-pathways because oral administration leads to poor absorption into the blood stream (bioavailability) due to enzymatic degradation within the gastrointestinal tract and poor permeability though the intestinal wall. Most oral drug delivery technologies attempting to overcome this hurdle nevertheless manage to attain only very low bioavailability (less than 1%). Orally-delivered large molecules with low systemic levels present high variability of dose exposure, both between patients and within the same patient at different times of administration since small changes in the level of absorption lead to significant changes in the bioavailability. Absorption variability is generally decreased as the drug bioavailability is increased.

Oral formulations of large molecules must therefore ensure that the large molecule is able to pass through the intestinal wall so that it can be absorbed into the bloodstream and that the large molecule therapeutic is not exposed to enzymatic degradation in order to protect its biological activity and availability for absorption. Our proprietary technology is designed to address both of these issues by utilizing a combination of a synthetic absorption enhancer, or carrier molecule, to facilitate the enhanced absorption of large molecules, and protease inhibitors to prevent enzymatic degradation. By designing our product candidates to address both the issues of absorption and degradation, we have been able to significantly increase bioavailability and decrease the variability of the PTH dose delivered in our clinical trials to date.

Our Product Candidates

Oral PTH Therapeutics

PTH is a hormone that regulates the levels of calcium and phosphorus in the blood. The naturally occurring form of PTH that is found in the human body is composed of 84 amino acids, although only the first 34 amino acids are believed to be responsible for its biological effects. A recombinant form of PTH that is comprised of only the first 34 amino acids, or PTH (1-34), can be used as a treatment for a number of indications, including hypoparathyroidism, osteoporosis and non-union fractures. An injectable form of PTH (1-34), marketed under the name Forteo, has been approved in the United States for more than ten years and has been used by millions of patients for the treatment of osteoporosis. An injectable form of full length PTH (1-84), marketed under the name Natpara, has also been approved for the treatment of hypoparathyroidism. We are developing a number of distinct oral PTH (1-34) products, with significant differences in dose and pharmacokinetic, or PK, profile that can be used for a number of proposed indications. We believe that our oral PTH product candidates, if approved, have the potential to become the standard of care for patients with hypoparathyroidism, osteoporosis and non-union bone fractures.

EB612 for Hypoparathyroidism

Our lead product candidate, EB612, is an oral formulation of PTH (1-34). EB612 is a synthetic form of the first 34 amino acids of human PTH to which we have applied our proprietary technology for the oral delivery of large molecule therapeutics. In the third quarter of 2015 we successfully completed our Phase 2a trial. The end points in the trial were met, and 17 subjects completed the four-month trial and reported no related adverse events. Although our Phase 2a trial involved a smaller number of patients, was conducted for a shorter duration and did not include an initial optimization period in comparison to the design of the pivotal trial used for regulatory approval of Natpara, the REPLACE study, our Phase 2a trial still showed similar efficacy. We expect to initiate a Phase 2b/3 clinical trial of EB612 in the first quarter of 2018 and we plan to submit applications for regulatory approval of EB612 in the first half of 2020. The FDA and EMA have granted EB612 orphan drug designation for the treatment of hypoparathyroidism.

Individuals with a deficiency of parathyroid hormone may exhibit hypocalcemia and hyperphosphatemia. Hypocalcemia can cause one or more of a variety of symptoms, including weakness, muscle cramps, excessive nervousness, headaches and uncontrollable twitching and cramping spasms of muscles such as those of the hands, feet, arms, legs and face, which is known as tetany. Acute hypocalcemia can result in cardiac failure, failure of nervous system functions and death. Hyperphosphatemia can result in soft tissue calcium deposition, which may lead to severe issues, including damage to the circulatory system and central nervous system.

The prevalence of hypoparathyroidism is estimated to be 37 per 100,000 in the United States, with 78% of cases caused by surgery, 7% due to genetic disorder and 6% due to idiopathic origin. Although incidence rates have been difficult to quantify, it is estimated that chronic hypoparathyroidism, which affects patients for more than six months, affects approximately 58,700 individuals in the United States, with an estimated 43% of these chronic cases characterized as mild, 39% characterized as moderate, and 18% characterized as severe.

If a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In January 2015, the FDA approved Natpara, an injectable form of PTH, for hypoparathyroidism, and awarded Natpara orphan drug exclusivity until January 23, 2022. In order for our biologics license application for EB612 to be approved by the FDA prior to this date, we will need to demonstrate that EB612 is clinically superior to Natpara in that it demonstrates greater effectiveness or safety than Natpara or that it otherwise makes a major contribution to patient care, which we believe we will be able to do.

EB613 for Osteoporosis

Osteoporosis

We are also developing a distinct oral PTH product candidate, EB613, for the treatment of osteoporosis. We are preparing a Phase 2a trial of EB613 in osteoporosis that we plan to conduct in Israel in the fourth quarter of 2017. We are also preparing an IND for a Phase 2 clinical trial of EB613 in osteoporosis that we plan to submit to the FDA in 2018. Prior to submission, we plan to solicit feedback from the FDA on our proposed clinical trial design in the fourth quarter of 2017.

Osteoporosis is a systemic skeletal disease characterized by low bone mass, deterioration of bone tissue and increased bone fragility and susceptibility to fracture. Osteoporosis often leads to loss of mobility, admission to nursing homes and dependence on caregivers. These debilitating effects of osteoporosis have substantial costs. The prevalence of osteoporosis is growing and, according to the National Osteoporosis Foundation, or NOF, is significantly under-recognized and under-treated in the population. While the aging of the population is a primary driver of an increase in cases, osteoporosis is also increasing from the use of drugs that induce bone loss, such as chronic use of glucocorticoids and aromatase inhibitors that are increasingly used for breast cancer and the hormone therapies used for prostate cancer.

The NOF has estimated that 10 million people in the United States already have osteoporosis, and another approximately 43 million have low bone mass placing them at increased risk for osteoporosis. In addition, the NOF has estimated that osteoporosis is responsible for more than two million fractures in the United States each year resulting in an estimated $19 billion in costs annually. The NOF expects that the number of fractures in the United States due to osteoporosis will rise to three million by 2025, resulting in an estimated $25.3 billion in costs each year. Worldwide, osteoporosis affects an estimated 200 million women according to the International Osteoporosis Foundation, or IOF, and causes more than 8.9 million fractures annually, which is equivalent to an osteoporotic fracture occurring approximately every three seconds. The IOF has estimated that 1.6 million hip fractures occur worldwide each year, and by 2050 this number could reach between 4.5 million and 6.3 million. The IOF estimates that in Europe alone, the annual cost of osteoporotic fractures could surpass €76 billion by 2050.

Bone Healing / Non-union Fractures

We intend to investigate the efficacy of our oral PTH product candidates for non-union bone fractures. We may either pursue fracture treatment as an additional use of EB613 or further modify the formulation if studies suggest we could achieve a PK profile that is more efficacious for bone fractures. As non-union fractures and bone healing are non-chronic conditions, generally entailing three to six months of treatment, we believe the acceptance of oral PTH will be higher than other potential pharmacological alternatives. We believe we will be able to use the data generated with EB613 in Phase 1 clinical trials relating to osteoporosis to progress directly to a Phase 2a clinical trial of our oral PTH product candidates for non-union bone fractures.

Non-union fractures occur when the normal process of bone healing is interrupted and a fracture does not heal properly or does not heal at all. By definition, a non-union fracture will not heal on its own. Most non-union fractures require surgery, which can involve bone grafts or stabilizing the affected bone by affixing rods, plates or screws. Risks of surgery include neurovascular injury, infection and hemorrhage. In the United States, there are approximately seven million new fractures each year, with approximately 300,000 delayed union or non-union fractures. Estimates for the average non-union treatment cost vary from approximately $25,000 to $45,000.

Future Development of Orally Delivered Large Molecule Therapeutics

We intend to use our technology as a platform for the oral delivery of protein and other large molecule therapeutics. We have conducted initial feasibility studies with a number of candidates and intend to commence clinical development for our next, non-PTH product candidate by the end of 2017. We expect that the key criteria in selecting our next clinical candidate will include: the size of the molecule and other chemical characteristics that would benefit from our technology, whether the molecule is best delivered through the intestinal tract rather than through injection, and the drug's dosing schedule (more specifically, whether it is prescribed for at least three months and would likely be best administered at least once a day). Additionally, we may target large proteins that are prone to inducing damaging immune responses when injected subcutaneously. In some cases, the immune response to the injection is so severe as to reduce or eliminate all physiological effect of the drug upon the illness, as in the case of interferon. We are also considering whether to partner the development of any such additional product candidates and are in early stage discussions with a number of external parties.

Risk Factors

Investing in our ordinary shares involves risks. You should carefully consider the risks described in "Risk Factors" before making a decision to invest in our ordinary shares. If any of these risks actually occurs, our business, financial condition or results of operations would likely be materially adversely affected. In such case, the trading price of our ordinary shares would likely decline, and you may lose all or part of your investment. The following is a summary of some of the principal risks we face:

- our operation as a development stage company with limited operating history and a history of operating losses;

- our ability to develop and advance product candidates into, and successfully complete, clinical studies;
- uncertainty surrounding whether any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized, including that we will be able to demonstrate to regulators the clinical superiority of EB612 over Natpara, which is required to overcome Natpara's drug exclusivity;
- our competitive position, especially with respect to Natpara, our key competitor for hypoparathyroidism treatment;
- our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern absent access to sources of liquidity;
- our ability to use and expand our drug delivery technology to other product candidates;
- the pricing and reimbursement of our product candidates, if approved;
- our being subject to ongoing regulatory obligations if our products secure regulatory approval;
- our ability to develop sales, marketing and distribution infrastructure;
- our reliance on third parties to conduct our clinical trials and on third-party suppliers to supply or produce our product candidates;
- our ability to achieve market acceptance for our product candidates;
- our ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights;
- our ability to retain key personnel and recruit additional qualified personnel;
- our expectations regarding the use of proceeds from this offering;
- our ability to manage growth; and
- other risk factors discussed under "Risk Factors."

Corporate Information

Our legal and commercial name is Entera Bio Ltd. We were incorporated in Israel in September 2009. Our principal executive offices are located at Kiryat Hadassah, Minrav Building – Fifth Floor, Jerusalem 9112002, Israel and our telephone number is +972.2.532.7151. Our website address is www.enterabio.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein. We have included our website address in this prospectus solely for informational purposes.

All trademarks or service marks appearing in this prospectus are trademarks or service marks of others.

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

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- a requirement to have only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure in its initial registration statement;

- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;

- an exemption from compliance with any requirement that the Public Company Accounting Oversight Board, or PCAOB, may adopt regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; and

- to the extent that we no longer qualify as a foreign private issuer, (1) reduced disclosure about the company's executive compensation arrangements, and (2) exemptions from the requirements to obtain a non-binding advisory vote on executive compensation or a shareholder approval of any golden parachute arrangements.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenue, have more than $700 million in market value of our ordinary shares held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. Given that we currently report and expect to continue to report under IFRS as issued by the IASB, we will not be able to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB.

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

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;

- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time;

- the rules under the Exchange Act requiring the filing with the Securities and Exchange Commission, or SEC, of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events; and

- Regulation Fair Disclosure, or Regulation FD, which regulates selective disclosures of material information by issuers.

We do, however, intend to make available to our shareholders quarterly reports containing unaudited financial information for each of the first three quarters of each fiscal year.

THE OFFERING

Ordinary shares offered by us	ordinary shares
Ordinary shares to be outstanding after this offering	ordinary shares
Over-allotment option	We have granted the underwriters a 30-day option to purchase up to an additional ordinary shares from us to cover over-allotments.
Use of Proceeds	We estimate that we will receive net proceeds of approximately $ million from our sale of ordinary shares in this offering, after deducting the estimated underwriting discount and the estimated offering expenses payable by us. This assumes an offering price of $ per share, which is the midpoint of the estimated offering price range on the cover page of this prospectus. We intend to use the net proceeds from this offering, together with cash and cash equivalents on hand, to fund research and development expenses of oral PTH, the development of other therapeutics, the repayment of outstanding indebtedness, and for working capital and general corporate purposes. See "Use of Proceeds."
Dividend Policy	We have never paid or declared any cash dividends on our ordinary shares, and we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. See "Dividend Policy."
Risk Factors	See "Risk Factors" and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our ordinary shares.
Listing	We expect to apply to list our ordinary shares on the under the symbol " ."

We have based the number of our ordinary shares to be outstanding immediately following this offering on ordinary shares outstanding as of , excluding:

- ordinary shares issuable upon the exercise of options outstanding as of December 31, 2016, at a weighted average exercise price of $ per share; and
- ordinary shares reserved for future grants under the Entera Bio Ltd. Share Incentive Plan, or the Plan.

Unless we specifically state otherwise, this prospectus reflects and assumes:

- no exercise of the outstanding options described above or warrants described below;
- no exercise by Centillion Fund, or Centillion, of the outstanding Centillion special pre-emptive rights provided for in our Fourth Amended and Restated Articles of Association currently in effect, or the current Articles, as described below in "Certain Relationships and Related Party Transactions";

- an initial public offering price of $ per share, which is the midpoint of the estimated offering price range on the cover page of this prospectus; and

- that the underwriters do not exercise their over-allotment option.

In addition, this prospectus reflects and assumes that a number of actions will be completed in connection with the closing of this offering, which we refer to as the "IPO Transactions." These actions include the following:

- the adoption of our Fifth Amended and Restated Articles of Association, or the amended Articles, immediately upon the closing of this offering, to replace the current Articles;

- a -for- split of our ordinary shares that will be effected immediately prior to the closing of this offering;

- the conversion of all of our issued and outstanding Series A Preferred Shares, par value NIS 0.01 per share, or the preferred shares, into of our ordinary shares upon the closing of this offering, as provided in our current Articles;

- the conversion of all outstanding convertible loans and warrants under the Convertible Financing Agreements to which we are a party into of our ordinary shares immediately prior to the closing of this offering, as described below in "Certain Relationships and Related Party Transactions";

- the issuance of the preferred shares and warrants to purchase of our ordinary shares to be issued to certain holders of our preferred shares upon the consummation of this offering, as described below in "Certain Relationships and Related Party Transactions," and the conversion into of our ordinary shares of all such preferred shares; and

- the automatic conversion of warrants to purchase of our preferred shares, at an exercise price of $ per share, into warrants to purchase of our ordinary shares, at an exercise price of $ per share, upon the closing of this offering, as described below in "Description of Share Capital—Warrants"; and

- additional warrants to purchase of our ordinary shares becoming exercisable following the closing of this offering, at an exercise price that will be discounted by 25% from the initial public offering price in this offering, or $, assuming an initial public offering price of $ per share, which is the midpoint of the estimated offering price range on the cover page of this prospectus.

SUMMARY FINANCIAL DATA

The following tables set forth summary financial and other data. You should read the following summary financial and other data in conjunction with "Presentation of Financial Information," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus. Historical results are not necessarily indicative of the results that may be expected in the future. Our financial statements have been prepared in accordance with IFRS as issued by the IASB.

The summary statements of comprehensive loss for each of the years in the two year period ended December 31, 2016 and the statement of financial position data as of December 31, 2016 are derived from our audited financial statements included elsewhere in this prospectus.

	Year Ended December 31,	
	2016	2015
	(In thousands, except shares and per share data)	
Statements of comprehensive loss:		
Research and development expenses	$ 2,648	$ 2,115
General and administrative expenses	2,719	1,586
Total operating loss	5,367	3,701
Financial (income) expenses:		
(Income) loss from change in fair value of financial liabilities at fair value	(4,311)	447
Other financial expenses, net	143	134
Financial (income) expenses, net	(4,168)	581
Net comprehensive loss	$ 1,199	$ 4,282
Loss per ordinary share (1)		
Basic	$ 35	$ 124
Diluted	$ 102	$ 124
Weighted average number of ordinary shares used in computing loss per share(1)		
Basic	34,409	34,396
Diluted	51,972	34,396
Pro forma loss per ordinary share (2) (unaudited)		
Basic	$	
Diluted	$	
Weighted average number of ordinary shares used in computing pro forma loss per share(2) (unaudited)		
Basic		
Diluted		

(1) Basic and diluted loss per ordinary share in 2015 is the same because the financial instruments as described in the financial statements are excluded from the calculation, since their effect was anti-dilutive. See Note 13 to our financial statements for further details on the calculation of basic and diluted loss per ordinary share.

(2) Pro forma basic and diluted loss per ordinary share gives effect to the assumed conversion of our outstanding convertible loans and preferred shares into ordinary shares upon the closing of this offering, including adjustment for the loss from the change in fair value of the convertible loans and preferred shares into ordinary shares, but not the exercise of any outstanding options or warrants, including those that will be issued immediately upon the consummation of this offering, as though the conversion had occurred as of the beginning of the period or the original date of issuance, if later. See Note 13 to our financial statements for further details on the calculation of basic and diluted pro forma loss per ordinary share.

	As of December 31, 2016		
	Actual	Pro Forma(1)	Pro Forma as Adjusted(2)
	(In thousands) (Unaudited)		
Statements of financial position data:			
Cash and cash equivalents	$ 4,163	$	$
Restricted deposits	1,075		
Other current assets	195		
Total current assets	5,433		
Property and equipment	199		
Intangible assets	654		
Total assets	$ 6,286	$	$
Accounts payable – Trade and other	657		
Short term convertible loans	9,885		
Total current liabilities	10,542		
Long-term convertible loans	4,835		
Preferred shares	11,031		
Warrants to purchase preferred shares and shares	4,800		
Liability to issue preferred shares and warrants	273		
Severance pay obligations, net	51		
Total liabilities	$ 31,532	$	$
Capital deficiency	$ (25,246)	$	$
Working capital (3)	$ (5,109)	$	$

(1) Pro forma amounts give effect to the IPO Transactions, as described in “Summary—The Offering.”

(2) Pro forma as adjusted amounts give effect to (a) the IPO Transactions and (b) our sale of ordinary shares at an assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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

RISK FACTORS

You should consider carefully the risks described below and all other information contained in this prospectus before you make a decision to invest in our ordinary shares. If any of the following risks actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of our ordinary shares could decline, and you might lose all or part of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

We are a research and development stage company with a history of operating losses and negative cash flow, and we may never achieve or maintain profitability.

We are a research and development stage company with no revenues from our research and development activities. Consequently, we have incurred net losses and negative cash flows since inception, including net losses of $4.3 million and $1.2 million for the years ended December 31, 2015 and 2016, respectively. As of December 31, 2016, we had an accumulated deficit of $30.6 million.

Our audited financial statements for the year ended December 31, 2016, included elsewhere in this prospectus, disclose our determination that there is substantial doubt about our ability to continue as a going concern, absent sources of additional liquidity. In order to fund further operations, we may need to raise capital in addition to the net proceeds of this offering. We may seek these funds through a combination of private and public equity offerings, debt financings, government grants, strategic collaborations and licensing arrangements. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. These conditions raise substantial doubt about our ability to continue as a going concern, and we will be required to raise additional funds, alternative means of financial support, or both, in order to continue operations. The accompanying financial statements have been prepared assuming that we will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty. If we are unable to raise the requisite funds, we will need to curtail or cease operations.

We currently have no product revenues and may not succeed in developing or commercializing any products that could generate revenues. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company. In addition, development of our product candidates requires a process of preclinical and clinical testing, during which our products could fail. We may not be able to enter into agreements with one or more companies experienced in the manufacturing and marketing of therapeutic drugs and, to the extent that we are unable to do so, we will not be able to market our product candidates. Our eventual profitability will depend on our success in developing, manufacturing, and marketing our product candidates, and we cannot assure you that we will be able to achieve profitability in the future.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. For example, our expenses could increase if we are required by the FDA, the EMA or other regulators to perform trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials or in the development of any of our product candidates.

To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages, including developing product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. 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 clinical development of our product candidates;
- obtaining marketing approvals for our product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for any approved product candidates 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 product candidates for which we obtain marketing approval, either directly or with a collaborator or distributor;
- establishing sales, marketing, and distribution capabilities in the United States;
- obtaining market acceptance of our product candidates as viable treatment options;
- 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;
- obtaining, maintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring and retaining qualified personnel.

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. Because of the numerous risks and uncertainties with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Even if this offering is successful, we will need substantial additional capital in order to satisfy our long-term growth strategy, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back, or cease our product development programs or operations.

Although we anticipate that our available resources, including proceeds from this offering, will be sufficient to meet our anticipated working capital needs for at least the next months, we will need to raise additional funds to support the execution of our long-term growth strategy. We may require substantial additional financing at various intervals in order to continue our research and development programs, including significant requirements for operating expenses including intellectual property protection and enforcement, pursuit of regulatory approvals, and commercialization of our products. We can provide no assurance that additional funding will be available on a timely basis, on terms acceptable to us, or at all. Because successful development of our product candidates is uncertain, we are unable to estimate the actual financing we will require to complete research and development and to commercialize our product candidates.

Our future financing requirements will depend on many factors, including but not limited to:

- the number and characteristics of other product candidates that we pursue;
- the scope, progress, timing, cost and results of research, preclinical development, and clinical trials;

- the costs, timing and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;
- the costs associated with manufacturing our product candidates and establishing sales, marketing, and distribution capabilities;
- the costs associated with obtaining, maintaining, expanding, defending and enforcing the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- the extent to which we acquire or in-license other products or technologies;
- our need and ability to hire additional management, scientific, and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- the amount and timing of revenues, if any, we receive from commercial sales of any product candidates for which we receive marketing approval in the future;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of achievement of milestones and receipt of any milestone or royalty payments under these agreements.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through a combination of public or private equity offerings, debt financings, strategic collaborations, and grant funding. If sufficient financing on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our development programs or our business operations or even go bankrupt.

Raising additional capital may cause dilution to our shareholders, including purchasers of ordinary shares in this offering, restrict our operations or require us to relinquish substantial rights.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, strategic collaborations and grant funding. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a holder of our ordinary shares. Debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. Further, we may incur substantial costs in pursuing future capital and/or financing, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which will adversely impact our financial condition.

In the past we have incurred indebtedness that may convert into equity securities, including our ordinary shares, upon the election of the lender or upon certain automatic triggering events. Any such conversion may cause our shareholders to experience substantial dilution of their ownership interest. In addition, if such convertible indebtedness is not converted before maturity upon the triggering events, we will be required to repay such indebtedness, which may adversely affect our liquidity. See “Dilution” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments—Convertible Loans.”

If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates, or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We began operations in 2010. Our operations to date have been limited to financing and staffing our company, developing our drug delivery technology and developing our product candidates. We have not yet demonstrated an ability successfully to complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

The requirements of being a public company may strain our resources and distract our management, which could make it difficult to manage our business, particularly after we are no longer an "emerging growth company."

Following the completion of this offering, we will be required to comply with various regulatory and reporting requirements, including those required by the Securities and Exchange Commission, or the SEC. Complying with these reporting and regulatory requirements will be time consuming, result in increased costs to us and could have a negative effect on our business, results of operations and financial condition.

As a public company, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the requirements of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act. These requirements may place a strain on our systems and resources. The Exchange Act requires that we file annual and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We will be implementing additional procedures and processes for the purpose of addressing the standards and requirements applicable to public companies. These activities may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

As an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, we may take advantage of certain temporary exemptions from various reporting requirements including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and the rules and regulations of the SEC thereunder. We will remain an "emerging growth company" until the earliest of: (a) the last day of our fiscal year during which we have total annual gross revenues of at least $1.07 billion; (b) the last day of our fiscal year following the fifth anniversary of the completion of this offering; (c) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs.

In addition, changing laws, regulations and standards, in the United States or Israel, relating to corporate governance and public disclosure and other matters, may be implemented in the future, which may increase our legal and financial compliance costs, make some activities more time consuming and divert management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. We also expect that being a publicly traded company in the United States and being subject to U.S. rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee, and qualified executive officers.

We manage our business and develop our technology with a small number of employees and key consultants, and in the event of their loss or unavailability we may not be able to grow our business or develop and commercialize our products.

We currently depend upon the efforts and abilities of our senior executives, including Dr. Phillip Schwartz, our Chief Executive Officer, and a small number of employees and key consultants. Our success depends upon the continued contributions of these senior executives, employees and consultants, many of whom have substantial scientific and technical experience with, and have been instrumental for, us and our technologies. The loss of our senior executives or senior scientists could delay our research and development activities. We do not maintain "key man" life insurance policies for any of our employees.

Recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. Competition for skilled personnel is intense and turnover rates are high, and our ability to attract and retain qualified personnel may be limited. The loss or unavailability of the services of any of these individuals for any significant period of time or our inability to attract and retain qualified skilled personnel could have a material adverse effect on our business, technology, prospects, financial condition and results of operations.

We will need to grow our organization, specifically to expand our clinical development and regulatory capabilities, and we may experience difficulties in managing this growth, which could disrupt our operations.

As our clinical development and commercialization plans and strategies develop, we expect to expand our employee base for development, regulatory, managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of senior executives, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, we may need to divert a disproportionate amount of their 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, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced and we may not be able to implement our strategy. Our future financial performance and our ability to develop our product candidates and compete effectively with others in our industry will depend, in part, on our ability to effectively manage any future growth.

Risks Related to the Clinical Development of Our Product Candidates

All of our product candidates are in preclinical or clinical development. Clinical drug development is expensive, time consuming and uncertain, and we may ultimately not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, European Union, and EU Member State legislators and agencies, such as the European Medicines Agency, or EMA, and other non-U.S. regulatory authorities, which enforce regulations that differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval of a biologics license application, or BLA, from the FDA or in any other country until we receive marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in drug development. We have not submitted an application, or received marketing approval, for any of our product candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA or the EMA. Obtaining approval of a BLA or other marketing application can be a lengthy, expensive and uncertain process.

At present, our lead product candidate is EB612, our oral PTH (1-34) tablet, which is under development for the treatment of hypoparathyroidism. We are also developing EB613, a distinct oral PTH (1-34) product candidate, with significant modifications to dose and formulation, for the treatment of osteoporosis. Each of our oral PTH product candidates, including EB612 and EB613, are in an early stage of clinical development and face a variety of risks and uncertainties, including the following:

- future clinical trial results may show that our oral PTH (1-34) is not effective for many reasons, including if our drug delivery technology is not effective, our product candidates are not effective, our clinical trial designs are flawed or clinical trial subjects do not comply with trial protocols;

- our product candidates may not be well tolerated or may cause negative side effects;

- our ability to complete the development and commercialization of our oral PTH for our intended uses may be significantly dependent upon our ability to obtain and maintain experienced and committed collaborators to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of, our oral PTH;

- even if our oral PTH is shown to be safe and effective for its intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities or at reasonable prices;

- even if our oral PTH is successfully developed, commercially produced and receives all necessary regulatory approvals, there is no guarantee that there will be market acceptance;

- even if our oral PTH is successfully developed, commercially produced and receives all necessary regulatory approvals for the treatment of hypoparathyroidism, there is no guarantee that we will successfully develop and commercialize it for other indications, including osteoporosis and nonunion fractures; and

- our competitors may develop therapeutics or other treatments that are superior to or less costly than our own with the result that our products, even if they are successfully developed, manufactured and approved, may not generate significant revenues.

If we are unsuccessful in dealing with any of these risks, or if we are unable to successfully commercialize our oral PTH for some other reason, it would likely have a material adverse effect on our business, prospects, financial condition and results of operations. In addition, in the event we are able to successfully commercialize our oral PTH, we may sell the tablets at a discounted sales price for the initial period in order to gain market acceptance of the product, which could adversely affect our financial condition and results of operations.

The commencement and completion of clinical trials can be delayed or prevented for a number of reasons.

We expect to initiate a Phase 2b/3 clinical trial of EB612 in hypoparathyroidism in the first quarter of 2018 and we plan to submit applications for regulatory approval of EB612 in the first half of 2020. For osteoporosis we intend to commence a Phase 2a clinical trial of EB613 in the fourth quarter of 2017 and an additional Phase 2b clinical trial in the United States in 2018. We also plan to conduct clinical trials of a formulation of oral PTH for the treatment of non-union fractures. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Clinical trials can be delayed or prevented for a number of reasons, including:

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;

- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, contract manufacturing organizations, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly;
- failure of our third-party contractors, such as contract research organizations and contract manufacturing organizations, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;
- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- difficulties obtaining institutional review board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site;
- the FDA, EMA or other regulatory authority requiring alterations to any of our study designs, our pre-clinical strategy or our manufacturing plans;
- various challenges recruiting and enrolling subjects to participate in clinical trials, including size and nature of subject population, proximity of subjects to clinical sites, eligibility criteria for the trial, budgetary limitations, nature of trial protocol, change in the readiness of subjects to volunteer for a trial, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- difficulties in maintaining contact with subjects after treatment, which results in incomplete data;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and
- varying interpretations of data by the FDA and foreign regulatory agencies.

Changes in regulatory requirements and guidance may also occur and we may need to significantly amend clinical trial protocols or submit new clinical trial protocols with appropriate regulatory authorities to reflect these changes. Amendments may require us to renegotiate terms with contract research organizations, or CROs, or resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB or ethics committee overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us, due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- unforeseen issues, including serious adverse events associated with a product candidate, or lack of effectiveness or any determination that a clinical trial presents unacceptable health risks;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions; and
- upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates.

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

If we do not succeed in conducting and managing our preclinical development activities or clinical trials, or in obtaining regulatory approvals, we might not be able to commercialize our product candidates, or might be significantly delayed in doing so, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

The results of previous clinical trials may not be predictive of future results, our progress in trials for one product candidate may not be indicative of progress in trials for other product candidates, and our trials may not be designed so as to support regulatory approval.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or preclinical testing. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future larger clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials. Similarly, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Progress in trials of one product candidate does not indicate that we will make similar progress in additional trials for that product candidate or in trials for our other product candidates. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

The design of a clinical trial can determine whether its results will support approval of a product. We may be unable to design and/or execute a clinical trial to support regulatory approval. Flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, we may have little control over whether subjects comply with important aspects of clinical trial protocols. In particular, in trials of our oral PTH, if subjects do not comply with restrictions on eating and drinking before and after administration of our product candidates, interaction between the drug and food in the gastrointestinal tract, or a “food effect,” may decrease the bioavailability and increase the variability of drug delivered to the subject, which may negatively affect efficacy.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols, modifications in the formulation throughout the course of development and the rate of dropout among clinical trial participants. While our oral PTH product candidates have exhibited negligible safety issues in our clinical trials to date, we may need to change future trial design in response to adverse events that occur during future clinical development. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be materially adversely affected.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of subjects. Trials may be subject to delays as a result of enrollment taking longer than anticipated or subject withdrawal. Enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for

the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies. Our product candidate EB612 has orphan drug designation for the treatment of hypoparathyroidism, which means that the potential patient population is limited. In addition, there may be other marketed drugs or drugs in development for hypoparathyroidism, and we may compete for patients with such marketed drugs, such as Natpara, or the sponsors of trials for drugs in development. These factors may make it difficult for us to enroll enough subjects to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may not be successful in our efforts to use and expand our drug delivery technology to other product candidates.

A key element of our strategy is to use and expand our oral drug delivery technology platform to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of a variety of different types of diseases. Our strategy is to focus on the development of our oral drug delivery technology in combination with a known active pharmaceutical ingredient, or API, to validate our platform and potentially minimize risk and development timelines. We intend, by utilizing this approach, to both validate and enhance the credibility of our platform. We intend to use our technology as a platform for the oral delivery of other protein and large molecule APIs.

Our initial product candidates combine our oral drug delivery technology with PTH, a hormone that has been used in injectable form for many years for osteoporosis. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for, and successfully commercialize our oral PTH product candidates in a timely manner. If we are unable to validate our oral drug delivery technology with our PTH product candidates, in particular our lead candidate EB612, we may be unsuccessful in leveraging our oral drug delivery technology for use with other APIs. In addition, we must significantly modify the formulation of EB612 to develop new formulations for applications in osteoporosis and other indications. If we are not successful in optimizing the formation of our PTH product candidates for additional indications, or if we are not otherwise able to obtain regulatory approval for them or successfully commercialize them, our business and prospects may be severely limited due to the small size of the population with hypoparathyroidism.

In addition, our technology makes use of synthetically bioengineered ingredients. Our oral PTH is a synthetic form of the first 34 amino acids of human PTH to which we have applied our proprietary drug delivery technology. Although our product candidates utilize a synthesized PTH molecule that has clinically proven efficacy, known mechanism of action and an established safety profile, they may cause patients to exhibit safety or immune responses that do not match the biological effect of a human protein. Such responses could result in increased regulatory scrutiny, delays or other impediments to our planned development or the public acceptance and commercialization of our products.

Even if we are successful in expanding our drug delivery technology to other APIs for other indications, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. We may never successfully develop or commercialize our technology with other APIs, which could limit our business and prospects.

Our product candidates may have serious adverse, undesirable or unacceptable side effects that may delay or prevent marketing approval. If any such side effects are identified during the development of our product candidates or following any regulatory approval, we may need to abandon our development of such product candidates, any approved label may be limited or we may be subject to other significant negative consequences following regulatory approval.

Although all of our product candidates have undergone or will undergo safety testing to the extent possible and agreed with health authorities, not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if such side effects are more rare, after our product candidates have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. All of our product candidates are still in clinical or preclinical development. While our oral PTH has exhibited negligible safety issues in our clinical trials to date, the results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA, the EMA and other regulatory authorities, or result in marketing approval from the FDA, the EMA and other regulatory authorities with restrictive label warnings or potential product liability claims. For instance, other PTH products have been issued with labels that disclose a potential risk of osteosarcoma.

If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

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

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. As such, we are currently primarily focused on the development of EB612 and EB613 for the treatment of hypoparathyroidism and osteoporosis, respectively. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular compounds, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected.

Risks Related to Regulatory Approval of Our Product Candidates

Obtaining regulatory approval even after clinical trials that are believed to be successful is an uncertain process.

Even if we complete our planned clinical trials and believe the results to be successful, all of which are uncertain, obtaining regulatory approval is an extensive, lengthy, expensive and uncertain process, and the FDA, EMA and other regulatory agencies may delay, limit or deny approval of our oral PTH for many reasons, including:

- we may not be able to demonstrate to the satisfaction of the FDA, EMA or other regulatory agencies that our oral PTH is safe and effective for any indication;
- the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA, EMA or other regulatory agencies for approval;
- the FDA, EMA or other regulatory agencies may require that EB613 meet additional requirements to obtain regulatory approval for the treatment of osteoporosis, a much larger indication than hypoparathyroidism;
- the FDA, EMA or other regulatory agencies may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA, EMA or other regulatory agencies may not find the data from pre-clinical studies and clinical trials sufficient to demonstrate that our oral PTH's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or other regulatory agencies may disagree with our interpretation of data from pre-clinical studies or clinical trials, or may not accept data generated at our clinical trial sites;
- the FDA, EMA or other regulatory agencies may not recognize a synthesized molecule like the synthesized PTH molecule that is used in our oral PTH formulation;
- the data collected from pre-clinical studies and clinical trials of our oral PTH may not be sufficient to support the submission of an application for regulatory approval;
- the FDA may have difficulties scheduling an advisory committee meeting in a timely manner, or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling, or distribution and use restrictions;
- the FDA may require development of a risk evaluation and mitigation strategy as a condition of approval;
- the FDA, EMA or other regulatory agencies may identify deficiencies in the manufacturing processes or facilities of third party manufacturers with which we enter into agreements for clinical and commercial supplies;
- the FDA, EMA or other regulatory agencies may change their approval policies or adopt new regulations; and
- the FDA, EMA or other regulatory agencies may require simultaneous approval for both adults and for children and adolescents delaying needed approvals, or we may have successful clinical trial results for adults but not children and adolescents, or vice versa.

Before we can submit an application for regulatory approval in the United States, we must conduct a pivotal trial that will be substantially broader than our completed Phase 2a trial. We will also need to agree on a protocol with the FDA for a clinical trial before commencing the trial. Phase 3 clinical trials frequently produce

unsatisfactory results even though prior clinical trials were successful. Therefore, even if the results of our Phase 2 trials are successful, the results of the additional trials that we conduct may or may not be successful. Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials. The FDA, the EMA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. Moreover, there is no FDA guidance on the acceptable level of variability in orally delivered products with large molecule APIs, and, therefore we are unable to be certain that we are designing our product candidates or clinical trials to satisfy the FDA in this regard. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical trial. The FDA, EMA or other regulatory agencies may require that we conduct additional clinical, nonclinical, manufacturing validation or drug product quality studies and submit those data before considering or reconsidering the application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA, EMA or other regulatory agencies. If any of these outcomes occur, we would not receive approval for our oral PTH (1-34) tablet.

In addition, the FDA, EMA or other regulatory agencies may also approve a product candidate for fewer or more limited indications than we request, may impose significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications or may grant approval contingent on the performance of costly post-marketing clinical trials or risk mitigation requirements. The FDA, EMA or other regulatory agencies may not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

In order to obtain FDA approval for EB612 prior to the expiration of Natpara's orphan drug exclusivity in 2022, we need to show that EB612 is clinically superior to Natpara. Moreover, although we have obtained orphan drug designation for EB612 for the treatment of hypoparathyroidism, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the drug for the disease or condition will be recovered from sales of the drug in the United States. In the European Union, the European Commission may designate a product candidate as an orphan medicinal product if it is a medicine for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affects not more than five in 10,000 persons in the European Union, or it is unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development and no satisfactory method of diagnosis, prevention or treatment of the condition concerned is authorized, or, if such method exists, that the medicinal product will be of significant benefit to those affected by the condition .. We have received orphan drug designation for oral PTH for the treatment of hypoparathyroidism from the FDA, but orphan drug designation may not ensure that we have market exclusivity in a particular market and there is no assurance we will be able to receive orphan drug designation for any additional product candidates. Further, the granting of a request for orphan drug designation does not alter the standard regulatory requirements and process for obtaining marketing approval.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which, subject to certain exceptions, precludes the FDA from approving another drug with the same active moiety for the same indication for that time period or precludes the EMA, and other national drug regulators in the European Union, from accepting the marketing application for a similar medicinal product for the same indication. The applicable period is seven years in the United States and ten years in the European Union. The EU period can be reduced to six years if, at the end of the fifth year of marketing exclusivity, a product no longer meets the criteria for orphan drug designation, for instance if the product is sufficiently profitable so that market exclusivity is no longer justified. In the European Union, orphan exclusivity may also be extended for an additional two years (i.e., a maximum of 12 years' orphan exclusivity) if the product is approved on the basis of a dossier that includes pediatric

clinical trial data generated in accordance with an approved pediatric investigation plan. Orphan drug exclusivity may be lost in the United States if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Orphan drug exclusivity may not effectively protect the product from competition because exclusivity can be suspended under certain circumstances. In the United States, even after an orphan drug is approved, the FDA can subsequently approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, orphan exclusivity will not prevent a marketing authorization being granted for a similar medicinal product in the same indication if the new product is safer, more effective or otherwise clinically superior to the first product or if the marketing authorization holder of the first product is unable to supply sufficient quantities of the product.

We believe that our key competitor in hypoparathyroidism treatment is Shire plc, whose product Natpara, an injectable bioengineered synthetic form of PTH (1-84), was approved by the FDA in January 2015. Natpara has been granted orphan drug designation for hypoparathyroidism by the FDA and, as the first approved product for this indication, has orphan drug market exclusivity for seven years in the United States and, if Natpara is approved by the EMA, ten years after receipt of market approval in the European Union. Therefore, we will only be able to obtain regulatory approval for EB612 prior to expiration of Natpara's orphan exclusivity period in the United States, which expires in January 2022, if we demonstrate EB612's clinical superiority over Natpara in that it demonstrates greater effectiveness or safety than Natpara or that it otherwise makes a major contribution to patient care. We believe that we will be able to demonstrate to the satisfaction of the FDA and EMA that our formulation of PTH is clinically superior to Natpara, and therefore we do not believe that the FDA or EMA will be precluded from approving a marketing application prior to Natpara's expiration of orphan exclusivity, but there can be no assurance that we will be able to demonstrate that EB612 is clinically superior to Natpara under the applicable FDA and EMA standards and obtain regulatory approval, even if EB612 would otherwise satisfy each regulator's standards for approval.

Even if we obtain regulatory approval of EB612, we may not enjoy the benefits of our orphan designation for EB612 for hypoparathyroidism. For example, even if we were to overcome Natpara's exclusivity, regulatory approval of EB612 would not create exclusivity vis-a-vis Natpara, and we would still have to compete with Natpara for market acceptance and on other factors that contribute to commercial success, such as reimbursement. Moreover, even if we obtain orphan drug exclusivity for EB612 vis-à-vis other products in development, that exclusivity may not effectively protect EB612 from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Even if regulatory approvals are obtained for our product candidates, we will be subject to ongoing government regulation. If we fail to comply with applicable current and future laws and government regulations, it could delay or prevent the promotion, marketing or sale of our products.

Even if marketing approval is obtained, a regulatory authority may still impose significant restrictions on a product's indications, conditions for use, distribution or marketing or impose ongoing requirements for potentially costly post-market surveillance, post-approval studies or clinical trials, all of which may result in significant expense and limit our ability to commercialize our products. Our products will also be subject to ongoing requirements governing the labeling, packaging, storage, advertising, distribution, promotion, recordkeeping and submission of safety and other post-market information, including adverse events, and any changes to the approved product, product labeling or manufacturing process. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practice, or cGMP, requirements and other regulations.

If we, our drug products or the manufacturing facilities for our drug products fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products or request that we initiate a product recall; or
- refuse to allow us to enter into supply contracts, including government contracts.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, and compliance with such regulation may be expensive and consume substantial financial and management resources. If we or any future marketing collaborators or contract manufacturers are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies or are not able to maintain regulatory compliance, it could delay or prevent the promotion, marketing or sale of our products, which would adversely affect our business and results of operations.

Healthcare legislative changes may harm our business and future prospects.

Healthcare costs have risen significantly over the past decade. Globally, governments are becoming increasingly aggressive in imposing health care cost-containment measures. Certain proposals, if passed, would impose limitations on the prices we will be able to charge for the products that we are developing, or the amounts of reimbursement available for these products from governmental agencies or third-party payors. These limitations could in turn reduce the amount of revenues that we will be able to generate in the future from sales of our products and licenses of our technology.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA changed the way Medicare covers and pays for pharmaceutical products. The MMA expanded Medicare coverage for outpatient drug purchases by those covered by Medicare under a new Part D and introduced a new reimbursement methodology based on average sales prices for Medicare Part B physician-administered drugs. In addition, the MMA authorized Medicare Part D prescription drug plans to limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of the MMA could decrease the coverage and price that we receive for any approved products and could seriously harm our future business prospects. While this law applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from this law may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Affordable Care Act, among other

things, increased rebates a manufacturer must pay to the Medicaid program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, established a new Medicare Part D coverage gap discount program, in which manufacturers must provide 50% point-of-sale discounts on products covered under Part D and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance were enacted, which may affect our business practices with health care practitioners. The ACA appears likely to continue the pressure on pharmaceutical pricing and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year effective April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025, unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

President Trump and the majorities of both houses of Congress have stated their intention to repeal and replace the ACA. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In May 2017, the House of Representatives voted to pass the American Healthcare Act of 2017, which repeals certain portions of the ACA and adds material new provisions. On June 22, 2017, the Senate introduced its own healthcare reform bill. Considerable uncertainty remains about whether the Senate bill will pass or how it will be reconciled with the House version, and if it does and President Trump signs it into law, about the ultimate content, timing or effect of any healthcare reform legislation on us, our industry or the market for drug products like ours. Though the full future impact of the new administration and the U.S. Congress on our business remains unclear, legislative and regulatory changes may continue the downward pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

Both in the United States and in the European Union, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

Our relationships with customers and payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, primarily in the United States, that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, 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;

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;

- the federal transparency requirements under the Affordable Care Act requires certain manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and the ownership and investment interests of such physicians or their family members;

- the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which requires specified manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians. All such reported information is publicly available;

- analogous state and non-U.S. laws and regulations, such as certain state anti-kickback and false claims laws which 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 industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; 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; and

- regulation by the Centers for Medicare and Medicaid Services and enforcement by the U.S. Department of Health and Human Services (Office of Inspector General) or the U.S. Department of Justice.

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 future business activities could be subject to challenge under one or more of such laws.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to Commercialization of Our Product Candidates

We are likely to face significant competition, and if our competitors' products are more effective, safer or less expensive than ours, our commercial opportunities will be negatively affected. Our lead product candidates, if approved, would compete with existing products.

Our industry is highly competitive and subject to rapid and significant technological change. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from many different sources, including large pharmaceutical, specialty pharmaceutical, biotechnology and generic drug companies and academic and government institutions. These organizations may have significantly greater resources than we do and conduct similar research, seek and obtain patent protection that may impact our freedom to operate and establish collaborative arrangements for research, development, manufacturing and marketing of products that compete with our product candidates. We believe that the key competitive factors that will affect the development and commercial success of our oral PTH product candidates, and any other product candidates that we develop, are efficacy, safety and tolerability profile, convenience in dosing, product labeling, price and availability of reimbursement from the government and other third-parties. Our commercial opportunity could be reduced or eliminated if our competitors have products that are better in one or more of these categories. Furthermore, our competitors may, among other things: develop and commercialize products that are safer, more effective, less expensive, or more convenient or easier to administer; obtain quicker regulatory approval; establish superior proprietary positions; have access to more manufacturing capacity; implement more effective approaches to sales and marketing; or form more advantageous strategic alliances.

Our primary innovation is our development of an oral drug delivery technology for large peptides, protein and other large molecules. If another company develops an alternative technology for oral delivery of such molecules that is equal to or better than our technology, we may be unable to compete.

We believe that our key competitor in hypoparathyroidism treatment is Natpara. If we obtain regulatory approval for EB612, it will compete with Natpara, which by that time will have been marketed for several years and may have wide-spread market acceptance that may be difficult to overcome. See "—In order to obtain FDA approval for EB612 prior to the expiration of Natpara's orphan drug exclusivity in 2022, we need to show that EB612 is clinically superior to Natpara. Moreover, although we have obtained orphan drug designation for EB612 for the treatment of hypoparathyroidism, we may be unable to maintain the benefits associated with orphan drug

designation, including the potential for market exclusivity." In addition, Ascendis Pharma has reported that it is developing a long-acting, oral prodrug formulation of PTH for the treatment of hypoparathyroidism. Ascendis' oral PTH product is currently in preclinical development, and Ascendis has reported that it plans to initiate a Phase 1 trial for the drug in the third quarter of 2017.

The osteoporosis market is already served by a variety of competing products based on a number of APIs. Many of these existing products have achieved widespread acceptance among physicians, patients and payors for the treatment of osteoporosis. The market has been dominated by bisphosphonates for many years, although bisphosphonates' market share has declined due to the occurrence of serious side effects, as well as the introduction of newly developed pharmacological treatments. Many of the new drugs have serious side effects of their own. Eli Lilly's Forteo, an injectable PTH (1-34), is one of the most effective osteoporosis medications. We anticipate that our product candidate EB613, if approved, will compete with Forteo and the rest of the pharmacological treatments for osteoporosis. Many of these products are available on a generic basis, and EB613 may not demonstrate sufficient additional clinical benefits to physicians, patients or payors to justify a higher price compared to generic products. In many cases, insurers or other third-party payors, particularly Medicare, seek to encourage the use of generic products. Furthermore, our competitors in this market are large pharmaceutical companies and the alternatives have been on the market for many years and have widespread market acceptance.

We are subject to manufacturing risks that could substantially increase our costs and limit supply of our products.

The process of manufacturing our products is complex, highly regulated and subject to several risks, including:

- We do not have experience in manufacturing our product candidates at commercial scale. We may not succeed in the scaling up of our process. We may need a larger-scale manufacturing process for our oral PTH than what we have planned, depending on the dose and regimen that will be determined in future studies. Any changes in our manufacturing processes as a result of scaling up may result in the need to obtain additional regulatory approvals. Difficulties in achieving commercial-scale production or the need for additional regulatory approvals as a result of scaling up could delay the development and regulatory approval of our product candidates and ultimately affect our success. Contract manufacturers may not have sufficient expertise to manufacture a dry oral formulation with a large molecule API, in which case we may have to establish our own commercial manufacturing capabilities, which could be expensive and delay launch of product candidates.

- The manufacturing process for biologics is more complex and subject to greater regulation than that of other drugs. The process of manufacturing biologics, such as our product candidates, is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

- The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

- We must comply with applicable current cGMP, regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize

our product candidates, including leading to significant delays in the availability of drug product for our clinical trials or the termination or hold on a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

- Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

- Our product candidates that have been produced and are stored for later use may degrade, become contaminated or suffer other quality defects, which may cause the affected product candidates to no longer be suitable for their intended use in clinical trials or other development activities. If the defective product candidates cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of such product candidates.

We currently have no sales, marketing or distribution infrastructure. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely affect the commercialization of our products. If we enter into collaborations to market and sell any approved products, our revenue may be lower and we will be dependent on the efforts of a third party.

We have not yet established sales, marketing or distribution operations because our product candidates are in early clinical development. Prior to receiving regulatory approval for EB612, we plan to build a focused sales and marketing organization in the United States and other jurisdictions where we anticipate obtaining approval to sell EB612. This would be expensive and time consuming. If we elect to fund and undertake commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. In addition, the costs of establishing sales and marketing operations may be incurred in advance of any approval of our product candidates. Moreover, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely affect the commercialization of our products.

Alternatively, we may consider entering into a collaboration to commercialize EB612, and we anticipate seeking a collaborator to develop EB613 and that any such collaborator would be responsible for, or substantially support, late stage clinical trials of EB613 as well as regulatory approvals and registrations. These arrangements are typically complex and time consuming to negotiate. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed and sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third-party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Even if approved, if any of our product candidates do not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, our revenue generated from their sales will be limited.

The commercial success of our product candidates will depend upon their acceptance among physicians, patients and the medical community. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- limitations or warnings contained in the approved labeling for a product candidate;
- changes in the standard of care for the targeted indications for any of our product candidates;
- limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability and extent of coverage and reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness of our product candidates;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;
- the extent to which the product candidate is approved for inclusion on formularies of hospitals and third-party payors, including managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular diseases;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- convenience and ease of administration of our products; and
- potential product liability claims.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients and the medical community, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, 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.

Even if we obtain regulatory approval of any of our product candidates in a major pharmaceutical market such as the United States or the European Union, we may never obtain approval or commercialize our products in other major markets, which would limit our ability to realize their full market potential.

In order to market any products in a country or territory, we must establish and comply with numerous and varying regulatory requirements of such countries or territories regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in all major markets could result in significant delays, difficulties and costs

for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and third-party payors establish adequate coverage and reimbursement levels and pricing policies.

The successful commercialization of our product candidates, if approved, will depend, in part, on the extent to which coverage and reimbursement for our products will be available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new technologies and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. In light of such challenges to prices and increasing levels of evidence of the benefits and clinical outcomes required of new technologies, we cannot be sure that coverage will be available for our oral PTH product candidates or any other product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. If we are unable to obtain adequate levels of coverage and reimbursement for our product candidates, their marketability will be negatively and materially impacted.

Third party payors may deny coverage and reimbursement status altogether of a given drug product, or cover the product but establish prices at levels that are too low to enable us to realize an appropriate return on our investment in product development. Because the coverage and reimbursement policies may change frequently, in some cases at short notice, even when there is favorable coverage and reimbursement, future changes may occur that adversely impact the favorable status. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

The unavailability or inadequacy of third-party coverage and reimbursement could have a material adverse effect on the market acceptance of our product candidates and the future revenues we may expect to receive from those products. In addition, we are unable to predict what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage; and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently we have no products that have been approved for commercial sale; however, the current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, our collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Although we maintain limited product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Dependence on Third Parties

We are highly dependent upon our ability to enter into agreements with collaborators to develop, commercialize and market our products.

We may enter into collaborations with third parties that we believe could provide us with valuable funding and other benefits. For example, we anticipate seeking a collaborator to develop EB613 for osteoporosis and that any such collaborator would be responsible for, or substantially support, late stage clinical trials of EB613 as well as regulatory approvals and registrations.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or similar regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay potential commercialization of a product candidate or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities ourselves, we may not be able to further develop our product candidates or bring them to market or continue to develop our technology platforms and our business may be materially and adversely affected.

Any collaboration we enter into may pose a number of risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

- collaborations may be terminated for convenience by the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates, we may suffer from negative publicity and we may find it more difficult to attract new collaborators.

All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of any of our future program collaborators.

We may not be able to secure and maintain research institutions to conduct our clinical trials.

We rely on research institutions to conduct our clinical trials. Specifically, the limited number of centers experienced with pharmaceutical product candidates heightens our dependence on such research institutions. Our reliance upon research institutions, including hospitals and clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects. If we are unable to reach agreements with suitable research institutions on acceptable terms, or if any resulting agreement is terminated, we may be unable to quickly replace the research institution with another qualified institution on acceptable terms. Furthermore, we may not be able to secure and maintain suitable research institutions to conduct our clinical trials.

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

We expect to continue to depend on independent clinical investigators and CROs to conduct our clinical trials. CROs may also assist us in the collection and analysis of data. There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. These investigators and CROs will not be our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Further, the FDA and other regulatory authorities require that we comply with standards, commonly referred to as Good Clinical Practice, or GCP, requirements for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable regulatory authorities may require us to perform additional clinical trials 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 trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Failure of clinical investigators or CROs to meet their obligations to us or comply with GCP procedures could adversely affect the clinical development of our product candidates and harm our business.

We contract with third parties for the supply of materials used in drug formulation for clinical testing and expect to contract with third parties for the manufacturing of our product candidates for large-scale testing. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We anticipate continuing our engagement of third parties to provide our clinical supply as we advance our product candidates into and through clinical development. We expect in the future to use third parties for the manufacture of our product candidates for clinical testing, as well as for commercial manufacture. We plan to enter into long-term supply agreements with several manufacturers for commercial supplies. We may be unable to reach agreement on satisfactory terms with contract manufacturers to manufacture our product candidates. Additionally, the facilities to manufacture our product candidates must be the subject of a satisfactory inspection before the FDA, the EMA or other regulatory authorities approve a BLA or grant a marketing authorization for the product candidate manufactured at that facility. We will depend on these third-party manufacturers for compliance with the FDA's and the EMA's requirements for the manufacture of our finished products. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with cGMPs. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA, European Commission and other regulatory authorities' cGMP requirements, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved, and may subject us to recalls or enforcement action for products already on the market.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- the possibility of a breach of the manufacturing agreements by the third parties because of factors beyond our control;

- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer; and

- the possibility that we may not be able to secure a manufacturer or manufacturing capacity in a timely manner and on satisfactory terms in order to meet our manufacturing needs.

Any of these factors could cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA, the EMA or any other relevant regulatory authorities.

Risks Related to Our Intellectual Property

If we fail to establish, maintain, defend and enforce intellectual property rights with respect to our technology, our business, prospects, financial condition and results of operations may be materially adversely affected.

Our success depends in large part on our ability to obtain and maintain protection with respect to our intellectual property and proprietary technology. Our product candidates utilize our proprietary technology relating to the oral delivery of large molecules for the treatment of certain conditions with oral PTH. We seek to protect our proprietary position by filing patent applications in the United States and certain foreign jurisdictions relating to our product candidates and technologies that are important to our business. This process is expensive, complex 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. If we do not adequately obtain, maintain, protect and enforce our proprietary rights in our technologies, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our business and our ability to achieve profitability.

We have limited patent protection with respect to our product candidates and technologies. We have been issued a patent that contains claims directed to compositions comprising a protein, an absorption enhancer and a protease inhibitor, as well as methods for oral administration of a protein with an enzymatic activity in each of the United States, Australia, Japan, China, Israel, Canada, New Zealand and Russia. Related patent applications are pending in the United States, the European Union, Hong Kong, Brazil, India, Israel and Russia. We have also filed five Patent Cooperation Treaty (PCT) applications (with a sixth application expected to be filed in August 2017), that currently contain claims directed to oral administration technologies, including compositions and drug delivery devices utilizing an absorption enhancer and methods of treating osteoporosis, hypoparathyroidism and bone fractures and related conditions with orally administered parathyroid hormone. We cannot be certain that patents will be issued or granted with respect to any of our pending or future patent applications, or that issued or granted patents will not later be found to be invalid or unenforceable. The patent position of pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably, and can change. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in pharmaceutical or biotechnology patents. Even if our pending patent applications issue as patents, such patents may not cover our product candidates in the United States or in other countries. Accordingly, we cannot predict whether additional patents protecting our technology will issue in the United States or in non-U.S. jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide us with a competitive advantage.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing technology and products similar or identical to ours, or limit the duration of the patent protection covering our technology and product candidates. In addition, patents have a limited lifespan. In the United States and most foreign jurisdictions, the natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available; however, the life of a patent and the protection it affords is limited. For example, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the useful patent term lost, if any, during the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product's approval by the FDA, only one patent applicable to an approved drug is eligible for the extension, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. We may not be granted an extension because we may fail to satisfy applicable requirements and even if we are granted an extension, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, if we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. Even if patents covering our product candidates are obtained, once such patents expire, we may be vulnerable to competition from similar or generic products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, we cannot provide any assurance that any of our issued patents or any patents that may issue to us in the future will provide sufficient protections for our technology or product candidates, in whole or in part, or will effectively prevent competitors from commercializing similar or identical technologies and products.

Our issued patents may not be sufficient to provide us with a competitive advantage. For example, competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. We may also grant licenses under our intellectual property that may limit our ability to exploit such intellectual property. For example, we are party to a patent transfer agreement with Oramed Ltd., or the Patent Transfer Agreement, pursuant to which we have granted Oramed Ltd. an exclusive, worldwide, royalty-free, irrevocable and perpetual license, with the right to sublicense, under certain of our patent rights to develop, manufacture and commercialize covered products or otherwise exploit such patent rights in the fields of diabetes and influenza and we have agreed not to, directly or indirectly, engage in any activities within the fields of diabetes and influenza. Even if such agreement were to be terminated, Oramed Ltd. would retain its exclusive license under such patent rights.

In the future, we may enter into collaborative agreements or license agreements with third parties which may subject us to obligations that must be fulfilled and require us to manage complex relationships with third parties. If we are unable to meet our obligations or manage our relationships with our collaborators under these agreements, our revenue may decrease. From the standpoint of our future strategic collaborators, the strength of the intellectual property under which we may grant licenses can be a determinant of the value of these relationships. If we are unable to secure, protect and enforce our intellectual property, it may become more difficult for us to attract strategic collaborators. The loss or diminution of our intellectual property rights could also result in a decision by future third-party collaborators to terminate their agreements with us. In addition, these agreements may be complex and may contain provisions that could give rise to legal disputes, including potential disputes concerning financial obligations or ownership of intellectual property and data under such agreements. Such disputes can lead to lengthy, expensive litigation or arbitration, requiring us to divert management time and resources to such dispute. Any such development could have a material adverse effect on our business, prospects, financial condition and results of operations.

We may become involved in proceedings to protect or enforce our proprietary rights, which could be expensive, time consuming and unsuccessful.

Competitors or other third parties may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property rights. To counter infringement or other violations, we may be required to file claims, which can be expensive and time consuming. Any such claims could provoke these parties to assert counterclaims against

us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable. 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. Third parties may also raise challenges to the validity of our patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review and *inter partes* review proceedings and equivalent proceedings in foreign jurisdictions such as opposition proceedings. If third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO, to determine priority of invention for patent applications filed before March 16, 2013, or in derivation proceedings to determine inventorship for patent applications filed after such date. Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our product candidates or provide us with any competitive advantage.

In addition, we may be subject to third-party challenges regarding our exclusive ownership of our intellectual property. If a third party were successful in challenging our exclusive ownership of any of our intellectual property, we may lose our right to use such intellectual property, such third party may be able to license such intellectual property to other third parties, including our competitors, and third parties could market competing products and technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. We may face claims that we are violating the intellectual property rights of others.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or other proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and future approved products or impair our competitive position. We may face claims, including from direct competitors, asserting that the commercial use of our technology infringes or otherwise violates the intellectual property rights of others. We cannot be certain that our technologies and processes do not violate the intellectual property rights of others. Third parties may assert infringement claims against us based on existing or future intellectual property rights. We expect that we may increasingly be subject to such claims as our product candidates approach commercialization, and as we gain greater visibility as a public company. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses. Thus, we do not know with certainty that our oral PTH (1-34) tablet or any other product candidate, or our commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property.

If we were found to infringe or otherwise violate the intellectual property rights of others, we could face significant costs to implement work-arounds, and we cannot provide any assurance that any such work-around would be available or technically equivalent to our current technology. In such cases, we might need to license a third party's intellectual property, and such required licenses might not be available on acceptable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could expose us to similar liabilities and have a similar negative impact on our business.

The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally, and these lawsuits can be very time consuming and costly. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be successful in doing so. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in defending these proceedings, which could have a material adverse effect on our business.

Also, to the extent that our agreements provide that we will defend and indemnify our suppliers, service providers, future strategic collaborators or any other party for claims against them relating to any alleged infringement of the intellectual property rights of third parties in connection with such suppliers', service providers', strategic collaborators' or other parties' use of our technologies, we may incur substantial costs defending and indemnifying such parties to the extent they are subject to these types of claims. Any claims brought against us, any suppliers, service providers, future strategic collaborators or any other party indemnified by us alleging that we have violated the intellectual property of others could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

We currently have limited patent protection for our product candidates and technologies, and filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, we may not pursue or obtain patent protection in all major markets. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Furthermore, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Competitors may use our technologies in jurisdictions where we have not obtained or are unable to adequately enforce patent protection to develop or commercialize their own products. These products may compete with our future products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Proceedings to enforce our patent rights in such jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, put our patent applications at risk of not issuing and 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.

In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and to enforce our intellectual property.

Changes in U.S. patent law could diminish the value of our future patents, if issued, thereby impairing our ability to protect our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted wide-ranging patent reform legislation, which includes provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent

litigation, and switch the U.S. patent system from a “first to invent” system to a “first to file” system. It is not clear what, if any, impact such legislation will have on the operation of our business. Additionally, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening 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 decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any U.S. patents that may issue to us in the future, all of which could have a material adverse effect on our business and financial condition.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our ordinary shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates or future products, services or intellectual property could be diminished and the market price of our ordinary shares may decline as a result. Furthermore, such negative publicity could severely impair our capability to enter into future agreements with key commercial collaborators.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned patents and/or applications and any patent rights we may own or license in the future. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our business.

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. In addition, our Israeli employees may be entitled to seek compensation for their inventions irrespective of their contractual agreements with us.

Our agreements with our employees and key consultants generally include non-competition provisions. These provisions prohibit such employees and 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 provisions under the laws of the jurisdictions in which our employees and consultants 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. In addition, we cannot guarantee that any waiver of rights by our employees and consultants to receive compensation for inventions made by such employees or consultants during or in consequence of their service for us, or Service Inventions, will be upheld by Israeli courts even when our agreements with them include provisions

regarding the assignment and waiver of rights to additional compensation in respect of inventions created within the course of their employment with us, including in respect of Service Inventions as defined under the Israel Patents Law, 5727-1967. This is primarily due to a recent ruling of the Israeli Supreme Court that left the validity of such provisions to further judicial review. If we are required to pay additional compensation or face other disputes relating to Service Inventions, our results of operations could be adversely affected.

We may not be able to protect the confidentiality of our technology, which, if disseminated, could negatively impact our plan of operations.

In addition to seeking patent protection, we also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain and/or enforce, and other elements of our technology. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, which would harm our competitive position. While we strive to maintain systems and procedures to protect the confidentiality of our trade secrets and technical know-how, these systems and procedures may fail to provide an adequate degree of protection. For example, although we generally enter into agreements with our employees, consultants, advisors, and other collaborators restricting the disclosure and use of trade secrets, technical know-how and confidential information, we cannot provide any assurance that these agreements will be sufficient to prevent unauthorized use or disclosure of our trade secrets and technical know-how, that these agreements will not be breached or that we have executed agreements with all parties who may have had access to our proprietary information. We may not have adequate remedies in the case of a breach of any such agreements, and our competitors or others may independently develop substantially equivalent or superior proprietary information and techniques or otherwise gain access to our trade secrets or know-how. Monitoring and policing unauthorized use and disclosure of intellectual property is difficult. Further, the laws of certain foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, or if our competitors or other third parties independently develop any of our trade secrets, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

We currently have relationships with different consultants who perform research and development activities for us and who are not employed by us, and we may enter into additional relationships of such nature in the future. We have limited control over the activities of these consultants and can expect only limited amounts of their time to be dedicated to our activities. These persons may have consulting, employment or advisory arrangements with other entities that may conflict with or compete with their obligations to us. We typically require our consultants to sign agreements that require such consultants treat our proprietary information and results of studies as confidential. However, in connection with each such relationship, we may not be able to maintain the confidentiality of our technology, the dissemination of which could hurt our competitive position and results of operations. To the extent that our scientific consultants develop inventions or processes independently that may be applicable to our product candidates, disputes may arise as to the ownership of the proprietary rights to such information, and we may expend significant resources in such disputes and we may not win those disputes.

We may be subject to claims by third parties asserting that we or our employees, consultants or contractors have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Certain of our employees, consultants and contractors were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and 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 these employees, consultants or contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's, consultant's or contractor's former employer.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Further, such assignment agreements may not be self-executing, may be insufficient in scope or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

We do not currently own or use any registered trademarks for our product candidates. In the future, our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential collaborators or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

Risks Related to Our Ordinary Shares and this Offering

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

The share price of publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. These fluctuations may result from a variety of factors, many of which are beyond our control. These factors include:

- actual or anticipated fluctuations in our results of operations;
- clinical trial results and the timing of the release of such results;
- the amount of our cash resources and our ability to obtain additional funding;
- announcements of research activities, business developments, technological innovations or new products, or acquisitions or expansion plans by us or our competitors;
- our entering into or terminating strategic relationships;
- changes in laws or government regulation;
- departure of our key personnel;
- disputes related to proprietary rights, including patents, litigation matters and our ability to obtain intellectual property protection for our technologies;
- our sale, or the sale by our significant shareholders, of ordinary shares or other securities in the future;
- public concern regarding the safety, efficacy or other aspects of the products or methodologies being developed;
- market conditions in our industry and changes in estimates of the future size and growth rate of our markets;

- variance in our financial performance from the expectations of market analysts;
- the trading volume of our ordinary shares; and
- general economic and market conditions.

In addition, the stock market in general has recently experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad market and industry factors may materially affect the market price of companies' stock, including ours, regardless of actual operating performance.

There was no public market for our ordinary shares prior to this offering, and an active market in our ordinary shares may not develop in which investors can resell our ordinary shares.

Prior to this offering there was no public market for our ordinary shares. We cannot predict the extent to which an active market for our ordinary shares will develop or be sustained after this offering, or how the development of such a market might affect the market price for our ordinary shares. The initial public offering price of our ordinary shares in this offering was agreed between us and the underwriters based on a number of factors, including market conditions in effect at the time of this offering, which may not be indicative of the price at which our ordinary shares will trade following completion of this offering. Investors may not be able to sell their ordinary shares at or above the initial public offering price.

Immediately following this offering, D.N.A Biomedical will beneficially own approximately % of our ordinary shares and may therefore be able to control the outcome of matters requiring shareholder approval.

Immediately following this offering, D.N.A Biomedical Solutions Ltd., or D.N.A Biomedical, will beneficially own approximately % of our outstanding shares. Accordingly, subject to special approvals required by Israeli law for transactions involving controlling shareholders, D.N.A Biomedical may be able to exercise significant influence over all matters requiring shareholder approval, including the election of directors and approval of significant corporate transactions, which could have the effect of delaying or preventing either a third party from acquiring control over us or engaging in other purchases of our ordinary shares that might otherwise give our shareholders the opportunity to realize a premium over the then-prevailing market price for our ordinary shares or any changes, or from making any changes to our management or board of directors. D.N.A Biomedical could also sell its stake in our company and effectively transfer control of our company to another party without your consent.

The market price of our ordinary shares could be negatively affected by future sales of our ordinary shares.

After this offering, we will have ordinary shares outstanding. If we or our shareholders sell substantial amounts of our ordinary shares or if there is a public perception that these sales may occur in the future, the market price of our ordinary shares may decline. We, together with our directors, officers and our significant shareholders, in the aggregate beneficially owning % of our outstanding ordinary shares as of , 2017.

, have agreed with the underwriters of this offering not to sell any ordinary shares, other than the shares offered through this prospectus, for a period of 180 days following the date of this prospectus, subject to certain exceptions. See "Shares Eligible for Future Sale" and "Underwriters."

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We intend to allocate the net proceeds from this offering to our different areas of activity. Our management may not apply the net proceeds in ways that ultimately increase the value of your investment in our ordinary shares. They will have broad discretion in the application of the use of proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. If we do not invest or apply the net proceeds from this offering in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause the price of our ordinary shares to decline.

If you purchase ordinary shares in this offering, you will suffer immediate dilution of your investment.

If you purchase ordinary shares in this offering, you will pay a price per ordinary share that exceeds our pro forma net tangible book value (deficit) per ordinary share. You will experience immediate dilution of $ per ordinary share, representing the difference between our pro forma net tangible book value (deficit) per ordinary share of $ as of December 31, 2016 and the assumed initial public offering price of $ per ordinary share (the midpoint of the estimated offering price range on the cover of this prospectus). Purchasers of ordinary shares in this offering will have contributed approximately % of the aggregate price paid by all purchasers of our ordinary shares but will own only approximately % of our ordinary shares outstanding after this offering. To the extent options or warrants for our ordinary shares are exercised, you will incur further dilution. See "Dilution."

We do not intend to pay dividends.

We have never declared or paid any cash dividends on our ordinary shares. In addition, Israeli law may limit our declaration or payment of dividends, and may subject our dividends to Israeli withholding taxes. We currently intend to retain any future earnings to finance operations and to expand our business and, therefore, do not expect to pay any cash dividends in the foreseeable future.

We will be a foreign private issuer and, as a result, we will not be subject to U.S. proxy rules and will be subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

Upon consummation of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act, (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. We do, however, intend to make available to our shareholders quarterly reports containing unaudited financial information for each of the first three quarters of each fiscal year. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

As a foreign private issuer and as permitted by the listing requirements of , we will follow certain home country governance practices rather than the corporate governance requirements of the .

As a foreign private issuer, we have the option to follow certain Israeli corporate governance practices rather than those of , except to the extent that such laws would be contrary to U.S. securities laws, and provided that we disclose the requirements we are not following and describe the home country practices we follow instead. We intend to rely on this "foreign private issuer exemption" with respect to the shareholder approval requirements in respect of equity issuances and equity-based compensation plans and the quorum requirement for meetings of our shareholders. In addition, we intend to rely on the "foreign private issuer exemption" in the future with respect to the compensation committee requirements. We may in the future elect to follow home country practices in Israel with regard to other matters. As a result, our shareholders may not have the same protections afforded to shareholders of companies that are subject to all corporate governance requirements.

We may lose our status as a foreign private issuer, which would increase our compliance costs and could thereby negatively impact our results of operations.

We may no longer be a foreign private issuer as of June 30, 2018 (the end of our second fiscal quarter in the fiscal year after this offering), which would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of January 1, 2019. We will not maintain our current status as a foreign private issuer, if (a) a majority of our ordinary shares is not either directly or indirectly owned of record by non-residents of the United States and (b) one of the following applies: (i) a majority of our executive officers or directors are United States citizens or residents, (ii) more than 50 percent of our assets are located in the United States or (iii) our business is administered principally inside the United States. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. We may also be required to modify certain of our policies to comply with governance practices associated with U.S. domestic issuers. Such modifications will involve additional costs. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on that are available to foreign private issuers. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

We may be a passive foreign investment company, or a PFIC, for U.S. federal income tax purposes for any taxable year, which generally would result in certain adverse U.S. federal income tax consequences to our U.S. shareholders.

In general, a non-U.S. corporation is a "passive foreign investment company," or a PFIC, for any taxable year in which (i) 75% or more of its gross income consists of passive income, or the income test, or (ii) 50% or more of the average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income, or the assets test. Generally, "passive income" includes interest, dividends, rents, royalties and certain gains, and cash (including cash raised in this offering) is a passive asset for PFIC purposes. The assets shown on our balance sheet are expected to consist primarily of cash and cash equivalents for the foreseeable future. Therefore, whether we will satisfy the assets test for the current or any future taxable year will depend largely on the quarterly value of our goodwill. Because the value of our goodwill may be determined by reference to the quarterly market price of our ordinary shares from time to time, which may be especially volatile given the nature and early stage of our business, and because a company's PFIC status is an annual determination that can be made only after the end of each taxable year, we cannot express a view as to whether we will be a PFIC for the current or any future taxable year. In addition, it is not clear how to apply the income test to a company such as our company, whose only income for a relevant taxable year is passive interest income but whose overall losses significantly exceed the amount of such passive income. We believe that it is reasonable to take the position that a company like us, whose overall losses exceed its passive income, would not be a PFIC if it otherwise would not be a PFIC under the assets test for the relevant taxable year, but there can be no assurance that the Internal Revenue Service will respect, or a court will uphold, such position. If we were a PFIC for any taxable year during which a U.S. investor owned our ordinary shares, such U.S. shareholder generally will be subject to certain adverse U.S. federal income tax consequences, including increased tax liability on gains from dispositions of the ordinary shares and certain distributions and a requirement to file annual reports with the Internal Revenue Service. See "Taxation and Government Programs—Material U.S. Federal Income Tax Considerations for U.S. Holders—Passive Foreign Investment Company Rules" for more information.

We are an "emerging growth company" and we cannot be certain whether the reduced requirements applicable to "emerging growth companies" will make our ordinary shares less attractive to investors.

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

companies." For instance, for so long as we remain an "emerging growth company," we will not be subject to the provision of Section 404(b) of the Sarbanes-Oxley Act that requires our independent registered public accounting firm to provide an attestation report on the effectiveness of our internal control over financial reporting. This may increase the risk that we will fail to detect and remedy any weaknesses or deficiencies in our internal control over financial reporting. We have also elected to include two years of audited financial statements and selected financial data, as permitted for an "emerging growth company" compared to three and five years, respectively, for comparable data reported by other public companies. In general, these reduced reporting requirements may allow us to refrain from disclosing information that you may find important.

We could be an "emerging growth company" for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates exceeds $700 million as of any June 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an "emerging growth company" as of the following December 31 (our fiscal year end). When we are no longer deemed to be an "emerging growth company," we will not be entitled to the exemptions provided in the JOBS Act. We cannot predict if investors will find our ordinary shares less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

We have not yet determined whether our existing internal control over financial reporting is compliant with Section 404 of the Sarbanes-Oxley Act, and we cannot provide any assurance that there are no material weaknesses or significant deficiencies in our existing internal controls.

Pursuant to Section 404 of the Sarbanes-Oxley Act and the related rules adopted by the SEC and the Public Company Accounting Oversight Board, or Section 404, starting with the second annual report that we file with the SEC after the consummation of this offering, our management will be required to report on the effectiveness of our internal control over financial reporting. In addition, once we no longer qualify as an "emerging growth company" under the JOBS Act and lose the ability to rely on the exemptions related thereto discussed above, our independent registered public accounting firm will also need to attest to the effectiveness of our internal control over financial reporting under Section 404.

We have only initially commenced the process of determining whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls. This process will require the investment of substantial time and resources, including by our Chief Financial Officer and other members of our senior management. As a result, this process may divert internal resources and take a significant amount of time and effort to complete.

In addition, we cannot predict the outcome of this determination and whether we will need to implement remedial actions in order to implement effective control over financial reporting. The determination and any remedial actions required could result in us incurring additional costs that we did not anticipate. Irrespective of compliance with Section 404, any failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently or are required to do so earlier than anticipated, it could adversely affect our operations, financial reporting and/or results of operations and could result in an adverse opinion on internal controls from our independent auditors.

If securities or industry analysts do not publish research or reports or publish unfavorable research about our business, our share price and trading volume could decline.

The trading market for our ordinary shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If securities or industry analysts do not commence coverage of our company, the trading price for our shares would be negatively affected. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our shares, our shares price would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, interest in the purchase of our shares could decrease, which could cause our share price or trading volume to decline.

Risks Relating to Our Incorporation and Location in Israel

The Israeli government grants we have received for research and development expenditures restrict our ability to manufacture products and transfer technologies outside of Israel and require us to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to refund grants previously received together with interest and penalties or to pay other amounts according to the formulas set out in the relevant laws.

Our research and development efforts have been financed, in part, through the grants that we have received from the Israeli Innovation Authority (formerly known as the Office of Chief Scientist of the Israeli Ministry of Economy), or the IIA. Pursuant to these grants, we must comply with the requirements of the Encouragement of Industrial Research, Development and Technological Innovation in Industry Law 5744-1984, or the Research Law. Until the grants are repaid with interest, royalties are payable to the IIA in the amount of 3% on revenues derived from sales of products or services developed in whole or in part using the IIA grants, including EB612, EB613 and any other oral PTH product candidates we may develop. The royalty rate may increase to 5%, with respect to approved applications filed after we achieve sales of over $70 million in the year prior to the application.

Under the Research Law, we are prohibited from manufacturing products developed using these grants outside of the State of Israel without special approvals. We may not receive the required approvals for any proposed transfer of manufacturing activities. Even if we do receive approval to manufacture products developed with government grants outside of Israel, the royalty rate may be increased and we may be required to pay up to three times the grant amounts plus interest, depending on the manufacturing volume that is performed outside of Israel. This restriction may impair our ability to outsource manufacturing or engage in our own manufacturing operations for those products or technologies. See “Business— The Israeli Innovation Authority Grant” for additional information.

Additionally, under the Research Law, we are prohibited from transferring in any manner (including by way of license), the IIA-financed technologies and related rights (including know-how and other intellectual property rights) outside of the State of Israel, except under limited circumstances and only with the approval of the IIA Research Committee. We may not receive the required approvals for any proposed transfer and, even if received, we may be required to pay the IIA a portion of the consideration that we receive upon any transfer of such technology to a non-Israeli entity up to 600% of the grant amounts plus interest. The scope of the IIA support received, the royalties that we have already paid to the IIA, the amount of time that has elapsed between the date on which the know-how or other intellectual property rights were transferred and the date on which the IIA grants were received and the sale price and the form of transaction will be taken into account in order to calculate the amount of the payment to the IIA. Approval to transfer the technology to residents of the State of Israel is also required, and may be granted in specific circumstances only if the recipient abides by the provisions of applicable laws, including the restrictions on the transfer of know-how and the obligation to pay royalties. No assurance can be made that approval to any such transfer, if requested, will be granted. Transfer of know-how or rights outside of the state of Israel without IIA approval is a criminal offense.

These restrictions may impair our ability to sell our technology assets or to perform or outsource manufacturing outside of Israel, engage in change of control transactions or otherwise transfer our know-how outside of Israel and may require us to obtain the approval of the IIA for certain actions and transactions and pay additional royalties and other amounts to the IIA. In addition, any change of control and any change of ownership of our ordinary shares (including by way of an initial public offering) that would make a non-Israeli citizen or resident an “interested party,” as defined in the Israeli Securities Law, 5728-1968, as amended, or the Securities Law, requires written notice to the IIA, and our failure to comply with this requirement could result in monetary fines. Such non-Israeli interested parties, which include 5% shareholders and shareholders who have the right to appoint a director to our board of directors, are required to sign an undertaking towards the IIA in which they would undertake to comply with the Research Law. Shareholders that purchase shares in an IPO would not be required to sign such an undertaking.

These restrictions will continue to apply even after we have repaid the full amount of the grants. If we fail to satisfy the conditions of the Research Law, we may be required to refund certain grants previously received together with interest and penalties, and may become subject to criminal charges.

Security, political and economic instability in the Middle East may harm our business.

Our principal offices and research and development facilities are located in Israel. Accordingly, political, economic and military conditions in the Middle East may affect our business directly. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors, Hamas (an Islamist militia and political group in the Gaza Strip) and Hezbollah (an Islamist militia and political group in Lebanon). Recent political uprisings, social unrest and violence in various countries in the Middle East and North Africa, including Israel's neighbors Egypt and Syria, are affecting the political stability of those countries. This instability may lead to deterioration of the political relationships that exist between Israel and these countries and have raised concerns regarding security in the region and the potential for armed conflict. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among the Syrian government, Hamas and Hezbollah. These situations may potentially escalate in the future to more violent events which may affect Israel and us. These situations, including conflicts which involved missile strikes against civilian targets in various parts of Israel have in the past negatively affected business conditions in Israel.

Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could have a material adverse effect on our business. Although such hostilities did not in the past have a material adverse impact on our business, we cannot guarantee that hostilities will not be renewed and have such an effect in the future. The political and security situation in Israel may result in parties with whom we have contracts claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions. These or other Israeli political or economic factors could harm our operations and product development. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could adversely affect our operations and could make it more difficult for us to raise capital. Furthermore, several countries restrict business with Israel and Israeli companies, which could have an adverse effect on our business. We could experience disruptions if acts associated with this conflict result in any serious damage to our facilities. Our business interruption insurance may not adequately compensate us for losses that may occur, and any losses or damages incurred by us could have a material adverse effect on our business.

Our operations may be disrupted by the obligations of personnel to perform military service.

Our employees in Israel, including executive officers, may be called upon to perform up to 36 days (and in some cases more) of annual military reserve duty until they reach the age of 40 (or older, for reservists with certain occupations) and, in emergency circumstances, could be called to active duty. In response to increased tension and hostilities, since September 2000 there have been occasional call-ups of military reservists, including in connection with the mid-2006 war in Lebanon and the December 2008, November 2012 and July 2014 conflicts with Hamas, and it is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees related to military service or the absence for extended periods of one or more of our key employees for military service. Such disruption could materially adversely affect our operations, business and results of operations.

Our business is subject to currency exchange risk and fluctuations between the U.S. dollar and other currencies may negatively affect our earnings and results of operations.

The U.S. dollar is both our functional and reporting currency. As a result, our results of operations may be adversely affected by exchange rate fluctuations between the U.S. dollar and the NIS. A significant portion of the expenses associated with our Israeli operations, including personnel and facilities related expenses, are incurred in NIS. Consequently, inflation in Israel will have the effect of increasing the cost of our operations in Israel unless it is offset on a timely basis by a devaluation of the NIS relative to the U.S. dollar. In addition, if the value of the U.S. dollar decreases against the NIS, our earnings may be negatively impacted. Moreover, exchange rate fluctuations in currency exchange rates in countries other than Israel where we operate, perform our clinical trials or conduct business may also negatively affect our earnings and results of operations.

Potential future revenue may be derived from abroad, including outside of the United States. As a result, our business and share price may be affected by fluctuations in foreign exchange rates with these other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place. Foreign currency fluctuations could materially adversely affect our results of operations or could positively affect our results of operations in ways that may not necessarily be repeated in future periods.

It may be difficult to enforce a U.S. judgment against us or our officers and directors and to assert U.S. securities laws claims in Israel.

We are incorporated under the laws of the State of Israel. Service of process upon us, our directors and officers and the Israeli experts, if any, named in this prospectus, substantially all of whom reside outside the United States, may be difficult to obtain within the United States. Furthermore, because the majority of our assets and investments, and substantially all of our directors, officers and such Israeli experts, if any, are located outside the United States, any judgment obtained in the United States against us or any of them may be difficult to collect within the United States.

In addition, it may be difficult for an investor to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. See the section entitled “Enforceability of Civil Liabilities.”

Provisions of Israeli law may delay, prevent or make difficult a change of control and therefore depress the price of our shares.

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 these types of transactions. For additional information regarding the regulation of mergers and tender offers under the Israeli Companies Law see “Description of Share Capital—Anti-Takeover Provisions; Mergers and Acquisitions.” For example, under the Israeli Companies Law, 5759-1999, or the Companies Law, upon the request of a creditor of either party to a 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.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances that makes the deferral contingent on the fulfillment of numerous conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when the time expires, tax then becomes payable even if no actual disposition of the shares has occurred.

These provisions could cause our ordinary shares to trade at prices below the price for which third parties might be willing to pay to gain control of us. Third parties who are otherwise willing to pay a premium over prevailing market prices to gain control of us may be unable or unwilling to do so because of these provisions of Israeli law.

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

We are incorporated under Israeli law. The rights and responsibilities of the holders of our ordinary shares are governed by our then-current Articles of association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders in typical U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith toward the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and interested party transactions requiring shareholder approval. In addition, a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the implications of these provisions that govern shareholders' actions, and these provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations. See "Description of Share Capital—Our Ordinary Shares."

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or *achievements* to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include all statements that are not historical facts and can be identified by words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "could," and similar expressions or phrases. We have based these forward-looking statements largely on our management's current expectations and future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Forward-looking statements include, but are not limited to, statements about:

- our operation as a development stage company with limited operating history and a history of operating losses;
- our ability to develop and advance product candidates into, and successfully complete, clinical studies;
- uncertainty surrounding whether any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized, including that we will be able to demonstrate to regulators the clinical superiority of EB612 over Natpara, which is required to overcome Natpara's drug exclusivity;
- our competitive position, especially with respect to Natpara, our key competitor for hypoparathyroidism treatment;
- our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern absent access to sources of liquidity;
- our ability to use and expand our drug delivery technology to other product candidates;
- the pricing and reimbursement of our product candidates, if approved;
- our being subject to ongoing regulatory obligations if our products secure regulatory approval;
- our ability to develop sales, marketing and distribution infrastructure;
- our reliance on third parties to conduct our clinical trials and on third-party suppliers to supply or produce our product candidates;
- our ability to achieve market acceptance for our product candidates;
- our ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights;
- our ability to retain key personnel and recruit additional qualified personnel;
- our expectations regarding the use of proceeds from this offering;
- our ability to manage growth; and
- other risk factors discussed under "Risk Factors."

All forward-looking statements involve risks, assumptions and uncertainties. You should not rely upon forward-looking statements as predictors of future events. The occurrence of the events described, and the achievement of the expected results, depend on many events, some or all of which are not predictable or within our control. Actual results may differ materially from expected results. See the sections below “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus for a more complete discussion of these risks, assumptions and uncertainties and for other risks and uncertainties. These risks, assumptions and uncertainties are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results. All of the forward-looking statements we have included in this prospectus are based on information available to us on the date of this prospectus. We undertake no obligation, and specifically decline any obligation, to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this prospectus might not occur.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $ million from our sale of ordinary shares (or approximately $ million if the underwriters fully exercise their over-allotment option), after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. This assumes an offering price of $ per share, which is the midpoint of the estimated offering price range on the cover page of this prospectus.

As of , we had cash and cash equivalents of $ million. We intend to use the net proceeds from this offering, together with our cash and cash equivalents to fund research and development expenses of oral PTH, the development of other therapeutics, the repayment of outstanding indebtedness and for working capital and general corporate purposes.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the relative success and cost of our research, preclinical and clinical development programs, including a change in our planned course of development or the termination of a clinical program necessitated by the results of data received from clinical trials, the amount and timing of additional revenues, if any, received from future collaborations. As a result, management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds of this offering. In addition, we might decide to postpone or not pursue other clinical trials or preclinical activities if the net proceeds from this offering and our other sources of cash are less than expected.

Based on our planned use of the net proceeds of this offering and our current cash and cash equivalents described above, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least the next months. We have based these estimates on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term interest-bearing financial assets and certificates of deposit.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the range set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by $ million (or $ million if the underwriters fully exercise their over-allotment option), assuming the number of shares offered by us remains the same.

We may also increase or decrease the number of shares we are offering. An increase (decrease) of shares in the number of shares offered by us would increase (decrease) our net proceeds from this offering by $ million, assuming the public offering price per share remains the same. The information on net proceeds payable to us discussed above is illustrative only and will adjust based on the actual initial public offering price, the actual number of ordinary shares offered by us, and other terms of the offering determined at pricing.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our ordinary shares and we do not anticipate paying any cash dividends on our ordinary shares in the future. We currently intend to retain all future earnings to finance our operations and to expand our business. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, which may include future earnings, capital requirements, financial condition and future prospects and other factors the board of directors may deem relevant. Our ability to distribute dividends is limited under Israeli law, as described below under "Description of Share Capital—Our Ordinary Shares—Dividends and Liquidation Rights."

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2016:

- on an actual basis;
- on a pro forma basis to give effect to the IPO Transactions, as described in "Summary—The Offering"; and
- on a pro forma as adjusted basis to give effect to (a) the IPO Transactions and (b) our sale in this offering of ordinary shares at an assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with our financial statements and the related notes, which we include elsewhere in this prospectus, and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Certain Relationships and Related Party Transactions" sections and other information contained in this prospectus.

	As of December 31, 2016		
	Actual	Pro forma	Pro forma as adjusted
	(In thousands)		
		(Unaudited)	(Unaudited)
Cash and cash equivalents	$ 4,163	$	$
Convertible loans	$ 14,720	$	$
Series A preferred shares of NIS 0.01 par value; 25,000 authorized, 10,222 issued and outstanding, actual; authorized, 0 issued and outstanding, pro forma; authorized, 0 issued and outstanding, pro forma as adjusted	11,031		
Warrants to purchase preferred shares and shares	4,800		
Liability to issue preferred shares and warrants	273		
Capital deficiency:			
Ordinary shares of NIS 0.01 par value; 1,000,000 authorized, 34,544 issued and outstanding, actual; authorized, issued and outstanding, pro forma; authorized, issued and outstanding, pro forma as adjusted	*		
Other comprehensive income	41		
Other reserves	2,844		
Additional paid-in capital	2,485		
Accumulated deficit	(30,616)		
Total capital deficiency	(25,246)		
Total capitalization	$ 5,578	$	$

* represents an amount less than one thousand

The table above does not reflect:

- ordinary shares issuable upon the exercise of options outstanding as of December 31, 2016, at a weighted average exercise price of $ per share; or
- ordinary shares reserved for future grants as of December 31, 2016 under the Plan.

DILUTION

Our historical deficit as of December 31, 2016, was $, or $, per share. Historical net tangible book value (deficit) per share is calculated by subtracting our total liabilities from our total tangible assets, which is total assets less intangible assets, and dividing this amount by the 34,544 issued and outstanding ordinary shares as of December 31, 2016.

Our pro forma net tangible book value (deficit) per share as of December 31, 2016, was $, or $ per share. Pro forma net tangible book value (deficit) per share is calculated by subtracting our total liabilities from our total tangible assets which is total assets less intangible assets, and dividing this amount by the issued and outstanding ordinary shares as of December 31, 2016, after giving pro forma effect to the IPO Transactions, as described in "Summary—The Offering."

After giving effect to the sale by us of the ordinary shares in this offering, at an assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, our pro forma as adjusted net tangible book value (deficit) at December 31, 2016, would have been $, or $ per share. This represents an immediate increase in pro forma net tangible book value (deficit) to existing shareholders of $ per share and immediate dilution to new investors of $ per share.

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

Assumed initial public offering price		$
Historical net tangible book value (deficit) per ordinary share as of December 31, 2016	$	
Increase in historical net tangible book value (deficit) per ordinary share attributable to the IPO Transactions		
Increase in pro forma net tangible book value (deficit) per share attributable to this offering		
Pro forma as adjusted net tangible book value (deficit) per ordinary share after this offering		
Dilution per ordinary share to new investors in this offering		$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value (deficit) at December 31, 2016 by approximately $, or approximately $ per share and the dilution to new investors of $ per share, assuming that the number of shares offered by us remains the same.

We may also increase or decrease the number of shares we are offering. An increase of shares in the number of shares offered by us would result in pro forma as adjusted net tangible book value (deficit) at December 31, 2016 of approximately $, or $ per share, and dilution to new investors of $ per share, assuming the public offering price per share remains the same. Similarly, a decrease of shares in the number of shares offered by us would result in pro forma as adjusted net tangible book value (deficit) at December 31, 2016 of approximately $, or $ per share, and dilution to new investors of $ per share, assuming the public offering price per share remains the same. The dilution information discussed above is illustrative only and will change based on the actual public offering price and other terms of this offering determined at pricing.

The following table sets forth, as of December 31, 2016, on a pro forma basis for the IPO Transactions, the number of ordinary shares purchased from us, the total consideration paid, or to be paid, and the average price per share paid, or to be paid, by existing shareholders and by the new investors, at an assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and offering expenses payable by us:

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

The foregoing tables assume no exercise of the underwriters' over-allotment option or of outstanding options or warrants to purchase our shares after December 31, 2016. At December 31, 2016, ordinary shares were subject to outstanding options at a weighted average exercise price of $, warrants were outstanding, at an exercise price of $ per share, and warrants were outstanding, at an exercise price of $ per share. Pro forma for the IPO Transactions, additional warrants exercisable for ordinary shares will be outstanding. See "Summary—The Offering." To the extent these options and warrants are exercised there will be further dilution to new investors.

If the underwriters exercise the over-allotment option in full in this offering, our pro forma as adjusted net tangible book value (deficit) will be $ million, or $ per share, representing an immediate increase in pro forma as adjusted net tangible book value (deficit) of approximately $ per share attributable to this offering to our existing shareholders and immediate dilution of $ per share to new investors purchasing ordinary shares in the offering.

EXCHANGE RATES

The following table sets forth, for the periods indicated, the high, low, average and period-end exchange rates for the purchase of U.S. dollars expressed in NIS per U.S. dollar. The average rate is calculated by using the average of the Bank of Israel's reported exchange rates on each day during a monthly period and on the last day of each month during an annual period. On July 13, 2017, the exchange rate as reported by the Bank of Israel was NIS 3.5340 to $1.00.

	Period-end	Average for Period	Low	High
		(NIS per U.S. dollar)		
Year Ended December 31:				
2012	3.7330	3.8438	3.7000	4.0840
2013	3.4710	3.6023	3.4710	3.7910
2014	3.8890	3.5928	3.4020	3.9940
2015	3.9020	3.8869	3.7610	4.0530
2016	3.8450	3.8406	3.7460	3.9830
Month Ended:				
October 31, 2016	3.8490	3.8217	3.7780	3.8560
November 30, 2016	3.8390	3.8429	3.7990	3.8760
December 31, 2016	3.8450	3.8287	3.7870	3.8670
January 31, 2017	3.7690	3.8182	3.7690	3.8600
February 28, 2017	3.6590	3.7291	3.6590	3.7680
March 31, 2017	3.6320	3.6493	3.6140	3.6930
April 28, 2017	3.6190	3.6497	3.6190	3.6810
May 30, 2017	3.5610	3.5794	3.5610	3.6160
June 30, 2017	3.4930	3.5319	3.4900	3.5580
July (through July 13, 2017)	3.5340	3.5331	3.4930	3.5760

SELECTED FINANCIAL DATA

The following tables set forth our selected financial data. You should read the following selected financial and other data in conjunction with "Summary 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. Historical results are not necessarily indicative of the results that may be expected in the future. Our financial statements have been prepared in accordance with IFRS as issued by the IASB.

The selected statements of comprehensive loss data for each of the years in the two-year period ended December 31, 2016 and the statements of financial position data as of December 31, 2016 and 2015 are derived from our audited financial statements appearing elsewhere in this prospectus.

	Year Ended December 31,	
	2016	2015
	(In thousands, except shares and per share data)	
Statements of comprehensive loss:		
Research and development expenses	$ 2,648	$ 2,115
General and administrative expenses	2,719	1,586
Total operating loss	5,367	3,701
Financial (income) expense:		
(Income) loss from change in fair value of financial liabilities at fair value	(4,311)	447
Other financial expenses, net	143	134
Financial (income) expenses, net	(4,168)	581
Net comprehensive loss	$ 1,199	$ 4,282
Loss per ordinary share (1)		
Basic	$ 35	$ 124
Diluted	102	124
Weighted average number of ordinary shares used in computing basic loss per ordinary share(1)	34,409	34,396
Weighted average number of ordinary shares used in computing diluted loss per ordinary share(1)	51,972	34,396

(1) Basic and diluted loss per ordinary share in 2015 is the same because the financial instruments as described in the financial statements excluded from the calculation since their effect was anti-dilutive. See Note 13 to our financial statements for further details on the calculation of basic and diluted loss per ordinary share.

	As of December 31,	
	2016	2015
	(In thousands)	
Statements of financial position data:		
Cash and cash equivalents	$ 4,163	$ 1,205
Restricted deposits	1,075	—
Other current assets	195	695
Total current assets	5,433	1,900
Property and equipment	199	193
Intangible assets	654	654
Total assets	$ 6,286	$ 2,747
Accounts payable- Trade and other	657	804
Short term convertible loans	9,885	—
Total current liabilities	10,542	804
Long term convertible loans	4,835	8,053
Preferred shares	11,031	13,062
Warrants to purchase preferred shares and shares	4,800	4,332
Liability to issue preferred shares and warrants	273	2,154
Severance pay obligations, net	51	29
Total liabilities	$ 31,532	$ 28,434
Capital deficiency	$ (25,246)	$ (25,687)
Working capital[(1)]	$ (5,109)	$ 1,096

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

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

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes included elsewhere in this prospectus. This discussion contains forward-looking statements that are subject to known and unknown risks and uncertainties. Actual results and the timing of events may differ significantly from those expressed or implied in such forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this prospectus. You should read the following discussion in conjunction with "Special Note Regarding Forward-Looking Statements" and "Risk Factors" included elsewhere in this prospectus. We have prepared our financial statements in accordance with IFRS as issued by IASB.

Overview

We are a biopharmaceutical company focused on the development and commercialization of orally delivered large molecule therapeutics for use in orphan indications and other areas with significant unmet medical need. We are initially applying our technology to develop an oral formulation of parathyroid hormone, or PTH, which has been approved in the United States in injectable form for over a decade. Our lead oral PTH product candidate, EB612,has successfully completed a Phase 2a trial in hyperparathyroidism, a rare condition in which the body fails to produce sufficient amounts of PTH. The FDA and the EMA have granted EB612 orphan drug designation for the treatment of hypoparathyroidism. We expect to initiate a Phase 2b/3 clinical trial of EB612 in the first quarter of 2018, and we plan to submit applications for regulatory approval of EB612 in the first half of 2020. We are also developing a distinct oral PTH product candidate, EB613, for the treatment of osteoporosis. We intend to commence a Phase 2a clinical trial of EB613 in the fourth quarter of 2017 and an additional Phase 2b clinical trial in the United States in 2018. We also are preparing to conduct a clinical trial of our oral PTH in bone healing. In addition, we intend to use our technology as a platform for the oral delivery of other protein and large molecule therapeutics as well as novel therapeutics.

To date, we have funded our operations through sales of ordinary shares, preferred shares and warrants, and the incurrence of convertible loans and receipt of government grants. We have no products that have received regulatory approval and have never generated revenue. From our inception through December 31, 2016, we have raised an aggregate of $18.3 million to fund our operations, including $7.2 million from sales of our ordinary shares, preferred shares and warrants, $10.6 million from convertible loans (of which an amount of approximately $1.1 million was repaid in February 2017) and approximately $0.5 million of government grants. We were originally capitalized with $0.6 million of cash from D.N.A Biomedical Solutions Ltd., or D.N.A Biomedical, and a license to certain patent rights relating to the oral administration of proteins from Oramed Ltd., or Oramed, a subsidiary of Oramed Pharmaceuticals, Inc., and accordingly $0.6 million was recorded on our statements of financial position as an intangible asset based on the fair value of the ordinary shares issued in exchange for the license.

Since inception, we have incurred significant losses. For the years ended December 31, 2015 and 2016, our losses were $4.3 million and $1.2 million, respectively. We expect to continue to incur significant expenses and losses for the next several years. As of December 31, 2016, we had an accumulated deficit of $30.6 million. Our losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials, our expenditures on any other research and development activities, the receipt of government grants and payments under any future collaborations into which we may enter.

As of December 31, 2016, we had cash and cash equivalents of $4.2 million. In order to fund further operations, we may need to raise capital in addition to the net proceeds of this offering. We may seek these funds through a combination of private and public equity offerings, debt financings, government grants, strategic collaborations and licensing arrangements. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. Our audited financial statements for the year ended December 31, 2016, included elsewhere in this prospectus, disclose our determination that there is substantial doubt about our ability to continue as a going concern absent sources of additional liquidity. The financial statements included herein have been prepared assuming that we will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty. If we are unable to raise the requisite funds, we will need to curtail or cease operations. See "Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital."

As of June 30, 2017, we had sixteen employees and one consultant, who provides consulting services to us on a full-time basis. In addition, we have entered into service agreements with three of our directors. Our operations are located in a single facility in Jerusalem, Israel.

Patent Transfer Agreement and Grant Funding

Oramed Patent Transfer Agreement

In 2011, we entered into a patent transfer agreement with Oramed, or the Patent Transfer Agreement, pursuant to which Oramed assigned to us all of its right, title and interest in the patent rights Oramed licensed to us when we were originally capitalized, subject to a worldwide, royalty-free, exclusive, irrevocable, perpetual and sublicensable license granted to Oramed under the assigned patent rights to develop, manufacture and commercialize products or otherwise exploit such patent rights in the fields of diabetes and influenza. Additionally, we agreed not to engage, directly or indirectly, in any activities in the fields of diabetes and influenza. Under the terms of the Patent Transfer Agreement, we agreed to pay Oramed royalties equal to 3% of our net revenues generated , directly or indirectly, from exploitation of the assigned patent rights, including the sale, lease or transfer of the assigned patent rights or sales of products or services covered by the assigned patent rights. See “Business—Oramed Patent Transfer Agreement.”

The Israeli Innovation Authority Grant (formerly: the Office of the Chief Scientist)

We have received grants of approximately $0.5 million from the IIA, to partially fund our research and development. The grants are subject to certain requirements and restrictions under the Israeli Encouragement of Industrial Research, Development and Technological Innovation in Industry Law 5477-1984, or the Research Law. In general, until the grants are repaid with interest, royalties are payable to the Israeli government in the amount of 3% on revenues derived from sales of products or services developed in whole or in part using the IIA grants, including EB612, EB613 and any other oral PTH product candidates we may develop. The royalty rate may increase to 5%, with respect to approved applications filed after we achieve sales of over $70 million in the year prior to the application.

The amount that must be repaid may be increased to three times the amount of the grant received, and the rate of royalties may be accelerated, if manufacturing of the products developed with the grant money is transferred outside of the State of Israel. Moreover, a payment of up to 600% of the grant received may be required upon the transfer of any IIA-funded know-how to a non-Israeli entity. As of December 31, 2016, the total royalty payable to the IIA, including accrued interest, was approximately $0.5 million and we had not paid any royalties to the IIA.

In addition to paying any royalties due, we must abide by other restrictions associated with receiving such grants under the Research Law that continue to apply following repayment to the IIA. See “Business— The Israeli Innovation Authority Grant.”

Financial Overview

Revenue

To date, we have not generated any revenue. We do not expect to receive any revenue from any product candidates that we develop unless and until we obtain regulatory approval and successfully commercialize our products or enter into collaborative agreements with third parties.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of our drug delivery technology and our product candidates. Those expenses include:

- employee-related expenses, including salaries, bonuses and share-based compensation expenses for employees and service providers in research and development functions;

- expenses incurred in operating our laboratories and small-scale manufacturing facility;
- expenses incurred under agreements with contract research organizations, or CROs, and investigative sites that conduct our clinical trials;
- expenses relating to outsourced and contracted services, such as external laboratories, consulting and advisory services;
- supply, development and manufacturing costs relating to clinical trial materials; and
- other costs associated with pre-clinical and clinical activities.

Research and development activities are the primary focus of our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will significantly increase in absolute dollars in future periods as we continue to invest in research and development activities related to the development of our product candidates.

Research expenses are recognized as incurred. An intangible asset arising from the development of our product candidates is recognized if certain capitalization conditions are met. During the years ended December 31, 2015 and 2016, we did not capitalize any development costs.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including due to timing of initiation of clinical trials and enrollment of patients in clinical trials. For the years ended December 31, 2015 and December 31, 2016, our research and development expenses were $2.1 million and $2.6 million, respectively. Research and development expenses in 2015 and 2016 were primarily for the development of EB612. Research and development expenses are expected to increase as we advance the clinical development of EB612 and EB613 and our preclinical work on additional product candidates. We currently anticipate such expenses in 2017 to be in the range of $ million. The successful development of our product candidates is highly uncertain. At this time we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing and other related activities;
- the cost of manufacturing clinical supplies and establishing commercial supplies of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- 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, including any milestone and royalty payments thereunder.

A change in the outcome of any of these variables with respect to the development of EB612, EB613 or any other product candidate that we may develop could mean a significant change in the costs and timing associated with the development of such product candidate. For example, if the FDA or other regulatory authority were to require us to conduct preclinical and/or clinical studies beyond those which we currently anticipate will be required for the completion of clinical development, if we experience significant delays in enrollment in any clinical trials or if we encounter difficulties in manufacturing our clinical supplies, we could be required to expend significant additional financial resources and time on the completion of the clinical development.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for directors and personnel in executive and finance functions, such as salaries, benefits and share-based compensation. Other general and administrative expenses include facility costs, communication expenses and professional fees for legal services, patent counseling and portfolio maintenance, consulting, auditing and accounting services.

We anticipate that our general and administrative expenses will increase following the completion of this offering due to many factors, the most significant of which include increased expenses associated with maintaining compliance with listing rules and SEC requirements as a result of becoming a publicly traded company, such as increased legal and accounting services, transfer agent and printing fees, addition of new headcount to support compliance and communication needs and increased insurance premiums.

Financial (Income) Expenses

Financial (income) expenses are comprised mainly of gains or losses resulting from the re-measurement of our convertible loan, preferred shares, warrants to purchase preferred shares and shares and liability to issue preferred shares and warrants. We will continue to record adjustments to the estimated fair value of the convertible loans, preferred shares, warrants to issue preferred shares and shares and liability to issue preferred shares and warrants until each are converted into our ordinary shares, after which we will no longer record any related periodic fair value adjustments.

Prior to the consummation of this offering we will adjust our convertible loan liability and our liability to issue preferred shares and warrants to their fair value as shall be evaluated based on the estimated public offering price. We expect to record additional financial expenses or income from the revaluation of our convertible loan liability, preferred shares and warrants. The liability to issue preferred shares and warrants will be extinguished upon fulfillment of the second milestones as described in the relevant share purchase agreements and as such liabilities will no longer exist once the underlying securities are issued. Under the terms of the applicable agreements, the convertible loans and preferred shares will be automatically converted into our ordinary shares, and the warrants to purchase preferred shares will be automatically converted into warrants to purchase ordinary shares, upon this offering.

Other financial expenses are comprised mainly of exchange rate differences of certain currencies against our functional currency.

Taxes on Income

We have not generated taxable income since our inception and as of December 31, 2016 had carry-forward tax losses of $9.9 million. We anticipate that we will be able to carry forward these tax losses indefinitely to future tax years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carryforward tax losses.

We recognize deferred tax assets on losses for tax purposes carried forward to subsequent years if utilization of the related tax benefit against a future taxable income is probable. We have not created deferred tax assets on our tax loss carryforwards because their utilization is not expected in the foreseeable future.

Critical Accounting Policies and Estimates

We describe our significant accounting policies more fully in Note 2 to our audited financial statements included elsewhere in this prospectus. We believe that the accounting policies below are critical in order to fully understand and evaluate our financial condition and results of operations. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

Share-Based Compensation

We have adopted a share-based compensation plan for employees, directors and service providers. As part of the plan, we grant employees, directors and service providers, from time to time and at our discretion, options to purchase our ordinary shares. The fair value of the services received in exchange for the grant of the options is recognized as an expense in our statements of comprehensive loss with a corresponding adjustment to equity in our statements of financial position. The total amount is recognized as an expense ratably over the vesting period of the options, which is the period during which all vesting conditions are expected to be met.

We estimate the fair value of our share-based compensation to employees, directors and service providers using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the expected volatility of our shares, (b) the expected term of the award, (c) the risk-free interest rate, (d) expected dividends and (e) the fair value of ordinary share at the date of grant. Due to the lack of a public market for the trading of our shares and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historic volatility of comparable companies that are publicly traded. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own share price becomes available.

For options granted in 2015 and 2016 , the fair value per ordinary share used in the Black-Scholes option pricing model was evaluated using a hybrid model that uses an option pricing model within each applicable exit scenario of our company. These valuations are highly subjective.

For the purpose of determining our enterprise value, we used the discounted cash flow, or DCF, method. Under the DCF method, our projected after-tax cash flows were discounted back to present value, using the discount rate. The discount rate, known as the weighted average cost of capital, or WACC, accounts for the time value of money and the appropriate degree of risk inherent in our business. The DCF method requires significant assumptions, in particular, regarding our projected cash flows and the discount rate applicable to our business. For the purpose of that valuation we applied applicable discount rate, commencement of sales and probability of reaching sales.

Following this offering, the fair value of our ordinary shares will be determined based on the closing price of our ordinary shares on the .

We are also required to estimate forfeitures at the time of grant, and we revise those estimates in subsequent periods if actual forfeitures differ from the estimates. Vesting conditions are included in assumptions about the number of options that are expected to vest. At the end of each reporting period, we revise our estimates of the number of options that are expected to vest based on the nonmarket vesting conditions. We recognize the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to equity.

The following table summarizes the allocation of our share-based compensation expense:

	Year ended December 31,	
	2016	2015
	(in thousands)	
Research and development	$ 130	$ 6
General and administrative	1,360	360
Total	$ 1,490	$ 366

Fair Value of Financial Liabilities Through Profit or Loss

The preferred shares and warrants to purchase preferred shares are classified as financial liabilities because of the liquidation rights and conversion rights associated with the preferred shares and therefore are accounted for at fair value through profit or loss at each balance sheet date. The liability to issue preferred shares and warrants are classified as contingent forward contracts and therefore are also accounted for at fair value through profit or loss at each balance sheet date. To determine the fair value of the convertible loans, preferred shares, warrants and liability to issue preferred shares and warrants, we use our judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at the end of each reporting period. The estimated fair value of these liabilities might have been different if we had used different estimates and assumptions.

To determine the fair value of the convertible loans, which is a valuation that is not based on observable market data, or a level 3 valuation, the debt component was evaluated based on the discounting of future payments of the debt. The convertible components of the loans (the option to convert the principal amount of the loans and accrued interest into our ordinary shares or those of D.N.A Biomedical, in each case subject to adjustment) and warrants to purchase additional shares upon conversion of the applicable convertible loans, were evaluated based on a combination of the probability weighted expected return method and the back solve option pricing method model using the following parameters:

	December 31,	
	2016	2015
WACC	22%	19%
Value of equity*	$71 million	$76 million
Volatility	77%	77%
Commencement of sales	2021-2025	2018-2020
Probability for success in phase 2	–	44%
Probability of entering Phase 2b/3 for EB612	70%	
Probability for IPO	50%	50%

* The value of equity in 2016 and 2015 was based on the valuation of cash generating unit based on DCF. The primary assumptions used in the valuations are as follows:

	December 31,	
	2016	2015
(“WACC”)	22%	19%
Commencement of sales	2021-2025	2018-2020
Probability of reaching sales	20.1%-37.9%	30%

The weighted average cost of capital, or the discount rate, was calculated by using the Capital Asset Pricing Model to determine the required return on equity and is based on certain assumptions used to determine the appropriate cost of debt and capital structure, as follows:

	December 31,	
	2016	2015
Risk free (1)	0.99%	0.81%
Market premium (2)	5.69%	5.81%
Specific risk (3)	16.29%	12.12%
Beta (4)	0.84	0.97
WACC	22%	19%

(1) U.S. Treasury Real Long-Term Rate.
(2) Based on publicly available estimates.
(3) Based on publicly available estimates and specific risk premium added, based on external appraiser opinion regarding the risk related to the capital raising required to execute the business plan.
(4) Based on a number of publicly traded companies which operate in the pharmaceuticals industry.

The probability of reaching sales was determined based on a publicly available research studies of a large number of clinical trials in various size and stages and indications and their associated success rates based on stage of clinical trials.

To determine the fair value of the preferred shares, warrants to purchase preferred shares and shares and liability to issue preferred shares and warrants to purchase preferred shares we prepared a valuation of the fair value of each of these components. The three components were evaluated using a combination of the probability weighted expected return method and the back solve option pricing method model using the following parameters:

	December 31,	
	2016	2015
WACC	22%	19%
Value of equity*	$71 million	$76 million
Volatility	77%	77%
Commencement of sales	2021-2025	2018-2020
Probability for success in phase 2	–	44%
Probability of entering Phase 2b/3 for EB612	70%	
Probability for IPO	50%	50%

* The value of equity in 2016 and 2015 and related key assumptions are described above.

Results of Operations

Comparison of Years Ended December 31, 2016 and 2015

	Year Ended December 31,		Increase (Decrease)	
	2016	2015	$	%
	(In thousands, except for percentage information)			
Expenses:				
Research and development	$ 2,648	$ 2,115	$ 533	25.2%
General and administrative	2,719	1,586	1,133	71.4%
Operating loss	5,367	3,701	1,666	45.0%
Financial (income) expenses, net	(4,168)	581	(4,749)	—
Net loss	$ 1,199	$ 4,282	$ (3,083)	—

Research and development expenses. Research and development expenses for the year ended December 31, 2016 were $2.6 million, compared to $2.1 million for the year ended December 31, 2015, an increase of $0.5 million, or 25.2%. The increase in research and development expenses was primarily due to an increase of $0.5 million in expenses for salaries and related employee expenses resulting from an increase in the number of employees (of which $0.1 million represented an increase in share-based compensation expenses), an increase of $0.3 million primarily due to expenses for materials and decrease of $0.3 million in expenses for subcontractors and CROs due to the successfully completion of Phase 2a trial in the third quarter of 2015.

General and administrative expenses. General and administrative expenses for the year ended December 31, 2016 were $2.7 million, compared to $1.6 million for the year ended December 31, 2015, an increase of $1.1 million, or 71.4%. The increase in general and administrative expenses was primarily due to an increase of $1.1 million in salaries and related employee expenses of which $1.0 million resulted from an increase in share-based compensation expenses.

Financial (income) expenses, net. Financial income, net for the year ended December 31, 2016 were $4.2 million, compared to financial expenses, net of $0.6 million for the year ended December 31, 2015. Financial income, net for the year ended December 31, 2016 resulted mainly from the change in the fair value of convertible loans, preferred shares , warrants to purchase preferred shares and shares and liability to issue preferred shares and warrants that were recorded as a financial liability at fair value through profit or loss. During the years ended December 31, 2016 and 2015, we recorded a gain of $4.3 million and a loss of $447,000, respectively, on the fair value of financial liabilities. For the assumptions used in the valuation of the convertible loans and preferred shares components see "—Critical Accounting Policies and Estimate—Fair Value of Financial Liabilities Through Profit or Loss."

Liquidity and Capital Resources

Since inception, we have incurred significant losses. For the years ended December 31, 2016 and 2015, our losses were $1.2 million and $4.3 million, respectively. In addition, during the years ended December 31, 2016 and 2015 and currently, we have been cash constrained due to our limited funds. We expect to continue to incur significant expenses and losses for the next several years. As of December 31, 2016, we had an accumulated deficit of $30.6 million. Since our inception and through December 31, 2016, we have raised a total of $7.2 million from sales of our ordinary shares, preferred shares and warrants, of which $0.6 million was recorded as an intangible asset based on the fair value of ordinary shares issued in exchange. In addition, we have raised $10.6 million from convertible loans of which an amount of approximately $1.1 million was repaid in February 2017) and $0.5 million from IIA grants. As of December 31, 2016, we had cash and cash equivalents totaling $4.2 million and additional $1.07 million in restricted cash that was used for the repayment of approximately $1.1 million of convertible loans in February 2017. Our primary uses of cash have been to fund research and development and working capital requirements, and we expect these will continue to be our primary uses of cash.

Funding Requirements

We expect that the net proceeds from this offering and our existing cash and cash equivalents will enable us to fund our research and development expenses, and working capital requirements for at least months after this offering and will be sufficient to enable us to:

- complete our planned Phase 2b/3 clinical trials of EB612;
- complete our planned Phase 2a clinical trial of EB613;
- fund research and development expenses for the development of an oral PTH product candidate for non-union bone fractures as well as oral formulations of additional large molecules; and
- expand our headcount and operations to carry out our planned activities and operate as a public company.

We have based these estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our product candidates, and the extent to which we may enter into collaborations with third parties for development of these or other product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current and future product candidates. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of clinical trials for, and regulatory review of, EB612, EB613 and any other product candidates we may develop;
- the costs of development activities for any other product candidates we may pursue;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies; and
- our ability to establish collaborations on favorable terms, if at all.

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

Our audited financial statements for the year ended December 31, 2016, included elsewhere in this prospectus, disclose our determination that there is substantial doubt about our ability to continue as a going concern as of such date; and in its report accompanying our audited financial statements included herein, our independent registered public accounting firm included an explanatory paragraph stating that our recurring losses from operations and lack of sufficient working capital raise substantial doubt as to our ability to continue as a going concern. This means that our management and our independent registered public accounting firm have substantial doubt about our ability to continue our operations without an additional infusion of capital from external sources. The audited financial statements have been prepared on a going concern basis and do not include any adjustments that may be necessary should we be unable to continue as a going concern. If we are unable to finance our operations, our business would be in jeopardy and we might not be able to continue operations and might have to liquidate our assets. In that case, investors might receive less than the value at which those assets are carried on our financial statements, and it is likely that investors in this offering would lose all or a part of their investment.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Year ended December 31,	
	2016	2015
	(in thousands)	
Cash used in operating activities	$ (3,142)	$ (3,495)
Cash used in investing activities	(1,116)	(54)
Cash provided by financing activities	7,216	4,465
Foreign exchange differences on cash and cash equivalents	-	(1)
Net increase in cash and cash equivalents	$ 2,958	$ 915

Cash Used in Operating Activities

Cash used in operating activities for the year ended December 31, 2016 was $3.1 million and consisted primarily of our operating loss of $5.4 million arising mainly from research and development expenses and general and administrative expenses, partially offset by $1.5 million of share based compensation and by a $0.4 million decrease in working capital.

Cash used in operating activities for the year ended December 31, 2015 was $3.5 million and consisted primarily of our operating loss of $ 3.7 million arising primarily from research and development activities and general and administrative expenses partially offset by $0.4 million of share based compensation. The decrease in cash used in operating activities by 10% from 2015 to 2016 was mainly due to a change in our working capital due to a decrease in prepaid expenses in the amount of $0.5 million of which $0.2 was for inventory of materials and $0.24 million for professional services, partially offset by $0.15 million decrease in account payables.

Cash Used in Investing Activities

Cash used in investing activities for the year ended December 31, 2016 consisted primarily of an investment in restricted deposits of $1.1 million to secure the repayment of short term convertible loans.

Cash used in investing activities for the year ended December 31, 2015 was immaterial and resulted from purchase of fixed assets.

Cash Provided by Financing Activities

Cash provided by financing activities for the year ended December 31, 2016 resulted from net proceeds of $7.2 million from convertible loan and warrants to purchase ordinary shares.

Cash provided by financing activities for the year ended December 31, 2015 in the amount of $4.5 million resulted from proceeds of $2.5 million from issuance of preferred shares and warrants and $2.0 million from the incurrence of convertible loans and issuance of warrants.

Contractual Obligations and Commitments

The following tables summarize our contractual obligations and commitments as of December 31, 2016 that will affect our future liquidity:

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
			(In thousands)		
Operating leases for facility and vehicles	$ 35	$ 35	—	—	—
2012 Convertible loan	1,288	34	—	—	1,254
2015 Convertible loan	1,053	1,053	—	—	—
2016 Convertible loan	9,135	9,135	—	—	—
Total	$ 11,511	$ 10,257	$ —	$ —	$ 1,254

Convertible Loans

2012 Convertible Loan

On November 13, 2012 and December 31, 2012, we entered into loan agreements with certain lenders (the “2012 Convertible Loans”). Pursuant to these agreements, the lenders loaned us an aggregate amount of $1.2 million. The 2012 Convertible Loans bear interest at a rate of 0.6% per year, which is to be repaid every five years, and are due and payable after a term of twenty years. Interest expenses of $138,000 to be incurred through maturity are included in the table above. Each of the lenders has the right during the term to convert its respective loan amount into our ordinary shares at a conversion price of $240.26 per ordinary share (subject to adjustment), and for a period of the initial five years of the term of the loan agreement to exchange all such ordinary shares received into ordinary

shares of D.N.A Biomedical at the rate of one of our ordinary shares for 5,590 ordinary shares of D.N.A Biomedical (also subject to adjustment). Under the terms of the 2012 Convertible Loans, the outstanding loan amounts will be automatically converted into our ordinary shares upon the consummation of this offering, and therefore these loans will no longer be outstanding after this offering.

2015 Convertible Loan

On August 5, 2015, the Company entered into a Convertible Promissory Note and Loan Agreement (the "2015 Convertible Loan") with certain lenders. Pursuant to the loan agreement for the 2015 Convertible Loan, the lenders loaned us an aggregate amount of $2.005 million. The 2015 Convertible Loan bore interest at a rate of 5% per year. The loan would also be automatically converted upon occurrence of the following events: an initial public offering, a private placement of equity securities or securities convertible into equity securities in an aggregate amount of no less than $10 million or a change of control (each, a "2015 Triggering Event"). In connection with any such 2015 Triggering Event, the 2015 Convertible Loans would have been converted into the equity securities and/ or securities convertible into equity securities of the Company that were issued in such a transaction, at a 25% discount.

In addition, the Company issued to each lender under the 2015 Convertible Loan warrants to purchase an additional 40% of the amount of our securities that would have been issued to such lender as a result of the automatic conversion following a 2015 Triggering Event (the "2015 Warrants"). The 2015 Warrants were exercisable for the earlier of two years from the warrant issuance date or one year from consummation of an IPO. As part of the 2016 Convertible Loan as detailed below, we granted the lenders a right to roll-over the 2015 Convertible Loan into the 2016 Convertible Loan. The lenders elected to roll-over an amount of $1.057 million into the 2016 Convertible Loan and the reminder, in an amount of $1.053 million (including interest and principal), was repaid by the Company in February 2017. There remain no amounts outstanding under the 2015 Convertible Loans, and no 2015 Warrants remain outstanding.

2016 Convertible Loan

On June 14, 2016, the Company entered into a convertible loan agreement (the "2016 Convertible Loan") with certain lenders for an aggregate amount of approximately $7.44 million. In addition, an amount of $1.057 million of the 2015 Convertible Loan rolled over to the 2016 Convertible Loan. The 2016 Convertible Loan is for a term of 18 months and bears interest at a rate of 5% per year. The 2016 Convertible Loan will automatically convert upon the occurrence of any of the following events: an initial public offering of at least $20 million, a private placement of the Company's equity securities in an aggregate amount of not less than $10 million, or a change of control (each, a "2016 Triggering Event"). Furthermore, in case of a private placement in an aggregate amount of between $4 million to $10 million the lenders have the right to convert the 2016 Convertible Loan. In each case of conversion, the 2016 Convertible Loan will convert into the same equity securities and/or securities convertible into equity securities of the Company that were issued in such a transaction at the lower of (i) a 25% discount to the applicable price per share of such security or (ii) the price per share of such securities calculated at a valuation of $65 million on a fully diluted basis.

In addition, the Company issued to each lender under the 2016 Convertible Loan warrants to purchase an additional 40% of the amount of our securities issued to such lender as a result of the automatic conversion following a 2016 Triggering Event (the "2016 Warrants"). The 2016 Warrants will be exercisable upon conversion of the 2016 Convertible Loan and thereafter until June 2020.

In addition, each lender in the 2016 Convertible Loan have the right to invest, in the next share issuance by the Company, an amount not to exceed the amount such lender invested in the 2016 Convertible Loan, at a price per share in such issuance.

Severance Obligations

We have long-term liabilities for severance pay that are calculated pursuant to Israeli law generally based on the most recent salary of the relevant employees multiplied by the number of years of employment to the extent not covered by our regular deposits with defined contribution plans. As of December 31, 2016, our severance pay liability, net was $51,000. Because the timing of any such payments is not fixed and determinable, we have not included these liabilities in the table above.

Contingencies

We also have obligations to make future payments to third parties that become due and payable on the achievement of certain milestones, such as royalties upon sale of products. We have not included these commitments in our statements of financial position or in the table above because the achievement and timing of these milestones is not fixed and determinable. These potential future commitments include:

- a commitment to pay Oramed royalties equal to 3% of our net revenues pursuant to the terms of the Patent Transfer Agreement between us and Oramed; and

- a commitment to pay royalties to the IIA. See "—Patent Transfer Agreement and Grant Funding."

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements.

Quantitative and Qualitative Disclosures 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 functional currency and reporting currency is the U.S. dollar. Fluctuations in the New Israel Shekel, or the NIS, to U.S. dollar exchange rate may affect our results because some of our assets and liabilities are linked to the NIS and a portion of our operating expenses are denominated in NIS. In the future, we also may be exposed to additional currency fluctuations against the U.S. dollar. 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 Risk

We do not believe that inflation had a material effect on our business, financial condition or results of operations in the last two fiscal years. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through hedging transactions. Our inability or failure to do so could harm our business, financial condition and results of operations.

Recently Issued and Adopted Accounting Pronouncements

IFRS 9 "Financial Instruments"

The complete version of IFRS 9 replaces most of the guidance in IAS 39. IFRS 9 retains but simplifies the mixed measurement model and establishes three primary measurement categories for financial assets: amortized cost, fair value through other comprehensive income and fair value through profit and loss. The basis of classification depends on the entity's business model and the contractual cash flow characteristics of the financial asset. Investments in equity instruments are required to be measured at fair value through profit or loss with the irrevocable option at inception to present changes in fair value in other comprehensive income. There is now a new expected credit losses model that replaces the incurred loss impairment model used in IAS 39. For financial liabilities, there were no changes to classification and measurement except for the recognition of changes in own credit risk in other comprehensive income, and for liabilities designated at fair value through profit or loss. The standard is effective for accounting periods beginning on or after January 1, 2018. The Company is currently evaluating the impact of adoption of this standard on its financial statements.

IFRS 16 "Leases"

In January 2016, the IASB issued IFRS 16, Leases, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract and replaces the previous leases standard, IAS 17, Leases. IFRS 16 eliminates the classification of leases for the lessee as either operating leases or finance leases as required by IAS 17 and instead introduces a single lessee accounting model whereby a lessee is required to recognize assets and liabilities for all leases with a term that is greater than 12 months, unless the underlying asset is of low value, and to recognize depreciation of lease assets separately from interest on lease liabilities in the income statement. As IFRS 16 substantially carries forward the lessor accounting requirements in IAS 17, a lessor will continue to classify its leases as operating leases or finance leases and to account for those two types of leases differently. IFRS 16 is effective from January 1, 2019 with early adoption allowed only if IFRS 15, Revenue from Contracts with Customers, is also applied. The Company is currently evaluating the impact of adoption of this standard on its financial statements.

JOBS Act Exemptions

On April 5, 2012, the U.S. Congress enacted the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This means that an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Accordingly, we are electing to delay such adoption of new or revised accounting standards. As a result, our financial statements may not be comparable to companies that comply with these standards.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on other 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." We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenue, have more than $700 million in market value of our ordinary shares held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. Given that we currently report and expect to continue to report under IFRS as issued by the IASB, we will not be able to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB.

BUSINESS

We are a biopharmaceutical company focused on the development and commercialization of orally delivered large molecule therapeutics for use in orphan indications and other areas with significant unmet medical need. We are initially applying our technology to develop an oral formulation of parathyroid hormone, or PTH, which has been approved in the United States in injectable form for over a decade. Our lead oral PTH product candidate, EB612, has successfully completed a Phase 2a trial for hypoparathyroidism, a rare condition in which the body fails to produce sufficient amounts of PTH. The U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, have granted EB612 orphan drug designation for the treatment of hypoparathyroidism. We expect to initiate a Phase 2b/3 clinical trial of EB612 in the first quarter of 2018, and we plan to submit applications for regulatory approval of EB612 in the first half of 2020.

Hypoparathyroidism is a rare condition in which the body does not produce sufficient amounts of PTH, or the PTH produced lacks biologic activity. Individuals with a deficiency of PTH typically exhibit abnormally low levels of calcium in the blood, or hypocalcemia, and high levels of phosphorus, or hyperphosphatemia. Hypoparathyroidism is estimated to affect approximately 58,700 individuals in the United States. Historically, the treatments for hypoparathyroidism have been calcium supplements, vitamin D supplements and phosphate binders, the chronic use of which results in serious side effects with significant costs to the healthcare system. Natpara®, a once-daily injectable form of PTH, has been approved for the treatment of hypoparathyroidism. Our lead product candidate, EB612, is delivered orally and can be administered in customized doses several times a day. Multiple dosing per day has been shown to more effectively treat the symptoms of hypoparathyroidism than a once-daily injection, thus reducing the serious side effects of supplement treatment and improving patient outcomes. We believe patients generally prefer oral drugs. For these reasons, we believe EB612 is clinically superior to existing therapies and has the potential to become the standard of care for hypoparathyroidism.

In the third quarter of 2015 we successfully completed our Phase 2a trial for EB612. The end points in the trial were met, and 17 subjects completed the four-month trial and reported no related adverse events. Although our trial Phase 2a trial involved a smaller number of patients, was conducted for a shorter duration and did not include an initial optimization period in comparison to the design of the pivotal trial used for regulatory approval of Natpara, the REPLACE study, our Phase 2a trial still showed similar efficacy. We believe that EB612 will have inherent advantages compared to injectable forms, including convenience of application, the fact that no special preparations are required and the fact that no restrictive storage conditions are necessary. Additionally, we believe that EB612 will have an enhanced clinical profile as compared to Natpara, with an additional positive effect on elevated urinary calcium, as well as reduced side effects. We believe this combination of advantages and long term clinical benefits will be very compelling to both patients and physicians.

Based on consultations with key opinion leaders in the hypoparathyroidism field who have reviewed our Phase 2a results and are familiar with the REPLACE study are planning for a Phase 2b/3 trial, designed to possibly be a pivotal study for registration. This Phase 2b/3 study will be designed to repeat the REPLACE study in virtually every aspect, as well as to achieve a reduction in urinary calcium.

We are also developing a distinct oral PTH product candidate, EB613, for the treatment of osteoporosis. Osteoporosis is a systemic skeletal disease characterized by low bone mass, deterioration of bone tissue and increased bone fragility and susceptibility to fracture. An estimated 10 million people in the United States already have osteoporosis, and another approximately 43 million have low bone mass placing them at increased risk for osteoporosis. PTH plays a key role in the ongoing process of formation and degradation of bones. Forteo®, a once-daily injectable form of PTH, has been approved for the treatment of osteoporosis in the United States for over 10 years and is widely considered one of the most effective treatments due to its ability to build bone. Because our product candidate EB613 is oral, we believe it will reduce the treatment burden on patients and lead to significantly higher patient and physician acceptance compared to an injectable form of PTH. We intend to commence a Phase 2a clinical trial of EB613 in the fourth quarter of 2017. After completing this trial we intend to collaborate with a strategic partner to further develop and commercialize EB613. We also are preparing to conduct a clinical trial of our oral PTH in non-union fractures, one indication within the field of bone healing.

Our product candidates utilize our proprietary technology for the oral delivery of large molecules. Drug development has shifted towards the use of peptides, proteins and other large molecules for the treatment of various diseases. Between 1993 and 2004, large-molecule clinical approval success rates have outpaced small molecules by about two-to-one. Large molecules have been particularly widely used in orphan indications. Oral drug delivery reduces the treatment burden on patients relative to injectable drugs and provides significantly more flexibility, both in size of dose and number of doses per day, than injectable drugs, which are frequently administered once per day by preset injection pen. However, peptides, proteins and other large molecule therapeutics can currently only be delivered via injections and other non-oral pathways because oral administration leads to poor absorption into the blood stream as well as enzymatic degradation within the gastrointestinal tract.

Our proprietary oral drug delivery technology is designed to address both of these issues by utilizing a combination of a synthetic absorption enhancer, to facilitate the enhanced absorption of large molecules and protease inhibitors to prevent enzymatic degradation.

We also intend to use our technology as a platform for the oral delivery of other protein and large molecule therapeutics. We initially intend to focus on the development of products based on previously approved therapeutic agents. We believe this will allow us to more efficiently and predictably advance product candidates through the development cycle based on well-defined clinical and regulatory approval pathways. We have conducted initial feasibility studies with a number of candidates and intend to commence clinical development for our next, non-PTH, product candidate by the end of 2018.

The following chart summarizes important information about each of our current product candidates, including their indications, and their current stage of development. We have not out-licensed any intellectual property rights to our PTH product candidates listed below, and, therefore, have retained the ability to pursue their worldwide commercialization.

Program	Indication	Pre-Clinical	Phase I	Phase II	Phase III	Status
EB612 PTH 1-34	Hypoparathyroidism	Phase 2a complete				• Phase 2a complete • Pivotal Phase 2b/3 initiation expected 1Q18 • Topline Data expected 1H19
EB613 PTH 1-34	Osteoporosis	Phase 1 complete				• Phase 2a initiation expected 4Q17
	Non-union fractures	Phase 1 complete				• Phase 2a initiation expected 1H18

We commenced operations in August 2010 after receiving startup financing in the form of $0.6 million in cash from D.N.A Biomedical Solutions Ltd. and a license from Oramed Ltd., a subsidiary of Oramed Pharmaceuticals, Inc., to certain patent rights relating to the oral administration of proteins. These previously licensed patent rights were assigned to us in 2011, subject to an exclusive, royalty-free license in specified fields under such patent rights that we granted to Oramed Ltd.

We subsequently advanced our oral PTH product candidates from preclinical studies in animals to a Phase 2a clinical trial of EB612 in hypoparathyroidism in less than five years.

While our operations are currently focused in our offices in Israel, we intend to build a substantial U.S. presence to execute on our later stage development of our products, including clinical operations, regulatory operations, and commercialization. The following chart summarizes important information about each of our current product candidates, including their indications, and their current stage of development. We have not out-licensed any intellectual property rights to our PTH product candidates listed below, and, therefore, have retained the ability to pursue their worldwide commercialization.

Our Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of orally delivered large molecule therapeutics in indications with significant unmet medical need. The key elements of our strategy to achieve this goal are to:

- *Advance our lead product candidate, EB612, through clinical development and into commercialization for the treatment of hypoparathyroidism*: We completed a Phase 2a clinical trial of EB612 for the treatment of hypoparathyroidism and reported supportive results in the third quarter of 2015. We plan to initiate a Phase 2b/3 clinical trial of EB612 in hypoparathyroidism in the United States commencing in the first quarter of 2018 and the filing of a biologics license application, or BLA, with the FDA for approval of EB612 in 2020.

- *Produce supportive clinical data for our second product candidate, EB613, for the treatment of osteoporosis, before advancing into late-stage clinical trials*: We are currently preparing to commence a Phase 2a clinical trial of EB613 in the fourth quarter of 2017. When we complete this trial in 2018, we subsequently intend to collaborate with a strategic partner to further develop and commercialize the product.

- *Leverage our expertise in the oral delivery of PTH to develop product candidates in additional indications*: We intend to conduct exploratory Phase 2 studies for the use of our oral PTH candidates in additional indications in which PTH plays a key biological role, including non-union fractures, one indication within the field of bone healing. We plan to use EB613, or a further modified formulation if studies suggest we could achieve a PK profile that is more efficacious, for these indications. We also plan to apply our drug delivery technology to other large molecules with chemical and other characteristics that would be advantageous with our technology in order to target orphan indications and other areas with significant unmet medical need.

- *Improve the efficacy profile of large molecule therapeutics through the application of our proprietary oral delivery technology*: Oral drug delivery lowers the treatment burden on patients relative to injectable drugs, leading to higher patient and physician acceptance. However, peptides, proteins and other large molecule therapeutics can currently only be delivered via injections and other non-oral pathways because oral administration leads to negligible absorption into the blood stream as well as enzymatic degradation within the gastrointestinal tract. Our technology is designed to overcome both of these issues by enabling enhanced systemic absorption of large molecules and slowing their enzymatic degradation.

- *Focus our development and commercialization efforts on indications with significant unmet medical need*: We are focused on the development of orally delivered large molecule therapeutics for the treatment of orphan indications and other indications with significant unmet medical need. Between 1993 and 2004, large-molecule clinical approval success rates have outpaced small molecules by about two-to-one and there are a wide range of large-molecules candidates within the orphan space for potential use with our oral drug delivery technology. For product candidates that target orphan indications, we intend to retain commercialization rights within key territories, including the United States, because of the ability to commercialize with a small sales force. For product candidates that target indications with larger patient populations, we may choose to partner with larger biopharmaceutical companies ahead of late stage development and commercialization.

- *Initially develop products based on FDA-approved large molecule therapeutics*: By initially focusing on the development of product candidates that apply our technology to FDA-approved large molecule therapeutic agents with clinically proven efficacy, known mechanisms of action and established safety profiles, we believe we can reduce the development risks associated with our product candidates. We believe this will allow us to advance our product candidates efficiently and predictably through the development cycle.

Our Technology

We are focused on the development and commercialization of product candidates that leverage our proprietary technology for the oral delivery of large molecule therapeutics. Recently, drug development has shifted towards the use of peptides, proteins and other large molecules for the treatment of various diseases. By lowering the treatment burden on patients, oral drug delivery leads to higher patient and physician acceptance. In addition, oral drug delivery provides significantly more flexibility, both in size of dose and number of doses per day, than injectable drugs, which are frequently administered by preset injection pen and only once per day.

Currently, peptides, proteins and other large molecule therapeutics can only be delivered via injections and other non-oral pathways because oral administration leads to poor absorption into the blood stream (bioavailability) due to enzymatic degradation within the gastrointestinal tract and poor permeability though the intestinal wall. Most oral drug delivery technologies attempting to overcome this hurdle nevertheless manage to attain only very low bioavailability (less than 1%). Orally-delivered large molecules with low systemic levels present high variability of dose exposure, both between patients and within the same patient at different times of administration since small changes in the level of absorption lead to significant changes in the bioavailability. Absorption variability is generally decreased as the drug bioavailability is increased.

Oral formulations of large molecules must therefore ensure that the large molecule is able to pass through the intestinal wall so that it can be absorbed into the bloodstream and that the large molecule therapeutic is not exposed to enzymatic degradation in order to protect its biological activity and availability for absorption.

Our proprietary technology is designed to address both of these issues by utilizing a combination of a synthetic absorption enhancer, or carrier molecule, to facilitate the enhanced absorption of large molecules, and protease inhibitors to prevent enzymatic degradation. By designing our product candidates to address both the issues of absorption and degradation, we have been able to significantly increase bioavailability and decrease the variability of the PTH dose delivered in our clinical trials to date.

Our carrier molecule is designed to create a weak association with our chosen large molecule therapeutic, leaving the therapeutic agent chemically unmodified. The carrier molecule enables transport across the intestinal membrane via transcellular absorption without compromising the integrity of the intestinal wall. Because of the weak association between the carrier molecule and the therapeutic agent, the interaction is designed to be reversible and occurs spontaneously by simple dilution on entering the blood. We selected protease inhibitors that act by specifically inhibiting a number of gastrointestinal enzymes designed to assist in the degradation and digestion of proteins without interfering with normal gastrointestinal activity.

In order for large molecule therapeutics to be benefit from the use of our oral delivery technology, they must demonstrate a number of specific characteristics, including:

- appropriate size, as measured by molecular weight, and other chemical/physical characteristics;
- a mechanism of action that favors delivery through the gastrointestinal tract rather than through injections, and;
- a dosing schedule that requires dosing one or more times per day for at least three months.

Based on these criteria, the first product candidate we chose to pursue was PTH, which has the potential for therapeutic use in a number of indications including hypoparathyroidism, osteoporosis and non-union fractures.

Our Product Candidates

The following chart summarizes important information about each of our current product candidates, including their indications and their current stage of development. We have not out-licensed any intellectual property rights to our PTH product candidates listed below, and, therefore, have retained the ability to pursue their worldwide commercialization.

Program	Indication	Description	Stage of Development	Status
EB612	Hypoparathyroidism	Oral PTH (1-34)	Phase 2a completed	Phase 2a successfully completed; results reported Q3 2015 PK/PD head to head with Natpara in hypoparathyroid patients expected in H2 2017 Phase 2b/3 initiation in United States , Europe, Israel and Canada expected Q1 2018
EB613	Osteoporosis	Oral PTH (1-34)	Phase 1	Phase 2a initiation expected Q4 2017 In 2019, expect to partner with a larger biopharmaceutical company for the clinical development and commercialization
Oral PTH	Non-union fractures	Oral PTH (1-34)	Preclinical	Phase 2a initiation expected 2018

Oral PTH Therapeutics

PTH is a hormone that regulates the levels of calcium and phosphorus in the blood. The naturally occurring form of PTH that is found in the human body is composed of 84 amino acids, although only the first 34 amino acids are believed to be responsible for its biological effects. A recombinant form of PTH that is comprised of only the first 34 amino acids, or PTH (1-34), can be used as a treatment for a number of indications, including hypoparathyroidism, osteoporosis and non-union fractures. An injectable form of PTH (1-34), marketed under the name Forteo, has been approved in the United States for more than ten years and has been used by millions of patients for the treatment of osteoporosis. An injectable form of full length PTH (1-84), marketed under the name Natpara, has also recently been approved for the treatment of hypoparathyroidism. We are developing a number of distinct oral PTH (1-34) tablets, with significant differences in dose and pharmacokinetic, or PK, profile that can be used for a number of proposed indications. We believe that our oral PTH product candidates, if approved, have the potential to become the standard of care for patients with hypoparathyroidism, osteoporosis and non-union fractures.

PTH regulates calcium and phosphate homeostasis and bone metabolism in the body. In normal healthy individuals, PTH is generally produced at a very low basal level of 15-25 pg/ml (pg = 10^{-12} g). On top of the basal PTH levels, there are physiological pulses two to three times per day presented as transient increases in PTH levels reaching up to 35 pg/ml. While the basal level helps maintain calcium and phosphate homeostasis, the pulses help encourage bone turnover through activation of both osteoblasts and osteoclasts, the two main types of cells that are responsible for the process through which bones are constantly being remodeled. These pulses also allow for the release of calcium from bone and the excretion of phosphorous by the kidneys during times when calcium is scarce and phosphorous is too high. Absent these pulses, it is difficult for the body to regulate normal homeostatic processes.

EB612 for Hypoparathyroidism

Hypoparathyroidism

We are focused on the development of oral PTH (1-34) for hypoparathyroidism, which, if approved, we believe has the potential to become the standard of care for hypoparathyroidism. Hypoparathyroidism is a rare condition in which the parathyroid glands fail to produce sufficient amounts of PTH or the PTH produced lacks biologic activity. Individuals with a deficiency of parathyroid hormone may exhibit hypocalcemia and hyperphosphatemia. Hypocalcemia can cause one or more of a variety of symptoms, including weakness, muscle cramps, excessive nervousness, headaches and uncontrollable twitching and cramping spasms of muscles such as those of the hands, feet, arms, legs and face, which is known as tetany. Numbness and tingling around the mouth and in the fingers and toes can also occur. Acute hypocalcemia can result in cardiac failure, failure of nervous system functions and death. Hyperphosphatemia can result in soft tissue calcium deposition, which may lead to severe issues, including damage to the circulatory system and central nervous system. The most common cause of hypoparathyroidism is damage to, or removal of, the parathyroid glands due to surgery for another condition. Hypoparathyroidism can also be caused by an autoimmune process, or idiopathic reasons or occur in association with a number of different underlying disorders. In rare cases, hypoparathyroidism may occur as a genetic disorder.

The prevalence of hypoparathyroidism is estimated to be 37 per 100,000 in the United States, with 78% of cases caused by surgery, 7% due to genetic disorder and 6% due to idiopathic origin. Although incidence rates have been difficult to quantify, it is estimated that chronic hypoparathyroidism, which affects patients for more than six months, affects approximately 58,700 individuals in the United States, with an estimated 43% of these chronic cases characterized as mild, 39% characterized as moderate, and 18% characterized as severe. The FDA has granted orphan drug designation to our oral PTH for the treatment of hypoparathyroidism.

Historically, the treatments for hypoparathyroidism have been calcium supplements, vitamin D supplements and phosphate binders. Although calcium and vitamin D can help alleviate hypocalcemia, their chronic use results in many serious side effects with significant costs to the healthcare system. Hypoparathyroid patients often need to take large doses of calcium throughout the day in order to maintain calcium homeostasis in the serum, or blood plasma, throughout the day for normal body functioning. It then falls upon the kidneys to dispose of excess calcium and maintain precise control of serum calcium levels. Over potentially years of treatment, kidney stones may develop, and ultimately kidney failure may occur. Even with the use of calcium and vitamin D supplements and other medications, the majority of patients with hypoparathyroidism continue to experience multiple severe physical and cognitive symptoms.

Until recently, hypoparathyroidism was the only hormonal insufficiency state that did not have an approved hormone replacement therapy. NPS Pharmaceuticals, Inc., a biopharmaceutical company that was acquired by Shire plc in February 2015, developed Natpara, a recombinant form of human PTH (1-84), as an injectable hormone replacement therapy for the underlying cause of hypoparathyroidism, lack of PTH. Natpara is administered once daily with a pre-set injection pen. Natpara was approved by the FDA in January 2015 launched commercially in the United States later in 2015.

In September 2014, an advisory committee of the FDA reviewed the Natpara BLA. This advisory committee review of Natpara highlighted a number of observations. In its briefing to the advisory committee, the FDA noted that Natpara had limited clinical benefit in controlling excessive calcium in the urine, or hypercalciuria, a condition commonly associated with hypoparathyroidism and the most commonly identifiable cause of calcium kidney stone disease. Additional analysis by the FDA also noted that, due to a change in trial protocol that was made after the initiation of the trial, the responder rate for the pivotal single-dose trial's primary efficacy endpoint was 32.1% under the original trial protocol versus the 54.8% that was ultimately reported. The FDA stated in its briefing report that the results of this alternate analysis may be more clinically relevant, particularly if a clinician's goal is to keep a patient's serum calcium in the lower half of the normal range.

We believe EB612 is differentiated from Natpara for the following reasons:

- *EB612 is designed to be dosed multiple times a day*. Studies performed by the NIH have shown that dosing PTH multiple times per day significantly increases the efficacy of therapy and would be more effective for treating hypoparathyroidism. These studies found that the total daily PTH dose required to maintain serum calcium in the normal or near-normal range was reduced by 50% with twice-daily PTH (1-34) and also demonstrated that twice-daily dosing achieved better control over serum calcium and urinary calcium excretion as compared to one-daily dosing.

- *EB612 is designed to be dosed according to patient needs*. The hypoparathyroid population is heterogeneous and patients have highly variable responsiveness to PTH. Therefore, the ability to customize PTH dosing throughout the day with an oral tablet is an advantage over a once-daily preset injection pen.

- *EB612is expected to have less adverse events of hypercalcemia*. Our planned treatment regimen would be increased gradually and in parallel as serum calcium increases slightly. As a result, calcium and vitamin D supplements would be reduced gradually, while maintaining a relatively stable level of serum calcium. This is in contrast with Natpara's initial high dose, which requires an immediate reduction in supplements in anticipation of a rapid increase in serum calcium levels. Furthermore, this immediate and prolonged increase in serum calcium increases risk of prolonged hypercalcemia compared to EB612.

- *EB612 can be administered in a more convenient manner*. Natpara must be stored under restrictive conditions (refrigeration requiring no freezing and no shaking), and a multiple step preparation must be performed every two weeks. EB612 will not require such additional preparations and will have no significant storage restrictions.

EB612, if approved, could be administered several times a day in customized doses and could therefore more specifically regulate calcium and phosphate levels throughout the day without the side effects associated with a highly concentrated once-daily injection. We believe this would alleviate the symptoms of hypoparathyroidism while reducing the need for calcium and vitamin D supplements, thus also lessening the side effects of supplement treatment. As a result of its dose flexibility and the greater patient acceptance of oral formulations, we believe EB612, if approved, will address a larger segment of the hypoparathyroid population than Natpara. For these reasons, we believe that EB612, if approved, has the potential to become the standard of care for hypoparathyroidism.

Overview of EB612

Our lead product candidate, EB612, is an oral formulation of PTH (1-34). To date, no oral PTH formulation has been successfully developed because PTH, like many other hormonally active peptides, degrades rapidly in the intestinal tract when taken orally. EB612 is a synthetic form of the first 34 amino acids of human PTH to which we have applied our proprietary technology for the oral delivery of large molecule therapeutics. This technology permits oral administration, enabling more frequent dosing throughout the day and greater sensitivity and flexibility in dosing than injectable formulations of PTH. The carrier molecule and selection of protease inhibitors that are used in our technology are well-characterized and have been used in large clinical trials. We have attempted to optimize EB612 to enable the most cost effective and safe formulation while maintaining the required effect. These components, when used separately, have been shown to be safe in doses significantly higher than those used in the clinical trials for our current product candidates.

Our oral PTH (1-34) also displayed positive pharmacokinetic profiles, or PK, and pharmacodynamic, or PD, properties, in particular compared to commercially available injectable PTH (1-34) (Forteo).

The following summarizes our clinical development of EB612 to date:

We have conducted a Phase 1a clinical trial with multiple formulations of our oral PTH to evaluate safety and collect bioavailability, PK and PD data in 42 healthy volunteers.

We conducted an extended Phase 1b clinical trial in an additional 30 subjects to test a variety of manufacturing technologies with multiple formulations and dosing regimens of our oral PTH.

We completed a Phase 2a trial. The end points in the trial were met, and 17 subjects completed the four-month trial and reported no related adverse events.

We believe that EB612 will have inherent advantages compared to injectable forms, including convenience of application, the fact that no special preparations are required and the fact that no restrictive storage conditions are necessary. Additionally, we believe that EB612 will have an enhanced clinical profile as compared to Natpara, with an additional positive effect on elevated urinary calcium, as well as reduced side effects. We believe this combination of advantages and long term clinical benefits will be very compelling to both patients and physicians.

Phase 2a Clinical Trial

In 2015, we successfully completed a Phase 2a clinical trial of EB612 in hypoparathyroidism patients. The end points in the trial were met, and 17 subjects completed the four-month trial and reported no related adverse events.

While we have not conducted direct head-to-head studies comparing EB612 to Natpara, based on a review of the clinical data presented in Natpara's REPLACE study and our Phase 2a results, we believe EB612 provides a more favorable therapy for hypoparathyroidism patients. Although our Phase 2a study involved a smaller number of subjects (N=17 vs. N=84 + 40 placebo), lasted for a shorter duration (4 month vs. 6 months) and did not include an optimization period of ~2-16 weeks prior to treatment initiation, our results showed a greater absolute reduction in calcium supplements (1278 ±880mg vs. 1152 ±1219mg) while the patients' albumin adjusted serum calcium increased slightly as opposed to a slight decrease in the REPLACE study (baseline vs. end of treatment). Furthermore, based on results from our Phase 2a trial, as compared to Natpara injection, we believe that EB612 carries a lower risk of adverse events.

In the Phase 2a trial there were no related serious or significant adverse events and there was one unrelated serious adverse event of hypercalcemia which occurred in one patient prior to the administration of the study drug for the first time. In addition, one patient who withdrew from the trial after the first day, reported possibly drug-related adverse events. The trial report concluded that the patient's events were unlikely related to EB612, but this conclusion could not be confirmed following the patient's withdrawal from the study.

Based on consultations with key opinion leaders in the hypoparathyroidism field who have reviewed our Phase 2a results and are familiar with the REPLACE study are planning for a Phase 2b/3 trial, designed to possibly be a pivotal study for registration. This Phase 2b/3 study will be designed to repeat the REPLACE study in virtually every aspect, as well as to achieve a reduction in urinary calcium.We anticipate commencing this Phase 2b/3 clinical trial in the first quarter of 2018 and that final data will be released in second half of 2019.

Phase 1b Clinical Trial

In order to continually improve our formulations and evaluate different manufacturing technologies, we undertook an extended Phase 1b clinical trial. This clinical trial was designed to emulate multiple Phase 1b clinical trials, in that it evaluated production methods, and multiple formulations and administration regimens of our oral PTH (1-34) for safety, bioavailability, PK and PD data. This open-label clinical trial is designed to compare our various oral formulations of PTH (1-34) to injectable PTH (1-34) in 30 healthy male volunteers. Each subject was administered a 20 µg dose of injectable PTH (1-34) during the first visit to establish a baseline for comparison. Subsequently, different formulations of our oral PTH are administered during eight successive visits, each separated by at least a 48-hour washout period. The different formulations include modifications in PTH dose (0.5mg – 2.5mg) and ratios of PTH to excipients, as well as changes in production method and administration parameters. The primary purpose of this clinical trial is to allow us to test a variety of manufacturing technologies. As a result of this clinical trial we have been able to further optimize the formulation and achieve an increased bioavailability and reduced variability.

Completed Phase 1 a Clinical Trial

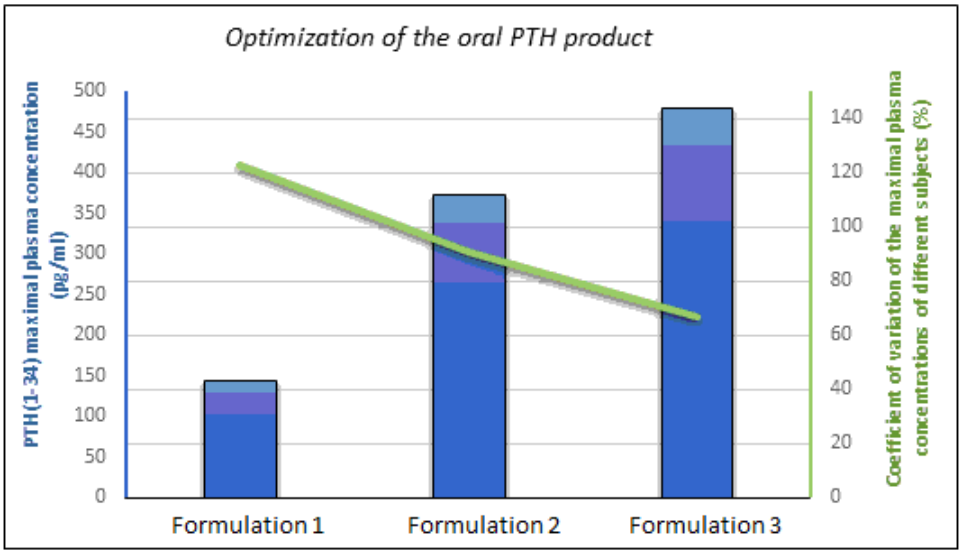
Following proof-of-concept and safety studies in various animal models, we conducted a Phase 1a clinical trial to assess the safety and pharmacokinetic profile of our oral PTH. The clinical trial was designed as a three-stage study in 42 healthy volunteers. The first stage, in which 24 subjects participated, was blinded and placebo-controlled for the study drug and placebo, and open label for subcutaneous injection of PTH (1-34). In the second, dose-escalation, stage, six new subjects were administered different formulations with modifications in PTH dose and ratios of PTH to excipients, with doses up to 1.5 mg. In the third stage, the best formulation of our oral PTH, selected based on data from the second stage, was compared to placebo and subcutaneous injection of PTH (1-34) in 12 healthy subjects. The primary endpoint of the clinical trial was safety. Bioavailability was also evaluated, and in the second and third stages PK and PD data were also collected.

The clinical trial began in August 2011 and was completed in early 2013. This clinical trial was conducted over an extended period of time as multiple formulations of oral PTH (1-34) were tested. In typical Phase 1 clinical trials, one formulation is tested for safety and, perhaps, PK and PD profile. Therefore, the results from our Phase 1a clinical trial effectively represent the equivalent of nine separate Phase 1 clinical trials. By combining these nine clinical trials into one protocol, we were able to achieve significant economies of scale and time.

No significant adverse events were reported in any of the 72 subjects participating in the Phase 1 clinical trials (including the Phase 1b clinical trial detailed above). However, there were some expected transient and minor drug related adverse events such as minor hypercalcemia in one subject and minor tachycardia in two subjects. There were also two possibly related mild adverse events: anemia (following a placebo treatment and likely to be unrelated) and nausea. There was also one subject who experienced three mild adverse musculoskeletal and connective tissue events that were considered possibly related to study treatment.

The PK and PD data indicated that our oral PTH (1-34) can successfully mimic injectable PTH (1-34)'s peak serum concentration levels after drug administration and prior to the administration of a second dose, or Cmax, as well as time to maximal concentration, or Tmax. The PK profile of the absorbed PTH (1-34) was characterized by a sharp increase in concentration, forming a peak concentration within 60 minutes post-drug administration, followed by a rapid decrease, which leads to the anabolic, or bone-building effect of PTH. In some formulations the average Cmax achieved by our oral PTH (1-34) was similar to the Cmax following the subcutaneous injection of the commercial PTH (1-34) or greater. There was a significant inter-patient and intra-patient variability, which is believed to be associated with the variability of the gastric state of the volunteers and on the various treatment visit days. In later visits of the clinical trial we were able to decrease the variability through optimization of our formulation.

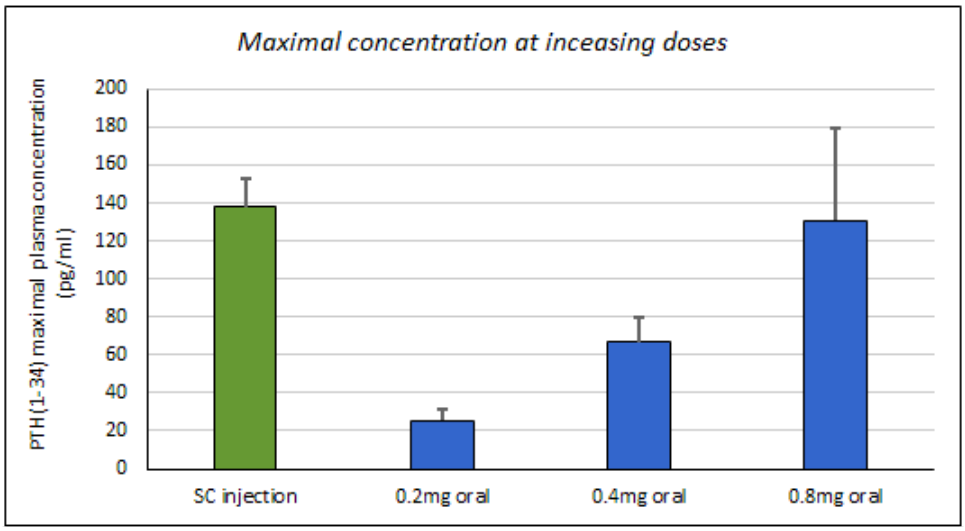
Analysis of the PD profile of our oral PTH (1-34) indicated that a biomarker of PTH activity, cyclic AMP, was activated in a similar manner to that of injectable PTH (1-34) Furthermore, analysis of serum calcium indicated that an increase can be obtained by a single dose of our oral PTH (1-34) as indicated in the graph below:



Change in serum concentrations of albumin corrected calcium (green line) and the plasma concentrations of PTH (1-34) (blue line) following the administration of oral PTH (1-34) (0.75mg) in ten healthy volunteers.

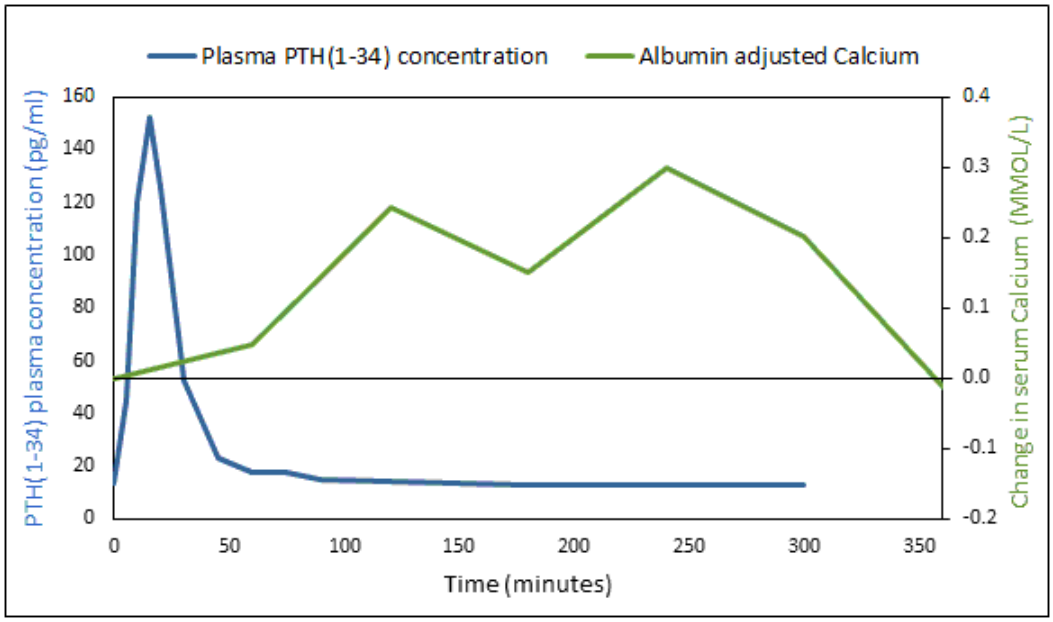
These data effectively show that oral PTH (1-34) reaches the circulation, remains intact and has biological potency similar to that observed with injectable PTH (1-34). At present, we estimate that there are at least four million patient years' experience with injectable PTH (1-34). We believe that reaching a similar peak plasma concentration and PD profile as with the injectable PTH (1-34) significantly decreases the risk that our oral PTH (1-34) will not have the desired clinical effect.

The graph below shows a linear dose/response relationship of oral PTH. An increase in absorption variability was observed with the dose increase in phase 1 studies.



Dose – response relationship of oral PTH(1-34) in healthy volunteers.

We then focused our efforts, along with the increase in bioavailability, on the reduction of the variability. An optimized formulation showed an approximately three-fold increase in bioavailability (from 0.5% to about 1.5%) and two-fold decrease in variability of the maximal plasma levels of PTH (1-34).



Optimization of oral PTH(1-34) product. A fixed dose of 1.5mg was administered using different formulations (N= 9-10). Along with the significant increase in bioavailability (blue bars) the variability (green line) of the maximal plasma levels was markedly decreased.

Preclinical and Clinical Development of EB612

In preclinical, Phase 1 and Phase 2 clinical development, EB612 exhibited negligible safety issues and displayed compelling PK and PD properties, in particular compared to commercially available injectable PTH (1-84) Natpara and PTH (1-34) (Forteo). We have refined our formulation of EB612 and tested the new formulation in a Phase 2a clinical trial in hypoparathyroid patients. In a triple cohort Phase 1b study, we continued to further optimize our production methods and formulation of EB612 following the Phase 2a and in anticipation of a larger Phase 2b that we expect will result in further improvements and reduction in the variability.

Planned Additional Clinical Development and Regulatory Pathway

As part of our regulatory pathway to conducting the Phase 2b/3 and based on initial feedback from the FDA and regulatory consultants, we intend to conduct a short four-arm PK/PD study comparing two of our dose regimens with two controls: placebo and Natpara. This PK/PD study will include 10 to 15 hypoparathyroidism patients for a treatment and monitoring duration of 24 hours per treatment arm. This study is designed to provide a bridge from our completed Phase 2a trial, which was conducted prior to the marketing approval of Natpara and our planned Phase 2b/3 study. This study may also provide valuable "head to head" data that will further inform our Phase 2b/3 study design.

We plan on submitting an IND for this study in the fourth quarter of 2017 and completing the study shortly after receiving an IND approval. We will then provide the additional data required to expand the IND to allow for the larger Phase 2b/3 study. We hope to initiate our Phase 2b/3 study in the first quarter of 2018. If our results from the Phase 2b/3 clinical trial are successful and the trial is acceptable as a pivotal trial, as intended, we plan to submit a BLA to the FDA for regulatory approval of EB612 in the second half of 2019. In parallel, we expect to pursue marketing approval in the European Union and Japan with the appropriate regulatory agencies.

In April 2014 we received orphan drug designation from the FDA for our oral PTH in hypoparathyroidism. If a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means that FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In January 2015, the FDA approved Natpara, an injectable form of PTH, for hypoparathyroidism, and awarded Natpara orphan drug exclusivity until January 23, 2022. While Natpara has orphan drug exclusivity for hypoparathyroidism, we believe that we will be able to demonstrate that our oral formulation of PTH is clinically superior to Natpara in that it demonstrates greater effectiveness or safety than Natpara or that it otherwise makes a major contribution to patient care, and therefore, we believe that Natpara's orphan drug exclusivity will not prevent the FDA from approving our BLA for EB612 prior to the expiration of Natpara's exclusivity period. In June 2016, we received approval from the European Commission granting orphan status to our oral PTH in Europe.

EB613 for Osteoporosis

Osteoporosis

We are also developing a distinct oral PTH product candidate, EB613, for the treatment of osteoporosis. Osteoporosis is a systemic skeletal disease characterized by low bone mass, deterioration of bone tissue and increased bone fragility and susceptibility to fracture. It most commonly affects older populations, primarily postmenopausal women. All bones are subject to an ongoing process of formation and degradation, whereby bone tissue is removed from the skeleton and new bone tissue is formed. Two main types of cells are responsible for this process: osteoclasts, which break down bone tissue, and osteoblasts, which secrete new bone tissue. Osteoporosis develops as the delicate balance between bone resorption by osteoclasts and bone formation by osteoblasts is not maintained, and not enough bone tissue is formed, leading to frail and fracture-prone bones. These weak and brittle bones become susceptible to fractures caused by fall, mild stress or even a cough. The condition can even be fatal, as 25% of those who fracture a hip will die within six months of injury.

Osteoporosis often leads to loss of mobility, admission to nursing homes and dependence on caregivers. These debilitating effects of osteoporosis have substantial costs. The prevalence of osteoporosis is growing and, according to the National Osteoporosis Foundation, or NOF, is significantly under-recognized and under-treated in the population. While the aging of the population is a primary driver of an increase in cases, osteoporosis is also increasing from the use of drugs that induce bone loss, such as chronic use of glucocorticoids and aromatase inhibitors that are increasingly used for breast cancer and the hormone therapies used for prostate cancer.

The NOF has estimated that 10 million people in the United States already have osteoporosis, and another approximately 43 million have low bone mass placing them at increased risk for osteoporosis. In addition, the NOF has estimated that osteoporosis is responsible for more than two million fractures in the United States each year resulting in an estimated $19 billion in costs annually. The NOF expects that the number of fractures in the United States due to osteoporosis will rise to three million by 2025, resulting in an estimated $25.3 billion in costs each year. Worldwide, osteoporosis affects an estimated 200 million women according to the International Osteoporosis Foundation, or IOF, and causes more than 8.9 million fractures annually, which is equivalent to an osteoporotic fracture occurring approximately every three seconds. The IOF has estimated that 1.6 million hip fractures occur worldwide each year, and by 2050 this number could reach between 4.5 million and 6.3 million. The IOF estimates that in Europe alone, the annual cost of osteoporotic fractures could surpass €76 billion by 2050.

The goal of pharmacological treatment of osteoporosis is to maintain or increase bone strength, to prevent factures throughout the patient's life and to minimize osteoporosis-related morbidity and mortality by reducing the risk of fracture. Current treatments for osteoporosis generally fall into two categories: antiresorptive medications to slow bone loss and anabolic medications to increase the rate of bone formation. The global osteoporosis drug market was dominated for many years by bisphosphonates, which slow bone loss, although bisphosphonates' market share has declined over recent years due to the occurrence of serious side effects, as well as the introduction of newly developed pharmacological treatments.

The primary current treatments for osteoporosis are summarized in the table below.

Class of Drug	Name (Producer)	Method of Action	Known Side Effects	2016 Branded Sales (in millions)
Injectable PTH	Forteo (Eli Lilly)	Increases bone mineral density by inhibiting the resorption of bone, promotes new bone formation	Decrease in blood pressure, increase in serum calcium in the blood; nausea, joint aches, pain, leg cramps, injection site reactions	$1,500
Monoclonal antibody	Prolia (Amgen)	Blocks the breakdown of bones by binding to RANKL protein that is essential to activate osteoclasts	Hypocalcemia, serious infections, dermatologic adverse reactions, osteonecrosis of the jaw, back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis	$1,635
Selective estrogen receptor modulators (SERMs)	Evista (Eli Lilly)	Binds to estrogen receptors at a selective tissue, with an agonist effect on bone tissue	Deep vein thrombosis, pulmonary embolism, retinal vein thrombosis, increased risk of death due to stroke, endometrial cancer, cardiovascular disease	$172
Bisphosphonate	Fosamax (Merck) Zometa (Novartis)	Prevent bone loss by inducing cell death (apoptosis) in the osteoclast cells	Irritation of the gastrointestinal mucosa, hypocalcemia, severe musculoskeletal pain, osteonecrosis of the jaw	N/A (Generic) N/A (Generic)

In osteoporosis patients, who have normal basal levels of PTH, therapeutic administration of PTH activates osteoclasts and osteoblasts. While both types of cells are activated when PTH is administered, osteoblasts are activated for a longer period, increasing bone formation and bone mass. Injectable PTH (1-34), in the form of Eli Lilly's Forteo, is therefore one of the most effective osteoporosis medications on the market today and demonstrably more efficacious than bisphosphonates. A study published in the New England Journal of Medicine found that over a period of 18 months bone mineral density at the lumbar spine in a group of patients with steroid-induced osteoporosis treated with Forteo increased twice as much as that in the group treated with a form of bisphosphonate.

Unlike our oral delivery system, Forteo is administered by injection, which has significant drawbacks. Patients may reject this treatment due to the discomfort and local irritation usually associated with a daily injectable regimen. Additionally, subcutaneous injection of PTH (1-34) has been shown to induce immunological reactions in approximately 3% of the patient population, often leading to discontinuance of therapy. We believe an oral form of PTH (1-34) would significantly improve patient and physician acceptance. Eli Lilly has attempted numerous collaborations with alternative delivery systems, including a micro needle patch system, which eventually did not reach fruition. An attempt with Zosano Pharma's patch terminated in 2015, as did another collaboration with Transpharma, also a patch, which was terminated in 2011. In 2005 Eli Lilly attempted a nasal delivery system with Alkermes only to be terminated in 2007. While the patch technology may reduce the discomfort associated with an injection, we believe patients will prefer an oral form of PTH (1-34) over a patch form of delivery.

Several pharmaceutical companies have previously attempted to develop an orally administered form of PTH. GlaxoSmithKline had partnered with Unigene Laboratories to develop a form of oral PTH but terminated the collaboration in 2011 following the release of Phase 2 clinical trial data, potentially due to poor control of kinetics and variability and the need for as much as 10 mg of PTH per tablet. Eli Lilly attempted to develop an oral PTH in collaboration with Emisphere, which Emisphere terminated following patent infringement claims in 2004. Emisphere then went on to develop their own oral PTH in collaboration with Novartis but suspended development in 2011 at the same time that they suspended their oral calcitonin program, which was subject to EMA safety restrictions. We believe Novartis discontinued the product for reasons that were unrelated to the product itself, and that our formulation of EB613 achieves the maximum concentration necessary for therapeutic effect with three times less active pharmaceutical ingredient, and lower variability, than that observed with Novartis' suspended product.

We also believe that our oral delivery technology is superior to other oral technologies that were and still may be in development for osteoporosis patients. The table below presents a comparison and integration of available clinical trial results to date.

Company/Technology	Molecule	API MW (g/mole)	Bioavailability (F)
Entera Bio	PTH (1-34)	4118	1.5%
Novartis / Emisphere (Eligen - CNAC) [(1)]	PTH(1-34)	4118	0.2 - 0.5%
Enteris Biopharma – Unigen (Peptelligence) [(2)]	PTH(1-31)	3719	0.52%
Multiple manufacturers[(3)]	Desmopressin	1069	0.16%
Chiasma (TPE) [(4)]	Octreotide	1019 (Cyclic peptide)	0.67%
Proxima Concepts (AXCESS) [(5)]	Insulin	5733	0.7%

(1) Source: The single dose pharmacokinetic profile of a novel oral human parathyroid hormone formulation in healthy postmenopausal women Sibylle P. Hämmerle, et al. Bone. 2012 Apr;50(4):965-73. doi: 10.1016/j.bone.2012.01.009. Epub 2012 Jan 25.

(2) Source: Pharmacokinetics of oral recombinant human parathyroid hormone rhPTH(1-31)NH2 in postmenopausal women with osteoporosis. Sturmer A1 et el. Clin Pharmacokinet. 2013 Nov;52(11):995-1004. doi: 10.1007/s40262-013-0083-4.

(3) Source: Public Assessment Report, Desmopressin Acetate 100 Microgram Tablet PL 24668/0177 and Desmopressin Acetate 200 Microgram Tablet PL 24668/0178. Medicines and Healthcare Products Regulatory Agency.

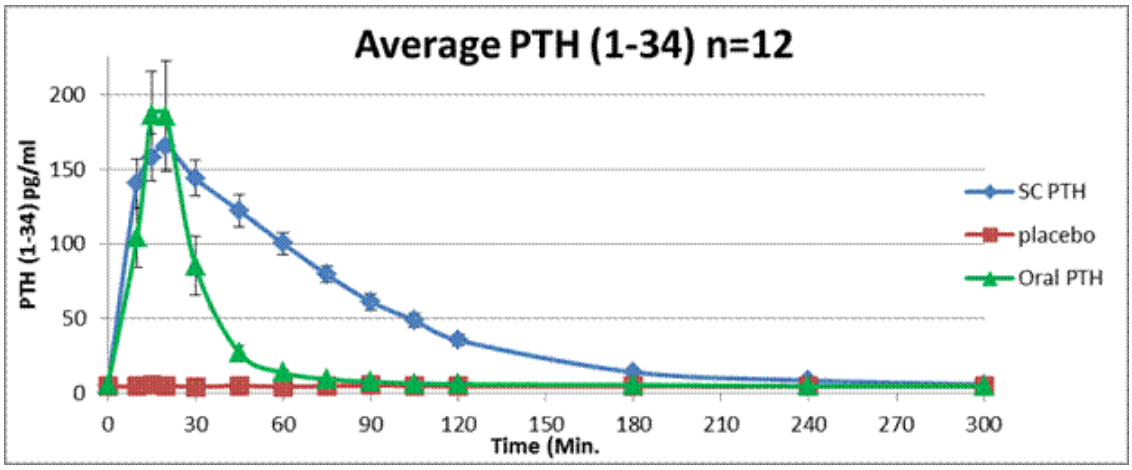
(4) Source: Pharmacokinetic Modeling of Oral Octreotide (Octreolin™) in Healthy Volunteers and Dosing Regimen Optimization for Acromegaly Patients. Shmuel Tuvia et al. Endocrine Society's 94th Annual Meeting June 2012, OR29-6-OR29-6.

(5) Source: The glucose lowering effect of an oral insulin (Capsulin) during an isoglycaemic clamp study in persons with type 2 diabetes S. D. Luzio et al. Diabetes Obes Metab. 2010 Jan;12(1):82-7. doi: 10.1111/j.1463-1326.2009.01146.x. Epub 2009 Sep 25.

Preclinical and Clinical Development of EB613

EB613 is PTH (1-34) combined with our proprietary technology for the oral delivery of large molecule therapeutics. We are optimizing the PK profile of EB613 specifically for the treatment of osteoporosis, and we expect that our dose and formulation will be significantly modified from that of EB612. Our development combines the proven efficacy of PTH in increasing bone formation in osteoporosis patients with the additional benefit of permitting oral administration, which reduces the treatment burden on patients, leading to higher patient and physician acceptance. We believe each dose of oral PTH would trigger a Cmax peak, stimulating osteoclasts and osteoblasts, thereby increasing overall bone formation.

In preclinical and Phase 1 clinical development, EB613 exhibited negligible safety issues and displayed compelling PK and PD properties, in particular compared to commercially available injectable PTH (1-34) (Forteo). The graph below shows the PK profile of a subcutaneous injection with injectable PTH (1-34), EB613 and placebo from our Phase 1 clinical trial. Both the injectable PTH (1-34) and the oral PTH (1-34) have a rapid increase in plasma concentrations followed by a fast elimination phase. This is significant for attaining the desired anabolic effect by transiently activating the biological pathways and possibly even more so with our oral PTH as its profile is sharper than the injection. In addition, the data show that the PK profile with EB613 is sharper and shows a more rapid return to baseline. It is believed that the prolonged increase in PTH levels may reduce the desired anabolic effect.



Planned Clinical Development

We are preparing a Phase 2a trial of EB613 in osteoporosis in the fourth quarter of 2017. With these Phase 2a results we plan to partner with a larger biopharmaceutical company for the clinical development and commercialization of this product.

Bone Healing / Non-union Fractures

Currently, no pharmacological treatments are available to stimulate bone healing. A number of studies suggest that PTH could be beneficial in the treatment of fractures and could thus be a potentially new treatment option for the induction of bone healing. Non-union fractures occur when the normal process of bone healing is interrupted and a fracture does not heal properly or does not heal at all. By definition, a non-union fracture will not heal on its own. Most non-union fractures require surgery, which can involve bone grafts or stabilizing the affected bone by affixing rods, plates or screws. Risks of surgery include neurovascular injury, infection and hemorrhage.

In the United States, there are approximately seven million new fractures each year, with approximately 300,000 delayed union or non-union fractures. Estimates for the average non-union treatment cost vary from approximately $25,000 to $45,000.

Depending on the nature of the fracture, non-surgical solutions can include electrical stimulation or fitting external braces. Other more experimental techniques exist as well, including ultrasound stimulation, which has been approved by the FDA for treating fresh fracture since the 1990s. Unlike in osteoporosis treatment, a pharmacological solution is not the norm for fractures. The major drawbacks of the more traditional methods are invasiveness and the risks inherent with surgery. In addition, bone grafting is associated with considerable morbidity, including chronic pain, injury to nerves and muscles and blood loss. Surgical cost is another significant concern. Experimental techniques, such as stimulation of the bone with electricity or sound show some promise for healing, but data demonstrating its effectiveness remains limited.

Entera's Potential Solution for Non-union Fractures

Studies have suggested that PTH can accelerate bone healing. PTH increases the activity and number of osteoblasts, which are responsible for bone formation, making it critical for cases where bone healing is delayed.

We intend to investigate the efficacy of EB613 for non-union fractures. We may either pursue fracture treatment as an additional use of EB613 or further modify the formulation if studies suggest we could achieve a PK profile that is more efficacious for bone fractures. As non-union fractures and bone healing are non-chronic conditions, generally entailing three to six months of treatment, we believe the acceptance of oral PTH will be higher than other potential pharmacological alternatives. We believe we will be able to use the data generated with EB613 in Phase 1 clinical trials relating to osteoporosis to progress directly to a Phase 2a clinical trial of our oral PTH product candidates for non-union bone fractures.

Future Development of Orally Delivered Large Molecule Therapeutics

We intend to use our technology as a platform for the oral delivery of low-bioavailability therapeutics, which may include small molecules with very low absorption due to their poor permeability properties (BCS class 3 drugs), proteins and other large molecule therapeutics. We have conducted initial feasibility studies with a number of candidates and intend to commence clinical development for our next, non-PTH product candidate by the end of 2017. We expect that the key criteria in selecting our next clinical candidate will include: the size of the molecule and other chemical characteristics that would be advantageous with our technology, whether the molecule is best delivered through the intestinal tract rather than through injection, and the drug's dosing schedule, more specifically, whether it is prescribed for at least three months and would be likely be best administered at least once a day. Additionally, we may target large proteins that are prone to inducing damaging immune responses when injected subcutaneously. In some cases, the immune response to the injection is so severe as to reduce or eliminate all physiological effect of the drug upon the illness, as in the case of interferon. We are also considering whether to partner the development of any such additional product candidates and are in early stage discussions with a number of external parties.

Commercialization Strategy

We are initially focused on developing an oral PTH (1-34), for the treatment of hypoparathyroidism, or EB612. We are also developing an oral PTH (1-34), with a significantly modified formulation for the treatment of osteoporosis, or EB613, and plan to also conduct clinical trials of EB613 for the treatment of non-union fractures. We are also investigating applying our oral drug delivery platform to other FDA-approved proteins or large molecule therapeutics.

We have not yet established sales, marketing or product distribution operations because our product candidates are in clinical development. Prior to receiving regulatory approval for EB612, if approved, we plan to build a focused sales and marketing organization in the United States and other jurisdictions where we anticipate obtaining approval to sell EB612 once approved. We believe that we can independently commercialize EB612 with a small salesforce by targeting a relatively small prescriber base of primarily endocrinologists in centers of excellence. We would, however, evaluate other opportunities to commercialize EB612 and other products candidates for orphan indications, if attractive. We may seek a partner to develop EB613, and anticipate that any such partner would be responsible for, or substantially support, late stage clinical trials of EB613 as well as submitting applications for regulatory approvals and registrations.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from many different sources, including large pharmaceutical, specialty pharmaceutical, biotechnology, and generic drug companies and academic and government institutions. We believe that the key competitive factors that will affect the development and commercial success of our oral PTH product candidates for hypoparathyroidism, osteoporosis and non-union fractures, and any other product candidates that we develop, are the efficacy, safety and tolerability profile, convenience in dosing, product labeling, price and availability of reimbursement from the government and other third-parties. Our commercial opportunity could be reduced or eliminated if our competitors have products that are better in one or more of these categories.

We expect that, if approved, our oral PTH product candidates for hypoparathyroidism, osteoporosis and non-union fractures, and other product candidates that we develop, would compete with a number of existing products. Furthermore, we believe that we face competition with regard to our oral drug delivery platform, as we believe that other non-invasive medical drug delivery technologies, including alternative oral delivery systems as well as transdermal patches, are being developed by other parties. Many of our potential competitors have substantially greater financial, technical, commercial and human resources than we do and significantly more experience in the discovery, development and regulatory approvals of product candidates, and the commercialization of those products. Accordingly, our competitors may be more successful than us in obtaining FDA approval for product candidates and achieving widespread market acceptance. See “Risk Factors—Risks Related to Commercialization of Our Product Candidates.”

EB612 for Hypoparathyroidism

Historically, the treatments for hypoparathyroidism have been calcium supplements, vitamin D supplements and phosphate binders, however many serious side effects result from this therapy. Our product candidate EB612 is designed to deliver PTH to hypoparathyroid patients to directly address the underlying PTH deficiency. Because our product would be a branded pharmaceutical, in contrast to the over-the-counter supplements currently used by those with the condition, we believe that the market acceptance will be strongest among patients whose disease is not well-controlled by over-the-counter supplements, or in those patients who continue to suffer from side effects associated with therapy or symptoms associated with poor management of their condition.

We believe that our key competitor in hypoparathyroidism treatment is Shire plc, which is marketing Natpara, an injectable bioengineered recombinant form of PTH (1-84) that was approved by the FDA in January 2015. Natpara has been granted orphan drug designation for hypoparathyroidism by the FDA as the first approved product for this indication, has orphan drug market exclusivity for seven years in the United States. Orphan drug market exclusivity means that the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. Therefore, we will only be able to obtain regulatory approval for EB612, which also has orphan drug designation for hypoparathyroidism, if we demonstrate EB612’s clinical superiority over Natpara in that it demonstrates greater effectiveness or safety than Natpara or that it otherwise makes a major contribution to patient care. We believe that we will be able to demonstrate that our oral formulation of PTH is clinically superior to Natpara in terms of efficacy and safety, and therefore, that Natpara’s orphan drug exclusivity will not prevent the FDA from approving our BLA for oral PTH prior to the expiration of Natpara’s market exclusivity period.

In addition, Ascendis Pharma has reported that it is developing a long-acting oral, prodrug formulation of PTH for the treatment of hypoparathyroidism. Ascendis’ oral PTH product is currently in preclinical development, and Ascendis has reported that it plans to initiate a Phase 1 trial for the drug in the third quarter of 2017.

EB613 for Osteoporosis

Current treatments for osteoporosis generally fall into two categories: antiresorptive medications to slow bone loss and anabolic medications to increase the rate of bone formation. The global osteoporosis drug market has traditionally been dominated by bisphosphonates, which slow bone loss. Although bisphosphonates’ market share has declined due to the occurrence of serious side effects, as well as the introduction of newly developed pharmacological treatments, many of the new drugs have serious side effects of their own. Eli Lilly’s Forteo, is one

of the most effective osteoporosis medications. We anticipate that our product candidate EB613 if approved, will compete with Forteo. We believe that EB613 may prove to be superior to Forteo due to its oral administration, potentially leading to greater patient acceptance and its sharper pharmacokinetic profile which is expected to have more potent anabolic effect. However, our competitors in this market are large pharmaceutical companies with greater resources than us and the alternatives therapies have been on the market for many years and have widespread market acceptance.

Bone Healing

There are currently no approved pharmacological treatments to stimulate bone healing. We anticipate that, if approved, our oral PTH product candidate for the treatment of non-union fractures would compete with non-pharmacological treatments such as electrical stimulation as well as off-label use of Forteo.

The Israeli Innovation Authority Grant

We have received grants of approximately $0.5 million from the IIA to partially fund our research and development. The grants are subject to certain requirements and restrictions in the Encouragement of Industrial Research, Development and Technological Innovation in Industry Law, 5744-1984, or the Research Law. In general, until the grants are repaid with interest, royalties are payable to the Israeli government in the amount of 3% on revenues derived from sales of products or services developed in whole or in part using the IIA grants, including EB612, EB613 and any other oral PTH product candidates we may develop. The royalty rate may increase to 5%, with respect to approved applications filed after we achieve sales of over $70 million in the year prior to the application.

The amount that must be repaid may be increased to three times the amount of the grant received, and the rate of royalties may be accelerated if manufacturing of the products developed with the grant money is transferred outside of the State of Israel. As of December 31, 2016, the total royalty payable to the IIA, including accrued interest, was approximately $0.5 million. As of December 31, 2016, we had not paid any royalties to the IIA.

In addition to paying any royalties due, we must abide by other restrictions associated with receiving such grants under the Research Law that continue to apply following repayment to the IIA. These restrictions may impair our ability to outsource manufacturing, engage in change of control transactions or otherwise transfer our “know-how” (as defined in the Research Law) outside of Israel, and may require us to obtain the approval of the IIA for certain actions and transactions and pay additional royalties and other amounts to the IIA. We may not receive the required approvals for any proposed transfer and, even if received, we may be required to pay the IIA a portion of the consideration that we receive upon any sale of such technology to a non-Israeli entity up to 600% of the grant amounts plus interest. In addition, any change of control and any change of ownership of our ordinary shares (including by way of an initial public offering) that would make a non-Israeli citizen or resident an “interested party,” as defined in the Research Law, requires written notice to the IIA. Such a non-Israeli interested party is required to sign an undertaking towards the IIA in which it undertakes to comply with the Research. An IPO of the Company requires the prior approval of the IIA. Shareholders in an IPO are not required to sign an IIA undertaking. If we fail to comply with the Research Law, we may be forced to return the grants and/or be subject to monetary fines and/or criminal charges.

Oramed Patent Transfer Agreement

In 2010, in connection with our establishment as a joint venture between D.N.A Biomedical Solutions Ltd., or D.N.A Biomedical, and Oramed Ltd., or Oramed, a subsidiary of Oramed Pharmaceuticals, Inc., we entered into a patent license agreement with Oramed pursuant to which Oramed granted us a worldwide, royalty-bearing, exclusive, irrevocable, perpetual and sublicensable license under certain Oramed patent rights to develop, manufacture and commercialize products for certain indications to be specified by us and Oramed, other than diabetes, obesity and influenza. In February 2011, D.N.A Biomedical and Oramed entered into a share purchase agreement for the sale by Oramed to D.N.A Biomedical of 47% of our ordinary shares. In connection with this transaction, in February 2011 we entered into a patent transfer agreement with Oramed, or the Patent Transfer Agreement, to replace the original 2010 license agreement. Pursuant to the terms of the Patent Transfer Agreement, Oramed assigned to us all of its right, title and interest in the previously licensed patent rights, and in return we granted to Oramed a worldwide, royalty-free, exclusive, irrevocable, perpetual and sublicensable license under the assigned patent rights to develop, manufacture and commercialize products or otherwise exploit such patent rights in the fields of diabetes and influenza. Additionally, we agreed not to engage, directly or indirectly, in any activities in

the fields of diabetes and influenza. In consideration for such assignment, we agreed to pay Oramed royalties equal to 3% of our net revenues generated, directly or indirectly, from exploitation of the assigned patent rights, including the sale, lease or transfer of the assigned patent rights or sales of products or services covered by the assigned patent rights. Either party may terminate the Patent Transfer Agreement for the other party's uncured material breach upon 45 days' written notice (and immediately upon written notice in the event of an incurable breach), or if the other party undergoes certain insolvency-related events. The royalty obligations imposed on us will survive termination of the Patent Transfer Agreement.

Intellectual Property

Our success depends in part on our ability to protect the proprietary nature of our product candidates, technology, and know-how; operate without infringing on the proprietary rights of others; and prevent others from infringing on our proprietary rights. We seek to protect our proprietary position by, among other methods, seeking patent protection in the United States and in certain other jurisdictions for our product candidates and other technology that we consider important to the development of our business, where such protection is available. We believe that our success will depend in part on our ability to obtain patent protection for our intellectual property. We also intend to rely on trade secret protection, know-how and the exploitation of in-licensing opportunities to develop our proprietary position.

Patent Rights

As of June 30, 2017, our global patent portfolio included the following patents and patent applications:

- Patents claiming compositions comprising a protein, an absorption enhancer and a protease inhibitor as well as methods for oral administration of a protein with an enzymatic activity, which compositions cover EB612 and EB613, have issued in the United States, Australia, Japan, China, Israel, Canada, New Zealand and Russia. Related patent applications are pending in the United States, the European Union, Hong Kong, Brazil, India, Israel and Russia. These issued patents and any patents that may issue from the pending patent applications are currently expected to expire in August 2029, assuming all annuity and maintenance payments are paid thereon. Rights to these patents and patent applications were assigned to us pursuant to the Patent Transfer Agreement with Oramed.

- Two Patent Cooperation Treaty (PCT) applications (with an additional application expected to be filed in August 2017), which we believe, if issued as national stage patents containing substantially the same claims as those in the applications, would cover certain oral administration technologies. These technologies include compositions and drug delivery devices which utilize an absorption enhancer to enable the absorption of a therapeutically active agent in a controlled manner. We believe that certain of the pending claims contained in these provisional patent applications, if issued in substantially the same form, would cover the formulations of EB612 and EB613.

- Three recently filed Patent Cooperation Treaty (PCT) applications, which we believe, if issued as patents containing substantially the same claims as those in the applications, would contain method of treatment claims covering the use of orally administered parathyroid hormone for the treatment of osteoporosis, hypoparathyroidism, and bone fractures and related conditions.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the useful patent term lost, if any, during the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product's approval by the FDA. The patent term extension period is generally one-half the time between the effective date of the IND and the submission date of the BLA for the product, plus the time between the submission date of the BLA and the approval of the application. Only one patent applicable to an approved drug is

eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. Only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Moreover, we may not receive an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. However, the length of any extension could be less than we request.

Trade Secrets

In addition to patent rights, we also rely on unpatented trade secrets and know-how to protect our proprietary technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements with our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, our board of directors, or our Board, technical review board, and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements generally provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not to be disclosed to third parties except in specific limited circumstances. We also generally require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants, and contractors, the agreements also generally provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as our exclusive property. There can be no assurance, however, that we have entered into agreements with all applicable parties, that all persons who we desire to sign such agreements will sign, or if they do, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our unpatented trade secrets or know-how will not otherwise become known or be independently developed by competitors. Additionally, to the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and a more comprehensive discussion of risks related to our intellectual property, see "Risk Factors—Risks Related to Our Intellectual Property."

Manufacturing

We do not own or operate facilities for large scale product manufacturing, storage and distribution, or testing, nor do we expect to in the future. Our current facility is limited to small-mid scale product manufacturing, storage and distribution of materials for clinical studies. Our facility has ISO:9001:2008 quality management systems accreditation from The Standards Institution of Israel for the production and development of functional excipients and oral drug formulations to be used in clinical trials. The facility includes a dedicated clean room designed as a Class C / ISO 8 clean room for tablet production and a dedicated chemical synthesis clean room designed as a Class C ISO 8 clean room. All personnel involved in these activities have the relevant background, expertise and training in the relevant company standard operating procedures.

Our manufacturing activities include the chemical synthesis of one of our non-active but functional drug components as well as the formulation and production of the final drug, packaging, storage and distribution. The testing and release of materials to be used in the manufacturing process as well as the testing and release of the manufactured products is overseen by our QA/QC department and relies on internal and external tests. We have signed a contract with a UK-based contract manufacturing organization, to produce and supply pills for trials performed worldwide. This contract is not exclusive and Entera may enter into additional contracts as it sees fit to support its activities and mitigate risk. Various materials included in the drug formulation and materials procured for the chemical synthesis are commercially available from various accredited suppliers. We do not have supply contracts with all these vendors and are not bound to any specific vendor at this point in time. However, it is our intention to complete such contracts in anticipation of commercial manufacturing activities, so that when approved, we will have such contracts in place.

In March 2017, we contracted with an FDA/ EMA inspected- GMP subcontractor in the UK to outsource activities for technical transfer and tablet production for our international clinical trials.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, pricing, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in other countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs and Biologics in the United States

In the United States, our product candidates are regulated by the FDA as biologics under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, or PHSA, and regulations implemented by the agency. The failure to comply with the applicable requirements at any time during the product development process, including preclinical testing, clinical testing, the approval process or post-approval process, may subject an applicant to delays in the conduct of clinical trials, regulatory review and approval, and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical testing, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, and civil or criminal investigations and penalties brought by the FDA or Department of Justice, or other governmental entities.

The process required by the FDA before a biologic may be marketed in the United States generally involves satisfactorily completing each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product candidate for each proposed indication and conducted in accordance with Good Clinical Practice, or GCP, requirements;
- submission of data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- preparation and submission to the FDA of a BLA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the non-clinical and clinical trial sites to assure compliance with GCP requirements and the integrity of clinical data in support of the NDA or BLA;
- payment of user fees and securing FDA approval of the BLA for the proposed indication; and
- compliance with any post-approval requirements, including risk evaluation and mitigation strategies, or REMS, and any post-approval studies required by the FDA.

Preclinical Studies and Investigational New Drug Application

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animals. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. Some preclinical tests may continue even after submission of the IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the clinical trials to commence or allowing the clinical trial to commence on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. This order issued by the FDA would delay either a proposed clinical trial or cause suspension of an ongoing clinical trial, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. This could cause significant delays or difficulties in completing planned clinical trials in a timely manner.

Clinical Trials

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator in accordance with cGCP requirements. Clinical trials are conducted under trial protocols detailing, among other things, the objectives of the clinical trial, inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a clinical trial outside the United States is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA so long as the clinical trial is conducted consistent with the spirit of GCP and in compliance with an international guideline for the ethical conduct of clinical research known as the Declaration of Helsinki and/or the laws and regulations of the country or countries in which the clinical trial is performed, whichever provides the greater protection to the participants in the clinical trial.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects and the possible liability of the institution. An IRB must operate in compliance with the FDA regulations. The FDA, IRB or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group may recommend continuing the clinical trial as planned, make changes in clinical trial conduct, or cessation of the clinical trial at designated check points based on access to certain data from the clinical trial.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Additional studies may be required after approval.

- *Phase 1* clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, metabolism, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as cancer patients.

- *Phase 2* clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.

- *Phase 3* clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken to further evaluate, in a larger number of patients, dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a drug: such Phase 3 studies are referred to as "pivotal."

In some cases, the FDA may approve a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the drug's safety and effectiveness after BLA approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs or biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Compliance with Current Good Manufacturing Practice Requirements

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both U.S. and non-U.S. manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether U.S. or non-U.S., is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and Approval of a Biologic License Application

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting approval to market the product. The BLA also must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee. According to the FDA's fee schedule, effective from October 1, 2016 through September 30, 2017, the user fee for an application requiring clinical data, such as an NDA, is $2,038,100.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether it is sufficient to accept for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies under the Prescription Drug User Fee Act, or the PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority applications. The review process may often be significantly extended by FDA

requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests, or the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Under the FDCA and the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA will issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. Such resubmissions are classified under PDUFA as either Class 1 or Class 2. The classification of a resubmission is based on the information submitted by an applicant in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has two months to review a Class 1 resubmission and six months to review a Class 2 resubmission from the date of receipt. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

The FDA may also refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides 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.

If the FDA approves a new product, it may limit the approved indications for use of the product. It may also require that contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including a REMS, to help ensure that the benefits of the product outweigh the potential risks. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-Approval Regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with post-approval regulatory requirements, including any post-approval requirements that the FDA may have imposed as a condition of approval. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon drug manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency, and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop drugs intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the drug for the disease or condition will be recovered from sales of the drug in the United States.

Orphan drug designation qualifies a company for tax credits, waiver of the BLA user fee and may confer market exclusivity for seven years following the date of the drug's marketing approval, if granted by the FDA, if a product that has orphan designation subsequently receives the first FDA approval of that drug for the disease for which it has such designation. This means that the FDA may not approve any other applications, including a BLA to market the same biologic even in a different formulation for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority over the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A product becomes an orphan product when it receives orphan drug designation from the Office of Orphan Products Development, or OOPD, at the FDA based on acceptable confidential requests made under the regulatory provisions. The product must then go through the review and approval process like any other product.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first, approved product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation, and only the first sponsor that obtains approval for that drug for the orphan indication will obtain market exclusivity, effectively preventing the FDA from approving products under development by competitors for the same drug and same indication, unless the competitor is able to demonstrate that the product under development is clinically superior to the approved product or the approved product is not available in sufficient quantities. To permit the FDA to end another manufacturer's orphan exclusivity period, the FDA must determine that the manufacturer has demonstrated clinical superiority by showing the later drug is safer, more effective, or makes a major contribution to patient care.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a subsequent application for a different drug for the same indication. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Biosimilars and Exclusivity

The 2010 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 or BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. To date, five biosimilars have been licensed under the BPCIA, although numerous biosimilars have been approved in Europe. The FDA has issued several draft guidance documents outlining an approach to review and approval of biosimilars. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation, which are still being worked out by the FDA.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

Patent Term Extension

A patent claiming a new drug or biologic product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the useful patent term lost, if any, during the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product's approval by the FDA. The patent term extension period granted is typically one-half the time between the effective date of the first IND and the submission date of the BLA for the product, plus the time between the submission date of the BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the products. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Regulation Outside the United States

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable non-U.S. regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Regulation and Marketing Authorization in the European Union

The EMA is the scientific agency of the European Union that coordinates the evaluation and monitoring of new and approved medicinal products. It is responsible for the scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors. The EMA decentralizes its scientific assessment of medicines by working through a network of about 4,500 experts throughout the European Union, nominated by the member states. The EMA draws on resources of over 40 National Competent Authorities, or the NCAs, of EU member states.

The process regarding approval of medicinal products in the European Union follows roughly the same lines as in the United States and likewise generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations;

- submission to the relevant national authorities of a clinical trial application, or CTA, for each clinical trial, which must be approved before human clinical trials may begin;

- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;

- submission to the relevant competent authorities of a marketing authorization application, or MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;

- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMP;

- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and

- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical Studies

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential efficacy and toxicity in animals. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant EU regulations and requirements. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA when seeking approval to start a clinical trial, and with the MAA when seeking marketing authorization.

Clinical Trial Approval

Requirements for the conduct of clinical trials in the European Union including cGCP, are implemented in the currently Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the EU member states. Under this system, approval must be obtained from the competent national authority of a EU member state in which a trial is planned to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the European Union legislative body passed the new Clinical Trials Regulation (EU) No 536/2014 which is set to replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the EU, the new EU clinical trials legislation was passed as a regulation which is directly applicable in all EU member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 will become applicable. According to the current plans of the EMA, the new Clinical Trials Regulation will become applicable in 2019. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for the old system.

The new Regulation (EU) No 536/2014 aims to simplify and streamline the approval of clinical trial in the European Union. The main characteristics of the regulation include:

- A streamlined application procedure via a single entry point, the EU portal;

- A single set of documents to be prepared and submitted for the application as well as simplified reporting procedures which will spare sponsors from submitting broadly identical information separately to various bodies and different Member States;

- A harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is jointly assessed by all Member States concerned. Part II is assessed by each Member State concerned separately;
- Strictly defined deadlines for the assessment of clinical trial application; and
- The involvement of the ethics committees in the assessment procedure in accordance with the national law of the Member State concerned but within the overall timelines defined by the Regulation (EU) No 536/2014.

Marketing Authorization

Authorization to market a product in the member states of the European Union proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

Centralized Authorization Procedure

The centralized procedure enables applicants to obtain a marketing authorization that is valid in all EU member states based on a single application. Certain medicinal products, including products developed by means of biotechnological processes must undergo the centralized authorization procedure for marketing authorization, which, if granted by the European Commission, is automatically valid in all – currently 28 – European Union member states. Sponsors may elect to file an MAA through the centralized procedures for other classes of products. The EMA and the European Commission administer this centralized authorization procedure pursuant to Regulation (EC) No 726/2004. The other European Economic Area member states (namely Norway, Iceland and Liechtenstein) are also obligated to recognize the Commission decision.

Pursuant to Regulation (EC) No 726/2004, this procedure is mandatory for:

- medicinal products developed by means of one of the following biotechnological processes:
  - recombinant DNA technology;
  - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; and
  - hybridoma and monoclonal antibody methods;
- advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No 1394/2007 on advanced therapy medicinal products;
- medicinal products for human use containing a new active substance which, on the date of entry into force of this Regulation, was not authorized in the European Union, for which the therapeutic indication is the treatment of any of the following diseases:
  - acquired immune deficiency syndrome;
  - cancer;
  - neurodegenerative disorder;
  - diabetes;
  - auto-immune diseases and other immune dysfunctions; and
  - viral diseases; and
- medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

The centralized authorization procedure is optional for other medicinal products if they contain a new active substance or if the applicant shows that the medicinal product concerned constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization is in the interest of patients in the European Union.

Administrative Procedure

Under the centralized authorization procedure, the EMA's Committee for Human Medicinal Products, or CHMP serves as the scientific committee that renders opinions about the safety, efficacy and quality of medicinal products for human use on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national authority for medicinal products, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP has 210 days, to adopt an opinion as to whether a marketing authorization should be granted. The process usually takes longer in case additional information is requested, which triggers clock-stops in the procedural timelines. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. When an application is submitted for a marketing authorization in respect of a drug which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may pursuant to Article 14(9) Regulation (EC) No 726/2004 request an accelerated assessment procedure. If the CHMP accepts such request, the time-limit of 210 days will be reduced to 150 days but it is possible that the CHMP can revert to the standard time-limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. Once the procedure is completed, a European Public Assessment Report, or EPAR, is produced. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. After the adoption of the CHMP opinion, a decision on the MAA must be adopted by the European Commission, after consulting the European Union member states, which in total can take more than 60 days. After a drug has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review.

Conditional Approval

In specific circumstances, EU legislation (Article 14(7) Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for products (including medicines designated as orphan medicinal products), if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs, and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Marketing Authorization Under Exceptional Circumstances

As per Art. 14(8) Regulation (EC) No 726/2004, products for which the applicant can demonstrate that comprehensive data (in line with the requirements laid down in Annex I of Directive 2001/83/EC, as amended) cannot be provided (due to specific reasons foreseen in the legislation) might be eligible for marketing authorization under exceptional circumstances. This type of authorization is reviewed annually to reassess the risk-benefit balance. The fulfillment of any specific procedures/obligations imposed as part of the marketing authorization under exceptional circumstances is aimed at the provision of information on the safe and effective use of the product and will normally not lead to the completion of a full dossier/approval.

Market Authorizations Granted by Authorities of EU Member States

In general, if the centralized procedure is not followed, there are three alternative procedures to obtain a marketing authorization in (one or several) EU member states as prescribed in Directive 2001/83/EC:

- The decentralized procedure allows applicants to file identical applications to several EU member states and receive simultaneous national approvals based on the recognition by EU member states of an assessment by a reference member state.

- The national procedure is only available for products intended to be authorized in a single EU member state.

- A mutual recognition procedure similar to the decentralized procedure is available when a marketing authorization has already been obtained in at least one European Union member state.

A marketing authorization may be granted only to an applicant established in the European Union.

Pediatric Studies

Prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Paediatric Investigation Plan, or PIP, covering all subsets of the paediatric population, unless the EMA has granted (1) a product-specific waiver, (2) a class waiver, or (3) a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are laid down in Regulation (EC) No 1901/2006, the so called Paediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Paediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

Period of Authorization and Renewals

A marketing authorization will be valid for five years in principle, and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization will be valid for an unlimited period, unless the Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization that is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization will cease to be valid (the so-called sunset clause).

Orphan Drug Designation and Exclusivity

Pursuant to Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 the European Commission can grant such orphan medicinal product designation to products for which the sponsor can establish that it is intended for the diagnosis, prevention, or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 people in the European Union, or (2) a life threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that sales of the drug in the European Union would generate a sufficient return to justify the necessary investment. In addition, the sponsor must establish that there is no other satisfactory method approved in the European Union of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients.

Orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized EU marketing authorization (see "Centralized Authorization Procedure"), as well as 10 years of market exclusivity following a marketing authorization. During this market exclusivity period, neither the EMA, nor the European Commission nor the Member States can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may be reduced to six years if, at the end of the fifth year, it is established that the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. In addition, a competing similar medicinal product may be authorized prior to the expiration of the market exclusivity period, including if it is shown to be safer, more effective or otherwise clinically superior to the already approved orphan drug or if the holder of the marketing authorization for the already approved orphan drug is unable to supply sufficient quantities of the product.

If the MAA of a medicinal product designated as an orphan drug includes the results of all studies conducted in compliance with an agreed PIP, and a corresponding statement is subsequently included in the marketing authorization granted, the ten-year period of market exclusivity will be extended to twelve years.

Regulatory Data Protection

European Union legislation also provides for a system of regulatory data and market exclusivity. According to Article 14(11) of Regulation (EC) No 726/2004, as amended, and Article 10(1) of Directive 2001/83/EC, as amended, upon receiving marketing authorization, new chemical entities approved on the basis of complete independent data package benefit from eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder, or MAH, obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the innovator is able to gain the period of data exclusivity, another company nevertheless could also market another version of the drug if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical test, pre-clinical tests and clinical trials. However, products designated as orphan medicinal products enjoy, upon receiving marketing authorization, a period of 10 years of orphan market exclusivity (see also "*Orphan Drug Designation and Exclusivity*"). Depending upon the timing and duration of the EU marketing authorization process, products may be eligible for up to five years' supplementary protection certificates, or SPCs, pursuant to Regulation (EC) No 469/2009. Such SPCs extend the rights under the basic patent for the drug.

Regulatory Requirements After a Marketing Authorization Has Been Obtained

If we obtain authorization for a medicinal product in the European Union, we will be required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products:

Pharmacovigilance and Other Requirements

We will, for example, have to comply with the EU's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed.

Other requirements relate to, for example, the manufacturing of products and active pharmaceutical ingredients in accordance with good manufacturing practice standards. EU regulators may conduct inspections to verify our compliance with applicable requirements, and we will have to continue to expend time, money and effort to remain compliant. Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties in the European Union. Similarly, failure to comply with the EU's requirements regarding the protection of individual personal data can also lead to significant penalties and sanctions. Individual European Union member states may also impose various sanctions and penalties in case we do not comply with locally applicable requirements.

Manufacturing

The manufacturing of authorized drugs, for which a separate manufacturer's license is mandatory, must be conducted in strict compliance with the EMA's cGMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. The EMA enforces its cGMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a coordinating role for these inspections while the responsibility for carrying them out rests with the member states competent authority under whose responsibility the manufacturer falls. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

Marketing and Promotion

The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union notably under Directive 2001/83/EC, as amended. The applicable regulations aim to ensure that information provided by holders of marketing authorizations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorized by the EMA or by the competent authority of the authorizing member state. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Clinical Testing in Israel

In order to conduct clinical trials on humans in Israel, prior authorization must be obtained (depending on the nature of the trial) from either the medical director of the institution in which the clinical studies are scheduled to be conducted, or from the general manager of the Israeli Ministry of Health, as required under the Guidelines for Clinical Trials in Human Subjects implemented pursuant to the Israeli Public Health Regulations (Clinical Trials in Human Subjects), 5740-1980, as amended from time to time. Pursuant to the Israeli Public Health Regulations, such authorization generally cannot be granted unless, among other things, the relevant institutions ethics committee has provided its prior approval of the testing. In certain circumstances, such as in the cases of genetic trials or special fertility trials, a written opinion provided by the Ministry of Health's ethics committee is also required in order to receive such authorization.

The institutional ethics committee must, among other things, evaluate the anticipated benefits that are likely to be derived from the project to determine if it justifies the risks and inconvenience to be inflicted on the participating human subjects, and it must also ensure that adequate protection exists for the rights and safety of the participants as well as the accuracy of the information gathered in the course of the clinical testing.

Other Healthcare Laws

Health care providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other health care laws and regulations. In the United States, such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, 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;

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;

- the federal transparency requirements under the ACA require certain manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and the ownership and investment interests of such physicians and their immediate family members;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;

- the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which requires specified manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians. All such reported information is publicly available;

- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws which may apply to items or services reimbursed by any payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require pharmaceutical 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; and

- regulation by the Centers for Medicare and Medicaid Services and enforcement by the U.S. Department of Health and Human Services (Office of Inspector General) or the U.S. Department of Justice.

Efforts to ensure that our business arrangements with third parties will comply with applicable laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

Environmental, Health and Safety

We are further subject to various foreign, national, federal, state and local laws and regulations relating to environmental, health and safety matters, including the handling, disposal, release, and use of and maintenance of a registry for hazardous materials, among others. Although we do not believe that we will be required to make material operating or capital expenditures in connection with such laws and regulations, we may be required to incur significant costs to comply with these laws and regulations in the future, and complying with these laws and regulations may result in a material adverse effect upon our business, financial condition and results of operations. Further, our failure to comply with such laws and regulations could have a material adverse effect on our business and reputation, result in an interruption or delay in the development or manufacture of our products, or increase the costs for the development or manufacture of our products.

Pharmaceutical Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we plan to seek regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. Concerns about drug pricing have been expressed by members of Congress and the new administration. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA, EMA or other comparable regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and non-U.S. governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the product candidates that we are developing and could adversely affect our net revenue and results.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. The conduct of such studies could be expensive and result in delays in our commercializing efforts. The European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very

intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Health Care Reform

In the United States, there have been and continue to be a number of significant legislative initiatives to contain healthcare costs. The ACA was enacted in the United States in March 2010 and contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs subject to the Medicaid Drug Rebate Program, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025, unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

President Trump and the majorities of both houses of Congress have stated their intention to repeal and replace the ACA. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In May 2017, the House of Representatives voted to pass the American Healthcare Act of 2017, which repeals certain portions of the ACA and adds material new provisions. On June 22, 2017, the Senate introduced its own healthcare reform bill. Considerable uncertainty remains about whether the Senate bill will pass or how it will be reconciled with the House version, and if it does and President Trump signs it into law, about the ultimate content, timing or effect of any healthcare reform legislation on us, our industry or the market for drug products like ours. Though the full future impact of the new administration and the U.S. Congress on our business remains unclear, legislative and regulatory changes may continue the downward pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

We expect that additional state and federal healthcare reform measures, as well as legal changes by foreign governments, will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Corporate History and Organization

We were established in June 2010 as a joint venture of D.N.A Biomedical and Oramed to pursue the development of pharmaceutical products for the oral delivery of proteins. In connection with our founding, Oramed licensed to us the use of certain of its patent rights relating to the oral delivery of drugs. In February 2011, Oramed sold the majority of its holdings in us to D.N.A Biomedical and, assigned to us its patent rights that it had previously licensed to us, in exchange for an exclusive license to use the assigned patent rights in the fields of diabetes and influenza and for royalties of 3% of our net revenues generated from the use or other exploitation of the assigned

patent rights. In March 2011, D.N.A Biomedical and Oramed terminated the joint venture. We began operations in August 2010, and our operations to date have included developing our drug delivery technology for the oral administration of proteins and large molecules, in particular our oral PTH (1-34) product candidates.

Employees

As of June 30, 2017, we had sixteen employees and one consultant who provides consulting services to us on a full-time basis. In addition, we have entered into service agreements with three of our directors. Four of our employees have either PhDs or MDs. All of our employees are located in Israel. We believe that we maintain good relations with all of our employees and consultants. We are not a party to any collective labor agreements.

Facilities

Our corporate headquarters and research facilities are located in Jerusalem, Israel, where we lease office and laboratory space pursuant to a lease agreement that will expire on June 30, 2023, with a one-time option for early termination by the Company on June 30, 2020. This facility also houses our clinical development, clinical operations, regulatory and management functions.

We believe that our existing facilities are adequate for our needs. We believe that suitable additional space would be available if required in the future on commercially reasonable terms.

Legal Proceedings

We are not currently a party to any material legal proceedings.

MANAGEMENT

Executive Officers and Directors

The following table sets forth the name, age and position of each of our executive officers and directors as of the date of this prospectus:

Name	Age	Position
Executive Officers		
Dr. Phillip Schwartz	54	Chief Executive Officer and Director
Mira Rosenzweig	45	Chief Financial Officer
Dr. Hillel Galitzer	38	Chief Operating Officer
Dr. Miriam Blum	53	Chief Medical Officer
Directors		
Luke M. Beshar	59	Chairman of the Board
Roger Garceau	64	Director
Zeev Bronfeld	65	Director
David Ben Ami	55	Director
Chaim Davis	39	Director
Gerald Lieberman	70	Director
Yonatan Malca	50	Director

(1) To be appointed a member of our Audit Committee.

(2) To be appointed a member of our Compensation Committee.

(3) To be appointed a member of our Nominating and Governance Committee.

(4) Independent director under the rules of .

(5) To be nominated as an external director under the Companies Law. See "—External Directors."

Executive Officers

Dr. Phillip Schwartz has served as our Chief Executive Officer and as a Director since our inception in 2010. He previously served as the manager of clinical affairs at Endo Pharmaceuticals from 2005 to 2010 and at Serono from 2002 to 2005, and held multiple positions in medical affairs, business development and clinical trial development at each of Endo Pharmaceuticals and Serono. He has also worked as an external consultant for a number of venture capital firms. Dr. Schwartz has more than twenty years of biotech and pharmaceutical industry experience. He has also consulted privately and as an associate of Health Advances, LLC for more than 20 large biotech and pharmaceutical companies from 2000 to 2002. He has multiple publications in peer-reviewed journals and has presented papers at numerous international conferences. Dr. Schwartz completed his B.A. in psychology and architecture at Columbia University in 1987, and during that time he also worked in the neurobiology laboratory of Nobel Laureate Professor Torsten Wiesel of the Rockefeller University. Dr. Schwartz then studied immunology with Professor Irun Cohen at the Weizmann Institute, receiving his M.Sc. in 1991. In 1997, Dr. Schwartz received his Ph.D. in neurobiology/development/oncology from Harvard Medical School. In addition to his scientific training, Dr. Schwartz completed numerous clinical courses as part of his program at Harvard Medical School. After completing his Ph.D., Dr. Schwartz was a fellow in pediatric oncology at the Dana Farber Cancer Institute and an officer of Harvard University Medical School.

Mira Rosenzweig has served as our Chief Financial Officer since May 2014. Ms. Rosenzweig served as the Chief Financial Officer of Paskal Technologies Ltd., a company that provides solutions for the agriculture industry, from May 2013 to May 2014. Prior to that, from September 2008 to November 2011, Ms. Rosenzweig served as the vice president and chief financial officer of Camtek Ltd. (NASDAQ: CAMT), a company that provides automated solutions for the semiconductors and printed circuit board industries. From August 2006 to August 2008, Ms. Rosenzweig served as director of finance and from August 2001 to 2006 as a controller and in various other positions for Elron Electronic Industries Ltd., then-traded on NASDAQ. Ms. Rosenzweig is a certified public accountant and holds a B.A. in Accounting and Economics from the University of Haifa, Israel.

Dr. Hillel Galitzer has served as our Chief Operating Officer since February 2014, and served as our Director of Scientific Development from July 2012. Between August 2010 and February 2014, Dr. Galitzer was an analyst and chief operating officer for Hadasit Bio Holdings Ltd., a publicly traded company on the Tel Aviv Stock Exchange and OTC markets. He has more than ten years of experience in medical research and molecular biology. He is the co-founder and former chief operating officer of Optivasive Inc. He has written numerous publications in peer-reviewed journals and has lectured and presented in international conferences and universities. Dr. Galitzer received his Ph.D. from the Hebrew University Medical School in Jerusalem, where he was mentored by two world renowned researchers in the areas of parathyroid hormone and calcium regulation, his M.B.A. from Bar Ilan University in Israel and his B.Med.Sc. from the Hebrew University Medical School in Jerusalem.

Dr. Miriam Blum has served as our Chief Medical Officer since January 2015. Dr. Blum completed her residency in internal medicine and fellowships in endocrinology and bone metabolism at Mount Sinai Medical Center. Dr. Blum has received multiple research grants in bone metabolism as well as the prestigious NIH K23 grant for exceptional young investigators. She has supervised multiple academic and pharmaceutical clinical trials in vitamin D and calcium metabolism. Dr. Blum was formerly Associate Professor and attending physician at Tufts University Medical School and The New England Medical Center. She received an M.D. from SUNY Downstate Medical School. Dr. Blum is the wife of Dr. Phillip Schwartz, our Chief Executive Officer and director.

Directors

Luke M. Beshar has served as a director since December 2015, and as the executive chairman of our board of directors since December 2016. Previously, Mr. Beshar served as Chief Financial Officer and Executive Vice President of NPS Pharmaceuticals, Inc. since November 2007 and January 2012, respectively, until February 2015, when NPS Pharmaceuticals was acquired by Shire plc. Prior to that he served in several managerial positions with NPS Pharmaceuticals, Netexit, Inc. Camberx Corporation, Cegedim Inc., Expanets, Inc., PNY Technologies, Inc., Dendrite International, WSR Corporation, the Genlyte Group, Inc. and Bairnco Corporation. Mr. Beshar has been an independent director of Trillium Therapeutics Inc. (NASDAQ: TRIL), since March 2014 and Regenxbio Inc. (NASDAQ: RGNX) since April 2015. He is a Member of the New York Society of Certified Public Accountants. He has a B.A. in Accounting and Finance from Michigan State University and is a graduate of the Executive Program of the Darden Graduate Business School at the University of Virginia.

Dr. Roger Garceau has served as director since March 2016 and as our Chief Development Advisor since December 2016. Prior to joining Entera, Dr. Garceau served as Chief Medical Officer and Executive Vice President of NPS Pharmaceuticals, Inc. since December 2008 and January 2013 respectively, until February 2015, when NPS Pharmaceuticals was acquired by Shire plc. Previously, Dr. Garceau has also served in several managerial positions with NPS Pharmaceuticals, Inc. Sanofi-aventis and Pharmacia Corporation. Dr Garceau has been a non-executive director of Enterome SA since December 2016. Dr. Garceau is a board-certified pediatrician and is a Fellow of the American Academy of Pediatrics. Dr. Garceau holds B.S. in Biology from Fairfield University in Fairfield, Connecticut and an M.D. from the University of Massachusetts Medical School.

Zeev Bronfeld has served as a member of our board of directors since 2010 and as chairman of our board of directors since September 2014 and until November 2016. Mr. Bronfeld, is a co-founder of Bio-Cell Ltd., an Israeli publicly traded holding company specializing in biotechnology companies, and served as its chief executive officer from 1986 until December 2014. Since 2003 Mr. Bronfeld also served as the chief executive officer of M.B.R.T Development and Investments Ltd. Mr. Bronfeld has vast experience in the management and value building of biotechnology companies. From 2010 through July 2014, he served as the chairman of the board of Protalix BioTherapeutics, Inc. (NYSE: PLX) and has been a director on its board since 2006. In addition, Mr. Bronfeld serves on the board of directors of D.N.A Biomedical Solutions Ltd. and of The Trendlines Group Ltd. Until December 2016 he served as a director of D. Medical Industries Ltd. and Nasvax Ltd. Until January 2017, Mr. Bronfeld also served as a director of Macrocure Ltd. Mr. Bronfeld is also a director of number of privately-held companies, including, Contipi Medical Ltd. and as chairman of the board of TransBiodiesel Ltd. Mr. Bronfeld holds a B.A. in Economics from the Hebrew University of Jerusalem. Mr. Bronfeld serves on our board of directors as a designee of D.N.A Biomedical.

David Ben Ami has served as a member of our board of directors since 2014. Mr. Ben-Ami has more than 25 years of experience with activities in management, business development and corporate strategy in the life sciences industry. He served as chief executive officer of NVR Labs from 2005 to 2010, country director of Boston Scientific, Israel from 2003 to 2005, and director of business development of Teva Israel from 1999 to 2003. In

2008, he co-founded Macrocure. Mr. Ben-Ami currently serves as the chairman of the board of directors of Macrocure and also sits on the board of directors of Degania Silicone Ltd. He received his M.B.A. and B.A. in Economics & Management from Tel-Aviv University. Mr. Ben Ami serves on our board of directors as a designee of the Centillion Fund.

Chaim Davis has served as a member of our board of directors since 2013. Mr. Davis is the managing member of the Revach Fund L.P., a sector-specific lifescience fund focusing on micro to mid-cap companies, which he founded in 2005. He has also served as a consultant to other hedge funds including Gem Partners, KOM Capital Management and Maot Group. From 2010 to 2014, he served as a director of AtheroNova Inc. (OTCBQ: AHRO), and from 2001 to 2004, he served as a healthcare analyst at The Garnet Group. Mr. Davis received his B.A. from Columbia University. Mr. Davis serves on our board of directors as a designee of the lenders under our convertible financing agreements.

Gerald Lieberman has served as a member of our board of directors since 2014. Mr. Lieberman was the former president and chief operating officer of AllianceBernstein L.P. until 2009. There, he was elected chief operating officer and a director in November 2003 and added the title of president in November 2004. Prior to that, Mr. Lieberman was senior vice president for finance and administration at Sanford C. Bernstein & Co., Inc. He has also held senior roles at Fidelity Investments and Citicorp. From 2011 to 2014 he served on the board of directors of Forest Laboratories Inc., which was acquired by Actavis plc in 2014. Mr. Lieberman currently serves on the board of Teva Pharmaceutical Industries Ltd. Mr. Lieberman earned a B.S. with honors from the University of Connecticut and attended New York University's Graduate School of Business Administration. He is a certified public accountant.

Yonatan Malca has served as a member of our board of directors since 2011. Mr. Malca currently serves as a Chief Executive Officer and Director of D.N.A Biomedical Solutions Ltd., a position he has held since 2010. Mr. Malca also serves as a director of Arko Holdings Ltd. and of Tamda Ltd., both of which are Israeli public companies. Mr. Malca also serves on the board of directors of a number of private companies, including as chairman of the board of directors of Cardioart Technologies LTD, a medical device company, and Beamed Ltd., a medical device company (a subsidiary of D.N.A. Biomedical). Mr. Malca received a B.A. and an M.A. from Bar Ilan University. Mr. Malca serves on our board of directors as a designee of D.N.A Biomedical.

Arrangements for Election of Directors

Pursuant to the terms of the amended and restated investors' rights agreement among us, the Centillion Fund, or Centillion, and the other parties thereto, following the consummation of this offering, for as long as Centillion and its affiliates hold an aggregate of at least 10% of our issued and outstanding ordinary shares, we will nominate, if so requested by Centillion and as permitted by applicable law, a designee of Centillion for election by our shareholders as a member of our board of directors and will recommend that our shareholders vote in favor of such election. David Ben Ami, a member of our board of directors, was nominated by Centillion pursuant to its director designation right. Following the consummation of this offering, Centillion will hold approximately % of our issued and outstanding ordinary shares, and in the event that Centillion exercises in full all of the warrants to purchase our ordinary shares that we will have issued to it as of such date, Centillion will hold approximately % of our issued and outstanding ordinary shares.

For as long as the 2016 Convertible Loan has not been repaid to Pontifax (Israre), Pontifax (Cayman) IV L.P. and Pontiax (China) IV Fund L.P., a lender group under the 2016 Convertible Loan (together, the "Pontifax Funds"), and thereafter for as long as the Pontifax Funds hold at least 1% of the issued and outstanding share capital of the Company on a fully diluted basis, the Pontifax Funds have the right to appoint one director to our Board, on behalf of the lenders under the 2016 Convertible Loan. The Pontifax Funds' right to appoint a director will terminate immediately prior to an IPO by the Company. The Pontifax Funds have not yet exercised this right.

Corporate Governance Practices

We are incorporated in Israel and therefore are subject to various corporate governance practices under the Israeli Companies Law, 5759-1999, or the Companies Law, relating to such matters as external directors, financial experts, our audit committee, our compensation committee and our internal auditor. These matters are in addition to the requirements of and other relevant provisions of U.S. securities laws. As a foreign private issuer whose shares will be listed on , we have the option to follow certain Israeli corporate governance practices rather

than those of , except to the extent that such laws would be contrary to U.S. securities laws and provided that we disclose the practices that we are not following and describe the home country practices we follow instead. We intend to rely on this "foreign private issuer exemption" with respect to the following requirements:

- *Shareholder Approval.* Although the listing requirements generally require shareholder approval of equity compensation plans and material amendments thereto, we follow Israeli practice, which is to have such plans and amendments approved only by the board of directors, unless such arrangements are for the compensation of chief executive officer or directors, in which case they also require the approval of the compensation committee and the shareholders. In addition, rather than follow the listing requirements requiring shareholder approval for the issuance of securities in certain circumstances, we follow Israeli law applicable to us, which requires shareholder approval in the event of issuances to certain related parties, as described below under "Fiduciary Duties and Approval of Related Party Transactions—Approval of Related Party Transactions".

- *Shareholder Quorum.* The listing requirements require that an issuer have a quorum requirement for shareholders meetings of at least one-third of the outstanding shares of the issuer's common voting stock. As permitted under the Companies Law, pursuant to our Fifth Amended and Restated Articles of Association, or the amended Articles, to be in effective immediately upon the closing of this offering, the quorum required for an ordinary meeting of shareholders will consist of at least two shareholders present in person or by proxy who hold in the aggregate at least 25% of the voting power of our shares and, in an adjourned meeting, any two shareholders.

- *Compensation Committee*. The listing requirements require a listed company to have a compensation committee composed entirely of independent directors that operates pursuant to a written charter addressing its purpose, responsibilities and membership qualifications and may receive counseling from independent consultants, after evaluating their independence. The purpose, responsibilities and membership qualifications of our compensation committee will be governed by the Companies Law, rather than the listing requirements. In addition, under the Companies Law there are no specific independence evaluation requirements for outside consultants.

Except as stated above, we intend to substantially comply with the rules applicable to U.S. companies listed on . We may in the future decide to avail ourselves of other foreign private issuer exemptions with respect to some or all of the other listing requirements from which exemptions are available to foreign private issuers. Following our home country governance practices, as opposed to the requirements that would otherwise apply to a company listed on , may provide less protection than is accorded to investors under listing requirements applicable to domestic issuers.

Board of Directors

Following this offering, our board of directors will consist of directors. In addition, we have nominated and as our external directors, and whose appointment would fulfill the requirements of the Companies Law that we have two external directors. See "—External Directors." These two directors, as well as , would also qualify as independent directors under the corporate governance standards of the listing requirements and the audit committee independence requirements of Rule 10A-3 of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

According to our amended Articles, the number of members of our board of directors must be at least and cannot be more than . The board will be divided into three classes, with staggered three-year terms and one director class coming up for election each year. The Class I, Class II and Class III directors will serve until our annual meetings of stockholders in , and , respectively. The members of the classes at the closing of this offering will be divided as follows:

- the Class I directors are and ;
- the Class II directors are and ; and
- the Class III directors are and .

At each annual meeting of shareholders, directors will be elected to succeed the class of directors whose term has expired. This classification of our board of directors could have the effect of increasing the length of time

necessary to change the composition of a majority of the board of directors. In general, at least two annual meetings of shareholders will be necessary for shareholders to effect a change in a majority of the members of the board of directors.

Our board of directors is also authorized to appoint directors in order to fill vacancies. Each of our directors, other than our external directors, will serve from the date of election or appointment until the next annual meeting of shareholders for which such director's class is due for reelection. The approval of at least a majority of the voting rights represented at a shareholders' meeting and voting on the matter is generally required to remove any of our directors from office (other than external directors).

External Directors

Under the Companies Law, companies incorporated under the laws of the States of Israel that are "public companies," including companies with shares listed on , are required to have at least two external directors who meet certain independence criteria to ensure that they are unaffiliated with us and our controlling shareholder. External directors must be elected by our shareholders no later than three months following the completion of this offering. We have nominated and as external directors.

An external director must also have either financial and accounting expertise or professional qualifications, as defined in regulations under the Companies Law, and at least one of the external directors is required to have financial and accounting expertise. An external director is entitled to reimbursement of expenses and compensation as provided in regulations promulgated under the Companies Law but is otherwise prohibited from receiving any other compensation from us, directly or indirectly, during his term and for two years thereafter.

Under the Companies Law, external directors must be elected at a shareholders' meeting by a simple majority of the votes cast on the matter, provided that such majority includes a majority of the votes cast by non-controlling shareholders and shareholders who do not have a personal interest in the election (excluding a personal interest that did not result from the shareholder's relationship with the controlling shareholder), unless the votes cast by such shareholders against the election did not exceed 2% of our aggregate voting rights. External directors serve for up to three terms of three years each, and our audit committee and board of directors may nominate them for additional terms under certain circumstances. Even if an external director is not nominated by our board of directors for re-election for a second or third term, shareholders holding at least 1% of our voting rights or the external director may nominate the external director for re-election. In such a case, the re-election can be approved without the approval of a controlling shareholder if it is approved by a majority of the votes cast by non-controlling shareholders and shareholders who do not have a personal interest in the election (excluding a personal interest that did not result from the shareholder's relationship with the controlling shareholder) and the votes cast by such shareholders approving the election exceed 2% of our aggregate voting rights. A term of an external director may be terminated prior to expiration only by a shareholder vote (by the same threshold required for election), or by a court, but in each case only if the external director ceases to meet the statutory qualifications for election or if the external director violates his duty of loyalty to us.

Each committee of a company's board of directors that is authorized to exercise powers of the board of directors is required to include at least one external director, and all external directors must be members of the company's audit committee and compensation committee.

Financial Experts

Our board of directors has resolved that at least one of its members must have financial and accounting expertise, as defined in regulations promulgated under the Companies Law. Our board of directors has determined that meets such qualifications.

In addition, our board of directors has determined that , and , who have been nominated to serve on our audit committee, are financially literate as determined in accordance with listing requirements and that is qualified to serve as an "audit committee financial expert" as defined by SEC rules.

Alternate Directors

Our Articles of Association provide that, as permitted under Israeli law, any director may appoint another person who is not a director or an alternate director to serve as his alternate director, subject to the approval of a majority of the members of the board of directors excluding such director. The term of an alternate director could be terminated at any time by the appointing director or our board of directors and would automatically terminate upon the termination of the term of the appointing director. The Companies Law stipulates that an external director may not appoint an alternate director except under very limited circumstances. An alternate director has the same rights and responsibilities as a director, except for the right to appoint an alternate director.

Our Committees

Our board of directors has established the following committees:

Audit Committee

Under the Companies Law, the board of directors of a public company must establish an audit committee. The audit committee must consist of at least three directors who meet certain independence criteria detailed below and must include all of the company's external directors, one of whom must serve as chairman of the committee. The audit committee may not include the chairman of the board, a controlling shareholder of the company, a relative of a controlling shareholder, a director employed by or providing services on a regular basis to the company, to a controlling shareholder or to an entity controlled by a controlling shareholder, or a director who derives most of his or her income from a controlling shareholder. In addition, under the Companies Law, the majority of the directors serving on the audit committee of a publicly traded company must be unaffiliated directors. In general, an "unaffiliated director" under the Companies Law for "public companies," including companies with shares listed on , is defined as either an external director or as a director who meets the following criteria:

- he or she meets the primary qualifications for being appointed as an external director, except for the requirements that the director possess accounting and financial expertise or professional qualifications; and

- he or she has not served as a director of the company for a period exceeding nine consecutive years, subject to extension for additional terms under certain circumstances. For this purpose, a break of less than two years in the service shall not be deemed to interrupt the continuation of the service.

Under the listing requirements, we are required to maintain an audit committee consisting of at least three independent directors, each of whom is financially literate and one of whom has accounting or related financial management expertise.

The responsibilities of an audit committee under the Companies Law include identifying and addressing flaws in the management of the company, reviewing and approving interested party transactions, establishing whistleblower procedures, overseeing the company's internal audit system and the performance of its internal auditor, and recommending the fees of the company's independent accounting firm. In addition, the audit committee is required to determine whether certain related party actions and transactions are "material" or "extraordinary" for the purpose of the requisite approval procedures under the Companies Law and to establish procedures for considering proposed transactions with a controlling shareholder.

Our audit committee is also responsible for the appointment, compensation and oversight of the work of our independent auditors and for assisting our board of directors in monitoring our financial statements, the effectiveness of our internal controls and our compliance with legal and regulatory requirements.

Upon completion of this offering our audit committee will consist of (Chairman), and , and will comply with the requirements of the Companies Law (subject to shareholder approval of our external directors within three months following the consummation of the offering), the Exchange Act and listing requirements. All of the members will be external directors or independent directors as defined in the Companies Law. All of the members will also be independent as defined in SEC rules and the listing requirements.

Compensation Committee

Under the Companies Law, the board of directors of a public company must establish a compensation committee. The compensation committee must consist of at least three directors who meet certain independence criteria and must include all of the company's external directors. The responsibilities of a compensation committee under the Companies Law include to recommend to the board of directors, for ultimate shareholder approval by a special majority, a policy governing the compensation of officers and directors based on specified criteria, to review modifications to the compensation policy from time to time, to review its implementation and to approve the actual compensation terms of officers and directors prior to approval by the board of directors.

Upon completion of this offering we will have a compensation committee consisting of (Chairman), and , and will comply with the requirements of the Companies Law (subject to shareholder approval of our external directors within three months following the consummation of the offering) but not the listing standards applicable to compensation committees. See "—Corporate Governance Practices" above. All of the members are external directors as defined in the Companies Law and independent as defined in listing requirements.

Nominating and Governance Committee

In accordance with the listing requirements, upon completion of this offering we will have a nominating and governance committee comprised solely of independent directors. Upon the completion of this offering, the nominating and governance committee will consist of (Chairman), and . The responsibilities of our nominating and governance committee include overseeing and assisting our board of directors in reviewing and recommending nominees for election as directors, assessing the performance of the members of our board of directors, and establishing and maintaining effective corporate governance policies and practices, including, but not limited to, developing and recommending to our board a set of corporate governance guidelines applicable to our company.

Internal Auditor

Under the Companies Law, the board of directors is required to appoint an internal auditor recommended by the audit committee. The role of the internal auditor is to examine, among other things, whether the company's actions comply with applicable law and proper business procedures. The internal auditor may not be an interested party, an officer or director of the company, or a relative of any of the foregoing, nor may the internal auditor be our independent accountant or a representative thereof. We will appoint an internal auditor following the completion of this offering.

Fiduciary Duties and Approval of Related Party Transactions

Fiduciary Duties of Directors and Officers

Israeli law imposes a duty of care and a duty of loyalty on all directors and officers of a company. The duty of care requires a director or officer to act with the level of care with which a reasonable director or officer in the same position would have acted under the same circumstances. The duty of care includes, among other things, a duty to use reasonable means, under the circumstances, to obtain information on the advisability of a given action brought for his approval or performed by virtue of his position and other important information pertaining to such action. The duty of loyalty requires the director or officer to act in good faith and for the benefit of the company.

Approval of Related Party Transactions

Under the Companies Law, a related party transaction may be approved only if it is for the benefit of the company. A transaction that is not an extraordinary transaction in which a director or officer has a personal interest requires the approval of the board of directors, unless the articles of association of the company provide otherwise. Our amended Articles provide that such a transaction, if it does not relate to the director's or officer's compensation terms, may be approved by any of our board of directors, our Audit Committee, or a disinterested officer or director. If the transaction is an extraordinary transaction, it must be approved by the audit committee and the board of directors, and, under certain circumstances, by the shareholders of the company, as well. An "extraordinary transaction" is a transaction other than in the ordinary course of business, other than on market terms or that is likely to have a material impact on the company's profitability, assets or liabilities.

Extraordinary transactions in which a controlling shareholder has a personal interest require the approval of the audit committee, the board of directors and the shareholders of the company. The shareholder approval must be by a simple majority of all votes cast, provided that (i) such majority includes a simple majority of the votes cast by non-controlling shareholders having no personal interest in the matter or (ii) the total number of votes of shareholders mentioned in clause (i) above who voted against such transaction does not exceed 2% of the total voting rights in the company.

The Companies Law prohibits any director who has a personal interest in an extraordinary transaction from being present for the discussion and voting pertaining to such transaction in the audit committee or board of directors, except in circumstances where the majority of the board of directors or the audit committee has a personal interest in the transaction, in which case such transaction also requires shareholder approval.

Approval of Director and Officer Compensation

Under the Companies Law, we are required to approve at least once every three years a compensation policy with respect to our officers and directors. Following the recommendation of our compensation committee, the compensation policy must be approved by our board of directors and shareholders. The shareholder approval must be by a simple majority of all votes cast, provided that (i) such majority includes a simple majority of the votes cast by non-controlling shareholders having no personal interest in the matter or (ii) the total number of votes of shareholders mentioned in clause (i) above who voted against such transaction does not exceed 2% of the total voting rights in the company. We will have nine months from the consummation of this offering to adopt a compensation policy, and intend to adopt a compensation policy by that date.

In general, the compensation terms of directors, the chief executive officer and any employee or service provider who is considered a controlling shareholder must be approved separately by the compensation committee, the board of directors and the shareholders. Shareholder approval is not required for director compensation payable in cash up to the maximum amount set forth in the regulations governing the compensation of external directors. The compensation terms of other officers who report directly to the chief executive officer require the approval of the compensation committee and the board of directors.

Employment Agreements with Executive Officers

We have entered into written employment agreements with all of our executive officers. Each of these agreements contains provisions regarding confidentiality, non-competition/non-solicitation and ownership of intellectual property. The non-competition provision applies for a period that is generally 12 months following termination of employment. The enforceability of covenants not to compete in Israel and the United States is subject to limitations. In addition, we are required to provide notice prior to terminating the employment of our executive officers, other than in the case of a termination under circumstances which deprive the executive officer of severance pay under Israeli law, a breach of trust, or the executive officer's breach of the terms of confidentiality, non-competition/non-solicitation and ownership of intellectual property provisions of the relevant employment agreement.

Compensation of Directors and Officers

External directors may be compensated only in accordance with regulations adopted under the Companies Law. These regulations permit the payment of cash compensation within a specified range, depending on the size of the company, or cash or equity compensation that is consistent with the compensation paid to the other independent directors. We do not have any agreement with directors providing for benefits upon termination of their service as directors or our company.

The aggregate compensation paid to all of the members of our directors and senior management was $2,286,692 in 2016. This amount includes approximately $1,351,781 for share based compensation and $93,186 set aside or accrued in the aggregate for pension or other retirement benefits for our directors and senior management in 2016.

Summary Compensation Table

The following table presents all compensation we incurred for the year ended December 31, 2016 to the five highest paid office holders, which includes our officers and directors, in U.S. dollars. The table does not include

any amounts we paid to reimburse any of these persons for costs incurred in providing us with services during this period:

Name	Position	Annual Compensation				
		Base Salary and Related Benefits [1]	Bonus	Retirement and Other Similar Benefits	Share Based Compensation[2]	Total
Luke M. Beshar	Chairman of the board of directors	$ —	$ —	$ 28,626	$ 757,691	$ 786,317
Dr. Roger Garceau	Chief Development Advisor	$ —	$ —	$ 15,136	$ 522,136	$ 537,272
Dr. Phillip Schwartz	Chief Executive Officer and Director	$ 255,955	$ 100,000	$ 48,553	$ —	$ 404,508
Dr. Hillel Galitzer	Chief Operating Officer	$ 175,879	$ 50,000	$ 25,270	$ 804	$ 251,953
Mira Rosenzweig	Chief Financial Officer	$ 151,652	$ 25,000	$ 16,331	$ 4,938	$ 197,921

(1) Includes base salary, social benefits and car allowances. The amounts shown in this column represent expenses recorded in our financial statements for the year ended December 31, 2016, and are based on actual exchange rate of each month in which the salary was recorded or the month in which the accrued salary expenses recorded.

(2) The amounts shown in this column represents expenses recorded in our financial statements for the year ended December 31, 2016, with respect to all options granted to such executive officers.

Share Incentive Plan

On March 17, 2013, our board of directors approved our Share Incentive Plan, or the Plan, for the granting of stock options, restricted share units, restricted share awards and performance-based awards, in order to provide incentives to our employees, directors, consultants and/or contractors. As of June 30, 2017, a total of 444 ordinary shares remained available for issuance under the Plan. As of that date, 9,638 ordinary shares were issuable upon the exercise of outstanding awards under the Plan, at a weighted-average exercise price of $218.25 per share. Of the foregoing outstanding awards, options to purchase 7,442 ordinary shares, in the aggregate, had vested under the Plan as of that date, with a weighted-average exercise price of $148.33 per share.

Awards granted under the Plan are subject to vesting schedules and generally vest following a period of four years from the applicable grant date, such that 25% of the awards vest on the first anniversary of the applicable grant date and 75% of the awards vest in twelve equal installments upon the lapse of each three-month period following the first anniversary of the applicable grant date. Subject to the discretion of the Plan administrator, if an award has not been exercised within six years after the date of the grant, the award expires. Any period in which a grantee is not our employee or has taken a leave of absence will not be included in such vesting period.

The Plan provides for granting awards in compliance with Section 102 of the Israeli Income Tax Ordinance, 1961, or the Ordinance, which provides to employees, directors and officers, who are not controlling shareholders and are Israeli residents, favorable tax treatment for compensation in the form of shares or awards issued or granted, as applicable, to a trustee under the “capital gains track” for the benefit of the relevant employee, director or officer and are, or were, to be held by the trustee for at least two years after the date of grant or issuance. Under the capital gains track, we are not allowed to deduct an expense with respect to the grant or issuance of such shares or awards.

The Plan addresses the treatment of vested and unvested awards upon the cessation of employment of the award holder as well as upon consummation of a merger, consolidation or similar transaction, or sale of all or substantially all of our assets or sale of at least 80% of our outstanding securities. The Plan also provides for certain lock-up arrangements upon consummation of a public offering.

The plan is administered by our board of directors or by a committee appointed by our board of directors.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of related party transactions we have entered into since March 1, 2012 with any of our directors, executive officers and holders of more than 5% of our ordinary shares.

Convertible Debt Financing

2012 Convertible Loans

On November 13, 2012 and December 31, 2012, we entered into the 2012 Convertible Loans, with D.N.A Biomedical Solutions Ltd., or D.N.A Biomedical, and the lenders thereto, including the Revach Fund L.P., or Revach, an entity controlled by our director Chaim Davis, and Europa International Inc., who later transferred its shares to Gakasa Holdings LLC, or Gakasa. The lenders loaned us an aggregate amount of $1.2 million, of which Revach loaned us $100,000, and Gakasa loaned us $550,000. Pursuant to the 2012 Convertible Loans, each of the loans bears interest at a rate of 0.6% per year, payable in five-year intervals, and matures after a term of 20 years, subject to the conversion rights noted below. Each of the lenders has the right during the term to convert all of its respective loan amount into our ordinary shares at a conversion price of $240.26 per ordinary share (subject to adjustment as detailed in the agreements governing the 2012 Convertible Loans), the Company Conversion Right, and for a period of the initial five years of the term of the applicable 2012 Convertible Loans to exchange all such ordinary shares received pursuant to the Company Conversion Right into ordinary shares of D.N.A Biomedical at the rate of one of our ordinary shares for 5,590 ordinary shares of D.N.A Biomedical (also subject to adjustment as detailed in the 2012 Convertible Loans). In addition, under the terms of the 2012 Convertible Loans, the outstanding loan amounts will be automatically converted into our ordinary shares on certain events, including in connection with the closing of this offering. In addition, pursuant to the terms of the 2012 Convertible Loans the lenders were granted piggyback registration rights, which were subsequently set forth in our investors' rights agreement as described below in "Share Eligible for Future Sale—Registration Rights."

2015 Convertible Loan

On August 5, 2015, the Company entered into the 2015 Convertible Loan with certain lenders. Pursuant to the loan agreement for the 2015 Convertible Loan, the lenders loaned us an aggregate amount of $2.005 million. The 2015 Convertible Loan bore interest at a rate of 5% per year. The loan would also be automatically converted upon occurrence of a 2015 Triggering Event into the equity securities and/ or securities convertible into equity securities of the Company that were issued in such a transaction, at a 25% discount.

In addition, the Company issued to each lender under the 2015 Convertible Loan the 2015 Warrants to purchase an additional 40% of the amount of our securities that would have been issued to such lender as a result of the automatic conversion following a 2015 Triggering Event. The 2015 Warrants were exercisable for the earlier of two years from the warrant issuance date or one year from consummation of an initial public offering. As part of the 2016 Convertible Loan, we granted the lenders a right to roll-over the 2015 Convertible Loan into the 2016 Convertible Loan. The lenders elected to roll-over an amount of $1.057 million into the 2016 Convertible Loan and the reminder, in an amount of $1.053 million (including interest and principal), was repaid by the Company in February 2017. There remain no amounts outstanding under the 2015 Convertible Loans, and no 2015 Warrants remain outstanding.

One of our directors, Gerald Lieberman, participated in the 2015 Convertible Loan in an amount of $50,000, which rolled-over to the 2016 Convertible Loan.

2016 Convertible Loan

On June 14, 2016, the Company entered into the 2016 Convertible Loan with certain lenders for an aggregate amount of approximately $7.44 million. In addition, an amount of $1.057 million of the 2015 Convertible Loan rolled over to the 2016 Convertible Loan. The 2016 Convertible Loan is for a term of 18 months and bears interest at a rate of 5% per year. The 2016 Convertible Loan will automatically convert upon the occurrence of a 2016 Triggering Event. Furthermore, in case of a private placement in an aggregate amount of between $4 million to $10 million the lenders have the right to convert the 2016 Convertible Loan. In each case of conversion, the 2016 Convertible Loan will convert into the same equity securities and/or securities convertible into equity securities of the Company that were issued in such a transaction at the lower of (i) a 25% discount to the applicable price per

share of such security or (ii) the price per share of such securities calculated at a valuation of $65 million on a fully diluted basis.

In addition, the Company issued to each lender under the 2016 Convertible Loan the 2016 Warrants to purchase an additional 40% of the amount of our securities issued to such lender as a result of the automatic conversion following a 2016 Triggering Event. The 2016 Warrants will be exercisable upon conversion of the 2016 Convertible Loan and thereafter until June 2020.

In addition, each lender in the 2016 Convertible Loan have the right to invest, in the next share issuance by the Company, an amount not to exceed the amount such lender invested in the 2016 Convertible Loan, at a price per share of the shares issued.

Our directors, Luke Beshar, Roger Garceau and Gerald Lieberman, each participated, in amounts of $50,000, $25,000 and $50,000, respectively. In addition, Corundum Open Innovation Fund, L.P., of which David Ben Ami, a member of our board of directors, is the managing partner, invested an amount of $1 million in our 2016 Convertible Loan.

Ordinary Share Purchases

In November 2012, we issued to D.N.A Biomedical 2,078 ordinary shares in consideration of $500,000, of which $445,000 represented the cancellation of debt we owed to D.N.A Biomedical. The remaining $55,000 was paid to us in cash.

On September 30, 2013 we entered into share purchase agreements, or the ordinary share purchase agreements, with our director Chaim Davis, Revach and Europa International Inc., who later transferred its shares to Gakasa. Pursuant to the ordinary share purchase agreements, Mr. Davis, Revach and Gakasa purchased 91, 365, and 1,369 of our ordinary shares, respectively, for aggregate purchase prices of $25,000, $100,000 and $375,000, respectively.

Series A Preferred Share Investment Rounds

On January 29, 2014, we entered into a Series A preferred share purchase agreement with the Centillion Fund, or Centillion, or the Centillion preferred share purchase agreement, pursuant to which Centillion purchased 4,172 of our preferred shares, for a purchase price of $2.0 million or $479.38 per share, or the per share purchase price, and we issued to Centillion a warrant to purchase up to 1,043 of our applicable shares (as discussed below in “Description of Share Capital—Warrants”) at the per share purchase price. Pursuant to the terms of the Centillion preferred share purchase agreement, upon our filing of a registration statement for an initial public offering with the SEC on or prior to June 29, 2014, or the first milestone, Centillion was required to purchase from us an additional 4,172 preferred shares at the per share purchase price (for additional proceeds to us of $2.0 million), and we were required to issue to Centillion a warrant to purchase an additional 1,043 applicable shares at the per share purchase price. In addition, pursuant to the Centillion preferred share purchase agreement, upon the consummation of an offering of our ordinary shares on or prior to December 29, 2014, pursuant to which our ordinary shares are listed on the NASDAQ or the NYSE MKT, or the second milestone, Centillion was required to purchase from us an additional 2,086 preferred shares at the per share purchase price (for additional proceeds to us of $1.0 million), and we were required to issue to Centillion a warrant to purchase an additional 522 preferred shares at the per share purchase price. Centillion also had the right to acquire the preferred shares and warrant to be issued upon either of the milestones prior to the applicable milestone date. Pursuant to the Centillion preferred share purchase agreement, Centillion’s obligations at milestone closings are subject to certain conditions, including that a clinical trial not have been terminated on account of safety concerns.

On June 18, 2014, Centillion and we entered into the first amendment to the Centillion preferred share purchase agreement, pursuant to which the date for the first milestone was extended from June 29, 2014 to November 1, 2014, and the date for the second milestone was extended from December 29, 2014 to May 1, 2015.

On January 21, 2015, Centillion and we entered into the second amendment to the Centillion preferred share purchase agreement, or the second amendment. Pursuant to the terms of second amendment, Centillion exercised its right to acquire the preferred shares and warrant to be issued upon the first milestone and paid us $2.0 million, although as of such date this milestone had not been achieved. The second milestone was also extended to October 1, 2015. In consideration therefor, we issued to Centillion an additional warrant, or the additional Centillion warrant, as described below in “Description of Share Capital—Additional Warrants.”

During the course of 2014 and January 2015 we entered into additional preferred share purchase agreements with other purchasers of our preferred shares. The additional preferred share purchase agreements also provide for the issuance of preferred shares and warrants upon the achievement of those milestones set forth in the Centillion preferred share purchase agreement on terms substantially identical to those contained in the Centillion preferred share purchase agreement. In March 2015, we entered into the first amendment to each of the additional preferred share purchase agreements, which contained terms substantially identical to those contained in the second amendment to the Centillion preferred share purchase agreement. We also issued to these additional preferred shareholders warrants upon terms substantially identical to those contained in the additional Centillion warrant, or together with the additional Centillion warrant, the additional warrants.

Service Agreements

In April 2017, the Company entered into a Service Agreement with our director Luke Beshar, pursuant to which Mr. Beshar will be entitled to a monthly fee in the amount of $21,500 per month, and to reimbursements for certain expenses. In addition, the Company has committed to grant Mr. Beshar options representing 6.5% of the Company's fully-diluted share capital, following the occurrence of an IPO of at least $20 million or a private placement of the Company's equity securities in an aggregate amount of not less than $10 million; provided however, that if the amount of new funds actually received by the Company in such a private placement exceeds $10,000,000, then it shall be deemed for the purpose of calculating the "fully diluted basis" under the Service Agreement as if such amount is equal to $10,000,000. Such options vest monthly over a three year period, beginning December 1, 2016, and are subject to certain acceleration provisions detailed within the Service Agreement. In addition, if a change of control of the Company were to occur prior to the issuance of options as described above, the Company would pay to Mr. Beshar, in lieu of the option grants, the lower of: (i) an amount that, taking into account all federal, state, local and foreign taxes (including excise taxes) arises from the payment of such amount, would yield net after-tax proceeds to Mr. Beshar of $1,000,000; or (ii) $3,619,254.

In April 2017, the Company entered into a Service Agreement with our director Roger Garceau, pursuant to which Mr. Garceau will be entitled to a monthly fee in the amount of $6,500 per month, and to reimbursements for certain expenses. In addition, the Company has committed to grant Mr. Garceau options representing 1.5% of the Company's fully-diluted share capital, following the occurrence of an IPO of at least $20 million or a private placement of the Company's equity securities in an aggregate amount of not less than $10 million; provided however, that if the amount of new funds actually received by the Company exceeds $10,000,000, then it shall be deemed for the purpose of calculating the "fully diluted basis" under the Service Agreement as if such amount is equal to $10,000,000. Such options vest monthly over a three year period, beginning December 1, 2016, and are subject to certain acceleration provisions detailed within the Service Agreement. In addition, if a change of control of the Company were to occur prior to the issuance of options as described above, the Company would pay to Mr. Garceau, in lieu of the option grants, the lower of: (i) an amount that, taking into account all federal, state, local and foreign taxes (including excise taxes) arises from the payment of such amount, would yield net after-tax proceeds to Mr. Garceau of $1,000,000; or (ii) $3,619,254.

Pursuant to an arrangement between us and Chaim Davis, a member of our Board of Directors, Mr. Davis provides us with certain services related to corporate business development in consideration for a one-time payment of $25,000, and $6,500 per month.

Registration Rights

We, certain of our shareholders and certain lenders under our 2012 Convertible Loan have entered into an amended and restated investors' rights agreement dated as of November 26, 2014, or the investors' rights agreement, pursuant to which these shareholders and lenders will have the right, following the closing of this offering, to demand that we file a registration statement or to request that their shares be covered by a registration statement that we are otherwise filing. See "Shares Eligible for Future Sale—Registration Rights" for a further description of these arrangements.

In addition to the above, the lenders of the 2016 Convertible Loan had committed to execute a joinder to the investors' rights agreement upon conversion of the 2016 Convertible Loan, and the investors' rights agreement will grant the lenders of the 2016 Convertible Loan the registration rights granted thereunder once executed.

Director Designation Rights

Pursuant to the terms of the investors' rights agreement, following this offering and as long as Centillion and its affiliates hold an aggregate of at least 10% of our issued and outstanding ordinary shares, we will nominate, if so requested by Centillion and as permitted by applicable law, a designee of Centillion for election by our shareholders

as a member of our board of directors and will recommend that our shareholders vote in favor of such election. David Ben Ami, a member of our board of directors, was nominated by Centillion pursuant to its director designation right.

In addition, Pontifax (Israel), Pontifax (Cayman) IV Fund L.P. and Pontifax (China) IV Fund L.P., a lender group under the 2016 Convertible Loan, has a currently-unexercised right to appoint a director to our board of directors on behalf of the lenders under the 2016 Convertible Loan. See "Management—Arrangements for Election of Directors."

Centillion Special Pre-emptive Rights

Pursuant to the terms of our current Articles, if we issue any equity interests to new investors that are not already our shareholders and subject to certain other conditions, Centillion is entitled to purchase, at any time until the second milestone date, which is defined to include this offering, 18.18% of the number of equity interests issued under such financings, at the same price per equity interest paid by the new shareholders (the "Centillion special pre-emptive rights").

Indemnification Agreements and Directors' and Officers' Liability Insurance

We have entered into indemnification agreements with each of our executive officers and directors. We also maintain an insurance policy that covers liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

Employment Agreements with Executive Officers

We have entered into employment agreements with our executive officers, which provide for, among other things, position, duties and compensation and benefits payable during the terms of employment and include certain restrictive covenants. See "Management—Employment Agreements with Executive Officers."

Related Party Transaction Policy

See "Management—Fiduciary Duties and Approval of Related Party Transactions" for a discussion of policies and procedures governing the approval of related party transactions.

Family Relationships

Dr. Miriam Blum, our Chief Medical Officer, is the wife of our Chief Executive Officer and Director, Dr. Phillip Schwartz. Other than such relationship, there are no family relationships between any of the executive officers or directors named above.

PRINCIPAL SHAREHOLDERS

The following table sets forth information regarding beneficial ownership of our ordinary shares as , by:

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

The percentage of shares beneficially owned prior to the offering is based on ordinary shares outstanding as of , including:

- ordinary shares to be issued upon the conversion of all outstanding preferred shares into ordinary shares upon the closing of this offering (including preferred shares to be issued to certain holders of our preferred shares upon the consummation of this offering);
- ordinary shares to be issued upon the exercise of all warrants outstanding (including warrants to be issued to certain holders of our preferred shares upon the consummation of this offering);
- and ordinary shares to be issued upon the conversion into ordinary shares of our outstanding convertible loans.

The percentage of beneficial ownership of our ordinary shares after the offering is based on ordinary shares outstanding after the offering (which includes the ordinary shares identified above) plus the ordinary shares to be sold by us in the offering, but not including any additional shares issuable upon exercise by Centillion of the Centillion special pre-emptive rights.

All of our shareholders, including the shareholders listed below, have the same voting rights attached to their ordinary shares. See “Description of Share Capital—Articles of Association—Voting.” Neither our principal shareholders nor our directors and executive officers have different or special voting rights.

Unless otherwise indicated, the address for each listed director and executive officer is Kiryat Hadassah, Minrav Building – Fifth Floor, Jerusalem 9112002, Israel. To our knowledge, except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares.

	Shares Beneficially Owned Prior to Offering(1)		Shares Beneficially Owned After Offering (Assuming No Exercise of the Over-Allotment Option)(1)		Shares Beneficially Owned After Offering (Assuming Full Exercise of the Over-Allotment Option)(1)	
Name of Beneficial Owner	Number	Percentage	Number	Percentage	Number	Percentage
Principal Shareholders:						
D.N.A Biomedical Solutions Ltd.	31,178	69.6%				
Centillion Fund (2)	13,571	27.1%				
Gakasa Holdings LLC (3)	3,658	7.8%				
Executive Officers and Directors:						
Dr. Phillip Schwartz (4)	4,451	9.0%				
Mira Rosenzweig (5)	*	*				
Dr. Hillel Galitzer (6)	*	*				
Dr. Miriam Blum (7)	4,451	9.0%				
Zeev Bronfeld (8)	31,178	69.6%				
Yonatan Malca (9)	31,178	69.6%				
Chaim Davis (10)	957	2.1%				
Luke M. Beshar (11)	756	1.7%				
Dr. Roger J. Garceau (12)	756	1.7%				

Name of Beneficial Owner	Shares Beneficially Owned Prior to Offering(1)		Shares Beneficially Owned After Offering (Assuming No Exercise of the Over-Allotment Option)(1)		Shares Beneficially Owned After Offering (Assuming Full Exercise of the Over-Allotment Option)(1)	
	Number	Percentage	Number	Percentage	Number	Percentage
David Ben Ami (13)	*	*				
Gerald Lieberman (14)	436	1.0%				
All executive officers and directors as a group (11 persons) (15)	39,327	75.0%				

* Less than 1%.

(1) The beneficial ownership of ordinary shares is determined in accordance with the rules of the SEC and generally includes any ordinary shares over which a person exercises sole or shared voting or investment power. For purposes of the table below, we deem shares subject to options or warrants that are currently exercisable or exercisable within 60 days of June 30, 2017, to be outstanding and to be beneficially owned by the person holding the options or warrants for the purposes of computing the percentage ownership of that person but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person.

(2) Consists of (i) 8,344 Series A preferred shares, (ii) warrants to purchase 2,086 Series A preferred shares that had been issued to Centillion as of June 30, 2016, (iii) 2,086 Series A preferred shares and a warrant to purchase 522 Series A preferred shares, which can be acquired by Centillion prior to the consummation of this offering to October 1, 2017 pursuant to the terms of our Series A preferred shares purchase agreement, and (iv) 427 Series A preferred shares and a warrant to purchase 107 Series A preferred shares, which can be acquired by Centillion prior to the consummation of this offering to October 1, 2017 pursuant to our Articles of Association. This number of ordinary shares does not include the number of ordinary shares that can be acquired by Centillion through the exercise of the Centillion warrant, as described in "Description of Share Capital—Additional Warrants".

(3) Consists of (i) 1,369 ordinary shares, and (ii) 2,289 ordinary shares that can be acquired by Gakasa Holdings LLC ("Gakasa") (this right was transferred to Gakasa by Europa International Inc.) upon conversion of the outstanding convertible loan under our Convertible Loan Financing Agreement with Gakasa.

(4) Consists of 4,451 ordinary shares underlying options to acquire ordinary shares exercisable within 60 days of June 30, 2017. The exercise price of these options is NIS 0.01 per share, and the options expire at various periods between and .

(5) Consists of 277 ordinary shares underlying options to acquire ordinary shares exercisable within 60 days of June 30, 2017, and expiring on May 29, 2020. The exercise price of these options is $316 per share.

(6) Consists of 277 ordinary shares underlying options to acquire ordinary shares, out of which 127 options have an exercise price of $240.26, and 150 options have an exercise price of NIS 0.01, all exercisable within 60 days of June 30, 2017, and expiring on September 1, 2019.

(7) Miriam Blum is the wife of Dr. Phillip Schwartz and may be deemed to have shared voting or investment power over the ordinary shares beneficially owned by Dr. Phillip Schwartz. Mrs. Blum disclaims beneficial ownership of such shares.

(8) Zeev Bronfeld is the Chairman of the Board of Directors of D.N.A Biomedical, and as such may be deemed to have shared voting or investment power over the ordinary shares owned by D.N.A Biomedical.

(9) Yonatan Malka is the C.E.O. and a director of D.N.A. Biomedical, and as such may be deemed to have shared voting or investment power over the ordinary shares owned by D.N.A Biomedical .

(10) Consists of (i) 91 ordinary shares, (ii) options to acquire 85 ordinary shares exercisable within 60 days of June 30, 2017, with an exercise price of $240.26 per share and expiring on September 1, 2019, (iii) 365 ordinary shares owned by Revach Fund, L.P. ("Revach") and (iv) 416 ordinary shares that can be acquired by Revach upon conversion of the outstanding convertible loan under our Convertible Loan Financing Agreement with Revach. Mr. Davis is the sole managing director and partner of Revach and may be deemed to beneficially own the ordinary shares owned or that can be acquired by Revach.

(11) Consist of 756 options to acquire our ordinary shares. This amount does not reflect the number of ordinary shares to be issued upon conversion of the outstanding convertible loan and the warrants to purchase ordinary shares under our 2016 Convertible Loan. In addition, this amount does not reflect the ordinary shares that can be acquired upon granting of certain options pursuant to the Service Agreement with Mr. Beshar, to be granted following the occurrence of this offering.

(12) Consist of 756 options to acquire our ordinary shares. This amount does not reflect the number of ordinary shares to be issued upon conversion of the outstanding convertible loan and the warrants to purchase ordinary shares under our 2016 Convertible Loan agreement. In addition, this amount does not reflect the ordinary shares that can be acquired upon granting of certain options pursuant to the Service Agreement with Dr. Garceau, to be granted following the occurrence of this offering.

(13) Consist of 242 underlying options to acquire ordinary shares with an exercise price of NIS 0.01, exercisable within 60 days of June 30, 2017, and expiring on March 19, 2019. This amount does not reflect the number of ordinary shares to be issued upon conversion of the outstanding convertible loan and the warrants to purchase ordinary shares under our 2016 Convertible Loan. Corundum Open Innovation Fund, L.P., of which David Ben Ami, a member of our board of directors, is the managing partner, invested an amount of $1 million in our 2016 Convertible Loan.

(14) Consist of 436 options to acquire our ordinary shares. This amount does not reflect the number of ordinary shares to be issued upon conversion of the outstanding convertible loan and the warrants to purchase ordinary shares under our 2016 Convertible Loan.

(15) Consists of (i) 31,634 ordinary shares, (ii) option to acquire 7,277 ordinary shares and (iii) 416 ordinary shares that can be acquired upon conversion of outstanding convertible loans under our Convertible Loan Financing Agreement.

DESCRIPTION OF SHARE CAPITAL

The following *description of our share capital and provisions of our Articles of Association are summaries and are qualified by reference to our amended Articles, which have been filed with the SEC as an exhibit to our registration statement of which this prospectus forms a part. Upon the closing of this offering, our current Articles will be replaced by our amended Articles. All references to our Articles of Association in this section refer to our amended Articles.*

General

We are an Israeli company incorporated with limited liability, and our affairs are governed by the provisions of our Articles of Association, as amended and restated from time to time, and by the provisions of applicable Israeli law, including the Companies Law. Upon the closing of this offering, our Fourth Amended and Restated Articles of Association currently in effect, or the current Articles, will be further amended and restated and replaced by our Fifth Amended and Restated Articles of Association, or the amended Articles. Other material terms and provisions of our ordinary shares under our amended Articles are described below in "—Ordinary Shares."

Ordinary Shares

Upon the closing of this offering, our authorized share capital will consist of ordinary shares, par value NIS per share, of which shares are issued and outstanding as of date of this prospectus and shares will be issued and outstanding immediately following the closing of this offering (assuming the underwriters do not exercise their option to purchase additional ordinary shares). All of our ordinary shares have been validly issued, fully paid and are non-assessable.

As of June 30, 2017, the number of our ordinary shares outstanding was 34,544, and an additional 9,638 ordinary shares were issuable upon the exercise of outstanding options granted to our officers and employees, at a weighted-average exercise price of $218.25 per share. See "Management—Share Incentive Plan" for more information about our outstanding option plans.

Preferred Shares

Under the terms of our amended Articles that will become effective upon the closing of this offering, we will not be authorized to issue preferred shares, and there will be no preferred shares outstanding.

Warrants

As of June 30, 2017, we had outstanding warrants to purchase 2,555 of our preferred shares, at an exercise price of $479.38, which, upon the closing of this offering will automatically convert into warrants to purchase 2,555 of our ordinary shares, at an exercise price of $479.38.

Pursuant to the terms of the preferred share purchase agreements with Centillion and certain other preferred shareholders, upon the consummation of this offering we will issue to Centillion and the other preferred shareholders warrants to purchase an additional 641 ordinary shares.

The following summary of certain material terms and provisions of such warrants is not complete and is subject to, and qualified in its entirety by the provisions of, the form of the warrant, which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Exercisability. The warrants are exercisable immediately upon issuance and at any time up to the date that is the earlier of (i) two years after the consummation of this offering or (ii) seven years from the date of issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the applicable number of our ordinary shares.

Applicable Shares. The class of shares that can be acquired upon exercise of the warrants will be (i) prior to the consummation of this offering, our preferred shares, (ii) upon and following the consummation of this offering and otherwise after the conversion of all of our preferred shares into ordinary shares, our ordinary shares, and (iii) upon any conversion, exchange, reclassification or change, any security into which our preferred shares or ordinary shares may be converted, exchanged, reclassified or otherwise changed.

Exercise Price. The initial exercise price per applicable share purchasable upon exercise of the warrants is $479.38 per share. The exercise price and the number of shares issuable upon exercise are subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock subdivisions and combinations, reclassifications or similar events affecting our ordinary shares.

Transferability. Absent an effective registration statement filed with the SEC covering the disposition or sale of the warrants or the shares issued or issuable upon exercise of the warrants, and registration or qualification under applicable state securities laws, the holder cannot transfer any or all of the warrants or the applicable shares unless such transfer is exempt from the registration requirements of the Securities Act and any applicable state securities laws.

Rights as a Shareholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of our ordinary shares, the holder of a warrant does not have the rights or privileges of a holder of ordinary shares, including any voting rights, until the holder exercises the warrant.

Additional Warrants

As discussed above under "Certain Relationships and Related Party Transactions," in connection with the second amendment to the Centillion preferred share purchase agreement and the first amendment to the additional preferred share purchase agreements with the certain other preferred shareholders, we issued additional warrants to such shareholders. As of June 30, 2017, we had outstanding additional warrants in an aggregate principal amount of $2.45 million, which upon the closing of this offering will become additional warrants to purchase of our ordinary shares at an exercise price of $, which represents a 25% discount from the initial public offering price in this offering, assuming an initial public offering price of $ per share, which is the midpoint of the estimated offering price range on the cover page of this prospectus.

The following summary of certain material terms and provisions of the additional warrants is not complete and is subject to, and qualified in its entirety by the provisions of, the form of the additional warrant, which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Exercisability. The additional warrants are exercisable upon, and for a period of one year following, a triggering event, which includes certain change of control transactions, certain private placement equity financings of at least $5 million or a public offering on NASDAQ or the New York Stock Exchange.

Applicable Shares. The class of shares that can be acquired upon exercise of the additional warrants will be type of shares issued in such a triggering event.

Exercise Price. The initial exercise price per applicable share purchasable upon exercise of the warrants will be discounted by 25% from the applicable per share price of the shares issued in the relevant triggering event, which, in the case of this offering would be $, which represents a 25% discount from the initial public offering price in this offering, assuming an initial public offering price of $ per share, which is the midpoint of the estimated offering price range on the cover page of this prospectus. The exercise price and the number of shares issuable upon exercise are subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock subdivisions and combinations, reclassifications or similar events affecting our ordinary shares.

Transferability. Absent an effective registration statement filed with the SEC covering the disposition or sale of the warrants or the shares issued or issuable upon exercise of the warrants, and registration or qualification under applicable state securities laws, the holder cannot transfer any or all of the warrants or the applicable underlying shares unless such transfer is exempt from the registration requirements of the Securities Act and any applicable state securities laws.

Rights as a Shareholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of our ordinary shares, the holder of a warrant does not have the rights or privileges of a holder of ordinary shares, including any voting rights, until the holder exercises the warrant.

2016 Warrants

In connection with the 2016 Convertible Loan, the Company granted to the lenders warrants in the 2016 Convertible Loan to purchase an additional 40% of the number of the Company's equity securities issued to such lender following the conversion of the loan into the Company's equity securities following a 2016 Triggering Event (the "2016 Warrants"). As of June 30, 2017, we had outstanding 2016 Warrants in an aggregate principal amount of $ million.

The following summary of certain material terms and provisions of the 2016 Warrants is not complete and is subject to, and qualified in its entirety by the provisions of, the form of the 2016 Warrants, which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Exercisability. The 2016 Warrants are first exercisable upon a conversion of the 2016 Convertible Loan due to the occurrence of a 2016 Triggering Event and from thereafter until June 2020.

Applicable Securities. Upon a 2016 Triggering Event, the 2016 Warrants will be exercisable for the type of securities that are issued in the 2016 Triggering Event.

Exercise Price. The initial exercise price will be the applicable price per share of the securities issued in the 2016 Triggering Event.

Transferability. Absent an effective registration statement filed with the SEC covering the disposition or sale of the warrants or the securities issued or issuable upon exercise of the 2016 Warrants, and registration or qualification under applicable state securities laws, the holder cannot transfer any or all of the warrants or the applicable underlying shares unless such transfer is exempt from the registration requirements of the Securities Act and any applicable state securities laws. In addition, the holder can transfer any or all of the 2016 Warrants to a Permitted Transferee, as defined in the Company's Amended and Restated Articles of Association.

Rights as a Shareholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of our ordinary shares, the holder of a 2016 Warrant does not have the rights or privileges of a holder of ordinary shares, including any voting rights, until the holder exercises the 2016 Warrant.

Registration Number, Purpose of the Company and Registered Office

Our number with the Israeli Registrar of Companies is 514330604. The purpose of our company appears in Article 2 of our Articles of Association, which authorize us to engage in any lawful activity. In addition, our Articles of Association authorize us to donate reasonable amounts to any charitable cause. Our registered office is at Kiryat Hadassah, Minrav Building – Fifth Floor, Jerusalem 9112002, Israel.

Board of Directors

Under the Israeli Companies Law, 5759-1999, or the Companies Law, and our Articles of Association, our board of directors may exercise all powers and take all actions that are not required under the Companies Law or under our Articles of Association to be exercised or taken by our shareholders or other corporate body, including the power to borrow money for the purposes of our company. Our directors are not subject to any age limit requirement, nor are they disqualified from serving on our board of directors because of a failure to own a certain amount of our shares. For more information about our board of directors, see "Management."

Our Ordinary Shares

Dividends and Liquidation Rights

Subject to the rights of holders of shares with preferential or special rights that may be authorized in the future, holders of our ordinary shares are entitled to participate in the payment of dividends pro rata in accordance with the amounts paid-up or credited as paid-up on the par value of such ordinary shares at the time of payment without taking into account any premium paid thereon. In the event of our liquidation, holders of our ordinary shares are entitled to a pro rata share of surplus assets remaining over liabilities, subject to rights conferred on any class of

shares which may be issued in the future, again in accordance with the amounts paid-up or credited as paid-up on the par value of such ordinary shares, without taking into account any premium paid thereon.

According to the Companies Law, a company may make a distribution of dividends out of its profits on the condition that there is no reasonable concern that the distribution may prevent the company from meeting its existing and expected obligations when they fall due. The Companies Law defines such profit as retained earnings or profits accrued in the last two years, whichever is greater, according to the last reviewed or audited financial statements of the company, provided that the date of the financial statements is not more than six months before the distribution. Declaration of dividends requires a resolution of our Board of Directors but does not require shareholder approval.

Under Israeli law, holders of ordinary shares are permitted to freely convert dividends and liquidation distributions into non-Israeli currencies, provided that we have withheld Israeli income tax with respect to such amounts. Certain reporting obligations may apply. Pursuant to Israeli, law currency control measures may be imposed by governmental action at any time.

Voting Rights

Holders of our ordinary shares are entitled to one vote for each share on all matters submitted to a vote of shareholders, subject to any special rights of any class of shares that may be authorized in the future. Cumulative voting for the election of directors is not permitted.

Quorum

The quorum required for a meeting of shareholders consists of at least two shareholders, present in person or by proxy, jointly holding at least 25% of the issued shares conferring voting rights. A shareholders' meeting will be adjourned for lack of a quorum, after half an hour from the time set for such meeting, to the same day in the following week at the same time and place, or any time and place as the board of directors designates in a notice to the shareholders. If at such adjourned meeting a quorum as specified above is not present within half an hour from the time designated for holding the meeting, any two shareholders present in person or by proxy shall constitute a quorum.

Shareholders' Meetings and Resolutions

The Chairman of our board of directors is entitled to preside as Chairman of each shareholders' meeting. If he is absent, his deputy or another person elected by the present shareholders will preside.

A simple majority is sufficient to approve most shareholders' resolutions, including any amendment to our Articles of Association, unless otherwise required by law or by our Articles of Association.

We are required to hold an annual meeting of our shareholders once every calendar year, but no later than 15 months after the date of the previous annual meeting. All meetings other than the annual 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 as it may determine. In addition, the Companies Law provides that the board of directors of a public company is required to convene a special meeting upon the request of:

- any two directors of the company or one quarter of the board of directors; or
- one or more shareholders holding, in the aggregate: (i) five percent of the outstanding shares of the company and one percent of the voting power in the company; or (ii) five percent of the voting power in the company.

The Companies Law enables our board of directors to fix a record date to allow us to determine the shareholders entitled to notice of, or to vote at, any meeting of our shareholders. Under current regulations, the record date may be not more than forty days and not less than four days prior to the date of the meeting and notice is required to be published at least 21 or 35 days prior to the meeting, depending on the type of items on the agenda.

Modification of Shareholders' Rights

The rights attached to a class of shares may be altered by the approval of the shareholders of such class holding a majority of the voting rights of such class. The provisions in our Articles of Association pertaining to general meetings also apply to any special meeting of a class of shareholders. The quorum required for such special meeting is at least two persons who are the holders of at least 25% of the outstanding shares of that class represented in person or by proxy at such meeting. If such special meeting is adjourned due to a lack of quorum, the quorum required at the subsequent meeting will be at least two persons who are holders of issued shares of that class or their proxies.

Preemptive Rights

Pursuant to our Articles of Association, no preemptive rights are attached to our ordinary shares following the consummation of this offering.

Restrictions on Non-Residents of Israel

The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our Articles of Association or the laws of Israel, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

Anti-Takeover Provisions; Mergers and Acquisitions

Mergers

The Companies Law permits merger transactions with the approval of each party's board of directors and shareholders. In accordance with the Companies Law, our Articles of Association provide that a merger may be approved at a shareholders meeting by a majority of the voting power represented at the meeting, in person or by proxy, and voting on that resolution. In determining whether the required majority has approved the merger, shares held by the other party to the merger, any person holding at least 25% of the outstanding voting shares or the means of appointing the board of directors of the other party to the merger, or relatives of or companies controlled by these persons, are excluded from the vote.

Under the Companies Law, a merging company must inform its creditors of the proposed merger. Any creditor of a party to the merger may seek a court order blocking the merger if there is a reasonable concern that the surviving company will not be able to satisfy all of the obligations of the parties to the merger. In addition, a merger may not be completed until at least 50 days have passed from the date that a merger proposal was filed with the Israeli Registrar of Companies by each party and 30 days have passed since the merger was approved by the shareholders of each party.

Tender Offers

The Companies Law also 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 would become a 25% shareholder of the company, unless there is already a 25% shareholder of the company. Similarly, the 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 would become a 45% shareholder of the company, unless there is already a 45% shareholder of the company. These requirements do not apply if the acquisition (i) occurs in the context of a private placement by the company that received shareholder approval or (ii) was from a 25% or 45% shareholder, as the case may be. The tender offer must be extended to all shareholders, but the offeror is not required to purchase more than 5% of the company's outstanding shares, regardless of how many shares are tendered by shareholders. The tender offer may be consummated only if (i) at least 5% of 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.

If as a result of an acquisition of shares the acquirer will hold more than 90% of a company's outstanding shares, the acquisition must be made by means of a tender offer for all of the outstanding shares. If as a result of a full tender offer the acquirer would own more than 95% of the outstanding shares, then all the shares that the acquirer offered to purchase will be transferred to it. The law provides for appraisal rights if any shareholder files a request in court within six months following the consummation of a full tender off, but the acquirer is entitled to

stipulate that tendering shareholders forfeit their appraisal rights. If as a result of a full tender offer the acquirer would own 95% or less of the outstanding shares, then the acquirer may not acquire shares that will cause his shareholding to exceed 90% of the outstanding shares.

Tax Law

Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of numerous conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when the time comes, tax then becomes payable even if no actual disposition of the shares has occurred.

Shareholder Duties

Under the Companies Law, a shareholder has a duty to act in good faith and customary manner toward the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at a meeting of shareholders on the following matters:

- an amendment to the company's articles of association;
- an increase of the company's authorized share capital;
- a merger; or
- interested party transactions that require shareholder approval.

In addition, specified shareholders have a duty of fairness toward the company. These shareholders include any controlling shareholder, any shareholder who knows that it possesses the power to determine the outcome of a shareholder vote and any shareholder who, under the company's articles of association, has the power to appoint or to prevent the appointment of a director or officer of the company or another power with respect to the company. The Companies Law does not define the substance of this duty of fairness. However, a shareholder's breach of the duty of fairness is subject to laws regarding breaches of contracts and takes into account the status of such shareholder with respect to the company.

Listing

We expect to list our ordinary shares on the under the symbol " ."

Transfer Agent and Registrar

Upon listing of our ordinary shares for trading on , the transfer agent and registrar for the ordinary shares will be .

TAXATION AND GOVERNMENT PROGRAMS

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You are encouraged to consult your 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 or other taxing jurisdiction.

Israeli Tax Considerations

The following are material Israeli income tax consequences of the ownership and disposition of our ordinary shares that were purchased on the date of our initial public offering. It does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to own or dispose of our ordinary shares. This discussion does not address all the aspects of Israeli tax laws that may be relevant to an investor in light of its particular circumstances or to certain types of investors subject to special treatment under applicable law. The following discussion also contains an overview of the current tax regime applicable to companies in Israel, with specific reference to its effect on us. This discussion is based upon the tax laws of Israel and regulations thereunder as of the date hereof, which are subject to change.

General Corporate Tax Structure

Israeli companies are generally subject to corporate tax on their taxable income currently at the rate of 24% in 2017 (23% in 2018 and thereafter). However, the effective tax rate payable by a company that derives income from a Preferred Enterprise, Preferred Technological Enterprise or Preferred Special Technological Enterprise (as discussed below) may be considerably lower. Israeli companies are generally subject to capital gains tax at the regular corporate tax rate.

Tax Benefits Under the Law for the Encouragement of Industry (Taxes)

According to the Law for the Encouragement of Industry (Taxes), 1969, or the Industry Encouragement Law, an “industrial company” is an Israeli resident company that was incorporated in Israel, of which 90% or more of its income in any tax year, (other than income from certain government loans), is derived from an “Industrial Enterprise” owned by it and located in Israel. An “Industrial Enterprise” is defined as an enterprise whose major activity in any tax year is industrial production.

Under the Industry Encouragement Law, industrial companies are entitled to the following corporate tax benefits:

- amortization over an eight-year period of the cost of purchased know-how and patents and rights to use a patent and know-how which are used for the development or advancement of the Industrial Enterprise, commencing on the year in which such rights were first exercised;
- deductions over a three-year period of expenses incurred in connection with the issuance and listing of shares on a stock market;
- the right to elect, under specified conditions, to file a consolidated tax return together with related Israeli industrial companies; and
- accelerated depreciation rates on certain equipment and buildings.

Eligibility for benefits under the Industry Encouragement Law is not subject to receipt of prior approval from any governmental authority.

As we have not generated income yet, there is no assurance that we qualify as an Industrial Company or that the benefits described above will be available to us in the future.

Law for the Encouragement of Capital Investments, 5719-1959

Tax Benefits for Income from Preferred Enterprise

The Law for the Encouragement of Capital Investments, 5719-1959, generally referred to as the Investment Law, currently provides certain tax benefits for income generated by "Preferred Companies" from their "Preferred Enterprises." The definition of a Preferred Company includes, inter alia, a company incorporated in Israel that (i) is not wholly-owned by a governmental entity; (ii) owns a Preferred Enterprise, which is defined as an "Industrial Enterprise" (as defined under the Investment Law) and (iii) is controlled and managed from Israel and subject to further conditions set forth in the Investment law.

A Preferred Company is entitled to a reduced corporate tax rate of 16% with respect to income attributable to its Preferred Enterprise, unless the Preferred Enterprise is located in a specified development zone, in which case the rate will be 7.5% in 2017.

Dividends paid out of income attributed to a Preferred Enterprise are generally subject to tax at the rate of 20% or such lower rate as may be provided in an applicable tax treaty. However, if such dividends are paid to an Israeli company, no tax is required to be withheld (although, if the funds are subsequently distributed to individuals or non-Israeli residents (individuals and corporations), the withholding tax would apply.

Moreover, an additional tax of 3% will be imposed on high income individuals whose annual taxable income exceeds a certain threshold (NIS 640,000 for 2017).

As we have not generated income yet, there is no assurance that we qualify as a Preferred Company or that the benefits described above will be available to us in the future.

New Tax Benefits for Income from Preferred Technology Enterprise

A new amendment to the Investment Law was enacted as part of the Economic Efficiency Law that was published on December 29, 2016, and is effective as of January 1, 2017 (and is referred to herein as the "2017 Amendment"). The 2017 Amendment provides new tax benefits to Preferred Companies for two types of "Technology Enterprises," as described below, and is in addition to the other existing tax beneficial programs under the Investment Law.

The 2017 Amendment provides that a technology company satisfying certain conditions will qualify as a "Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 12% on income that qualifies as "Preferred Technology Income", as defined in the Investment Law. The tax rate is further reduced to 7.5% for a Preferred Technology Enterprise located in development zone A. In addition, a Preferred Technology Enterprise will enjoy a reduced corporate tax rate of 12% on capital gain derived from the sale of certain "Benefitted Intangible Assets" (as defined in the Investment Law) to a related foreign company if the Benefitted Intangible Assets were acquired from a foreign company on or after January 1, 2017 for at least NIS 200 million, and the sale receives prior approval from the National Authority for Technological Innovation (referred to as NATI).

The 2017 Amendment further provides that a technology company satisfying certain conditions (including an annual turnover of NIS 10 billion or more) will qualify as a "Special Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 6% on "Preferred Technology Income" regardless of the company's geographic location within Israel. In addition, a Special Preferred Technology Enterprise will enjoy a reduced corporate tax rate of 6% on capital gain derived from the sale of certain "Benefitted Intangible Assets" to a related foreign company if the Benefitted Intangible Assets were either developed by an Israeli company or acquired from a foreign company in each case if the Benefited Intangible Assets were acquired on or after January 1, 2017, and the sale received prior approval from NATI. A Special Preferred Technology Enterprise that acquires Benefitted Intangible Assets from a foreign company for more than NIS 500 million will be eligible for these benefits for at least ten years, subject to satisfying the program's conditions and certain approvals as specified in the Investment Law.

Dividends distributed by a Preferred Technology Enterprise or a Special Preferred Technology Enterprise, paid out of Preferred Technology Income, are subject to tax at the rate of 20%, and if distributed to a foreign company and other conditions are met the tax rate will be 4%.

As we have not generated income yet, there is no assurance that we qualify as a Preferred Technology Enterprise or Special Preferred Technology Enterprise or that the benefits described above will be available to us in the future.

If in the future we generate taxable income, to the extent that we qualify as a "Preferred Company," the benefits provided under the Investment Law could potentially reduce our corporate tax liabilities. Therefore, the

termination or substantial reduction of the benefits available under the Investment Law could materially increase our tax liabilities.

Capital Gains Tax

Israeli law generally imposes a capital gains tax on the sale of any capital assets by residents of Israel, as defined for Israeli tax purposes, and on the sale of capital assets located in Israel, including shares of Israeli companies by non-residents of Israel, unless a specific exemption under the domestic law is available or unless a tax treaty between Israel and the shareholder's country of residence provides otherwise. The Israeli law distinguishes between real capital gain and inflationary surplus. The inflationary surplus is a portion of the total capital gain that is attributable to the increase in the Israeli consumer price index or, in certain circumstances, a foreign currency exchange rate between the date of purchase and the date of sale. The real capital gain is the excess of the total capital gain over the inflationary surplus.

Israeli Resident Shareholders

Generally, the tax rate applicable to real capital gains derived from the sale of shares acquired on our initial public offering is 25% for Israeli individuals, unless such shareholder claims a deduction for interest and linkage differences expenses in connection with such shares, in which case the gain will generally be taxed at a rate of 30%. Additionally, if such shareholder is considered a "significant shareholder" at the time of the sale or at any time during the 12-month period preceding such sale, the tax rate will be 30%. A "significant shareholder" is defined as a person who holds, directly or indirectly, including together with others, at least 10% of any means of control in the company (including, among other things, the right to receive profits of the company, voting rights, the right to receive the company's liquidation proceeds and the right to appoint a director).. However, different tax rates will apply to dealers in securities, whose income from the sale of securities is considered "business income". . Israeli companies are subject to the corporate tax rate on real capital gains derived from the sale of shares.

Moreover, an additional tax of 3% will be imposed on high income individuals whose annual taxable income exceeds a certain threshold (NIS 640,000 for 2017).

Non-Israeli Resident Shareholders

Non-Israeli residents (individuals and corporations) are generally exempt from Israeli capital gains tax on any gains derived from the sale, exchange or disposition of shares of Israeli companies publicly traded on a recognized stock exchange outside of Israel, provided, among other things, that such shareholders did not acquire their shares prior to the company's initial public offering and the gains were not derived from a permanent establishment of such shareholders in Israel. However, shareholders that are non-Israeli entities will not be entitled to such exemption if Israeli residents hold an interest of more than 25% in such non-Israeli entities or are the beneficiaries of or are entitled to 25% or more of the revenues or profits of such non-Israeli entity, whether directly or indirectly. This exemption is not applicable to a person whose gains from selling or otherwise disposing of the shares are deemed to be business income.

In addition, a sale of securities may be exempt from Israeli capital gains tax under the provisions of an applicable tax treaty. For example, pursuant to the Convention between the Government of the United States of America and the Government of Israel with respect to Taxes on Income, as amended, or the U.S.-Israel Tax Treaty, capital gains arising from the sale, exchange or disposition of ordinary shares by a person who qualifies as a resident of the United States within the meaning of the U.S.-Israel Tax Treaty and who holds the shares as a capital asset and is entitled to claim the benefits afforded to such person by the U.S.-Israel Tax Treaty generally will not be subject to the Israeli capital gains tax unless (i) such person holds, directly or indirectly, shares representing 10% or more of our voting power during any part of the 12-month period preceding such sale, exchange or disposition, subject to particular conditions, (ii) the capital gains from such sale, exchange or disposition can be allocated to a permanent establishment of the shareholder in Israel or (iii) such person is an individual and was present in Israel for a period or periods of 183 days or more in the aggregate during the relevant tax year. In any such case, the sale, exchange or disposition of such shares would be subject to Israeli tax, to the extent applicable. Eligibility to benefit from tax treaties is conditioned upon the shareholder presenting to us a withholding certificate issued by the Israel Tax Authority prior to the applicable payment.

In some instances where our shareholders may be liable for Israeli tax on the sale of their ordinary shares, the payment of the consideration may be subject to the withholding of Israeli tax at source. Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale. Specifically, in transactions involving a sale of all of the shares of an Israeli resident company, in the form of a merger or otherwise, the Israel Tax Authority may require shareholders who are not liable for Israeli

tax to sign a declaration in a form specified by the Israel Tax Authority or obtain a specific exemption from the Israel Tax Authority to confirm their status as non-resident of Israel, and, in the absence of such declarations or exemptions, may require the purchaser of the shares to withhold taxes at source.

Withholding and Reporting

Either the purchaser, the Israeli stockbrokers or financial institutions through which the shares are held is obliged to withhold tax on the amount of consideration paid upon the sale of securities (or on the capital gain realized on the sale, if known) at the Israeli corporate tax rate for Israeli companies. In case the seller is an individual, the applicable withholding tax rate would be 25%.

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

Taxation of Dividend Distributions

Israeli Residents

Israeli resident individuals are generally subject to Israeli income tax on the receipt of dividends paid on our ordinary shares, (other than bonus shares or share dividends). The tax rate applicable to such dividends is 25% or 30% for a shareholder that is considered a "significant shareholder" at any time during the 12-month period preceding such distribution. Dividends paid from income attributed to Preferred Enterprises are generally subject to tax at the rate of 20%. Dividends distributed by a Preferred Technology Enterprise or a Special Preferred Technology Enterprise, paid out of Preferred Technology Income, are generally subject to tax at the rate of 20%.

Israeli resident companies are generally exempt from tax on the receipt of dividends paid on our ordinary shares.

If the dividend is attributable partly to income derived from a Preferred Enterprise or to Preferred Technology Income of a Preferred Technology Enterprise or a Special Preferred Technology Enterprise and partly to other sources of income, the tax rate will be a blended rate reflecting the relative portions of the two types of income. We cannot assure you that we will designate the profits that are being distributed in a way that will reduce shareholders' tax liability.

Moreover, an additional tax of 3% will be imposed on high income individuals whose annual taxable income exceeds a certain threshold (NIS 640,000 for 2017).

Non-Israeli Residents

Non-residents of Israel (whether individuals or corporations) are generally subject to Israeli income tax on the receipt of dividends paid on ordinary shares at the rate of 25%, or 30% for a shareholder that is considered a "significant shareholder" (as defined above) at any time during the 12-month period preceding such distribution, or 20% if the dividend is distributed from income attributable to a Preferred Enterprise, Preferred Technology Enterprise or Special Preferred Technology Enterprise, which tax is to be withheld at source. Dividends not derived from income attributable to a Preferred Enterprise, Preferred Technology Enterprise or Special Preferred Technology Enterprise, are generally subject to Israeli withholding tax at a rate of 25% so long as the shares of a publicly traded company are registered with a nominee company (regardless of whether the recipient is a significant shareholder), unless a different rate is provided in a treaty between Israel and the shareholder's country of residence.

Under the U.S.-Israel Tax Treaty, the maximum rate of tax withheld in Israel on dividends paid to a holder of ordinary shares who qualifies as a resident of the United States within the meaning of the U.S.-Israel Tax Treaty is 25%. Such tax rate is generally reduced to 12.5% (for distribution of income that is not attributable to a Preferred Enterprise Preferred Technology Enterprise or Special Preferred Technology Enterprise) if the shareholder is a U.S. corporation and holds at least 10% of our issued voting power during the tax year in which the dividend is distributed as well as during the whole of its prior tax year provided that not more than 25% of the gross income for such preceding year consists of certain types of interest or dividends and if a certificate for a reduced withholding tax rate is obtained in advance from the Israeli authorities...

The aforementioned rates under the Israel U.S. Double Tax Treaty will not apply if the dividend income was derived through a permanent establishment of the U.S. resident in Israel.

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

Excess Tax

Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 3% on annual income exceeding a certain threshold (NIS 640,000 for 2017) for 2017, which amount linked to the annual change in the Israeli consumer price index, including, but not limited to, dividends, interest and capital gain, subject to the provisions of an applicable tax treaty.

Material U.S. Federal Income Tax Considerations for U.S. Holders

In the opinion of Davis Polk & Wardwell LLP, the following are material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of our ordinary shares, but it does not purport to be a comprehensive description of all the tax considerations that may be relevant to a particular person's decision to

acquire the ordinary shares. This discussion applies only to a U.S. Holder that acquires our ordinary shares in this offering and holds the ordinary shares as capital assets for U.S. federal income tax purposes. In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including alternative minimum tax consequences, any aspect of the provisions of the Internal Revenue Code of 1986, as amended, or the Code, commonly known as the Medicare tax and tax consequences applicable to U.S. Holders subject to special rules, such as:

- certain financial institutions;
- dealers or traders in securities that use a mark-to-market method of tax accounting;
- persons holding ordinary shares as part of a "straddle" or integrated transaction or persons entering into a constructive sale with respect to the ordinary shares;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- entities classified as partnerships for U.S. federal income tax purposes;
- tax exempt entities, "individual retirement accounts" or "Roth IRAs";
- persons that own or are deemed to own 10% or more of our voting stock; or
- persons holding our ordinary shares in connection with a trade or business conducted outside of the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes owns our ordinary shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships owning our ordinary shares and partners in such partnerships should consult their tax advisers as to the particular U.S. federal tax consequences of owning and disposing of the ordinary shares.

This discussion is based on the Code, administrative pronouncements, judicial decisions, and final and proposed Treasury regulations, changes to any of which subsequent to the date of this offering may affect the tax consequences described herein.

For purposes of this discussion, a "U.S. Holder" is a person who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares and is:

- a citizen or individual resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia; or
- an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source.

U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and foreign tax consequences of owning and disposing of our ordinary shares in their particular circumstances.

Taxation of Distributions

Subject to the discussion below under "Passive Foreign Investment Company Rules," distributions, if any, paid on our ordinary shares (other than certain pro-rata distributions of ordinary shares) will be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we do not calculate our earnings and profits under U.S. federal income tax principles, it is expected that distributions generally will be reported to U.S. Holders as dividends. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be taxable at the favorable tax rates applicable to "qualified dividend income". Non-corporate U.S. Holders should consult their tax advisers regarding the availability

of these favorable rates on dividends in their particular circumstances. Dividends will not be eligible for the dividends received deduction generally available to U.S. corporations under the Code and will generally be included in a U.S. Holder's income on the date of receipt.

Dividend income will include any amounts withheld by us in respect of Israeli taxes, and will be treated as foreign source income for foreign tax credit purposes. Subject to applicable limitations, some of which vary depending upon the U.S. Holder's circumstances, Israeli taxes withheld from dividends on our ordinary shares will be creditable against the U.S. Holder's U.S. federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisers regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may elect to deduct foreign taxes (including Israeli taxes) in computing their taxable income, subject to applicable limitations. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

If any dividend is paid in foreign currency, the amount of dividend income will be the dividend's U.S. dollar amount calculated by reference to the exchange rate in effect on the date of receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss.

Sale or Other Taxable Disposition of Ordinary Shares

Subject to the discussion below under "Passive Foreign Investment Company Rules," gain or loss realized on the sale or other taxable disposition of our ordinary shares will be capital gain or loss and will be long-term capital gain or loss if the U.S. Holder held the ordinary shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ordinary shares disposed of and the amount realized on the disposition. This gain or loss will generally be U.S. source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

Passive Foreign Investment Company Rules

We may be a "passive foreign investment company," or a PFIC, for our current or any future taxable year. In general, a non-U.S. corporation is a PFIC for any taxable year in which (i) 75% or more of its gross income consists of passive income, the income test or (ii) 50% or more of the average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income, the assets test. Generally, "passive income" includes interest, dividends, rents, royalties and certain gains, and cash (including cash raised in this offering) is a passive asset for PFIC purposes.

The assets shown on our balance sheet are expected to consist primarily of cash and cash equivalents for the foreseeable future. Therefore, whether we will satisfy the assets test for the current or any future taxable year will depend largely on the quarterly value of our goodwill. Because the value of our goodwill may be determined by reference to the market price of our ordinary shares from time to time, which may be especially volatile given the nature and early stage of our business, and because a company's PFIC status is an annual determination that can be made only after the end of each taxable year, we cannot express a view as to whether we will be a PFIC for the current or any other taxable year. In addition, it is not clear how to apply the income test to a company such as our company, whose only income for a relevant taxable year is passive interest income but whose overall losses significantly exceed the amount of such passive income. We believe that it is reasonable to take the position that a company like us, whose overall losses exceed its passive income, would not be a PFIC if it otherwise would not be a PFIC under the assets test for the relevant taxable year, but there can be no assurance that the Internal Revenue Service will respect, or a court will uphold, such position.

For purposes of the assets test and income test, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation.

Under attribution rules, if we were a PFIC for any taxable year and had any subsidiaries or other entities in which we held a direct or indirect equity interest that are also PFICs, or Lower-tier PFICs, U.S. Holders would be

deemed to own their proportionate share of any such Lower-tier PFICs and would be subject to U.S. federal income tax according to the rules described in the following paragraph on (i) certain distributions by a Lower-tier PFIC and (ii) a disposition of shares of a Lower-tier PFIC, in each case as if the U.S. Holders held such shares or equity interests directly, even if the U.S. Holders do not receive the proceeds of those distributions or dispositions.

If we were a PFIC for any taxable year during which a U.S. Holder held our ordinary shares, an adverse tax regime would apply to the U.S. Holder's investment in our ordinary shares. Generally, gain recognized upon a disposition (including, under certain circumstances, a pledge) of ordinary shares by the U.S. Holder would be allocated ratably over the U.S. Holder's holding period for such ordinary shares. The amounts allocated to the taxable year of disposition and to taxable years prior to the first taxable year in which we were a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest tax rate in effect for that taxable year for individuals or corporations, as appropriate, and an interest charge would be imposed on the resulting tax liability for each such year. Further, to the extent that any distribution received by a U.S. Holder on ordinary shares exceeded 125% of the average of the annual distributions received on such ordinary shares during the preceding three years or the U.S. Holder's holding period, whichever is shorter, that distribution would be subject to taxation in the same manner.

Alternatively, if we were a PFIC and if the ordinary shares were "regularly traded" on a "qualified exchange," a U.S. Holder might be able to make a mark-to-market election with respect to our ordinary shares (but generally not with respect to Lower-tier PFICs, if any) that would result in tax treatment different from the general tax treatment for PFICs described above. The ordinary shares would be treated as "regularly traded" in any calendar year in which more than a *de minimis* quantity of the ordinary shares were traded on a qualified exchange on at least 15 days during each calendar quarter. The , where our ordinary shares are expected to be listed, is a qualified exchange for this purpose. If a U.S. Holder makes the mark-to-market election, the U.S. Holder generally will recognize in each year that we are a PFIC as ordinary income any excess of the fair market value of the ordinary shares at the end of the taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in the ordinary shares will be adjusted to reflect these income or loss amounts. In addition, if a U.S. Holder makes the mark-to-market election, any gain that the U.S. Holder recognizes on the sale or other disposition of ordinary shares in a year in which we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). U.S. Holders should consult their tax advisers regarding the availability and advisability of making a mark-to-market election in their particular circumstances.

We do not intend to provide information necessary for U.S. Holders to make qualified electing fund elections, which, if available, would result in a further alternative tax treatment.

If we were a PFIC for any year during which a U.S. Holder owns ordinary shares, we generally would continue to be treated as a PFIC with respect to such U.S. Holder's ordinary shares unless (a) we ceased to be a PFIC and (b) the U.S. Holder has made a "deemed sale" election under the PFIC rules which may result in recognition of gain (but not loss), taxable under the PFIC rules described above, without the receipt of any corresponding cash.

If we were a PFIC or, with respect to a particular U.S. Holder, were treated as a PFIC for the taxable year in which we pay a dividend or the prior taxable year, the preferential rates discussed above with respect to dividends paid to certain non-corporate U.S. Holders would not apply. In addition, if we were a PFIC for any taxable year during which a U.S. Holder owns ordinary shares, the U.S. Holder would be required to file annual reports with the Internal Revenue Service, subject to certain exceptions.

U.S. Holders should consult their tax advisers regarding the potential application of the PFIC rules to an investment in our ordinary shares.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S. related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding. Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the Internal Revenue Service.

Information with Respect to Foreign Financial Assets

Certain U.S. Holders who are individuals and certain closely-held entities may be required to report information relating to the ordinary shares, unless the ordinary shares are held in an account maintained by a financial institution (in which case the account itself may be reportable if maintained by a non-U.S. financial institution). U.S. Holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the ordinary shares.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our ordinary shares. Future sales of our ordinary shares in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our ordinary shares in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of ordinary shares outstanding as of June 30**,** 2017, upon completion of this offering ordinary shares will be outstanding (which includes ordinary shares issuable upon the conversion of our preferred shares that will be outstanding upon the closing and ordinary shares issuable upon the conversion of our convertible loans that will be outstanding upon the closing), assuming no exercise of options or outstanding warrants or the underwriters' option to purchase additional ordinary shares from us.

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 our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining ordinary shares outstanding after this offering will be "restricted securities" under Rule 144, and we expect that substantially all of these restricted securities will be subject to the 180-day lock-up period under the lock-up agreements described below. Following the expiration of these lock-up periods, those shares may be registered or may be eligible for resale in compliance with Rules 144 or 701 under the Securities Act, as described below.

Lock-up Agreements

We and our executive officers, directors, and certain of our shareholders and lenders have agreed not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of any ordinary shares or any securities convertible into or exchangeable for ordinary shares except for the ordinary shares offered in this offering without the prior written consent of and for a period of 180 days after the date of this prospectus, subject to certain exceptions. After the expiration of the 180-day period, the shares may be sold subject to the restrictions under Rule 144 or 701 under the Securities Act or by means of registered public offerings. The underwriters may, in their sole discretion, at any time without prior notice, release all or any portion of the shares from the restrictions in any such agreement.

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned part of our shares for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our shares then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume of our ordinary shares on during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 also are subject to the availability of current public information about us. In addition, if the number of securities being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 securities or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Nonaffiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our shares for at least six months but less than a year, is entitled to sell such securities subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement. Nonaffiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701 of the Securities Act, each of our employees, consultants or advisors who acquires our ordinary shares from us in connection with a compensatory share plan or other written agreement executed prior to the closing of this offering is eligible to resell such ordinary shares in reliance on Rule 144, but without compliance with some of the restrictions, including the holding period, contained in Rule 144.

Form S-8 Registration Statement

After the completion of this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act covering our shares subject to outstanding options and shares issuable under our share-based incentive plan. We expect to file the registration statement covering shares offered pursuant to our share-based incentive plan on or shortly after the date of this prospectus, permitting the resale of such shares by nonaffiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144. Accordingly, our shares registered under any such registration statement will be available for sale in the open market upon exercise by the holders, subject to vesting and holding restrictions, as applicable, Rule 144 limitations applicable to our affiliates and the contractual lock-up provisions described above.

Selling Stockholder Resale Prospectus

As described in the Explanatory Note to the registration statement of which this prospectus forms a part, the registration statement also contains the Selling Stockholder Resale Prospectus to be used in connection with the potential resale by certain selling stockholders of our ordinary shares issued. These ordinary shares have been registered to permit public resale of such shares, and the selling stockholders may offer the shares for resale from time to time pursuant to the Selling Stockholder Resale Prospectus. The selling stockholders may also sell, transfer or otherwise dispose of all or a portion of their shares in transactions exempt from the registration requirements of the Securities Act or pursuant to another effective registration statement covering those shares.

Registration Rights

We, certain of our shareholders and certain lenders under our convertible financing agreements have entered into an investors rights agreement. Upon completion of this offering, the holders of ordinary shares will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the registered sale of such securities.

Demand Registration Rights

Pursuant to the investors' rights agreement, at any time beginning 180 days after the closing of this offering and for so long as we are eligible to file a registration statement on Form F-3, any shareholder or group of shareholders holding an aggregate of at least 10% of the registrable securities under the investors' rights agreement that are not held by D.N.A Biomedical, may request in writing that we effect the registration under the Securities Act of the sale or other transfer of such shareholder or shareholders' ordinary shares, provided that we are not required to effect more than three such registrations.

Form F-3 Registration Statement

After we become eligible to file a registration statement on Form F-3, which will not be until at least 12 months after the date of this prospectus, any shareholder or group of shareholders holding an aggregate of at least 10% of the registrable securities under the investors' rights agreement that are not held by D.N.A Biomedical may request in writing that we effect a registration of the sale or other transfer of such shares, provided that the aggregate anticipated proceeds from the sale of such shares equals at least $1.0 million and that we are not required to effect more than three such registrations.

We will not be obligated to file a registration statement on Form F-3 in certain cases including if in the good faith judgment of our board of directors (as reflected in a certificate delivered by our chief executive officer), such registration would be seriously detrimental to our company or its shareholders, provided that we do not use this exemption more than once in any 12-month period. We also have the right not to effect a Form F-3 registration statement during the period from 60 days prior to the filing of, to 6 months following the effective date of, a previous registration.

Piggyback Registration Rights

The investors' rights agreement also provides our shareholders with "piggy back" registration rights in the event that we determine to register the sale of any of our securities following this offering.

UNDERWRITERS

Under the terms and subject to the conditions contained in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom and are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of ordinary shares indicated below:

Name	Number of Shares
Total	

The address of is . The address of is , United States.

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the ordinary shares subject to their acceptance of the ordinary shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the ordinary shares offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the ordinary shares offered by this prospectus if any such ordinary shares are taken. However, the underwriters are not required to take or pay for the ordinary shares covered by the underwriters' over-allotment option described below.

The underwriters initially propose to offer part of the ordinary shares directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers. After the initial offering of the ordinary shares, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional ordinary shares at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the ordinary shares offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional ordinary shares as the number listed next to the underwriter's name in the preceding table bears to the total number of ordinary shares listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to additional ordinary shares.

		Total	
	Per Share	No exercise	Full exercise
Public offering price	$	$	$
Underwriting discount and commissions to be paid by us	$	$	$
Proceeds, before expenses, to us	$	$	$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately $ million (including approximately $ in connection with the qualification of the offering with FINRA by counsel to the underwriters). We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority, Inc. and the qualification of our ordinary shares under state securities laws (in an amount not to exceed in the aggregate $).

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of ordinary shares offered by them.

We expect to list our ordinary shares on the under the symbol " ."

We and our executive officers, directors, and certain of our shareholders and lenders have agreed not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of any ordinary shares or any securities convertible into or exchangeable for ordinary shares except for the ordinary shares offered in this offering without the prior written consent of and for a period of days after the date of this prospectus, subject to certain exceptions. See "Share Eligible for Future Sale."

In order to facilitate the offering of the ordinary shares, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the ordinary shares. Specifically, the underwriters may sell more ordinary shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of ordinary shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing ordinary shares in the open market. In determining the source of ordinary shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of ordinary shares compared to the price available under the over-allotment option. The underwriters may also sell ordinary shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing ordinary shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ordinary shares in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, ordinary shares in the open market to stabilize the price of the ordinary shares. These activities may raise or maintain the market price of the ordinary shares above independent market levels or prevent or retard a decline in the market price of the ordinary shares. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of ordinary shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Pricing of the Offering

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. Among the factors to be considered in determining the initial public offering price will be our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios,

price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

Selling Restrictions

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 of our ordinary shares may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any of our ordinary 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 representatives for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of our ordinary 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 of our ordinary shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any of our ordinary shares to be offered so as to enable an investor to decide to purchase any of our ordinary shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (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 Financial Services and Markets Act, or the FSMA) received by it in connection with the issue or sale of our ordinary 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 our ordinary shares in, from or otherwise involving the United Kingdom.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters purchasing for their own account, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors. Qualified investors may be required to submit written confirmation that they fall within the scope of the Addendum.

EXPENSES RELATED TO THE OFFERING

The following table sets forth the costs and expenses, other than underwriting discounts and underwriting expenses, payable by us in connection with this offering. With the exception of the SEC registration fee, the listing fee and the FINRA filing fee, all amounts are estimates.

SEC registration fee	$
listing fee	
FINRA filing fee	
Printing expenses	
Legal fees and expenses	
Accounting fees and expenses	
Transfer agent’s fees	
Miscellaneous	
Total	$

VALIDITY OF ORDINARY SHARES

The validity of the ordinary shares being offered by this prospectus and other legal matters concerning this offering relating to Israeli law will be passed upon for us by Herzog Fox & Neeman, Tel Aviv, Israel. Certain legal matters in connection with this offering relating to U.S. law will be passed upon for us by Davis Polk & Wardwell LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by , with respect to Israeli law, and by , with respect to U.S. law.

EXPERTS

The financial statements as of December 31, 2016 and 2015 and for each of the two years in the period ended December 31, 2016 included in this Prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the financial statements) of Kesselman & Kesselman, Certified Public Accountants (Israel), a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. The current address of Kesselman & Kesselman, Certified Public Accountants (Israel) is 25 Hamered Street, Tel Aviv, Israel 6812508.

ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the State of Israel. Service of process upon us, our directors and officers and the Israeli experts, if any, named in this prospectus, many whom reside outside the United States, may be difficult to obtain within the United States. Furthermore, because the majority of our assets and investments, and substantially all of our directors, officers and such Israeli experts, if any, are located outside the United States, any judgment obtained in the United States against us or any of them may be difficult to collect within the United States.

We have been informed by our legal counsel in Israel that it may also be difficult to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. There is little binding case law in Israel addressing these matters. 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, under the rules of private international law currently prevailing in Israel, Israeli courts may enforce a U.S. judgment in a civil matter, including a judgment based upon the civil liability provisions of the U.S. securities laws, as well as a monetary or compensatory judgment in a non-civil matter, provided that the following conditions are met:

- the judgment is enforceable in the state in which it was given;
- the judgment was rendered by a court of competent jurisdiction under the rules of private international law prevailing in Israel;
- the laws of the state in which the judgment was given provides 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;
- the judgment and the enforcement of the judgment are not contrary to the law, public policy, security or sovereignty of the State of Israel;
- the judgment was not obtained by fraudulent means and does not conflict with any other valid judgment in the same matter between the same parties; and
- 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.

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 fluctuations.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act relating to this offering of our ordinary shares. This prospectus does not contain all of the information contained in the registration statement. The rules and regulations of the SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

You may read and copy the registration statement, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, 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.

We are not currently subject to the informational requirements of the Exchange Act. 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 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 U.S. companies whose securities are registered under the Exchange Act. However, we will file with the SEC, within

four months 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 for the first three quarters of each fiscal year.

We maintain a corporate website at www.enterabio.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein. We have included our website address in this prospectus solely for informational purposes.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders of

ENTERA BIO LTD.

We have audited the accompanying statements of financial position of Entera Bio Ltd. (the "Company") as of December 31, 2016 and 2015 and the related statements of comprehensive loss, changes in capital deficiency and cash flows for the years then ended. These financial statements are the responsibility of the Company's board of directors and management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2016 and 2015 and the results of its operations and its cash flows for the years then ended, in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1a.2 to the financial statements, the Company has suffered recurring losses from operations, has negative working capital and has cash outflows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1a.2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Tel-Aviv, Israel
July 13, 2017

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

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,
P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

ENTERA BIO LTD.

STATEMENTS OF FINANCIAL POSITION

	Note	December 31 2016	December 31 2015
		U.S. dollars in thousands	
Assets			
CURRENT ASSETS:			
Cash and cash equivalents	5	4,163	1,205
Restricted deposits	7a2	1,075	-
Other current assets	12a	195	695
TOTAL CURRENT ASSETS		5,433	1,900
NON-CURRENT ASSETS:			
Property and equipment		199	193
Intangible assets	6	654	654
TOTAL NON-CURRENT ASSETS		853	847
TOTAL ASSETS		6,286	2,747
Liabilities net of capital deficiency			
CURRENT LIABILITIES:			
Accounts payable:			
Trade		53	351
Other	12b	604	453
Convertible loans	7	9,885	-
TOTAL CURRENT LIABILITIES		10,542	804
NON-CURRENT LIABILITIES:			
Convertible loans	7	4,835	8,053
Preferred shares	8	11,031	13,062
Warrants to purchase preferred shares and shares	7,8	4,800	4,332
Liability to issue preferred shares and warrants	8	273	2,154
Severance pay obligations, net		51	29
TOTAL NON-CURRENT LIABILITIES		20,990	27,630
TOTAL LIABILITIES		31,532	28,434
COMMITMENTS AND CONTINGENCIES	9		
CAPITAL DEFICIENCY:	10		
Ordinary Shares, NIS 0.01 par value: Authorized - as of December 31, 2016 and 2015, 1,000,000 shares; issued and outstanding as of December 31, 2016 -34,544 shares and as of December 31, 2015 - 34,396 shares		*	*
Accumulated other comprehensive income		41	41
Other reserves		2,844	1,354
Additional paid in capital		2,485	2,335
Accumulated deficit		(30,616)	(29,417)
TOTAL CAPITAL DEFICIENCY		(25,246)	(25,687)
TOTAL LIABILITIES NET OF CAPITAL DEFICIENCY		6,286	2,747

* Represents an amount less than one thousand.

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

ENTERA BIO LTD.

STATEMENTS OF COMPREHENSIVE LOSS

	Note	Year ended December 31	
		2016	2015
		U.S. dollars in thousands	
RESEARCH AND DEVELOPMENT EXPENSES		2,648	2,115
GENERAL AND ADMINISTRATIVE EXPENSES		2,719	1,586
OPERATING LOSS		5,367	3,701
FINANCIAL (INCOME) EXPENSES:	7,8		
(Income) loss from change in fair value of financial liabilities at fair value		(4,311)	447
Other financial expenses, net		143	134
FINANCIAL (INCOME) EXPENSES, net		(4,168)	581
NET COMPREHENSIVE LOSS		1,199	4,282
		U.S. dollars (except for share numbers)	
LOSS PER ORDINARY SHARE -	13		
Basic		35	124
Diluted		102	124
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES -			
Basic		34,409	34,396
Diluted		51,972	34,396

The accompanying notes are an integral part of the financial statements

ENTERA BIO LTD.

STATEMENTS OF CHANGES IN CAPITAL DEFICIENCY

	Number of ordinary shares	Ordinary Shares- Amount	Accumulated other comprehensive income	Other reserves	Additional paid in capital	Accumulated deficit	Total
				U.S. dollars in thousands			
BALANCE AT JANUARY 1, 2015	34,396	*	41	988	2,335	(25,135)	(21,771)
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2015:							
Loss for the year						(4,282)	(4,282)
Share-based compensation				366			366
BALANCE AT DECEMBER 31, 2015	34,396	*	41	1,354	2,335	(29,417)	(25,687)
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2016:							
Issuance of shares	148	*			150		150
Loss for the year						(1,199)	(1,199)
Share-based compensation				1,490			1,490
BALANCE AT DECEMBER 31, 2016	34,544	*	41	2,844	2,485	(30,616)	(25,246)

* Represents an amount of less than one thousand.

The accompanying notes are an integral part of the financial statements

ENTERA BIO LTD.

STATEMENTS OF CASH FLOWS

	Year ended December 31	
	2016	2015
	U.S dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Loss for the year	(1,199)	(4,282)
Adjustments required to reflect net cash		
Adjustments required to reflect net cash used in operating activities (see appendix A)	(1,943)	787
Net cash used in operating activities	(3,142)	(3,495)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Investment in restricted deposits	(1,075)	-
Purchase of property and equipment	(41)	(54)
Net cash used in investing activities	(1,116)	(54)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of preferred shares and warrants	-	2,460
Proceeds from convertible loan and warrants, net	7,216	2,005
Net cash generated from financing activities	7,216	4,465
NET INCREASE IN CASH AND CASH EQUIVALENTS	2,958	916
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR	1,205	290
FOREIGN EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS		(1)
CASH AND CASH EQUIVALENTS AT END OF THE YEAR	4,163	1,205
APPENDIX A:		
Adjustments required to reflect net cash used in operating activities:		
Depreciation	35	28
(Gain) loss from change in fair value of financial liabilities at fair value	(4,311)	447
Issuance costs related to convertible loan and warrants	363	-
Financial expenses	105	129
Net changes in severance pay	22	-
Share-based compensation	1,490	366
	(2,296)	970
Changes in working capital:		
Decrease (increase) in other current assets	500	(593)
(Decrease) increase in accounts payable:		
Trade	(298)	227
Other	151	183
	353	(183)
	(1,943)	787

SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:

As to extinguishment of convertible loans see note 7.

The accompanying notes are an integral part of the financial statements

NOTE 1 - GENERAL INFORMATION:

a. General:

1) Entera Bio Ltd. (the "Company") was incorporated on June 1, 2010. The Company is a clinical-stage biopharmaceutical company, focused on the development and commercialization of orally delivered large molecule therapeutics in areas with significant unmet medical needs. Currently the Company is focused on the development of oral capsules for the treatment of hypoparathyroidism and osteoporosis.

2) Since the Company is engaged in research and development activities, it has not yet derived income from its activity and has incurred through December 31, 2016, accumulated losses in the amount of $30,616 thousand. The Company also has negative working capital and has cash outflows from operating activities. The Company's management is of the opinion that its available funds as of December 31, 2016 will not allow the Company to execute its development plans in the upcoming year. These factors raise substantial doubt as to the Company's ability to continue as a going concern.

   Management is in the process of evaluating various financing alternatives in the public or private equity markets, as the Company will need to finance future research and development activities and general and administrative expenses through fund raising. However, there is no certainty about the Company's ability to obtain such funding.

   The financial information has been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. If the Company does not raise the requisite funds, it will need to curtail or cease operations. These financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

b. Approval of financial statements

These financial statements were approved by the Board of Directors on July 13, 2017.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a. Basis of preparation of the financial statements:

The financial statements of the Company as of December 31, 2016 and 2015 and for each of the two years then ended have been prepared in accordance with International Financial Reporting Standards, ("IFRS"), as issued by the International Accounting Standards Board ("IASB").

The significant accounting policies described below have been applied consistently in relation to all the periods presented, unless otherwise stated.

The financial statements have been prepared under the historical cost convention, subject to adjustments in respect of revaluation of financial liabilities at fair value through profit or loss. The Company's financial liabilities at fair value through profit or loss include convertible loans, preferred shares, warrants to preferred shares and shares and liability to issue preferred shares and warrants.

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

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

b. Functional and presentation currency:

1) Functional and presentation currency

Items included in the financial statements of the Company are measured using the currency of the primary economic environment in which the entity operates ("the functional currency"). The U.S. dollar is the currency of the primary economic environment in which the operations of the Company is conducted. The financial statements are presented in U.S dollars.

2) Transactions and balances

Foreign currency transactions are translated into the functional currency using exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the statements of comprehensive loss within financial income or expenses.

Translation differences on non-monetary financial assets and liabilities at fair value through profit or loss are recognized in profit or loss as part of the fair value gain or loss within financial income or expenses.

c. Cash and cash equivalents:

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

d. Restricted deposits:

Restricted cash deposits relate to accounts where withdrawals are restricted under contractual agreements.

e. Property and equipment:

1) Property and equipment are stated at historical cost less accumulated depreciation and impairment. Historical cost includes expenditures that are directly attributable to the acquisition of the items. Repairs and maintenance are charged to the statement of comprehensive loss during the period in which they are incurred.

2) Assets are depreciated using the straight-line method to allocate their cost over their estimated useful lives.

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

f. Intangible assets:

1) Research and development expenses

Research expenses are charged to profit or loss as incurred. An intangible asset arising from development of the Company's products is recognized if all of the following conditions are met:

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

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

During the years ended December 31, 2016 and 2015, the Company has not capitalized development costs.

2) In process research and development (IPR&D)

IPR&D acquired is presented based on the fair value at the date of the acquisition and is not depreciated during the research and development period. Such assets are tested annually for impairment.

g. Impairment of non-financial assets

Intangible assets not ready to use are not subject to amortization and are tested annually for impairment. Assets that are subject to depreciation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to dispose and its value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units).

For the years ended December 31, 2016 and 2015, no impairment has been recognized.

h. Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments. The Company operates in one operating segment.

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

i. Financial Liabilities:

1) Financial liabilities at fair value through profit or loss

This category includes the Company's 2016 Convertible Loan (see note 7), 2012 Convertible Loan (see note 7), preferred shares, warrants to purchase preferred shares and shares and liability to issue preferred shares and warrants (see note 8). The convertible loans and preferred shares are convertible into a variable number of ordinary shares. Gains or losses arising from changes in the fair value of financial liabilities at fair value through profit or loss are presented in the statement of comprehensive loss under "financial income" or "financial expenses".

2) Other financial liabilities

Other financial liabilities, including the 2015 Convertible Loan (see note 7a(2)), are initially measured at fair value. In subsequent periods, the other financial liabilities are measured at amortized cost. Any difference between the consideration (net of transaction costs) and the redemption value is accreted to profit or loss over the term of the liability, using the effective interest method.

Interest expense is calculated using the effective interest rate method as described in IAS 39 "Financial instruments".

Financial liabilities are classified as current liabilities, unless the Company has an unconditional right to defer settlement of the liability for at least 12 months after the end of the reporting period, in which case they are classified as noncurrent liabilities.

j. Share capital

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares are included in equity as a deduction from the proceeds.

k. Deferred income tax

Deferred income taxes are recognized using the liability method on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements. Deferred income tax assets are recognized only to the extent that it is probable that future taxable income will be available against which the temporary differences can be utilized. Deferred income tax is determined using tax rates and laws that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

In the absence of expectation of taxable income in the future, no deferred tax assets are recorded in the financial statements.

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

l. Share-based payments

The Company adopted a share-based compensation plan for employees, directors and service providers. As part of the plan, the Company grants employees, directors and service providers, from time to time and at its discretion, options to purchase Company's ordinary shares. The fair value of the employees', directors' and service providers' services received in exchange for the grant of the options is recognized as an expense in the statement of comprehensive loss. The total amount recognized as an expense over the vesting period of the options was determined by reference to the fair value of the options granted at the date of grant.

Service conditions and performance vesting conditions are included in assumptions about the number of options that are expected to vest. The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied.

At the end of each reporting period, the Company revises its estimates of the number of options that are expected to vest based on the service conditions and performance conditions. The Company recognizes the impact of the revision to original estimates, if any, in the statement of comprehensive loss, with a corresponding adjustment to "other reserves".

When options are exercised, the Company issues new shares, with proceeds less directly attributable transaction costs recognized as share capital (par value) and additional paid in capital.

m. Government grants

Government grants, which are received from Israel Innovation Authority (the "IIA") by way of participation in research and development that is conducted by the Company, fall within the scope of "forgivable loans", as set forth in International Accounting Standard Number 20 "The Accounting Treatment of Government Grants and Disclosure in respect of Government Assistance" ("IAS 20"). Since at the time of the receipt of the grants there is no reasonable assurance that the grants that have been received will be repaid, at the time of their receipt they are offset against the related research and development expenses in the statement of comprehensive loss. To the extent that it will be considered "more likely than not" that the grants will be repaid in the future, the Company would record a financial liability. To date, the Company has not recorded government grants as a financial liability.

n. Loss per ordinary share

Basic loss per share is calculated by dividing the loss attributable to equity holders of the Company by the weighted average number of ordinary shares issued and outstanding during the year. In computing diluted loss per share, basic loss per share are adjusted to take into account the potential dilution that could occur upon the conversion of the dilutive series of convertible debentures and preferred stock, and warrants, by subtracting from net loss fair value changes of such financial instruments, and by adjusting the weighted average number of outstanding ordinary shares, assuming conversion of all such dilutive potential shares. The Company’s dilutive potential shares consist of shares issuable upon conversion of convertible loan and preferred shares, warrants and options. Potential shares are only dilutive if their conversion would increase the loss per share. If the loss per share would decrease, the shares are anti-dilutive and are excluded from the diluted loss per share calculation.

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

o. New standards, amendments to standards or interpretations

The following new standards, amendments to standards or interpretations have been issued, but are not effective, and have not been early adopted:

1. IFRS 9, "Financial Instruments"

   The complete version of IFRS 9 replaces most of the guidance in IAS 39. IFRS 9 retains but simplifies the mixed measurement model and establishes three primary measurement categories for financial assets: amortised cost, fair value through other comprehensive income and fair value through profit and loss. The basis of classification depends on the entity's business model and the contractual cash flow characteristics of the financial asset. Investments in equity instruments are required to be measured at fair value through profit or loss with the irrevocable option at inception to present changes in fair value in other comprehensive income. There is now a new expected credit losses model that replaces the incurred loss impairment model used in IAS 39. For financial liabilities, there were no changes to classification and measurement except for the recognition of changes in own credit risk in other comprehensive income, and for liabilities designated at fair value through profit or loss. The standard is effective for accounting periods beginning on or after January 1, 2018. The Company is currently evaluating the impact of adoption on its financial statements.

2. IFRS 16, "Leases"

   In January 2016, the IASB issued IFRS 16, Leases, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract and replaces the previous leases standard, IAS 17, Leases. IFRS 16 eliminates the classification of leases for the lessee as either operating leases or finance leases as required by IAS 17 and instead introduces a single lessee accounting model whereby a lessee is required to recognize assets and liabilities for all leases with a term that is greater than 12 months, unless the underlying asset is of low value, and to recognize depreciation of leased assets separately from interest on lease liabilities in the income statement. As IFRS 16 substantially carries forward the lessor accounting requirements in IAS 17, a lessor will continue to classify its leases as operating leases or finance leases and to account for those two types of leases differently. IFRS 16 is effective from January 1, 2019 with early adoption allowed only if IFRS 15, Revenue from Contracts with Customers, is also applied. The Company is currently evaluating the impact of adoption on its financial statements.

NOTE 3 - CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

The Company makes estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below:

Share-based payment

With respect to grants to employees, service providers and directors, the value of the labor services received in return is measured on the date of grant, based on the fair value of the equity instruments granted to the employees and directors. In order to measure the fair value of the labor service received, the Company uses the Black-Scholes model to value the equity instrument. See also note 10b.

Fair value of financial liabilities at fair value through profit or loss

To determine the fair value of the 2016 Convertible Loan, 2012 Convertible Loan, preferred shares, warrants to purchase preferred shares and shares and liability to issue preferred shares and warrants, the Company uses its judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at the end of each reporting period. The estimated fair value of these financial liabilities might have been different had Company's management used different estimates and assumptions. See also note 7 and 8.

The main parameter which affects the value of the financial liabilities that are measured periodically at fair value is the Company's equity value. The following table presents a sensitivity analysis of the effect of increases and decreases in the Company's equity value on the carrying amount, as of December 31, 2016, of the financial liabilities measured periodically at fair value:

	December 31, 2016				
	Decrease of 10%	**Decrease of 5%**	**Actual Value**	**Increase of 5%**	**Increase of 10%**
	U.S. dollars in thousands				
Value of equity	63,900	67,450	71,000	74,550	78,100
Convertible loans	13,127	13,422	13,715	14,009	14,298
Preferred shares	9,945	10,492	11,031	11,584	12,137
Warrants to purchase preferred shares and shares	4,331	4,568	4,800	5,035	5,266
Liability to issue preferred shares and warrants	227	250	273	296	319

NOTE 4 - FINANCIAL INSTRUMENTS:

a. Financial risk management:

1) Financial risk factors

The Company's activities expose it to a variety of financial risks. The Company's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Company's financial performance.

Risk management is performed by the Chief Financial Officer of the Company, who identifies and evaluates financial risks in close cooperation with the Company's Chief Executive Officer.

The Company does not use financial instruments for hedging activity.

2) Credit risk

Credit and interest risk arises from cash and cash equivalents and deposits with banks. A portion of the liquid instruments of the Company is invested in short-term deposits in leading Israeli banks. The Company estimates that since the liquid instruments are mainly invested for the short-term and with a highly-rated institution, the credit and interest risk associated with these balances is immaterial.

3) Liquidity risk

Prudent liquidity risk management implies maintaining sufficient cash.

The Company is in a research stage and has not yet generated revenues. It is therefore exposed to liquidity risk, taking into consideration the forecasts of cash flows required to finance its investments and other activities.

4) Market risk—Foreign exchange risk

The Company might be exposed to foreign exchange risk as a result of making payments to employees or service providers and investment of some liquidity in currencies other than the Company's functional currency. The Company manages the foreign exchange risk by aligning the currencies for holding liquidity with the currencies of expected expenses, based on the expected cash flows of the Company.

b. Capital risk management

The Company's objectives when managing capital are to safeguard the Company's ability to continue as a going concern in order to provide returns for shareholders and to maintain an optimal capital structure to reduce the cost of capital. It should be noted that the Company is in the research and development stage and has not yet generated revenues.

NOTE 4 - FINANCIAL INSTRUMENTS (continued)**:**

c. Fair value of financial instruments

The different levels of valuation of financial instruments are defined as follows:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 Inputs, other than quoted prices included within level 1 that are observable for the asset or liability, either directly (as prices) or indirectly (derived from prices).

Level 3 Inputs for the asset or liability that are not based on observable market data (unobservable inputs).

The fair value of financial instruments traded in active markets is based on quoted market prices at the dates of the statements of financial position.

A market is regarded as active if quoted prices are readily and regularly available from an exchange, dealer, broker, industry group, pricing service, or regulatory agency, and those prices represent actual and regularly occurring market transactions on an arm's length basis. These instruments are included in level 1.

The fair value of financial instruments that are not traded in an active market is determined by using valuation techniques. These valuation techniques maximize the use of observable market data where it is available and rely as little as possible on entity specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3.

As of December 31, 2016 and 2015, the fair value of certain financial instruments (cash and cash equivalents, restricted cash, other receivables and accounts payable) approximates their carrying value.

NOTE 4 - FINANCIAL INSTRUMENTS (continued)**:**

d. Classification of financial instruments by groups:

	Loans and receivables
	U.S. dollars in thousands
As of December 31, 2016:	
Cash and cash equivalents	4,163
Restricted deposits	1,075
Receivables (excluding prepaid expenses)	157
	5,395
As of December 31, 2015:	
Cash and cash equivalents	1,205
Receivables (excluding prepaid expenses)	160
	1,365

	Financial liabilities at fair value through profit or loss (Level 3)	Financial liabilities at amortized cost	Total
	U.S. dollars in thousands		
As of December 31, 2016:			
Trade and other payable	-	657	657
Convertible loans	13,715	1,005	14,720
Preferred shares	11,031	-	11,031
Warrants to purchase preferred shares and shares	4,800	-	4,800
Liability to issue preferred shares and warrants	273	-	273
	29,819	1,662	31,481
As of December 31, 2015:			
Trade and other payable	-	804	804
Convertible loan	6,160	1,893	8,053
Preferred shares	13,062	-	13,062
Warrants to purchase preferred shares and shares	4,332	-	4,332
Liability to issue preferred shares and warrants	2,154	-	2,154
	25,708	2,697	28,405

NOTE 5 - CASH AND CASH EQUIVALENTS

	December 31,	
	2016	**2015**
	U.S. dollars in thousands	
Cash in bank	4,159	1,201
Short-term bank deposits	4	4
	4,163	1,205

NOTE 6 - INTANGIBLE ASSETS:

a. On June 1, 2010 D.N.A. Biomedical Solutions Ltd. ("D.N.A.") and Oramed Ltd., ("Oramed") entered into a joint venture agreement, (the "Joint Venture Agreement") for the establishment of Entera Bio Ltd.. According to the Joint Venture Agreement each of D.N.A. and Oramed acquired 50% of the Company's ordinary shares. D.N.A invested $600,000 in the Company, and Oramed and the Company entered into a Patent License Agreement pursuant to which Oramed licensed to the Company certain of Oramed's patent (the “IPR&D”). The IPR&D was recorded as an intangible asset based on its fair value.

On February 22, 2011, Oramed and the Company entered into a patent transfer agreement, (the "Patent Transfer Agreement"), that superseded the Patent License Agreement, whereby Oramed assigned to the Company all of its rights, title and interest to its patent that Oramed licensed to the Company since 2010, under certain conditions. Under this agreement, the Company is obligated to pay Oramed royalties equal to 3% of its net revenues (as defined in the Patent Transfer Agreement). The IPR&D is not yet ready to use and as such is not subject to amortization.

b. The Company tests intangible assets for impairment at least once a year at December 31 by calculating the recoverable amount of the cash generating unit to which the intangible asset belongs, which is the Company as a whole. The recoverable amount was calculated based on a fair value less cost to sell. For the purpose of calculating fair value of the Company's equity as of December 31, 2016 the Company prepared a valuation of the cash generating unit based on discounted cash flows (DCF). For both years, based on such assessments, the Company concluded that the recoverable amount of the cash generating unit to which the IPR&D intangible asset belongs is significantly higher than its book value, and there is no need for impairment. The DCF model is based on the assumption that the Company will raise the necessary funds to serve the projected activities. Main assumptions used in the valuations are as follows:

	December 31,	
	2016	**2015**
Weighted average cost of capital (WACC)	22%	19%
Commencement of sales	2021-2025	2018-2020
Probability of reaching sales	20.1%-37.9%	30%

NOTE 7 - CONVERTIBLE LOANS:

a.

1. 2012 Convertible Loan

In 2012, the Company entered into loan agreements with certain lenders for an aggregate amount of $1.15 million. Each of the loans bears interest at a rate of 0.6% per year, which is to be repaid every five years, and is due and payable after a term of twenty years. Each of the investors has the right during the term to convert its respective loan amount into ordinary shares at a conversion price of $240.26 per ordinary share (subject to adjustment), and for a period of the initial five years of the term of the loan agreement to exchange all such ordinary shares received into ordinary shares of D.N.A at the rate of one of the Company's ordinary shares for 5,590 ordinary shares of D.N.A or 2,795 ordinary shares after the stock merge performed by D.N.A in October 2015 (also subject to adjustment) (the "D.N.A option"). In addition, under the terms of the loan agreements the outstanding loan amounts will be automatically converted into the Company's ordinary shares upon the closing of an initial public offering and certain merger and acquisition transactions. The Company has designated the 2012 Convertible Loan on initial recognition as a financial liability at fair value through profit or loss.

2. 2015 Convertible Loan

On August 5, 2015, the Company entered into a Convertible Promissory Note and Loan Agreement ("2015 Convertible Loan") with certain lenders. Pursuant to the loan agreement, the lenders loaned the Company an aggregate amount of $2.005 million. The loan would have been automatically converted upon occurrence of the following events as described in the agreement: initial public offering (IPO), private placement in an aggregate amount of no less than $10 million or change of control (Triggering Event). The loan would have converted into the same class of shares issued in such a transaction at a 25% discount to the applicable price per share in the Triggering Event. The loan was due to mature in February 2017 and bore interest at a rate of 5% per year.

In addition the Company issued to the lenders warrants to purchase an additional shares equal to 40% of the shares issued upon conversion of the loan (for the earlier of 2 years from the warrant date or 1 year from consummation of an IPO).

The Company allocated the total consideration of $2,005 thousand between the warrants and the loan as following: $240 thousand was allocated to the warrants based on their fair value and the remaining consideration was allocated to the loan agreement. The Company measures the loan according to the amortized cost using the effective interest method. The Company treated the warrants as a liability at fair value through profit or loss. As part of the 2016 Convertible Loan agreement as detailed below (See Note 7(a)(3)), the Company provided the right to the lenders of the 2015 Convertible Loan to exchange the 2015 Convertible Loan to the 2016 Convertible Loan including the maturity date. As a result, from total amount of $2,005 thousand, an amount of $1,057 thousand (consisting of $ 1,025 thousand principal amount plus interest accrued up to June 14, 2016 less withholding tax) exchanged to the new convertible loan.

Since the terms of the loans are substantially different, the exchange was considered as an extinguishment, which in essence means recording a loss due to 2015 Convertible Loan that were exchanged for the new convertible loan recorded at fair value. The loss of extinguishment of $64 thousand was recognized.
According to the 2016 Convertible Loan agreement, the Company deposited at the trustee an amount of $1,053 thousand to be held until the earlier of the conversion of the 2015 Convertible Loan into shares or the 2015 Convertible Loan maturity date, February 5, 2017. The deposit is presented as a separate line item as restricted cash on the balance sheet. On the maturity date, February 5, 2017, the Company repaid the amount of $1,053 thousand using the cash deposited at the trustee.

NOTE 7 - CONVERTIBLE LOANS (continued):

3. 2016 Convertible Loan

In June 2016, the Company closed a private placement (the "2016 Convertible Loan") with certain lenders in an aggregate amount of approximately $7.44 million in exchange for the following instruments:

a) Loan for a term of 18 months. The loan bears interest at a rate of 5% per year. The loan will be automatically converted upon occurrence of the following events as described in the agreement: initial public offering (IPO) of at least $20 million, private placement in an aggregate amount of no less than $10 million or change of control (the "Triggering Event"). Furthermore, in case of private placement in an aggregate amount of $4-$10 million the lenders shall have the right to convert the loan to shares. The loan will convert into the same class of shares issued in such a transaction at the lower of a 25% discount to the applicable price per share in the Triggering Event or value of equity on a fully diluted basis of $65 million.

The Company has designated the 2016 Convertible Loan on initial recognition as a financial liability at fair value through profit or loss.

b) Warrants to purchase additional shares equal to 40% of the shares issued upon conversion in exchange for an exercise price of the fair value of the shares in a Triggering Event. The warrant will be exercisable for 4 years from the grant date.

Total transaction expenses amounted to $363 thousand, out of which $150 thousand were payable in Company shares. The proceeds were allocated to the convertible loan and the warrants according to their fair value.

As part of the agreement, the Company gave the right to the lenders of the 2015 Convertible Loan to exchange the 2015 Convertible Loan to the 2016 Convertible Loan including the maturity date. As a result from total amount of $2,005 thousand, an amount of $1,057 thousand (consisting of $1,025 thousand principal amount plus interest accrued up to June 14, 2016 less withholding taxes) exchanged to the 2016 Convertible Loan.

The Company prepared a valuation of the financial liabilities presented above (a Level 3 valuation). The debt component of the convertible loans was valued based on the discounting of future payments of the debt. The convertible components (conversion option to the Company's ordinary shares) were valued based on a combination of the Probability-Weighted Expected Return Method and Back Solve option pricing method model. The following parameters were used:

	December 31,	
	2016	**2015**
WACC	22%	19%
Value of equity*	$71 million	$76 million
Volatility	77%	77%
Commencement of sales	2021-2025	2018-2020
Probability for success in phase 2	-	44%
Probability of entering Phase 2b/3 for Hypo	70%	-
Probability for IPO	50%	50%

* The value of equity as of December 31, 2016 and 2015 was based on the valuations performed as detailed in note 6.

NOTE 7 - CONVERTIBLE LOANS (continued):

b.

	Convertible loans
	U.S. dollars in thousands
Balance as of January 1, 2015	6,158
Additions during 2015	1,765
Financial expenses	128
Changes in fair value	2
Balance as of December 31, 2015	8,053
Additions during 2016	6,110
Financial expenses	105
Changes in fair value	452
Balance as of December 31, 2016	14,720

	Warrants to purchase preferred shares and shares
	U.S. dollars in thousands
Balance as of January 1, 2015	-
Additions during 2015	240
Changes in fair value	(25)
Balance as of December 31, 2015	215
Additions during 2016	1,319
Changes in fair value	103
Balance as of December 31, 2016	1,637

NOTE 8 - PREFERRED SHARES AND WARRANTS TO PREFERED SHARES:

a. On January 29, 2014, the Company and Centillion entered into a Series A Preferred Share Purchase Agreement (the "Centillion preferred share purchase agreement"). According to the Centillion preferred share purchase agreement, Centillion purchased 4,172 of the Company's preferred shares, for an aggregate purchase price of $2,000 thousand at a purchase price of $479.38 per share (the "per share purchase price"). The Company also issued to Centillion a warrant to purchase up to 1,043 of its applicable shares upon exercise of the warrant ("applicable shares") at the per share purchase price. According to the Centillion Preferred share purchase agreement, upon the Company's filing of a registration statement for an initial public offering with the SEC no later than June 29, 2014, or the "first milestone", Centillion was required to purchase from the Company an additional 4,172 preferred shares at the per share purchase price (for additional proceeds of $2,000 thousand) and the Company was required to issue to Centillion a warrant to purchase an additional 1,043 applicable shares at the per share purchase price. Finally, pursuant to the terms of the Centillion preferred share purchase agreement, upon the consummation of an initial public offering of the Company's ordinary shares on or prior to December 29, 2014, pursuant to which the ordinary shares are listed on the Nasdaq or AMEX, or a "Qualified IPO" and such event the "second milestone", Centillion was required to purchase from the Company an additional 2,086 preferred shares at the per share purchase price (for additional proceeds of $1,000 thousand) and the Company was required to issue to Centillion a warrant to purchase an additional 522 preferred shares at the per share purchase price. Centillion also had the right to acquire the preferred shares and warrant to be issued upon either of the milestones prior to the applicable milestone date.

On June 18, 2014, the Company and Centillion entered into the first amendment to the Centillion preferred share purchase agreement, pursuant to which the date for the first milestone was extended from June 29, 2014 to November 1, 2014, and the date for the second milestone was extended from December 29, 2014 to May 1, 2015.

On January 21, 2015, the Company and Centillion entered into the second amendment to the Centillion preferred share purchase agreement, or the "second amendment". Pursuant to the second amendment, Centillion exercised its right to acquire the preferred shares and warrant to be issued upon the first milestone although as of such date the Company had not filed a registration statement for its initial public offering, and paid the Company $2,000 thousand. In consideration therefor, the Company also issued to Centillion an additional warrant, or the "additional Centillion warrant". The additional Centillion warrant is exercisable upon (and for a period of one year following) the first to occur of a significant financing round, an M&A event (as defined in the warrant agreement) or the Company's initial public offering, to purchase up to $2,000 thousand of the type of shares issued in such a transaction at a 25% discount to the applicable price per share. In addition, pursuant to the second amendment the date for the second milestone was extended from May 1, 2015 to October 1, 2015. According to the second amendment as the second milestone was not achieved by October 1, 2015, Centillion has extended it until October 1, 2017.

NOTE 8 - PREFERRED SHARES AND WARRANTS TO PREFERED SHARES (continued)**:**

In the course of 2014, the Company consummated the closings of the Series A Preferred Share Purchase Agreements it had entered into with each of WFI E Bio LLC., or WFI, and White Car Group Ltd., or "White Car", and on January 11, 2015 the Company consummated the closing of the Series A Preferred Share Purchase Agreement it had entered into with HFN Trust Company 2013 Ltd., or "HFN Trust", and such agreements together the "additional preferred share purchase agreements". Pursuant to the terms of the additional share purchase agreements WFI, White Car and HFN Trust purchased from the Company 501, 417 and 21 preferred shares for an aggregate purchase price of $240 thousand, $200 thousand and $10 thousand, respectively, and the Company issued to each of WFI, White Car and HFN Trust a warrant to purchase up to 125, 104 and five of its applicable shares, respectively, each upon substantially the same terms as the Centillion preferred share purchase agreement and the form of warrants the Company issued to Centillion. The additional preferred share purchase agreements also provide for the issuance of preferred shares and warrants upon the achievement of those milestones set forth in the Centillion preferred share purchase agreement on terms substantially identical to those contained in the Centillion preferred share purchase agreement.

In March 2015, the Company entered into the first Amendment to each of the additional preferred share purchase agreements, which contained terms substantially identical to those contained in the second amendment to the Centillion preferred share purchase agreement, and the Company issued to each of WFI, White Car and HFN Trust an additional warrant, or together with the additional Centillion warrant the "additional warrants", to purchase up to $240 thousand, $200 thousand and $10 thousand, respectively, upon terms substantially identical to those contained in the additional warrant the Company issued to Centillion in connection with the second amendment to the Centillion preferred share purchase agreement including the extension of the second milestone to October 1, 2017.

b. The preferred shares confer on the holders thereof all rights accruing to holders of Ordinary Shares in the Company, on an as-converted basis, and in addition, the preferred shares have the rights, preferences and privileges granted to the preferred shares *inter alia* as follows:

i. Each holder of preferred shares has the right to convert such preferred shares into the Company's ordinary shares at the then-applicable conversion price. In addition, the preferred shares will be automatically converted into ordinary shares at the then-applicable conversion price upon the consummation of a Qualified IPO.

ii. In any liquidation, bankruptcy, reorganization, dissolution or winding up of the Company as defined in Article 66(d) of the Company's Fourth Amended and Restated Articles of Association, whether voluntary or involuntary (each, a "Liquidation Event") or "Deemed Liquidation Event", the assets available for distribution will be applied, first to the holders of preferred shares. Each preferred share shall be entitled to receive an amount per share equal to the original preferred share price, plus all declared but unpaid dividends and annual 5% interest on the original preferred share price ("Preferred Shares Preference"). If such assets available for distribution shall be insufficient to permit the payment of the full Preferred Shares Preference, then the assets available for distribution shall be distributed pro rata among the holders of the Preferred Shares. Any remaining assets available for distribution to shareholders shall be distributed among the holders of Ordinary Shares and Preferred Shares on a pro rata basis and on an as-converted basis. In the event that the holders of Preferred Shares, upon distribution pro rata to all shareholders on as converted basis receive an aggregate amount per Preferred Share greater than three (3) times the original preferred share price then the holders of preferred shares shall not be entitled to the Preferred Shares Preference described above and all the assets available for distribution shall be distributed among the holders of ordinary shares and preferred shares on a pro rata basis on an as-converted basis.

NOTE 8 - PREFERRED SHARES AND WARRANTS TO PREFERED SHARES (continued)**:**

c. For accounting of purposes, the preferred shares are classified as a financial liability considering, inter alia, the deemed liquidation events mechanism described above. In addition, the conversion ratio of Series A Preferred Shares into ordinary shares is subject to certain adjustments, which do not meet the 'fixed for fixed' requirement of IAS 32. Therefore, the conversion option represents an embedded derivative, which should be bifurcated and accounted for separately at fair value through profit or loss.
The Company elected to designate the entire instrument at fair value through profit or loss, as permitted by IAS 39.

The Warrants to purchase preferred shares issued concurrently with the Series A Preferred Shares also meet the definition of a financial liability since they are exercisable into a financial liability. These warrants are measured at fair value through profit or loss at each balance sheet date.

The liability for future issuances of preferred shares and warrants upon fulfillment of the first and second milestones as described in a) above, are contingent forward contracts, and are therefore accounted for at fair value through profit or loss at each balance sheet date.

d. The consideration received in 2015 and 2014 pursuant to the transactions described above, amounted to $2,460 thousand and $2,440 thousand, respectively, and were allocated to the components based on their relative fair values. The table below presents the movements in the three components during 2016 and 2015:

	Preferred shares	Warrants to purchase preferred shares and shares	Liability to issue preferred shares and warrants	Total
	U.S. dollars in thousands			
Balance as of January 1, 2015	6,550	1,380	8,473	16,403
Additions during 2015	1,903	557	-	2,460
Changes in fair value	4,609	2,180	(6,319)	470
Balance as of December 31, 2015	13,062	4,117	2,154	19,333
Changes in fair value	(2,031)	(954)	(1,881)	(4,866)
Balance as of December 31, 2016	11,031	3,163	273	14,467

e. The Company prepared valuations of the fair value of the three components described above (Level 3 valuations) using a combination of the Probability-Weighted Expected Return Method and Back Solve option pricing method model. The following parameters were used:

	December 31,	
	2016	2015
WACC	22%	19%
Value of equity*	$71 million	$76 million
Volatility	77%	77%
Commencement of sales	2021-2025	2018-2020
Probability for success in phase 2	-	44%
Probability of entering Phase 2b/3 for Hypo	70%	
Probability for IPO	50%	50%

* The value of equity was based on the valuation performed as detailed in note 6.

NOTE 9 - COMMITMENTS:

a. On June 29, 2014, the Company entered into a lease agreement for the building it uses in consideration of approximately $58 thousand per year. The lease agreement expired on June 30, 2016 and the Company utilized its option to extend it for an additional one year period until June 30, 2017.

b. In 2014, the Company entered into operating lease agreements for two vehicles and in 2015 for an additional vehicle. The leases will expire during the years 2017 and 2018. The projected annual lease payments are approximately $26 thousand per year.

c. The Company is committed to pay royalties to Oramed –see also note 6.

d. The Company is committed to pay royalties to the Government of Israel on proceeds from sales of products in the research and development of which the Government participates by way of grants. At the time the grants were received, successful development of the related project was not assumed. In the case of failure of the project that was partly financed by the Government of Israel, the Company is not obligated to pay any such royalties. Under the terms of the Company's funding from the Israeli Government, royalties are payable on sales of products developed from projects so funded of 3% during the first three years, from commencement of revenues, 4% during the subsequent three years and 5% commencing the seventh year up to 100% of the amount of the grant received by the Company (dollar linked) with the addition of an annual interest based on Libor. The amount that must be repaid may be increased to three times the amount of the grant received, and the rate of royalties may be accelerated, if manufacturing of the products developed with the grant money is transferred outside of the State of Israel. As of December 31, 2016, the total royalty amount that would be payable by the Company, before the additional Libor interest, is approximately $460 thousand.

NOTE 10 - SHARE CAPITAL:

a. Composed of ordinary shares of NIS 0.01 par value, as follows:

	Number of shares	
	December 31	
	2016	2015
Authorized	1,000,000	1,000,000
Issued	34,544	34,396

The Ordinary Shares confer upon their holders the following rights: (i) the right to vote in any general meeting of the Company, (ii) the right to receive dividends, and (iii) the right to receive upon liquidation of the Company a sum equal to the nominal value of the share, and if a surplus remains, to receive such surplus, subject to the rights conferred on any class of shares which may be issued in the future.

b. Share based compensation:

1) Share based compensation plan

On March 17, 2013, the Company's board of directors approved a Share Incentive Plan (the “Plan”). Under the Plan, the Company shall reserve sufficient number of Ordinary Shares, NIS 0.01 par value, of the Company for allocation of stock options, restricted share units, restricted share awards and performance-based awards (the "Option"), to employees and non-employees. Each Option is exercisable to acquire one ordinary share.

Any option granted under the Plan that is not exercised within six years from the date upon which it becomes exercisable will expire.

The options granted to employees are subject to the terms stipulated by section 102(b)(2) of the Israeli Income Tax Ordinance (the “Ordinance”). According to these provisions, the Company will not be allowed to claim as an expense for tax purposes the amounts credited to the employees as a capital gain benefit in respect of the options granted.

Options granted to related parties or non-employees of the Company are governed by Section 3(i) of the Ordinance. The Company will be allowed to claim as an expense for tax purposes in the year in which the related parties or non-employees exercised the options into shares.

NOTE 10 - SHARE CAPITAL (continued)**:**

2) Options grants:

a) As part of the Joint Venture Agreement, the Company granted to its CEO 3,296 options, that reflected upon exercise 9.9% of the Company's equity at the date of grant, with an exercise price of NIS 0.01 (par value). The options vested over a period of three years from the grant date. The fair value of the options at the date of grant was $132 thousand.

b) In January 2014, the Company granted to two service providers (which were accounted for as "employees and others providing similar services" under IFRS 2) 500 options with an exercise price of $273.88. 100 options were granted immediately and will vest over 4 years from the date of grant; 1/4 vest on the first anniversary of the date of grant and the remaining vest in twelve equal quarterly installments following the first anniversary of the applicable grant date. The grant of the remaining 400 options is subject to the fulfillment of certain milestones with respect to certain trials conducted by the subcontractors as part of the Company's development plans. The fair value of the options at the date of grant was $70 thousand. In March 2016, the Company terminated a service agreement with one of the service providers, but the Company did not forfeit the options granted. As such, the Company accelerated the vesting period.

c) In March 2015, the Company granted options to purchase 327 ordinary shares to certain of the Company's directors, out of which 85 options were with an exercise price of $240, and 242 options were with an exercise price of NIS 0.01 (par value). The options vest over 4 years from the date of appointment as directors; 1/4 vest on the first anniversary of the date of grant and the remaining vest in twelve equal quarterly installments following the first anniversary of the applicable grant date. The fair value of the options at the date of grant was $398 thousand.

d) In December 2015, the Company granted options to purchase 1,133 ordinary shares to a certain director with an exercise price of $479.38. 1/3 of the options vested on April 23, 2016, 1/3 of the options shall vest on April 23, 2017 and the remaining shall vest on April 23, 2018. The fair value of the options at the date of grant was $1,067 thousand.

e) In March 2016, the Company granted options to purchase 1,133 ordinary shares to a certain director with an exercise price of $479.38. 1/3 of the options vested on April 29, 2016, 1/3 of the options shall vest on July 29, 2017 and the remaining shall vest on July 29, 2018. The fair value of the options at the date of grant was $827 thousand.

f) Through May and during November 2016, the Company granted options to purchase 24 ordinary shares to a certain consultant, with an exercise price of par value (0.01 NIS). The options vested immediately. The fair value of the options at the date of grant was $24 thousand.

g) In August 2016, the Company granted options to purchase 494 ordinary shares to certain employees with an exercise price of $479. The options vest over 4 years from the date of grant; 1/4 vest on the first anniversary of the date of grant and the remaining vest in twelve equal quarterly installments following the first anniversary of the applicable grant date. The fair value of the options at the date of grant was $362 thousand.

NOTE 10 - SHARE CAPITAL (continued)**:**

3) The fair value of each option granted (except options with an exercise price of par value, as described below) is estimated at the date of grant using the Black-Scholes option-pricing model, with the following weighted average assumptions:

	2016	2015
Ordinary share price	$ 1,018	$ 1,269
Exercise price	$ 479	$ 463
Dividend yield	-	-
Expected volatility	76%	74%
Risk-free interest rate	1.05%	1.28%
Expected life – in years	4.11	3.8

The fair value of each option with an exercise price of NIS 0.01 is based on the fair value of ordinary share at the date of grant. The ordinary share price is derived from the value of equity and was based on the valuation performed (as detailed in note 6). The expected volatility is based on comparable companies. The risk-free interest rate is determined based on rates of return on maturity of unlinked treasury bonds with a time to maturity that equals the average life of the options.

4) Changes in the number of options and weighted average exercise prices are as follows:

	Year ended December 31,			
	2016		2015	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of year	7,092	$ 119.7	5,632	$ 50.69
Granted	1,651	$ 472.3	1,460	$ 386
Outstanding at end of year	8,743	$ 186.3	7,092	$ 119.7
Exercisable at end of year	6,426	$ 93.73	5,097	$ 20.71

5) The following is information about the exercise price and remaining contractual life of outstanding options at year-end:

December 31, 2016			December 31, 2015		
Number of options outstanding at end of year	Exercise price range	Weighted average of remaining contractual life	Number of options outstanding at end of year	Exercise price range	Weighted average of remaining contractual life
4,867	*	3.29	4,843	*	4.3
254	$ 240.26	2.7	254	$ 240.26	3.7
277	$ 316	3.42	277	$ 316	4.42
500	$ 273.88	1.54	500	$ 273.88	4.08
85	$ 240	4.21	85	$ 240	5.21
2,266	$ 479.38	5.11	1,133	$ 479.38	5.98
494	$ 479	5.65			

* Par value

6) The remaining unrecognized compensation expense as of December 31, 2016 is $914 thousand. This amount will be expensed in full by August 2020.

NOTE 11 - TAXES ON INCOME:

The Company is taxed according to Israeli tax laws:

a. Measurement of results for tax purposes

The Company measures its results for tax purposes in nominal terms in NIS based on financial reporting under Israeli accounting principles, while (as detailed in note 2) the functional currency of the Company is the U.S. dollar and the Company's financial statements are measured in U.S. dollars and in accordance with IFRS. Therefore, there are differences between the Company's taxable income (loss) and income (loss) reflected in these financial statements.

b. Tax rates

The income of the Company is subject to the Israel corporate tax rates which was 25% for 2016 and 26.5% for 2015.

In January 2016, the Law for the Amendment of the Income Tax Ordinance (No.216) was published, which enacted a reduction of the corporate tax rate beginning in 2016 and thereafter, from 26.5% to 25%. There is no impact on the financial statements of the Company as a result of the changes in the Israeli corporate tax rate as the Israeli subsidiary is in a loss position for tax purposes.
In December 2016, the Economic Efficiency Law (Legislative Amendments for Implementing the Economic Policy for the 2017 and 2018 Budget Year), 2016 was published, introducing a gradual reduction in corporate tax rate from 25% to 23%. However, the law also included a temporary provision setting the corporate tax rate in 2017 at 24%. As a result, the corporate tax rate will be 24% in 2017 and 23% in 2018 and thereafter.

Capital gains are subject to capital gain tax according to the corporate tax rate for the year during which the assets are sold.

c. Losses for tax purposes carried forward to future years

The balance of carryforward losses as of December 31, 2016 and 2015 are approximately $9.9 million and $6.3 million, respectively.

Under Israeli tax law, tax loss carry forwards have no expiration date.

Deferred tax assets on losses for tax purposes carried forward to subsequent years are recognized if utilization of the related tax benefit against a future taxable income is expected. The Company has not created deferred tax assets on its carry forward losses and other temporary assets since their utilization is not expected in the foreseeable future.

d. Tax assessments

In accordance with the Income Tax Ordinance, as of December 31, 2016, all of the Company's tax assessments through tax year 2012 are considered final.

NOTE 12 - SUPPLEMENTARY FINANCIAL INFORMATION:

	December 31,	
	2016	2015
	U.S. dollars in thousands	
a. Other current assets:		
Prepaid expenses	38	535
Other	157	160
	195	695

NOTE 12 - SUPPLEMENTARY FINANCIAL INFORMATION (continued)**:**

b. Accounts payable - other:

	Year ended December 31,	
	2016	**2015**
	U.S. dollars in thousands	
Employees and employees related	139	103
Provision for vacation	155	107
Accrued expenses and other	310	243
	604	453

NOTE 13 – BASIC AND DILUTED LOSS PER SHARE:

Basic

Basic loss per share is calculated by dividing the result attributable to equity holders of the Company by the weighted average number of Ordinary Shares in issue during the year.

Diluted

All outstanding options, 2012 Convertible Loan, preferred shares and warrants to preferred shares have been excluded from the calculation of the diluted loss per share for the year ended December 31, 2015 since their effect was anti-dilutive. The total number of ordinary shares related to the 2012 Convertible Loan, preferred shares and warrants to issue preferred shares excluded from the calculation of diluted loss per share was 23,213 for the year ended December 31, 2015.
All outstanding options have been excluded from the calculation of the diluted loss per share for the year ended December 31, 2016 since their effect was anti-dilutive. The total number of ordinary shares related to the outstanding options excluded from the calculation of diluted loss per share was 8,136 for the year ended December 31, 2016.

The 2015 Convertible Loan, the 2016 Convertible Loan, warrants and liability to issue preferred shares and are not taken into account in the diluted loss per share calculation for the years ended December 31, 2016 and 2015, as the conversion terms depend on future events.

	Year ended December 31,	
	2016	**2015**
	U.S. dollars (except for share numbers)	
Loss attributable to equity holders of the Company	1,199,000	4,282,000
Income from change in fair value of financial liabilities at fair value	4,125,000	-
Loss used for the computation of diluted loss per share	5,324,000	4,282,000
Weighted average number of Ordinary Shares used in the computation of basic loss per share	34,409	34,396
Add:		
Weighted average number of additional shares issuable upon the assumed conversion of 2012 convertible loan, preferred shares and warrants to issue preferred shares	17,563	-
Weighted average number of Ordinary Shares used in the computation of diluted loss per share	51,972	34,396
Basic loss per Ordinary Share	35	124
Diluted loss per Ordinary Share	102	124

NOTE 14 - RELATED PARTIES - TRANSACTIONS AND BALANCES:

a. Transactions with related parties:

1) Key management personnel include members of the Board of Directors, the Chief Executive Officer, Chief Operating Officer and Chief Financial Officer.

2) During 2016 and 2015, the Company granted stock options to certain key management personnel and directors, see note 10b.

	Year ended December 31,	
	2016	2015
	U.S. dollars in thousands	
3) Key management compensation:		
Labor cost and related expenses	830	552
Share-based compensation	1,351	363
Others	98	28
	2,279	943

b. Balances with related parties:

	December 31,	
	2016	2015
	U.S. dollars in thousands	
Key management:		
Payables and accrued expenses	57	29
Severance pay obligations	51	29
Provision for vacation	138	98
Directors fee	28	23

NOTE 15 - SUBSEQUENT EVENTS

a. In February 2017, the Company repaid the amount of 1.053 million of the 2015 convertible loan (See Note 7(a)(2)).

b. In March, 2017, the Company entered into a new lease agreement for the building it uses in consideration of approximately $61 thousand per year. The lease agreement expired on June 30, 2023 with a onetime option for the Company to early terminate the agreement on June 30, 2020 subject to a notice period of 6 months.

c. On March 27, 2017, the board of directors approved the nomination of Mr. Luke Beshar as Executive chairman of the board and Dr. Roger Graceau as Chief Development Advisor. The nominations and the compensation were subject to shareholder approval that was received on April 6, 2017.

According to the agreements with Mr. Luke Beshar, and Dr. Graceau , Mr. Beshar and Dr. Graceau will receive a monthly fees in the amount of $21,500 and $6,500, respectively. In addition upon the occurrence of a private placement or IPO, which are defined as a Triggering Event as described in Note 7(a)(3) (“the Qualified Event”), Mr. Beshar and Dr. Graceau will be granted options to purchase ordinary shares of the Company representing 6.5% and 1.5%, respectively, of the Company’s share capital on a “fully diluted basis” as determined immediately following the Qualified Event, provided however, that if the amount of new funds actually received by the Company in a Qualified Event exceeds $10 million, then it shall be deemed for the purpose of calculating the "fully diluted basis" under this Agreement as if such amount is equal to $10 million. The exercise price of the Options shall be equal to the per share fair market value of ordinary shares immediately following the Qualified Event. The Options will vest in 36 equal monthly installments over a period of 36 months, commencing as of the Commencement Date, and are subject to acceleration under certain circumstances as described in the service agreement. If a Change of Control that constitutes a “change in control event” described in Treas. Reg. § 1.409A-3(i)(5) occurs before a Qualified Event, then in lieu of the issuance of Options as described above, the Company will pay to each of Mr. Beshar and Dr. Graceau an amount that, taking into account all federal, state, local and foreign taxes (including excise taxes) arising from the payment of such amount, will yield net after-tax proceeds to each of Mr. Beshar and Dr. Graceau of $1,000,000; or (ii) $3,619,254.

d. On April 6, 2017, the Company granted options to purchase 1,133 ordinary shares to a certain director, with an exercise price of $980. 1/3 of the options are vested on the grant date, 1/3 of the options shall vest on September 21, 2017 and the remaining shall vest on September 21, 2018. The fair value of the options at the date of grant is $574 thousand.

Until , 2017 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

[Alternate Page for Selling Stockholder Resale Prospectus]

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 we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS (Subject to Completion)
Issued , 2017

ORDINARY SHARES

This prospectus relates to the offer for sale of ordinary shares by the existing holders of the securities named in this prospectus, referred to as selling shareholders throughout this prospectus. We will not receive any of the proceeds from the sale of ordinary shares by the selling shareholders named in this prospectus.

The distribution of securities offered hereby may be effected in one or more transactions that may take place on the , including ordinary brokers' transactions, privately negotiated transactions or through sales to one or more dealers for resale of such securities as principals, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the selling shareholders. No sales of the shares covered by this prospectus shall occur until the ordinary shares sold in our initial public offering begin trading on the . Currently, there is no public market for our ordinary shares. We have been authorized to list our ordinary shares on the under the symbol " ".

The selling shareholders and intermediaries through whom such securities are sold may be deemed "underwriters" within the meaning of the Securities Act of 1933, as amended (the Securities Act), with respect to the securities offered hereby, and any profits realized or commissions received may be deemed underwriting compensation.

On , 2017, a registration statement under the Securities Act with respect to our initial public offering underwritten by and , as the underwriters, of $ of our ordinary shares (or ordinary shares assuming a $ per share initial public offering price) was declared effective by the Securities and Exchange Commission. We received approximately $ million in net proceeds from the offering (assuming no exercise of the underwriters' over-allotment option) after payment of underwriting discounts and commissions and estimated expenses of the offering.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act and will therefore be subject to reduced reporting requirements.

Investing in our ordinary shares involves risks. See "Risk Factors" beginning on page 15.

The Securities and Exchange Commission and state securities regulators have not approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the ordinary shares to purchasers on , 2017.

, 2017

[Alternate Page for Selling Stockholder Resale Prospectus]

SHARES REGISTERED FOR RESALE

Registration Rights

We, certain of our shareholders and certain lenders under our convertible financing agreements have entered into an investors rights agreement. Holders of ordinary shares are entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the registered sale of such securities.

Demand Registration Rights

Pursuant to the investors' rights agreement, at any time beginning 180 days after the closing of the primary offering of our ordinary shares and for so long as we are eligible to file a registration statement on Form F-3, any shareholder or group of shareholders holding an aggregate of at least 10% of the registrable securities under the investors' rights agreement that are not held by D.N.A Biomedical, may request in writing that we effect the registration under the Securities Act of the sale or other transfer of such shareholder or shareholders' ordinary shares, provided that we are not required to effect more than three such registrations.

Form F-3 Registration Statement

After we become eligible to file a registration statement on Form F-3, which will not be until at least 12 months after the date of this prospectus, any shareholder or group of shareholders holding an aggregate of at least 10% of the registrable securities under the investors' rights agreement that are not held by D.N.A Biomedical may request in writing that we effect a registration of the sale or other transfer of such shares, provided that the aggregate anticipated proceeds from the sale of such shares equals at least $1.0 million and that we are not required to effect more than three such registrations.

We will not be obligated to file a registration statement on Form F-3 in certain cases including if in the good faith judgment of our board of directors (as reflected in a certificate delivered by our chief executive officer), such registration would be seriously detrimental to our company or its shareholders, provided that we do not use this exemption more than once in any 12-month period. We also have the right not to effect a Form F-3 registration statement during the period from 60 days prior to the filing of, to 6 months following the effective date of, a previous registration.

Piggyback Registration Rights

The investors' rights agreement also provides our shareholders with "piggy back" registration rights in the event that we determine to register the sale of any of our securities following a primary offering of our ordinary shares.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of our ordinary shares by the selling shareholders named in this prospectus. All proceeds from the sale of the conversion shares will be paid directly to the selling shareholders.

[Alternate Page for Selling Stockholder Resale Prospectus]

SELLING SHAREHOLDERS

An aggregate of up to ordinary shares are currently being offered under this prospectus by certain shareholders who were previously holders of our Convertible Loans.

The following table sets forth certain information with respect to each selling shareholder for whom we are registering ordinary shares for resale to the public. The selling shareholders have not had a material relationship with us within the past three years other than as described in the footnotes to the table below. To our knowledge, each person named in the table has sole voting and investment power with respect to the ordinary shares set forth opposite such person's name. None of the selling shareholders are broker-dealers or affiliates of broker-dealers, unless otherwise noted.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. The percentage of shares beneficially owned after the offering is based on ordinary shares to be outstanding after this offering, including ordinary shares sold in our initial public offering.

Name of Beneficial Owner	Shares Beneficially Owned Prior to Offering(1)		Shares Being Offered	Shares Beneficially Owned After Offering(1)	
	Number	Percentage		Number	Percentage

* No selling shareholder is a broker dealer or an affiliate of a broker-dealer.

(1) Estimate based on an assumed initial public offering price of $ per share

(2)

(3)

(4)

(5)

(6)

(7)

Each of the selling shareholders that is an affiliate of a broker-dealer has represented to us that it purchased the shares offered by this prospectus in the ordinary course of business and, at the time of purchase of those shares, did not have any agreements, understandings or other plans, directly or indirectly, with any person to distribute those shares.

[Alternate Page for Selling Stockholder Resale Prospectus]

PLAN OF DISTRIBUTION

Each selling shareholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling shareholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker dealer solicits purchasers;
- block trades in which the broker dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- in transactions through broker dealers that agree with the selling shareholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling shareholders may also sell securities under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker dealers engaged by the selling shareholders may arrange for other broker dealers to participate in sales. Broker dealers may receive commissions or discounts from the selling shareholders (or, if any broker dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the selling shareholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling shareholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling shareholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling shareholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling shareholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

[Alternate Page for Selling Stockholder Resale Prospectus]

We have been authorized to list our ordinary shares on the under the symbol “ ”.

We are required to pay certain fees and expenses incurred by us incident to the registration of the securities. We have agreed to indemnify the selling shareholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

To the extent required, the number of our securities to be sold, the names of the selling security holders, the respective purchase prices and public offering prices, the names of any agent, dealer or underwriter and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or a post-effective amendment to the registration statement that includes this prospectus.

Because selling shareholders may be deemed to be “underwriters” within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act, including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. The selling shareholders have advised us that there is no underwriter or coordinating broker acting in connection with the proposed sale of the resale securities by the selling shareholders.

We have agreed to keep this Registration Statement effective until the date on which all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act, or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the ordinary shares for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling shareholders will be subject to applicable provisions of the Exchange Act, and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of securities of the ordinary shares by the selling shareholders or any other person. We will make copies of this prospectus available to the selling shareholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

[Alternate Page for Selling Stockholder Resale Prospectus]

LEGAL MATTERS

The validity of the ordinary shares being offered by this prospectus and other legal matters concerning this offering relating to Israeli law will be passed upon for us by Herzog Fox & Neeman, Tel Aviv, Israel. Certain legal matters in connection with this offering relating to U.S. law will be passed upon for us by Davis Polk & Wardwell LLP, New York, New York.

EXPERTS

The financial statements as of December 31, 2016 and 2015 and for each of the two years in the period ended December 31, 2016 included in this Prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the financial statements) of Kesselman & Kesselman, Certified Public Accountants (Israel), a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. The current address of Kesselman & Kesselman, Certified Public Accountants (Israel) is 25 Hamered Street, Tel Aviv, Israel 6812508.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the U.S. Securities and Exchange Commission a registration statement on Form F-1 under the Securities Act with respect to the shares of ordinary offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the ordinary shares offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon the closing of this offering, we will be required to file periodic reports, proxy statements, and other information with the U.S. Securities and Exchange Commission pursuant to the Exchange Act. You may read and copy this information at the Public Reference Room of the U.S. Securities and Exchange Commission, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the public reference rooms by calling the U.S. Securities and Exchange Commission at 1 800 SEC 0330. The U.S. Securities and Exchange Commission also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the U.S. Securities and Exchange Commission. The address of that site is www.sec.gov.

[Alternate Page for Selling Stockholder Resale Prospectus]

, 2017

Until , 2017 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 6. Indemnification of Directors and Officers

General. Our Articles of Association set forth the following provisions regarding the grant of insurance coverage, indemnification and an exemption from liability to any of our directors or officers, all subject to the provisions of applicable law. In accordance with such provisions and pursuant to the requisite corporate approvals, we have obtained liability insurance covering our directors and officers, have granted indemnification undertakings to our directors and officers and have agreed to exempt our directors and officers from liability for breach of the duty of care.

Insurance. We are entitled to insure the liability of any director or officer to the fullest extent permitted by law. Without derogating from the aforesaid, we may enter into a contract to insure the liability of a director or officer for an obligation imposed on him in consequence of an act done in his capacity as such, in any of the following cases:

- a breach of the duty of care toward us or a third party;
- a breach of the duty of loyalty toward us, provided that the director or officer acted in good faith and had reasonable basis to believe that the act would not harm us;
- a monetary obligation imposed on him in favor of a third party;
- a payment imposed on him in favor of an injured party as set forth in Section 52(54)(a)(1)(a) of the Israeli Securities Law; or
- reasonable litigation expenses, including attorney fees, incurred by him as a result of an administrative enforcement proceeding instituted against him.

Indemnification. We are entitled to indemnify a director or officer to the fullest extent permitted by law, either retroactively or pursuant to an undertaking given in advance. Without derogating from the aforesaid, we may indemnify our directors or officers for liability or expense imposed on him in consequence of an action taken by him in his capacity as such, as follows:

- a financial obligation imposed on him pursuant to a judgment in favor of another person, including a judgment imposed on him in a settlement or in an arbitration decision that was approved by a court of law;
- reasonable legal expenses, including attorney's fees, expended by him as a result of an investigation or proceeding instituted against him by a competent authority, provided that such investigation or proceeding concluded without the filing of an indictment against him and either (A) concluded without the imposition of any financial liability in lieu of criminal proceedings, or (B) concluded with the imposition of a financial liability in lieu of criminal proceedings but relates to a criminal offense that does not require proof of criminal intent or in connection with a financial sanction;
- reasonable legal expenses, including attorney's fees, which he incurred or with which he was charged by a court of law, in a proceeding brought against him, by us or on our behalf or by another person, or in a criminal prosecution in which him was acquitted, or in a criminal prosecution in which he was convicted of an offense that does not require proof of criminal intent
- a payment imposed on him in favor of an injured party as set forth in Section 52(54)(a)(1)(a) of the Israeli Securities Law; or
- reasonable litigation expenses, including attorney fees, incurred by the director or officer as a result of an administrative enforcement proceeding instituted against him.

Exemption. We are entitled to exempt a director or officer in advance from any or all of his liability for damage in consequence of a breach of the duty of care toward us, except in connection with illegal distributions to shareholders.

Limitations. The Companies Law provides that a company may not provide its directors or officers with insurance or indemnification or exempt its directors or officers from liability with respect to the following:

- a breach of the duty of loyalty toward the company, unless, with respect to insurance coverage or indemnification, the director or officer acted in good faith and had a reasonable basis to believe that the act would not harm us;
- an intentional or reckless breach of the duty of care;
- an act done with the intention of illegally deriving a personal profit; or
- a fine imposed on the director or officer.

The proposed form of Underwriting Agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of our directors and officers by the underwriters against certain liabilities.

Item 7. Recent Sales of Unregistered Securities.

During the past three years, we issued securities that were not registered under the Securities Act of 1933, as amended, or the "Securities Act," as set forth below. We believe that each of such issuances was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act, Rule 701 and/or Regulation S under the Securities Act.

The following is a summary of transactions during the preceding three fiscal years involving sales of our securities that were not registered under the Securities Act:

- Pursuant to Convertible Financing Agreements entered into between us, the lenders thereto, or the "lenders," and D.N.A Biomedical, between November 2012 and January 2013, the lenders loaned to us an aggregate amount of $1.15 million. Each of the investors has the right during the term to convert its respective loan amount (subject to adjustment) into our ordinary shares at a conversion price of $240.26 per ordinary share, and the outstanding loan amounts will be automatically converted into our ordinary shares immediately prior to the closing of this offering. The total number of our ordinary shares that can be acquired upon conversion of the current outstanding loan amounts is 4,786 ordinary shares;
- Pursuant to the share purchase agreements entered into between us and the other parties identified therein in September and October 2013, we issued an aggregate of 2,318 of our ordinary shares for an aggregate purchase price of $635,000;
- Pursuant to the Series A Preferred Share Purchase Agreement with Centillion on January 29, 2014, Centillion purchased 4,172 of our Series A preferred shares (which can be converted into 4,172 of our ordinary shares at the current conversion rate of one ordinary share for one Series A preferred share and will be automatically converted into our ordinary shares at the then-current conversion rate upon the consummation of this offering), for a purchase price of $2.0 million, and we issued to Centillion a warrant to purchase up to 1,043 of our (i) preferred shares prior to the consummation of this offering and (ii) ordinary shares upon the consummation of this offering and otherwise after the conversion of all of our Series A preferred shares into our ordinary shares (the shares described in (i) and (ii), the "applicable shares").
- Pursuant to the Series A Preferred Share Purchase Agreements we entered into during the course of 2014 and January 2015 with the other parties identified therein, such parties purchased from us an aggregate of 939 of our Series A preferred shares (which can be converted into 939 of our ordinary shares at the current conversion rate of one ordinary share for one Series A preferred share and will be automatically converted into our ordinary shares at the then-current conversion rate upon the consummation of this offering), for an aggregate purchase price of $450,000, and we issued to such parties warrant to purchase up to 234 of the applicable shares.
- Pursuant to the second Amendment to the Series A Preferred Share Purchase Agreement with Centillion that we entered into on January 21, 2015, Centillion purchased 4,172 of our Series A preferred shares

(which can be converted into 4,172 of our ordinary shares at the current conversion rate of one ordinary share for one Series A preferred share and will be automatically converted into our ordinary shares at the then-current conversion rate upon the consummation of this offering), for a purchase price of $2.0 million, and we issued to Centillion a warrant to purchase up to 1,043 of our applicable shares. In addition, we issued to Centillion an additional warrant that is exercisable upon (and for a period of one year following) the first to occur of a significant financing round, an M&A event (as defined in the warrant), or our initial public offering, or a triggering event, to purchase up to $2.0 million of the type of shares issued in such triggering event at a 25% discount to the applicable price per share.

- Pursuant to the first Amendment to the Series A Preferred Share Purchase Agreements with other purchasers of our Series A Preferred Shares that we entered into in March 2015, such other purchasers purchased 939 of our Series A preferred shares (which can be converted into 939 of our ordinary shares at the current conversion rate of one ordinary share for one Series A preferred share and will be automatically converted into our ordinary shares at the then-current conversion rate upon the consummation of this offering), for an aggregate purchase price of $450,000, and we issued to such other purchasers of our Series A Preferred Shares warrants to purchase up to 234 of our applicable shares. In addition, we issued to such other purchasers of our Series A Preferred Shares additional warrants that are exercisable upon a triggering event to purchase up to $450,000 of the type of shares issued in such triggering event at a 25% discount to the applicable price per share.

- On August 5, 2015, the Company entered into the 2015 Convertible Loan with certain lenders. Pursuant to the loan agreement for the 2015 Convertible Loan, the lenders loaned us an aggregate amount of $2.005 million. The 2015 Convertible Loan bore interest at a rate of 5% per year. The loan would also be automatically converted upon occurrence of the a 2015 Triggering Event into the equity securities and/ or securities convertible into equity securities of the Company that were issued in such a transaction, at a 25% discount. In addition, the Company issued to each lender under the 2015 Convertible Loan the 2015 Warrants to purchase an additional 40% of the amount of our securities that would have been issued to such lender as a result of the automatic conversion following a 2015 Triggering Event. The 2015 Warrants were exercisable for the earlier of two years from the warrant issuance date or one year from consummation of an initial public offering. As part of the 2016 Convertible Loan, we granted the lenders a right to roll-over the 2015 Convertible Loan into the 2016 Convertible Loan. The lenders elected to roll-over an amount of $1.057 million into the 2016 Convertible Loan and the reminder, in an amount of $1.053 million (including interest and principal), was repaid by the Company in February 2017. There remain no amounts outstanding under the 2015 Convertible Loans, and no 2015 Warrants remain outstanding.

- On June 14, 2016, the Company entered into the 2016 Convertible Loan with certain lenders for an aggregate amount of approximately $7.44 million. In addition, an amount of $1.057 million of the 2015 Convertible Loan rolled over to the 2016 Convertible Loan. The 2016 Convertible Loan is for a term of 18 months and bears interest at a rate of 5% per year. The 2016 Convertible Loan will automatically convert upon the occurrence of a 2016 Triggering Event. Furthermore, in case of a private placement in an aggregate amount of between $4 million to $10 million the lenders have the right to convert the 2016 Convertible Loan. In each case of conversion, the 2016 Convertible Loan will convert into the same equity securities and/or securities convertible into equity securities of the Company that were issued in such a transaction at the lower of (i) a 25% discount to the applicable price per share of such security or (ii) the price per share of such securities calculated at a valuation of $65 million on a fully diluted basis. In addition, the Company issued to each lender under the 2016 Convertible Loan the 2016 Warrants to purchase an additional 40% of the amount of our securities issued to such lender as a result of the automatic conversion following a 2016 Triggering Event. The 2016 Warrants will be exercisable upon conversion of the 2016 Convertible Loan and thereafter until June 2020. In addition, each lender in the 2016 Convertible Loan have the right to invest, in the next share issuance by the Company, an amount not to exceed the amount such lender invested in the 2016 Convertible Loan, at a price per share in such issuance.

No underwriter or underwriting discount or commission was involved in any of the transactions set forth in Item 7.

Item 8. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this registration statement:

Exhibit No.	Description
1.1*	Form of Underwriting Agreement.
3.1*	Fourth Amended and Restated Articles of Association of the Registrant (currently in effect).
3.2*	Fifth Amended and Restated Articles of Association of the Registrant (to be effective upon the closing of this offering).
4.1*	Specimen Form of Ordinary Share Certificate.
4.2*	Form of Warrant issued by the Registrant to Centillion Fund on each of January 29, 2014 and January 21, 2015.
4.3*	Form of additional Warrant issued by the Registrant to Centillion Fund on January 21, 2015.
4.4*	Form of Warrant issued by the Registrant to the lenders on June 24, 2016.
5.1*	Opinion of Herzog Fox & Neeman, Israeli counsel to the Registrant, as to the validity of the ordinary shares.
8.1*	Opinion of Herzog Fox & Neeman, Israeli counsel to the Registrant, as to Israeli tax matters.
8.2*	Opinion of Davis Polk & Wardwell LLP as to U.S. tax matters.
10.1*	Patent Transfer Agreement, dated as of February 22, 2011, between the Registrant and Oramed Ltd.
10.2*	Convertible Financing Agreement, dated as of November 13, 2012, among the Registrant, D.N.A Biomedical Solutions, Ltd. and the lenders thereto.
10.3*	Convertible Financing Agreement, dated as of December 31, 2012, among the Registrant, D.N.A Biomedical Solutions, Ltd. and the lenders thereto.
10.4*	The Entera Bio Ltd. Share Incentive Plan.
10.5*	Series A Preferred Share Purchase Agreement, dated as of January 29, 2014, between the Registrant and Centillion Fund.
10.6*	First Amendment to Series A Preferred Share Purchase Agreement, dated as of June 18, 2014, between the Registrant and Centillion Fund.
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10.8*	Amended and Restated Investors' Rights Agreement, dated as of November 26, 2014, between the Registrant and the other parties thereto.
10.9*	Form of indemnification agreement between the Registrant and its directors and executive officers.
10.10*	Convertible Financing Agreement, dated as of June 14, 2016, among the Registrant and the lenders thereto.
10.11*	Service Agreement, dated April 6, 2017, between Roger Garceau and the Company.
10.12*	Service Agreement, dated April 6, 2017, between Luke Beshar and the Company.
23.1*	Consent of Kesselman & Kesselman, Certified Public Accountants, a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm.
23.2*	Consent of Herzog Fox & Neeman (included in Exhibits 5.1 and 8.1).
23.3*	Consent of Davis Polk & Wardwell LLP (included in Exhibit 8.2)
24.1*	Powers of Attorney (included on signature page).

*To be filed by amendment.

(b) Financial Statement Schedules.

All schedules have been omitted because they are not required, are not applicable or the information is otherwise set forth in the Financial Statements and related notes thereto.

Item 9. Undertakings

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 referenced in Item 6 hereof, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) (§ 230.424(b) of this chapter) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment 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.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) If the registrant is a foreign private issuer, to file a post-effective amendment to the registration statement to include any financial statements required by “Item 8.A. of Form 20-F (17 CFR 249.220f)” at the start of any delayed offering or throughout a continuous offering. Financial statements and information otherwise required by Section 10(a)(3) of the Act need not be furnished, provided that the registrant includes in the prospectus, by means of a post-effective amendment, financial statements required pursuant to this paragraph (a)(4) and other information necessary to ensure that all other information in the prospectus is at least as current as the date of those financial statements. Notwithstanding the foregoing, with respect to registration statements on Form F-3 (§ 239.33 of this chapter), a post-effective amendment need not be filed to include financial statements and information required by Section 10(a)(3) of the Act or § 210.3-19 of this chapter if such financial statements and information are contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the Form F-3.

(5) To provide to the underwriter specified in the Underwriting Agreement, at the closing, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(6) That for the purpose 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.

(7) 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 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Jerusalem, Israel, on
, 2017.

ENTERA BIO LTD.

By: _____
Name: Dr. Phillip Schwartz
Title: Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Phillip Schwartz and Mira Rosenzweig, and each of them, as attorney-in-fact with full power of substitution, for him or her in any and all capacities, to do any and all acts and all things and to execute any and all instruments which said attorney and agent may deem necessary or desirable to enable the registrant to comply with the Securities Act, and any rules, regulations and requirements of the SEC thereunder, in connection with the registration under the Securities Act of ordinary shares of the registrant (the "Shares"), including, without limitation, the power and authority to sign the name of each of the undersigned in the capacities indicated below to the Registration Statement on Form F-1 (the "Registration Statement") to be filed with the SEC with respect to such Shares, to any and all amendments or supplements to such Registration Statement, whether such amendments or supplements are filed before or after the effective date of such Registration Statement, to any related Registration Statement filed pursuant to Rule 462(b) under the Securities Act, and to any and all instruments or documents filed as part of or in connection with such Registration Statement or any and all amendments thereto, whether such amendments are filed before or after the effective date of such Registration Statement, and each of the undersigned hereby ratifies and confirms all that such attorney and agent shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Dr. Phillip Schwartz	Chief Executive Officer (Principal Executive Officer) and Director	, 2017
Mira Rosenzweig	Chief Financial Officer (Principal Financial and Accounting Officer)	, 2017
Luke M. Beshar	Chairman of the Board	, 2017
David Ben Ami	Director	, 2017
Chaim Davis	Director	, 2017
Roger Garceau	Director	, 2017
Gerald Lieberman	Director	, 2017
Yonatan Malca	Director	, 2017
Zeev Bronfeld	Director	, 2017

SIGNATURE OF AUTHORIZED REPRESENTATIVE IN THE UNITED STATES

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned has signed this registration statement, solely in its capacity as the duly authorized representative of the Registrant, in on ,2017.

By: _____
Name:
Title:

EXHIBIT INDEX

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*To be filed by amendment.