As filed with the Securities and Exchange Commission on June 15, 2018.

Registration No. 333-221472

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

AMENDMENT NO. 5
TO
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)

Cogency Global Inc.
10 E 40th Street, 10th Floor
New York, New York 10016
+1 (800) 221-0102
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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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.

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee[2]
Units consisting of:		
Ordinary shares, par value NIS 0.0000769 per share	$15,318,006.66	$1,907.09
Warrants to purchase ordinary shares, par value NIS 0.0000769 per share[3]	—	—
Ordinary shares, par value NIS 0.0000769 per share, issuable upon exercise of the warrants to purchase ordinary shares	$ 9,583,337.50	$1,193.13
Total		$3,100.22

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933. Includes the aggregate offering price of additional securities that the underwriters have the option to purchase, if any.
(2) The Registrant has previously paid $10,062 in connection with this Registration Statement.
(3) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended, this registration statement shall also cover an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.

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.

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 jurisdiction where the offer or sale is not permitted.

PROSPECTUS (Subject to Completion)
Dated June 15, 2018

1,333,334 ORDINARY SHARES

WARRANTS TO PURCHASE 666,667 ORDINARY SHARES

Entera Bio Ltd. is offering 1,333,334 ordinary shares and warrants (the "warrants") to purchase up to 666,667 ordinary shares (and the ordinary shares that are issuable from time to time upon exercise of the warrants). The ordinary shares and warrants will be sold in units (each a "unit"), with each unit consisting of one ordinary share and one warrant to purchase 0.5 of an ordinary share. This is our initial public offering and no public market exists for our ordinary shares or warrants. We anticipate that the initial public offering price will be between $8.00 and $10.00 per unit. The ordinary shares and warrants are immediately separable and will be issued separately and are expected to trade separately following the effectiveness of the registration statement for this offering.

The warrants will become exercisable on the date of issuance, and will remain exercisable until , 2023, unless earlier repurchased by us or subject to early expiration as described herein. The exercise price for the warrants initially will be $11.25 per ordinary share (which is 125% of the assumed initial public offering price per unit), and will be subject to adjustments as described herein.

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

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 and warrants involves risks. See "Risk Factors" beginning on page 14.

PRICE $ PER UNIT

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

(1) We have agreed to reimburse the underwriters for certain expenses. We have also agreed to issue to the representative 10,000 ordinary shares upon the closing of this offering, as well as underwriter warrants, certain terms of which are described under "Underwriting", to purchase a number of ordinary shares equal to an aggregate of 5.0% of the ordinary shares sold as part of the units in this offering. See "Underwriting" for additional information regarding underwriting compensation.

Entera Bio Ltd. has granted the underwriters the right to purchase up to an additional 200,000 ordinary shares and/or 200,000 additional warrants to purchase up to a total of 100,000 ordinary shares to cover over-allotments, if any, at the initial public offering price per unit less the underwriting discounts and commissions payable by us, for 30 days after the date of this prospectus. The public offering price per unit corresponds to a public offering price per ordinary share of $8.99 and a public offering price per warrant of $0.01, which together constitute the midpoint of the estimated offering price range on the cover of this prospectus.

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.

Certain of our existing shareholders and parties affiliated with our existing shareholders have indicated an interest in purchasing an aggregate of up to approximately $5.0 million of the units in this offering at the initial public offering price per unit. However, indications of interest are not binding agreements or commitments to purchase, and these entities may determine to purchase a greater or lesser number of units than they have indicated an interest in purchasing or to not purchase any units in this offering. In addition, we and the underwriters could determine to sell a greater or lesser number of units to any of these entities than the entities have indicated an interest in purchasing or to not sell any units to these entities.

The underwriters expect to deliver the ordinary shares and warrants to purchasers on , 2018.

Sole Bookrunning Manager

Maxim Group LLC

Co-Manager

Joseph Gunnar & Co.

, 2018

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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 or warrants. This prospectus is not an offer to sell or the solicitation of an offer to buy these ordinary shares or warrants 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 and warrants 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 warrants, 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 precede 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 and warrants. You should read this entire prospectus carefully, including the "Risk Factors" section and the financial statements included elsewhere in this prospectus and the notes to those financial statements, before making an investment decision. In this prospectus, the terms "Entera," "we," "us," "our," "the Company" and "our company" refer to Entera Bio Ltd.

Our Business

We are a clinical-stage 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 intend to utilize future funds, as available, to prepare EB612 for advanced clinical studies and ultimately for regulatory approval.

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 insured 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. Studies performed by researchers at the National Institutes of Health, or 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 once-daily dosing. In addition, 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 confirmed related serious or significant adverse events as defined by the study protocol. 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 showed the potential for similar efficacy, a result that we plan to confirm by conducting a Phase 2b/3 trial, which will further evaluate the dosage, effectiveness and safety profile of EB612 in an expanded patient population at multiple trial sites. We believe that EB612 will have inherent advantages compared to injectable forms of PTH, including convenience of application, that no special preparation is required and that it can be stored under convenient storage conditions (room temperature or refrigeration for long term storage). Additionally, based on the results of our preliminary study, we believe that EB612 will have an enhanced clinical profile as compared to Natpara, with an additional normalizing effect on elevated urinary calcium, as well as reduced side effects. If our preliminary results are borne out in additional trials, 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 have begun planning for a future Phase 2b/3 trial, designed to possibly be a pivotal study for registration. We expect that this Phase 2b/3 study, when initiated, will be designed to replicate the REPLACE study in many aspects and to achieve a significant reduction in urinary calcium.

We are also developing an 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 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 delivered orally, 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 pursue approval of EB613 utilizing the alternative Section 505(b)(2) pathway permitted under the Federal Food, Drug and Cosmetic Act. Based on recent changes in guidance issued by the FDA and the similarity of our product's pharmokinetic profile, or PK profile, to that of Forteo, we believe it is feasible to complete an NDA submission for EB613 with one or two pivotal Phase 3 studies, conducted with approximately 400-500 osteoporosis patients, that will examine bone mineral density and particular biochemical markers of bone activity. These studies would be conducted in anticipation of a 505(b)(2) application to the FDA and would include a comparison to the currently marketed drug, Forteo. In pursuit of this pathway, our intent is to seek FDA guidance as part of a Pre-IND meeting in the second half of 2018. Based on the responses of the FDA, we intend to conduct a dose ranging Phase 2a study in approximately 150 osteoporosis patients. Following analysis of this data, we intend to design and execute pivotal trial(s) in osteoporosis patients guided by the feedback of the FDA. We currently do not anticipate that the FDA will request that we examine the effects on bone mineral density in these trials past 12 months. We therefore believe that this alternative pathway will be significantly shorter than a pathway that utilizes bone fracture studies in significantly larger numbers of patients over greater periods of time.

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 in the future.

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
EB613 PTH 1-34	Osteoporosis	Phase 1 complete				• Phase 1 complete

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 in coming years to build a substantial U.S. presence to execute on the later stage development of our products, including by expanding our executive management team, 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, submit a pre-IND for the treatment of osteoporosis and commence a dose finding Phase 2a study;
- 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 10 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 oral PTH (1-34) programs 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 serious or significant related adverse events as defined by the study protocol. 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 showed the potential for similar efficacy, a result that we plan to confirm by conducting a Phase 2b/3 trial. The FDA and EMA have granted EB612 orphan drug designation for the treatment of hypoparathyroidism. We intend to utilize future funds, as available, to prepare EB612 for advanced clinical studies and ultimately for regulatory approval.

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 insured 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, or BLA, 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 an additional but similar oral PTH product candidate, EB613, for the treatment of osteoporosis. Our intent is to seek FDA guidance on our proposed clinical trial design as part of a Pre-IND meeting in the second half of 2018. Based on the responses from the FDA, we intend to conduct a dose finding Phase 2a study of EB613 in osteoporosis in approximately 150 patients. Following this Phase 2a trial, we intend to design and execute pivotal trial(s) in osteoporosis patients guided by the feedback of the FDA.

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 due to 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 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.

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, including human growth hormone, and intend to commence clinical development for our next, non-PTH, product candidate in the future. For example, in initial rodent studies utilizing Entera’s drug delivery technology, an oral formulation of human growth hormone obtained significant concentrations of intact human growth hormone throughout the blood stream. 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. 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. For instance, we may choose to license our technology to external parties for the development of non-PTH product candidates.

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 costs vary from approximately $25,000 to $45,000.

Recent Developments

Chief Medical Officer Appointment

On January 10, 2018, the Company appointed Eric Lang, MD, as the Company’s Chief Medical Officer, effective January 15, 2018. Dr. Lang replaced Dr. Miriam Blum, who had served as the Company’s Chief Medical Officer since January 2015. As the Company’s Chief Medical Officer, Dr. Lang will be responsible for building and leading our clinical development group, as well as all aspects (including strategy and implementation) of the Company’s clinical development and regulatory strategy.

Dr. Lang has extensive experience in designing drug development programs from early stages through phase III, including the successful filing of several recent INDs and NDAs. From 2012 to 2017, Dr. Lang worked at Covance, Inc., most recently as the Vice President and Global Head of Clinical Drug Development Strategists. From 2010 to 2011, Dr. Lang worked at Grunenthal USA Inc. where he acted as Vice President, US Clinical Development. Prior to these positions, Dr. Lang worked at both Javelin Pharmaceuticals, Novartis Consumer Health and Johnson and Johnson. He received his M.D. from Ben Gurion University of the Negev in Israel, is licensed in both the United States and Israel and is board certified as an Anesthesiologist.

In connection with Dr. Lang’s appointment as the Company’s new Chief Medical Officer, the Company’s Board of Directors approved an increase to the available pool of ordinary shares reserved under the Company’s current share incentive plan and granted Dr. Lang options to purchase 110,500 of our ordinary shares at an exercise price of $6.30 per share.

Risk Factors

Investing in our ordinary shares and warrants involves risks. You should carefully consider the risks described in “Risk Factors” before making a decision to invest in our ordinary shares and warrants. 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 whether 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, if EB612 is approved, especially with respect to Natpara, our key competitor for hypoparathyroidism treatment;
- our recurring losses from operations, which 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 of and reimbursement for our product candidates, if approved;
- our being subject to ongoing regulatory obligations if our products secure regulatory approval and compliance therewith;
- 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 an 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 share 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

Units	The ordinary shares and warrants will be sold in units, with each unit consisting of one ordinary share and one warrant to purchase 0.5 of an ordinary share. The ordinary shares and warrants are immediately separable and will be issued separately, and are expected to trade separately following the effectiveness of the registration statement for this offering.
Ordinary shares offered by us and included in the Units	1,333,334 ordinary shares (or 1,533,334 ordinary shares if the underwriters exercise in full their option to purchase additional ordinary shares)
Ordinary shares to be outstanding after this offering	11,361,654 ordinary shares (or 11,561,654 ordinary shares if the underwriters exercise in full their option to purchase additional ordinary shares), in each case including 10,000 ordinary shares to be issued to the representative upon the closing of this offering).
Warrants offered by us and included in the Units	1,333,334 warrants, with each warrant exercisable for 0.5 of an ordinary share (or 1,533,334 warrants if the underwriters exercise in full their option to purchase additional warrants) at an initial exercise price of $11.25 per ordinary share (which is 125% of the assumed initial public offering price per unit), subject to adjustments as described herein. The warrants will be exercisable upon issuance and will expire five years after issuance, unless earlier repurchased by us or subject to early expiration as described herein. See "Description of Warrants." We are also offering the ordinary shares that are issuable upon the exercise of the warrants offered pursuant to this prospectus.
Over-allotment option to purchase additional ordinary shares and/or warrants	The underwriters have an option to purchase up to 200,000 additional ordinary shares and/or 200,000 additional warrants to purchase up to a total of 100,000 ordinary shares from us to cover over allotments, if any. The underwriters can exercise this option at any time and from time to time within 30 days from the date of this prospectus. The public offering price per unit corresponds to a public offering price per ordinary share of $8.99 and a public offering price per warrant of $0.01, which together constitute the midpoint of the estimated offering price range on the cover of this prospectus.
Use of Proceeds	We estimate that we will receive net proceeds of approximately $10.00 million from our sale of units in this offering, after deducting the estimated underwriting discount and the estimated offering expenses payable by us. This assumes an offering price of $9.00 per unit, 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 $9.2 million of cash and cash equivalents on hand as of March 31, 2018, as follows:

	• approximately $8.5 million to fund research and development expenses of our oral PTH candidate, EB612 required to conduct and complete the preparatory work for our planned Phase 2b/3 trial related to hypoparathyroidism; • approximately $7.0 million to fund research and development expenses of our oral PTH candidate, EB613 required to conduct our planned Phase 2a study related to osteoporosis; and • the remainder 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 and warrants.
Proposed Listing	We have applied to list our ordinary shares on the NASDAQ Capital Market under the symbol "ENTX". We have applied to list our warrants on the NASDAQ Capital Market under the symbol "ENTXW".

We have based the number of our ordinary shares to be outstanding immediately following this offering on 10,018,320 ordinary shares outstanding as of March 31, 2018, assuming there is no exercise of the warrants offered hereby and after giving effect to the 1-for- 130 split of our ordinary shares that will be effected immediately following the pricing of this offering (as described below) and after giving effect to the 10,000 ordinary shares (on a post-split basis) to be issued to the representative upon the closing of this offering, excluding:

- 3,573,700 ordinary shares issuable upon the exercise of options consisting of (i) options to purchase 3,186,170 ordinary shares under our 2013 Share Incentive Plan at a weighted average exercise price of $4.63 per share outstanding as of March 31, 2018 and (ii) options to purchase 343,070 ordinary shares granted to certain holders of our Series A preferred shares to be exercisable upon the closing of this offering and options to purchase 44,460 ordinary shares held by certain Series A preferred shares shareholder, at a weighted average exercise price of $3.69, as described below;
- 1,652,691 ordinary shares issuable upon exercise of other warrants, as described below;
- 1,363,398 ordinary shares reserved for future grants under the 2018 Equity Incentive Plan (the "2018 Plan"), which we intend to adopt in connection with this offering; and
- 66,667 ordinary shares issuable upon exercise of the representative's underwriter warrants as described under "Underwriting".

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

- no exercise of the outstanding options or warrants described above;
- no exercise of the warrants offered hereby;
- an initial public offering price of $9.00 per unit, 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 or the warrants issued to the representative in connection with this offering.

In addition, unless otherwise indicated, 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 Sixth Amended and Restated Articles of Association (the "amended Articles"), immediately upon the closing of this offering, to replace the current Articles;
- a 1-for- 130 split of our ordinary shares that will be effected immediately following the pricing of this offering (which ordinary share split is not reflected in our historical financial statements included in this prospectus);
- the automatic conversion of all of our issued and outstanding Series A preferred shares, par value NIS 0.01 per share, into 1,328,860 of our ordinary shares, par value NIS 0.0000769, upon the closing of this offering, as provided in our current Articles; the automatic conversion of all of our issued and outstanding Series B preferred shares, par value NIS 0.01 per share, into 1,856,790 of our ordinary shares, par value NIS 0.0000769, upon the closing of this offering, as provided in our current Articles; the automatic conversion of all of our issued and outstanding Series B-1 Preferred Shares, par value NIS 0.01 per share, into 1,719,770 of our ordinary shares, par value NIS 0.0000769, upon the closing of this offering, as provided in our current Articles; and
- the automatic conversion of all outstanding convertible loans under the Convertible Financing Agreements to which we are a party into 622,180 of our ordinary shares immediately prior to the closing of this offering, as described below in "Certain Relationships and Related Party Transactions";
- the automatic conversion of existing options to purchase 2,981 of our Series A preferred shares at an exercise price of $479.38 per share, into options to purchase 387,530 ordinary shares at a weighted average exercise price of $3.69 and warrants to purchase 661 of our Series A preferred shares, at an exercise price of $479.38 per share, into warrants to purchase 85,931 ordinary shares at a weighted average exercise price of $3.69 granted to certain holders of our Series A preferred shares that are exercisable upon the closing of this offering, as described below in "Certain Relationships and Related Party Transactions;
- the automatic conversion of warrants to purchase 2,640 of our Series A preferred shares, at an exercise price of $479.38 per share, into warrants to purchase 343,200 of our ordinary shares, at an exercise price of $3.69 per share; the automatic conversion of warrants to purchase 5,818 of our Series B preferred shares, at an exercise price of $908.78 per share, into warrants to purchase 756,340 of our ordinary shares, at an exercise price of $6.99 per share; and the automatic conversion of warrants to purchase 3,594 of our Series B-1 preferred shares, at an exercise price of $681.585 per share, into warrants to purchase 467,220 of our ordinary shares, at an exercise price of $5.24 per share, all upon the closing of this offering, as described below in "Description of Share Capital — Warrants."

Certain of our existing shareholders and parties affiliated with our existing shareholders have indicated an interest in purchasing an aggregate of up to approximately $5.0 million of the units in this offering at the initial public offering price per unit. However, indications of interest are not binding agreements or commitments to purchase, and these entities may determine to purchase a greater or lesser number of units than they have indicated an interest in purchasing or to not purchase any units in this offering. In addition, we and the underwriters could determine to sell a greater or lesser number of units to any of these entities than the entities have indicated an interest in purchasing or to not sell any units to these entities.

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 data for each of the years in the two-year period ended December 31, 2017 and the summary statements of financial position data as of December 31, 2017 are derived from our audited financial statements included elsewhere in this prospectus.

	Year Ended December 31,	
	2017	2016
	(In thousands, except shares and per share data)	
Statements of comprehensive loss:		
Research and development expenses	$ 2,768	$ 2,648
General and administrative expenses	8,575	2,719
Total operating loss	11,343	5,367
Financial income:		
Income from change in fair value of financial liabilities at fair value	(251)	(4,311)
Other financial expenses, net	105	143
Financial income, net	(146)	(4,168)
Net comprehensive loss	$ 11,197	$ 1,199
Loss per ordinary share[(1)]		
Basic	$ 324	$ 35
Diluted	$ 324	$ 102
Weighted average number of ordinary shares used in computing loss per ordinary share[(1)]		
Basic	34,544	34,409
Diluted	34,544	51,972
Pro forma loss per ordinary share[(2)] (unaudited)		
Basic	1.35	0.38
Diluted	1.39	0.65
Weighted average number of ordinary shares used in computing pro forma loss per share[(2)] (unaudited)		
Basic	8,573,391	7,366,662
Diluted	8,918,229	8,650,509

(1) Basic and diluted loss per ordinary share in 2017 are 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 included elsewhere in this prospectus for further details on the calculation of basic and diluted loss per ordinary share.

(2) Pro forma basic and diluted loss per ordinary share give effect to the 1-for-130 ordinary share split described in this prospectus and the assumed conversion of our outstanding convertible loans and preferred shares into ordinary shares upon the closing of this offering, but not the exercise of any

outstanding options or warrants, as though the conversion had occurred as of the beginning of the period or the original date of issuance, if later, and do not reflect the issuance of shares and warrants in connection with this offering.

	As of December 31, 2017		
	Actual	Pro forma(1)	Pro forma as Adjusted(2)
		(In thousands)	
Statements of financial position data:			
Cash and cash equivalents	$ 11,746	$11,746	$21,771
Other current assets	671	671	671
Total current assets	12,417	12,417	22,442
Property and equipment	207	207	207
Intangible assets	654	654	654
Total assets	$ 13,278	$13,278	$23,303
Accounts payable – Trade and other	2,020	2,020	2,020
Total current liabilities	2,020	2,020	2,020
Long-term convertible loans	3,893	—	—
Preferred shares	33,455	—	—
Warrants to purchase preferred shares and ordinary shares	5,398	—	2,240(3)
Severance pay obligations, net	70	70	70
Total liabilities	$ 44,836	$ 2,090	$ 4,330
Equity (capital deficiency)	$(31,558)	$11,188	$18,973
Working capital(4)	$ 10,397	$10,397	$20,422

(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 1,333,334 units at an assumed initial public offering price of $9.00 per unit, 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 (of which $85,000 was paid as of December 31, 2017).

(3) For accounting purposes, the warrants included in the Units offered hereby are classified as a financial liability considering, inter alia, certain adjustments to exercise price which do not meet the ‘fixed for fixed’ requirement of IAS 32 “Financial Instruments: Presentation.” Therefore, the warrants included in the Units offered are measured at fair value. The fair value of the warrants is estimated using the Monte Carlo simulation method. The main assumption used were ordinary share price of $7.32 which was valued based on the expected price of the Unit to be offered in this Offering, exercise price of $11.25 per share, expected volatility of 72%, risk free interest of 2.77% and dividend distributions of 0%.

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

RISK FACTORS

Any investment in our securities involves a high degree of risk. 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 and warrants. 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 our inception in 2009, including operating losses of $5.4 million and $11.3 million for the years ended December 31, 2016 and 2017. As of December 31, 2017, we had an accumulated deficit of $41.8 million.

Our audited financial statements for the year ended December 31, 2017 included elsewhere in this prospectus, note that there is substantial doubt about our ability to continue as a going concern, absent sources of additional liquidity. From October to December 2017, we raised $13.0 million from sales of our Series B preferred shares. In order to fund further operations, we will 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, seek 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 period 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 that generate significant market revenues. 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, completing pre-clinical and clinical trials for such 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, even if we do, we 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 for any of our product candidates that receive marketing approval, if any, 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, excluding the proceeds from this offering, will be sufficient to meet our anticipated working capital needs for at least the next four months, we believe that we would need to raise approximately $12.0 million in additional funds in order to fund our operations for at least 12 months, mainly to support our research and development programs for EB612 and EB613. We anticipate that our current resources, together with the proceeds from this offering, will be sufficient to meet our anticipated working capital needs for at least 12 months, although we expect that we would still need to raise additional funds to support the execution of our long-term growth strategy, including for our planned Phase 2b/3 trial of EB612 as well as further development, trials and commercialization of our product candidates. 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 to support our operations as a public company; 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 the units in this offering, and these financings, or disputes with pre-IPO shareholders in connection therewith, may restrict our operations or require us to relinquish substantial rights or otherwise be costly.

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 sources 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, and may be secured by all or a portion of our assets. 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 and such efforts may divert our management from their day-to-day activities, which may compromise our ability to develop and market our product candidates. 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 holders of our ordinary shares 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.” In addition, shareholders who invested prior to the Company’s initial public offering may raise claims concerning their pre-existing contractual rights as lenders or shareholders or oppose actions taken by the Company with respect to the terms of existing or future financing transactions. Any such dispute could be time-consuming or costly to the Company or require us to seek alternative financing arrangements.

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 plan to take advantage of these exemptions but we cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. 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.

We have applied to list our ordinary shares and warrants on the NASDAQ Capital Market and, although no assurance can be given that our application will be approved, we expect that our ordinary shares and warrants will be listed on the NASDAQ Capital Market prior to the completion of this offering. As a public company listed on the NASDAQ Capital Market, we will incur significant legal, accounting and other expenses that we did not incur prior to the listing of our ordinary shares on the NASDAQ Capital Market.

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 expect to grow our organization, particularly in the United States, specifically to supplement and expand our senior management, clinical development and regulatory capabilities and marketing infrastructure, and we may experience difficulties in managing these changes and this growth, which could disrupt our operations.

As our clinical development and commercialization plans and strategies develop, we expect to supplement and expand our employee base, particularly in the United States, for clinical development, regulatory, operational, sales, marketing, financial and other capabilities and with senior managers who are either based in the U.S. or who have significant U.S. public company experience. In particular, following this offering, we intend to make significant additions and changes to our executive management team. These changes may result in significant shifting of responsibilities or replacement of key personnel. The need to identify, recruit, maintain, motivate and integrate additional employees and senior members of management, including senior executives, is expected to impose significant responsibilities on our senior executives and may divert a disproportionate amount of their attention away from our day-to-day activities. The addition of such employees and managers may have an impact on the decisions that we make over time.

In conjunction with the addition of these employees and senior members of management, we intend to grow our company. Due to our limited financial resources and the limited experience of our management team, it is possible that our management, finance, development personnel, systems and facilities currently in place may not be adequate to support this future growth. 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. In addition, pursuant to both Israeli law and the NASDAQ Capital Market listing requirements, and in accordance with the applicable transition rules, we will be required to appoint additional independent directors, which may result in a change in the company's direction over time, as discussed in further detail in "Management — Board of Directors."

If we are unable to retain or hire additional qualified executive talent, our ability to grow our business may be harmed.

Following this offering, and as part of our efforts to grow our organization, we intend to add to our senior executive ranks. There can be no assurances concerning the timing or outcome of our search for new senior executive talent. Any transition in executive leadership can be inherently difficult to manage and may cause disruption to our business or loss of institutional knowledge, and our results of operations and financial condition could suffer as a result.

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 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, an additional oral PTH (1-34) product candidate, with significant modifications to dose and potentially to 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 at reasonable prices, or at all;
- 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.

Upon the completion and evaluation of our planned pharmacokinetic/pharmacodynamic, or PK/PD, clinical trial in EB612 and, subject to receipt of additional funding, we plan to initiate a Phase 2b/3 clinical trial of EB612 in hypoparathyroidism that would potentially support a submission for regulatory approval of EB612. For our EB613 product candidate in osteoporosis, our intent is to seek FDA guidance regarding our clinical trial design, endpoints and other parameters as part of a Pre-IND meeting with the FDA in the second half of 2018. We also plan in the future 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, the patient referral practices of physicians, changes 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;
- findings of an 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. The 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 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 no serious related adverse events 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 with a known mechanism of action, 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 no serious related adverse events 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.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a disruption of our drug development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from cyber-security threats, including computer viruses, harmful code and unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If a disruption event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

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 or otherwise makes a major contribution to patient care. 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, including the development time or regulatory review time of a drug.

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 10 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 otherwise 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 recombinant 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, 10 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 or otherwise makes a major contribution to patient care 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 otherwise makes a major contribution to patient care.

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 or take similar enforcement actions;
- 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, exclude products from federal healthcare programs, 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. 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. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. Although none of these measures have been enacted by Congress to date, Congress may consider other legislation to repeal and replace all or elements of the ACA. In December 2017, the Tax Cuts and Jobs Act was enacted and signed into law, one part of which repeals the “individual mandate” introduced by the ACA starting in 2019. The repeal of the “individual mandate” may have an adverse effect on ACA insurance markets and lead to further legislative changes. Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session. 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. In September 2017, Ascendis reported that it had initiated a Phase 1 trial with their drug in Australia. Ascendis expects to advance their drug directly into Phase 3 development in the first quarter of 2019.

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;
- collaborators may fail to comply with applicable laws, rules or regulations when performing services for us, which may expose us to legal proceedings 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 and Russia. Related patent applications are pending in the United States, the European Union, Hong Kong, Brazil, India, Israel, Canada, New Zealand and Russia. We have also filed five patent applications in various jurisdictions and one Patent Cooperation Treaty (PCT) application 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 and time consuming, and may ultimately be 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.

Emisphere Technologies, Inc., or Emisphere, has notified us that it believes that, among other things, it is the exclusive owner of certain U.S. and related foreign patents and patent applications we acquired from Oramed Ltd. We are currently investigating the merits of this claim. If Emisphere were to initiate a legal proceeding against us regarding its claim of ownership, we would vigorously defend against such claim. However, if Emisphere is ultimately successful in obtaining ownership of the patent rights that are the subject of its claim, then we may lose our ability to enforce such patent rights against any third party infringers. Moreover, if Emisphere is ultimately successful in obtaining ownership of such patent rights and could successfully demonstrate that, absent a license from Emisphere, our product candidates, including EB612, or technologies infringe such patent rights, then we would be required to redesign our product candidates or technologies so they are no longer infringing or obtain a license from Emisphere to such patent rights, which may not be available on commercially reasonable terms or at all. Even if we are successful in defending against Emisphere’s claim, litigation could result in substantial costs and be a distraction to management. 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 inventor 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, a significant portion of our intellectual property has been developed by our employees and consultants in the course of their employment or consulting relationship with us. Under the Israeli Patent Law, 5727-1967, inventions conceived by an employee or consultant during the scope of his or her employment or consulting relationship with a company are regarded as "service inventions." Even when our agreements with our employees and consultants include provisions regarding the assignment and waiver of rights to additional compensation in respect of inventions created within the course of their employment or consulting relationship with us, including in respect of service inventions, we cannot guarantee that such provisions will be upheld by Israeli courts, as a result of uncertainty under Israeli law with respect to the efficacy of such provisions. If we are required to pay additional compensation or face 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, Warrants and this Offering

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

The price of securities for 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, warrants 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 warrants; 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 or warrants prior to this offering, and an active market in our ordinary shares and warrants may not develop in which investors can resell our ordinary shares or warrants.

Prior to this offering there was no public market for our ordinary shares or warrants. Although we have applied to list our ordinary shares and warrants on the NASDAQ Capital Market and expect that our ordinary shares and warrants will be listed on the NASDAQ Capital Market prior to the completion of this offering, we cannot predict the extent to which an active market for our ordinary shares and warrants 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 or warrants. The initial public offering price of our ordinary shares and warrants 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 and warrants will trade following completion of this offering. Investors may not be able to sell their ordinary shares and warrants at terms that are attractive, if at all.

The warrants are speculative in nature and are a risky investment. You may not be able to recover your investment in the warrants, and the warrants may expire worthless.

The value of the warrants will depend on the value of our ordinary shares, which will depend on factors related and unrelated to the success of our clinical development program and cannot be predicted at this time.

If the price per share of our ordinary shares does not increase to an amount sufficiently above the applicable exercise price of the warrants during the period the warrants are exercisable, and if a public market for our warrants does not develop, the warrants may not have any value, and you may be unable to recover any or all of your investment in the warrants. There can be no assurance that the market price of the ordinary shares will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

Holders of the warrants will have no rights as shareholders until they acquire our ordinary shares.

Until you acquire our ordinary shares upon exercise of the warrants, you will have no rights with respect to our ordinary shares issuable upon exercise of the warrants, except as set forth in the warrants. Upon exercise of your warrants, you will be entitled to exercise the rights of a shareholder only as to matters for which the record date occurs on or after the exercise date, unless the warrants are settled via “cashless exercise” in which case you will be entitled to exercise such rights only after the end of the relevant calculation period (as defined under “Description of Warrants — Exercisability, Exercise Price and Term”).

Future sales by our shareholders may adversely affect our stock price and our ability to raise funds in new stock offerings.

Sales of our ordinary shares or warrants in the public market following this offering could lower the market price of our ordinary shares or warrants. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable or at all. Most of our outstanding ordinary shares and warrants will be restricted from resale immediately after the consummation of this offering. In the event of a sale of ordinary shares or warrants offered by selling shareholders, the price of our ordinary shares or warrants could decline, and such decline could be material.

Immediately following this offering, D.N.A Biomedical will beneficially own approximately 35% of our ordinary shares and may therefore be able to significantly influence 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 35% 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 and warrants could be negatively affected by future sales of our securities.

After this offering, we will have 11,361,654 ordinary shares outstanding. If we or our shareholders sell substantial amounts of our ordinary shares or warrants or if there is a public perception that these sales may occur in the future, the market price of our ordinary shares or warrants may decline. We, together with our directors, officers and our significant shareholders that, in the aggregate, beneficially own approximately 87.25% of our outstanding ordinary shares as of March 31, 2018, have agreed with the underwriters of this offering not to sell any ordinary shares, other than the shares offered through this prospectus and shares purchased in the open market, 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 units. 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 the units in this offering, you will suffer immediate dilution of your investment.

If you purchase the units in this offering, you will pay a price per unit that exceeds our pro forma as adjusted net tangible book value per ordinary share. You will experience immediate dilution of approximately $7.39 per ordinary share, representing the difference between our pro forma as adjusted net tangible book value per ordinary share of $1.61 as of December 31, 2017 and the assumed initial public offering price of $9.00 per unit (the midpoint of the estimated offering price range on the cover of this prospectus, not taking into account the value of the warrants included in such units or other warrants and options issued by the Company. Purchasers of the units in this offering will have contributed approximately 28.2% of the aggregate price paid by all purchasers of our ordinary shares but will own only approximately 11.7% 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 the NASDAQ Capital Market, we will follow certain home country governance practices rather than the corporate governance requirements of the NASDAQ Capital Market.

As a foreign private issuer, we have the option to follow certain Israeli corporate governance practices rather than those of the NASDAQ Capital Market, 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 NASDAQ Capital Market 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” with respect to the NASDAQ Capital Market compensation committee requirements, independent approval of board nominations, the requirement to have a majority of independent directors on our board, third party compensation of directors and director nominees and the requirement for independent directors to hold executive sessions. 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 NASDAQ Capital Market 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 the NASDAQ Capital Market 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.

There is a risk that we will 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 and on how quickly we utilize our cash in our business. Because (i) the value of our goodwill may be determined by reference to the market price of our ordinary shares, which may be volatile given the nature and early stage of our business, (ii) we expect to hold a significant amount of cash following this offering, and (iii) a company’s PFIC status is determined on an annual basis 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 (or under proposed Treasury regulations, warrants), 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 (or warrants) 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 following any year in which we achieve sales of over $70 million.

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 neighboring countries, 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 certain countries and have raised concerns regarding security in the region and the potential for armed conflict. In addition, Iran has threatened to attack Israel. Iran is also believed to have a strong influence among the Syrian government, Hamas and Hezbollah. These situations may potentially escalate in the future into 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. We could experience disruptions if acts associated with this conflict result in any serious damage to our facilities. Furthermore, several countries restrict business with Israel and Israeli companies, which could have an adverse effect on our business. Our business interruption insurance may not adequately compensate us for losses, if at all, that may occur as a result of an event associated with a security situation in the Middle East, 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 in some cases) 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, such judgment may not be enforced by an Israeli court.

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 and our amended Articles may give rise to withholding obligations or 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 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. 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.”

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, subject to certain exceptions, 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.

Our amended Articles provide that our directors (other than external directors) are elected on a staggered basis such that a potential acquirer cannot readily replace our entire board of directors at a single general shareholders meeting.

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 and our amended Articles.

Certain of the IPO Transactions that will be completed in connection with the closing of this offering may be treated, for Israeli income tax purposes, as taxable exchanges, which may give rise to withholding obligations applicable to us, absent a ruling or other written instructions issued by the Israel Tax Authority providing otherwise. We have not applied to the Israel Tax Authority for a ruling or other instructions with respect to any potential withholding obligations we may have in connection with such IPO Transactions. In the event that it is determined that we failed to withhold any applicable withholding tax in connection with such IPO Transactions, in addition to the liability to pay such taxes, we may be liable for payment of interest, and certain penalties and fines.

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 and our ability to fund our operations going forward;
- 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 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 $10.0 million from our sale of units in this offering (or approximately $11.7 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. The foregoing description of estimated net proceeds does not give effect to the proceeds, if any, from the potential exercise of the warrants offered hereby. This assumes an initial public offering price of $9.00 per unit, which is the midpoint of the estimated offering price range on the cover page of this prospectus.

As of March 31, 2018, we had cash and cash equivalents of $9.2 million. We intend to use the net proceeds from this offering, together with our cash and cash equivalents, as follows:

- approximately $8.5 million to fund research and development expenses of our oral PTH candidate, EB612 required to conduct and complete the preparatory work for our planned Phase 2b/3 trial related to hypoparathyroidism;
- approximately $7.0 million to fund research and development expenses of our oral PTH candidate, EB613 required to conduct our planned Phase 2a study related to osteoporosis; and
- the remainder 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 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 12 months. Following the completion of this offering, we will need additional capital for the Phase 2b/3 trial of our oral PTH candidate EB612 (following the preparatory work funded from the proceeds of this offering) and for other trials, marketing and sales development for EB612, if approved. 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. For additional information regarding our capital requirements, see “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.” under the heading “Risk Factors.”

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 $9.00 per unit, the midpoint of the range set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by approximately $1.2 million (or $1.4 million if the underwriters fully exercise their over-allotment option), assuming the number of units offered by us remains the same.

We may also increase or decrease the number of units we are offering. An increase (decrease) of 200,000 units offered by us would increase (decrease) our net proceeds from this offering by $1.66 million, assuming the public offering price per unit 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 units 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, 2017:

- 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; (b) our sale in this offering of 1,333,334 units (which does not include the 30-day option to purchase up to an additional 200,000 ordinary shares and/or 200,000 additional warrants to purchase up to a total of 100,000 ordinary shares that we have granted to the underwriters to cover over-allotments, if any, or the ordinary shares issuable upon exercise of the warrants offered hereby) at an assumed initial public offering price of $9.00 per unit, 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; and (c) the issuance of 10,000 ordinary shares to the representative upon the closing of this offering.

You should read this table together with our financial statements and the related notes included 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, 2017		
	Actual (Audited)	Pro forma	Pro forma as Adjusted
		(In thousands)	
Cash and cash equivalents	$ 11,746	$ 11,746	$ 21,771
Convertible loans	$ 3,893	$ —	$ —
Series A preferred shares of NIS 0.01 par value; 25,000 authorized, 10,222 issued and outstanding, actual; no authorized, no issued and outstanding, pro forma; no shares authorized, issued and outstanding, pro forma as adjusted	8,810	—	—
Series B preferred shares of NIS 0.01 par value; 35,000 authorized, 14,283 shares issued and outstanding, actual; no authorized, no issued and outstanding, pro forma; no shares authorized, issued and outstanding, pro forma as adjusted	12,980	—	—
Series B-1 preferred shares of NIS 0.01 par value; 17,000 authorized, 13,229 shares issued and outstanding, actual; no authorized, no issued and outstanding, pro forma; no shares authorized, issued and outstanding, pro forma as adjusted	11,665	—	—
Warrants to purchase preferred shares and ordinary shares	5,398	—	2,240[(1)]
Equity (capital deficiency):			
Ordinary shares; 1,000,000 authorized, 34,544 issued and outstanding, actual, of NIS 0.01 par value; 130,000,000 authorized, 10,018,320 issued and outstanding, pro forma of NIS 0.0000769 par value; 130,000,000 authorized, 11,361,654 issued and outstanding, pro forma as adjusted of NIS 0.0000769 par value;	*	*	*
Other comprehensive income	41	41	41
Other reserves	7,361	12,759	12,759
Additional paid-in capital	2,853	40,201	48,420
Accumulated deficit	(41,813)	(41,813)	(42,247)
Total equity (capital deficiency)	(31,558)	11,188	18,973
Total capitalization	$ 11,188	$ 11,188	$ 21,213

* represents an amount less than one thousand

(1) For accounting purposes, the warrants included in the Units offered hereby are classified as a financial liability considering, inter alia, certain adjustments to exercise price which do not meet the ‘fixed for fixed’ requirement of IAS 32 “Financial Instruments: Presentation.” Therefore, the warrants included in the Units offered are measured at fair value. The fair value of the warrants is estimated using the Monte Carlo simulation method. The main assumption used were ordinary share price of $7.32 which was valued based on the expected price of the Unit to be offered in this Offering, exercise price of $11.25 per share, expected volatility of 72%, risk free interest of 2.77% and dividend distributions of 0%.

The number of shares listed in the table above does not reflect:

- 3,573,700 ordinary shares issuable upon the exercise of options outstanding as of March 31, 2018 and issuable upon the closing of this offering, at a weighted average exercise price of $4.53 per share;
- 1,652,691 ordinary shares issuable upon the exercise of warrants and options outstanding as of March 31, 2018 and issuable upon the closing of this offering, at a weighted average exercise price of $5.64 per share; and
- 666,667 ordinary shares issuable upon exercise of the warrants offered hereby; and
- 66,667 ordinary shares issuable upon exercise of the representative’s underwriter warrants as described in “Underwriting”.

DILUTION

Our historical net tangible book value (deficit) as of December 31, 2017, was ($32.2 million), or ($7.17) 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 4,490,720 issued and outstanding ordinary shares as of December 31, 2017.

Our pro forma net tangible book value as of December 31, 2017, was $10.5 million, or $1.05 per share. Pro forma net tangible book value 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 10,018,320 issued and outstanding ordinary shares as of December 31, 2017, after giving pro forma effect to the IPO Transactions, as described in "Summary — The Offering."

After giving effect to the IPO transactions and the sale by us of the 1,333,334 units in this offering (which does not include the 30-day option to purchase up to an additional 200,000 ordinary shares and/or 200,000 additional warrants to purchase up to a total of 100,000 ordinary shares that we have granted to the underwriters to cover over-allotments, if any, or the proceeds, if any, we may receive from the exercise of the warrants issued pursuant to this offering and/or the warrants issued to the representative in connection with this offering), at an assumed initial public offering price of $9.00 per unit, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and to the issuance of 10,000 shares to the representative immediately following this offering, our pro forma as adjusted net tangible book value at December 31, 2017, would have been $18.3 million, or $1.61 per share. This represents an immediate increase in pro forma as adjusted net tangible book value to existing shareholders of $0.56 per share and immediate dilution to new investors of $7.39 per share.

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

Assumed initial public offering price per ordinary share		$9.00
Pro forma as adjusted net tangible book value per ordinary share	$1.05	
Increase in pro forma net tangible book value per share attributable to this offering	$0.56	
Dilution per ordinary share to new investors in this offering		$7.39

A $1.00 increase (decrease) in the assumed initial public offering price of $9.00 per unit, 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 at December 31, 2017 by approximately $1.2 million, or approximately $0.11 per share and the dilution to new investors of $0.89 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 100,000 units offered by us would result in pro forma as adjusted net tangible book value at December 31, 2017 of approximately $19.0 million, or $1.66 per share, and dilution to new investors of $7.34 per share, assuming the public offering price per share remains the same. Similarly, a decrease of 100,000 units offered by us would result in pro forma as adjusted net tangible book value at December 31, 2017 of approximately $17.7 million, or $1.57 per share, and dilution to new investors of $7.43 per share, assuming the public offering price per unit 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, 2017, on a pro forma as adjusted basis, the number of units 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 $9.00 per unit, 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 (thousands)		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing shareholders	10,018,320	88.2%	$30,532	71.8%	$3.0
Representative shares	10,000	0.1%	—	—	—
New investors	1,333,334	11.7%	12,000	28.2%	9.0
Total	11,361,654	100%	$42,532	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, 2017 or the warrants issued to the representative in connection with this offering. At March 31, 2018 and after giving effect to the IPO Transactions and the stock split, 3,573,700 ordinary shares were subject to outstanding options at a weighted average exercise price of $4.53; warrants to purchase 429,331 ordinary shares were outstanding, at an exercise price of $3.69 per share; warrants to purchase 756,340 ordinary shares were outstanding, at an exercise price of $6.99 per share; and warrants to purchase 467,220 ordinary shares were outstanding, at an exercise price of $5.24 per share. 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 will be $19.6 million, or $1.70 per share (assuming an initial public offering price of $9.00 per unit, the midpoint of the estimated offering price range set forth on the cover page of this prospectus), representing an immediate increase in pro forma as adjusted net tangible book value of approximately $0.09 per share attributable to this offering to our existing shareholders and immediate dilution of $0.09 per share to new investors purchasing units 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 June 11, 2018, the exchange rate as reported by the Bank of Israel was NIS 3.5720 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
2017	3.4670	3.5997	3.4670	3.8600
Month Ended:				
January 31, 2018	3.4050	3.4232	3.3880	3.4600
February 28, 2018	3.4850	3.4944	3.4270	3.5350
March 31, 2018	3.5140	3.4689	3.4310	3.5140
April 30, 2018	3.5880	3.5385	3.5030	3.5970
May 31, 2018	3.5660	3.5910	3.6540	3.6320
June (through June 11, 2018)	3.5720	3.5697	3.5650	3.5750

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, 2017 and the selected statements of financial position data as of December 31, 2017 are derived from our audited financial statements included elsewhere in this prospectus.

	Year Ended December 31,	
	2017	**2016**
	(In thousands, except shares and per share data)	
Statements of comprehensive loss:		
Research and development expenses	$ 2,768	$ 2,648
General and administrative expenses	8,575	2,719
Total operating loss	11,343	5,367
Financial income:		
Income from change in fair value of financial liabilities at fair value	(251)	(4,311)
Other financial expenses, net	105	143
Financial (income) expenses, net	(146)	(4,168)
Net comprehensive loss	$11,197	$ 1,199
Loss per ordinary share[(1)]		
Basic	$ 324	$ 35
Diluted	$ 324	$ 102
Weighted average number of ordinary shares used in computing basic loss per ordinary share[(1)]	34,544	34,409
Weighted average number of ordinary shares used in computing diluted loss per ordinary share[(1)]	34,544	51,972

(1) Basic and diluted loss per ordinary share in 2017 are 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 included elsewhere in this prospectus for further details on the calculation of basic and diluted loss per ordinary share.

	As of December 31, 2017
	(In thousands)
Statements of financial position data:	
Cash and cash equivalents	11,746
Other current assets	671
Total current assets	12,417
Property and equipment	207
Intangible assets	654
Total assets	$ 13,278
Accounts payable-Trade and other	2,020
Total current liabilities	2,020
Long term convertible loans	3,893
Preferred shares	33,453
Warrants to purchase preferred shares and shares	5,398
Severance pay obligations, net	70
Total liabilities	$ 44,836
Capital deficiency	$(31,558)
Working capital[(1)]	$ 10,397

(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 clinical-stage 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. We are planning to conduct a clinical trial to evaluate the PK/PD profile of various EB612 dose regimens in the second half of 2018. Upon the completion and evaluation of our planned PK/PD clinical trial and subject to receipt of additional funding, we expect in the future to initiate a Phase 2b/3 clinical trial of EB612 in hypoparathyroidism which would potentially support a submission for regulatory approval of EB612. The FDA and the EMA have granted EB612 orphan drug designation for the treatment of hypoparathyroidism. We are also developing an additional oral PTH product candidate, EB613, for the treatment of osteoporosis. Our intent is to seek FDA guidance on our proposed clinical trial design as part of a Pre-IND meeting in the second half of 2018, followed by an additional Phase 2a dose finding clinical trial. 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. We intend to utilize future funds, as available, to prepare EB612 for advanced clinical studies and ultimately for regulatory approval.

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, we have raised an aggregate of $31.3 million to fund our operations, including $7.2 million from sales of our ordinary shares, Series A preferred shares and warrants, $10.6 million from convertible loans (of which an amount of approximately $1.0 million ($1.1 million including interest) was repaid in February 2017) and $8.5 million ($9.0 million including interest) was converted in October 2017 into Series B-1 preferred shares, $13.0 million from sales of our Series B preferred shares from October to December 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., 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, 2016 and 2017, our operating losses were $5.4 million and $11.3 million, respectively. We expect to continue to incur significant expenses and losses for the next several years. As of December 31, 2017, we had an accumulated deficit of $41.8 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 March 31, 2018, we had cash and cash equivalents of $9.2 million. In order to fund further operations, we will 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, 2017, included elsewhere in this prospectus, note 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 March 31, 2018, we had 19 employees, one consultant who provides consulting services to us on a full-time basis and two consultants who provide services to us on a part-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 as well as in a facility belonging to our fully-owned subsidiary in New Jersey.

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 rights, 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 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 following any year in which we achieve sales of over $70 million.

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. In addition, as disclosed under "Business — Manufacturing," we have signed a contract with a UK-based contract manufacturing organization, to produce and supply pills for trials performed worldwide. We believe that, because production is not being done for commercial purposes, the entry into the production agreement in the UK will not affect the royalty rates to be paid to the IIA. Should it turn out that this position is not acceptable to the IIA, the maximum royalties to be paid to the IIA will be approximately $1.5 million, which is three times the amount of the original grants of $0.5 million.

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, 2016 and 2017, 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, 2016 and December 31, 2017, our research and development expenses were $2.6 million and $2.8 million, respectively. Research and development expenses for the years ended December 31, 2016 and 2017 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. 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 and certain expenses with respect to this offering.

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

Financial income is comprised mainly of gains resulting from the re-measurement of our convertible loan, Series A preferred shares, warrants to purchase Series A preferred shares and ordinary shares, Series B preferred shares issued from October to December 2017 and Series B-1 preferred shares issued as a result of the conversion of the Convertible Loans. We will continue to record adjustments to the estimated fair value of the convertible loans, preferred shares, warrants to issue preferred shares and ordinary shares 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, 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. Under the terms of the applicable agreements and pursuant to the IPO Transactions, 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 the closing of this offering. From October to December 2017, we raised a total of $13.0 million from sales of our Series B preferred shares ($12.1, net of issuance costs). In connection with the Series B Private Placement, the 2016 Convertible Loans were converted to our Series B-1 preferred shares.

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, 2017 had carry-forward tax losses of $15.3 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 our ordinary shares 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 2016 and 2017, 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 the applicable discount rate, projected commencement of sales and the probability of reaching sales. Following the Series B Private Placement, the fair value of our ordinary shares was based on the market approach and used a price per share of $908.78 per Series B preferred share from the Company’s preferred share issuance starting in October 2017 as a basis for fair market value.

Following this offering, the fair value of our ordinary shares and warrants will be determined based on the closing price of our ordinary shares and warrants on the NASDAQ Capital Market.

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,	
	2017	2016
	(in thousands)	
Research and development	$ 323	$ 130
General and administrative	4,562	1,360
Total	$4,885	$1,490

Fair Value of Financial Liabilities Through Profit or Loss

The Series A preferred shares and warrants to purchase Series A preferred shares, Series B preferred shares and Series B-1 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. To determine the fair value of the convertible loans, 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, subject to adjustment), were evaluated based on a combination of the probability weighted expected return method and the back solve option pricing method model.

To determine the fair value of the preferred shares, warrants to purchase Series A preferred shares and warrants to purchase Series B preferred shares and Series B-1 preferred shares, we prepared a valuation of the fair value of each of these components. The components were evaluated using a combination of the probability weighted expected return method and the back solve option pricing method model.

As of December 31, 2017, the valuation of the Company’s financial liabilities was based on the market approach and used a price per share of $908.78 per Series B preferred share from the Company’s preferred share issuance starting in October 2017 as a basis for fair market value. The value of equity as of December 31, 2016 was based on the valuation of cash generating unit based on DCF.

The following parameters were used:

	December 31,	
	2017	2016
Preferred B price per share*	$908.78	
Value of equity*	$78 million	$71 million
Volatility	55%	77%
Probability of entering Phase 2b/3 trial for EB612	70%	70%
Probability for IPO/shares registration	85%	50%

* The value of equity as of December 31, 2017 was based on the market approach as described above. The value of equity as of December 31, 2016 was based on the valuation of cash generating unit based on DCF. The value of equity includes ordinary shares, preferred shares, warrants and options to preferred shares and shares.

The primary assumptions used in the DCF valuations are as follows:

	December 31, 2016
WACC	22%
Commencement of sales	2021 – 2025
Probability of reaching sales	20.1% – 37.9%

The weighted average cost of capital in the DCF model used to evaluate the equity as of December 31, 2016, 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
Risk free(1)	0.99%
Market premium(2)	5.69%
Specific risk(3)	16.29%
Beta(4)	0.84
WACC	22%

(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 our 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.

Results of Operations

Comparison of Years Ended December 31, 2017 and 2016

	Year Ended December 31,		Increase (Decrease)	
	2017	2016	$	%
	(In thousands, except for percentage information)			
Expenses:				
Research and development	$ 2,768	$ 2,648	$ 120	4.5%
General and administrative	8,575	2,719	5,856	215.4%
Operating loss	11,343	5,367	5,976	111.4%
Financial income, net	(146)	(4,168)	4,022	—
Net loss (income)	$11,197	$ 1,199	$9,998	—

Research and development expenses. Research and development expenses for the year ended December 31, 2017 were $2.8 million, compared to $2.6 million for the year ended December 31, 2016, an increase of $0.2 million, or 4.5%. The increase in research and development expenses was primarily due to an increase of $0.6 million in expenses for salaries and related employee expenses resulting mainly from an increase in salaries and bonuses (of which $0.2 million represented an increase in share-based compensation expenses), offset by $0.3 million primarily due to lower expenses for materials and decrease of $0.1 million in expenses for subcontractors and CROs.

General and administrative expenses. General and administrative expenses for the year ended December 31, 2017 were $8.6 million, compared to $2.7 million for the year ended December 31, 2016, an increase of $5.9 million, or 215.4%. The increase in general and administrative expenses was primarily due to an increase of $3.7 million in salaries and related employee expenses of which $3.2 million resulted from an increase in share-based compensation expenses, $1.1 million issuance costs of preferred B shares and $1.0 million in professional and other expenses related to the Company's initial public offering expenses.

Financial income expenses, net. Financial income, net for the year ended December 31, 2017 was $0.1 million, compared to financial income, net of $4.2 million for the year ended December 31, 2016. Financial income, net for the year ended December 31, 2017 resulted mainly from the change in the fair value of convertible loans, preferred shares, warrants to purchase Series A preferred shares and warrants to purchase Series B preferred shares that were recorded as a financial liability at fair value through profit or loss. During the years ended December 31, 2017 and 2016, we recorded a gain of $0.25 million and $4.3 million, 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 2017, our operating losses were $5.4 million and $11.3 million, respectively. In addition, during the years ended December 31, 2016 and 2017 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, 2017, we had an accumulated deficit of $41.8 million. Since our inception and through December 31, 2017, we have raised a total of $31.3 million, including $7.2 million from sales of our ordinary shares, Series A 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, $10.6 million from convertible loans (of which an amount of approximately $1.0 million ($1.1 million including interest) was repaid in February 2017) and an amount of $8.5 million ($9.0 million including interest) was converted in October 2017 to Series B-1 preferred shares), $13.0 million from sales of our Series B preferred shares from October to December 2017 and $0.5 million from IIA grants. As of March 31, 2018, we had cash and cash equivalents of $9.2 million. 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 estimate 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 12 months, during which we intend to conduct various development work designed to support advanced clinical trials such as the Phase 2b/3 clinical trial with EB612 and to conduct our planned Phase 2a trial with EB613 that may potentially support regulatory submissions for market approval.

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, 2017, included elsewhere in this prospectus, note 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

Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

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

	(audited) Year ended December 31,	
	2017	**2016**
	(in thousands)	
Cash used in operating activities	$ (4,526)	$(3,142)
Cash provided by (used in) investing activities	1,002	(1,116)
Cash provided by financing activities	11,107	7,216
Net increase in cash and cash equivalents	$ 7,583	$ 2,958

Net Cash Used in Operating Activities

Net Cash used in operating activities for the year ended December 31, 2017 was $4.5 million and consisted primarily of our operating loss of $11.3 million arising mainly from research and development expenses and general and administrative expenses, partially offset by $4.9 million of share-based compensation, $1.1 million of issuance costs related to preferred B shares, of which $0.9 million in issuance costs in cash was related to investing activities, and by a $0.9 million decrease in working capital.

Net 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 activities and general and administrative expenses, partially offset by $1.5 million of share-based compensation and by $0.4 million decrease in working capital.

The increase in cash used in operating activities from 2016 to 2017 was mainly due to an increase of $0.5 million in expenses for salaries and related employee expenses and $0.5 million for services. In addition, there was an increase in professional services costs of $0.6 million, mainly related to the initial public offering process.

Net Cash Provided by (Used in) Investing Activities

Net Cash provided by investing activities for the year ended December 31, 2017 consisted primarily of a decrease in restricted deposits of $1.1 million used for the repayment of a portion of the 2015 Convertible Loan in February 2017.

Net 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.

Net Cash Provided by Financing Activities

Net Cash provided by financing activities for the year ended December 31, 2017 resulted from net proceeds of $12.1 million from the issuance of preferred B shares during October and December 2017 and a $1.0 million decrease from the repayment of a portion of the 2015 Convertible Loan.

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

Contractual Obligations and Commitments

The following tables summarize our contractual obligations and commitments as of December 31, 2017 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	$ 231	$ 98	$133	$—	$ —
2012 Convertible Loans	1,288	34	—	—	1,254
Total	$1,519	$132	$133	$—	$1,254

Convertible Loans

2012 Convertible Loan

On November 8, 2012 and December 31, 2012, we entered into loan agreements with certain lenders, or 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 paid every five years, and are due and payable after a term of 20 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 (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 closing of this offering, and therefore these loans will no longer be outstanding after this offering.

2015 Convertible Loan

On August 5, 2015, we entered into a Convertible Promissory Note and Loan Agreement with certain lenders, or the 2015 Convertible Loan. 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. Under its terms, the 2015 Convertible Loan was to be automatically converted into shares upon the occurrence of the following events, each a 2015 Triggering Event: 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. 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, we issued to each lender under the 2015 Convertible Loan warrants, or 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 upon a 2015 Triggering Event at an exercise price of 125% of the applicable price per share. The 2015 Warrants were exercisable for the earlier of two years from the warrant issuance date or one year from the consummation of an initial public offering. As part of the 2016 Convertible Loan as discussed 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 remainder, in an amount of $1.053 million (including interest and principal), was repaid by us in February 2017. There are no amounts outstanding under the 2015 Convertible Loans, and none of the 2015 Warrants remain outstanding, and as a result, the 2015 Convertible Loan agreement is no longer in force.

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, or the 2016 Convertible Loan. In addition, an amount of $1.057 million of the 2015 Convertible Loan rolled over to the 2016 Convertible Loan. The 2016 Convertible Loan provided for a term of 18 months and bore interest at a rate of 5% per year. The 2016 Convertible Loan also granted each lender 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 in such issuance.

The 2016 Convertible Loan was to be automatically converted into shares upon the occurrence of any of the following events, each a 2016 Triggering Event: an initial public offering in which we raise at least $20 million, a private placement of our equity securities in an aggregate amount of not less than $10 million, or a change of control. In addition, we 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.

Following the completion of the Series B preferred shares purchase agreement (as discussed below), which constituted a 2016 Triggering Event, the loan amount, together with all accrued interest, was converted into Series B-1 preferred shares. In addition, the Series B preferred shares purchase agreement set the price and the amount of shares for which the holders of the previously issued 2016 Warrants (as described below) are entitled to exercise their 2016 Warrants. The 2016 Warrants are exercisable until June 2020, and will be exercisable into an aggregate of 687,960 ordinary shares following the completion of this offering.

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, 2017, our severance pay liability, net was $70,000. 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 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 implementation of this standard is not expected to have a material impact on our ,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. We are currently evaluating the impact of adoption of this standard on our 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. Given that we currently report and expect to continue to report our financial results 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.

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.

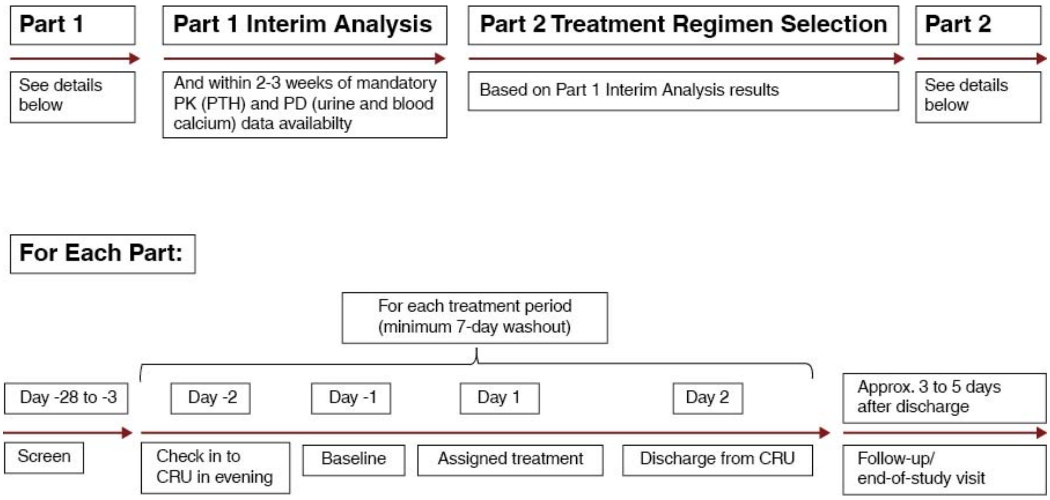
BUSINESS

We are a clinical-stage 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. We are planning a clinical trial to evaluate the PK/PD profile of various EB612 dose regimens for the second half of 2018. In the future, after the completion and evaluation of our planned PK/PD clinical trial and subject to available funds, we expect to initiate a Phase 2b/3 clinical trial of EB612 in hypoparathyroidism, which would potentially support a submission for regulatory approval of EB612. The FDA and the EMA have granted EB612 orphan drug designation for the treatment of hypoparathyroidism. We intend to utilize future funds, as available, to prepare EB612 for advanced clinical studies and ultimately for regulatory approval.

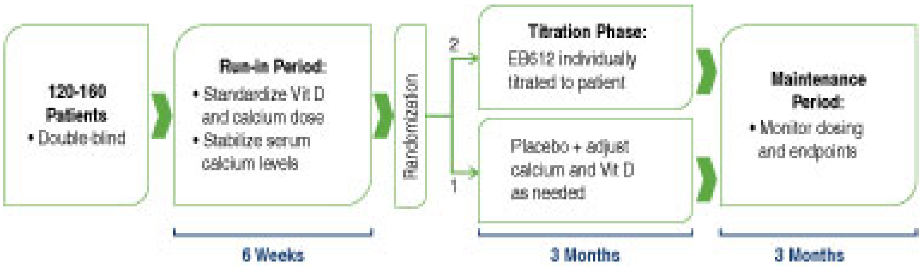
Hypoparathyroidism is a rare condition in which the body does not produce sufficient amounts of PTH, or the PTH produced lacks biologic activity. Individuals with a deficiency of PTH typically exhibit abnormally low levels of calcium in the blood, or hypocalcemia, and high levels of phosphorus, or hyperphosphatemia. Hypoparathyroidism is estimated to affect approximately 58,700 insured 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. Studies performed by researchers at 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 once-daily dosing. In addition, 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 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 the potential for similar efficacy, a result that we plan to confirm by conducting a Phase 2b/3 trial, which will further evaluate the dosage, effectiveness and safety profile of EB612 in an expanded patient population at multiple trial sites. We believe that EB612 will have inherent advantages compared to injectable forms, including convenience of application, that no special preparation is required and that it can be stored under convenient storage conditions (room temperature or refrigeration for long term storage). Additionally, based on the results of our preliminary studies, 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. If our preliminary results are borne out in additional trials, 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 have begun planning for a future Phase 2b/3 trial, designed to possibly be a pivotal study for registration. We expect that this Phase 2b/3 study, when initiated, will be designed to replicate the REPLACE study in many aspects and to achieve a significant reduction in urinary calcium.



Proposed design for EB612 PK/PD study



Proposed design for EB612 Phase 2b/3 pivotal trial

We are also developing an 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 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 delivered orally, 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.

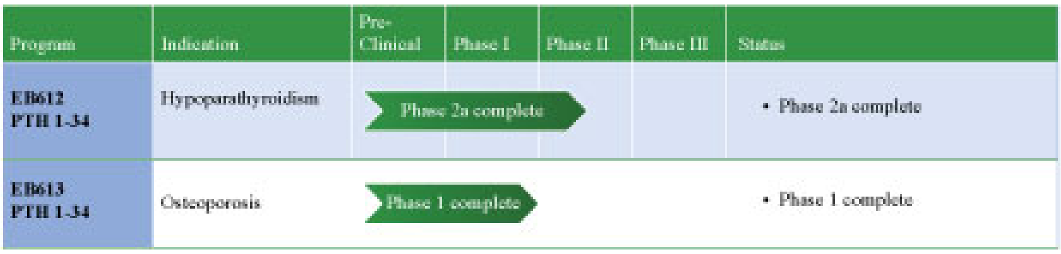
We intend to pursue approval of EB613 utilizing the alternative Section 505(b)(2) pathway permitted under the Federal Food, Drug and Cosmetic Act. Based on recent changes in guidance issued by the FDA and the similarity of our product's PK profile, to that of Forteo, we believe it is feasible to complete an NDA submission for EB613 with one or two pivotal Phase 3 studies, conducted with approximately 400 – 500 osteoporosis patients, that will examine bone mineral density and particular biochemical markers of bone activity. These studies would be conducted in anticipation of a 505(b)(2) application to the FDA and would include a comparison to the currently marketed drug, Forteo. In pursuit of this pathway, our intent is to seek FDA guidance as part of a Pre-IND meeting in the second half of 2018. Based on the responses of the FDA, we intend to conduct a dose ranging Phase 2a study in approximately 150 osteoporosis patients. Following analysis of this data, we intend to design and execute pivotal trial(s) in osteoporosis patients guided by the feedback of the FDA. We currently do not anticipate that the FDA will request that we examine the effects on bone mineral density in these trials past 12 months. We therefore believe that this alternative pathway will be significantly shorter than a pathway that utilizes bone fracture studies in significantly larger numbers of patients over greater periods of time.

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 in the future.

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.



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 in coming years to build a substantial U.S. presence to execute on the later stage development of our products, including by expanding our executive management team, 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 are planning a clinical trial to evaluate the PK/PD profile of various EB612 dose regimens for the second half of 2018. Upon the completion and evaluation of our planned PK/PD clinical trial and subject to receipt of additional funding, we expect to initiate a Phase 2b/3 clinical trial of EB612 in hypoparathyroidism which would potentially support a submission for regulatory approval of EB612.

- *Produce supportive clinical data for our second product candidate, EB613, for the treatment of osteoporosis, before advancing into late-stage clinical trials*: Our intent is to seek FDA guidance on our proposed clinical trial design as part of a Pre-IND meeting in the second half of 2018. After we receive feedback from the FDA, we intend to conduct a Phase 2a dose finding study in osteoporosis patients in 2019.

- *Leverage our expertise in the oral delivery of PTH to develop product candidates in additional indications*: In the future, 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 or to license our technology to third parties for their additional indications.

- *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 known mechanisms of action, 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 study head to head with Natpara in hypoparathyroid patients expected in H2 2018
EB613	Osteoporosis	Oral PTH (1-34)	Phase 1	Pre-IND submission expected H2 2018 Phase 2a initiation expected 2019

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 10 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 oral PTH (1-34) tablet programs 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. 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 insured 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 once-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.

- *EB612 is 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, except potentially for refrigeration.

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 PK profiles and 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, administration parameters 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 confirmed related serious or significant adverse events as defined by the study protocol.

Throughout the above clinical trials, various formulations were evaluated to achieve an optimal formulation with minimal variability and maximal bioavailability. The various formulations were based on the same basic components and presented a similar pharmacokinetic profile. We believe that the optimal formulation is more likely to attain regulatory approval.

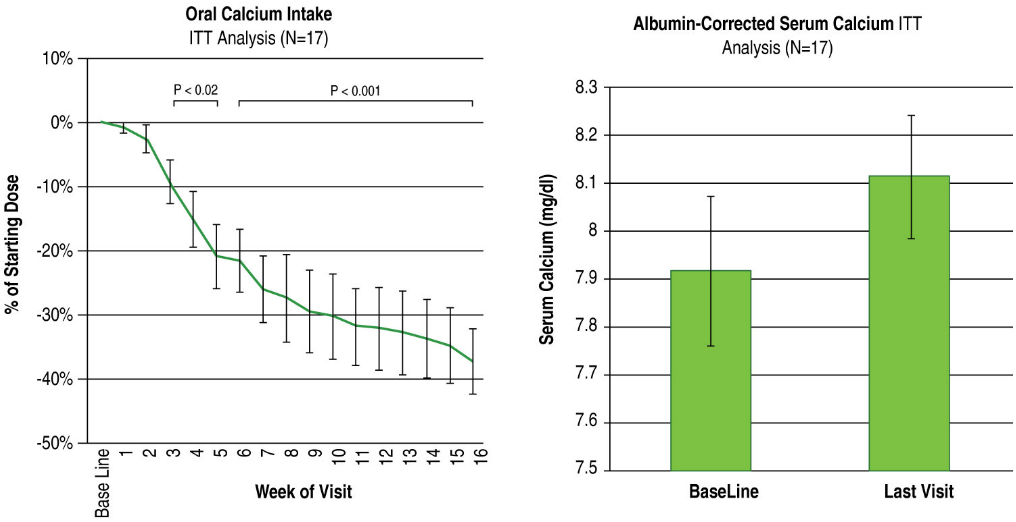
We believe that EB612 will have inherent advantages compared to injectable forms, including convenience of application, that no special preparation is required and that it can be stored under convenient storage conditions (room temperature or refrigeration for long term storage). Additionally, based on the results of our preliminary studies, 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. If our preliminary results are borne out in additional trials, we believe this combination of advantages and long term clinical benefits will be very compelling to both patients and physicians.

Phase 2a Clinical Trial

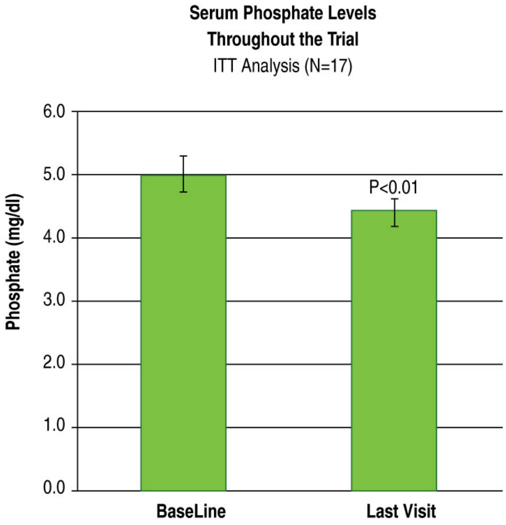
In 2015, we successfully completed a Phase 2a clinical trial of EB612 in hypoparathyroidism patients. The end points in the trial were met, and 17 subjects completed the four-month trial and reported no related serious adverse events.

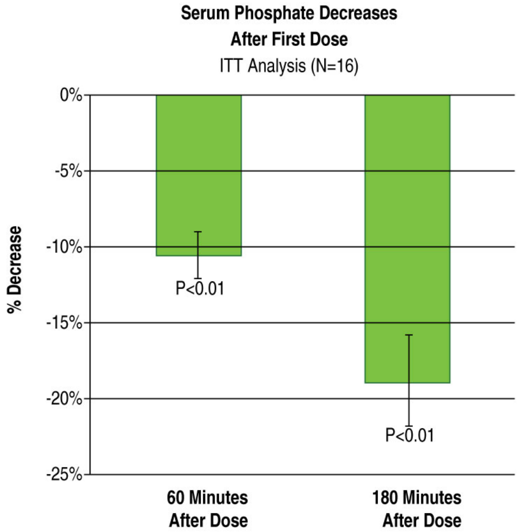
While we have not conducted direct head-to-head studies comparing EB612 to Natpara, based on a review of the clinical data presented in Natpara's REPLACE study and our Phase 2a results, we believe EB612 potentially provides a more favorable therapy for hypoparathyroidism patients. Although our Phase 2a study involved a smaller number of subjects (N=17 vs. N=84 + 40 placebo), lasted for a shorter duration (four months vs. six 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). In addition, serum phosphate levels were significantly reduced into their normal range an hour after the first study drug was taken (11% reduction, p<0.01), and lower serum phosphate levels were maintained for the duration of the study and until the final treatment day (14% reduction, p<0.01). Furthermore, based on our preliminary results from our Phase 2a trial, as compared to Natpara injection, we believe that EB612 may carry a lower risk of adverse events.

Primary endpoints: Calcium intake reduced while serum levels were maintained or improved during Phase 2a



Secondary endpoints: *decrease in phosphate levels observed during Phase 2a*





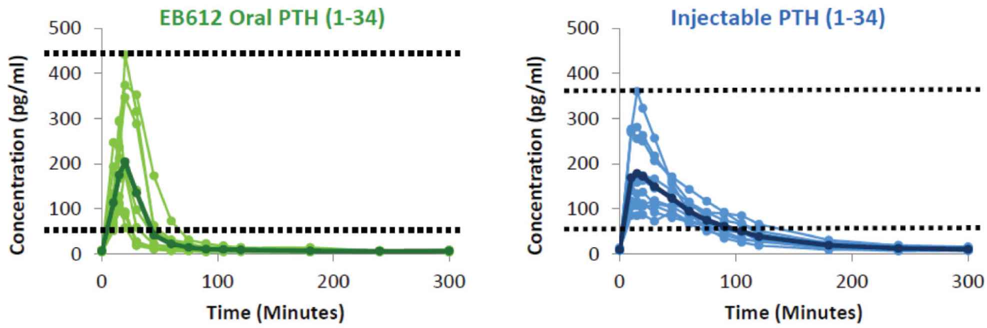
In the Phase 2a trial there were no confirmed related serious or significant adverse events as defined by the study protocol. There was one unrelated serious adverse event of hypercalcemia which occurred in one patient prior to the administration of the study drug for the first time. One other subject, who withdrew from the trial in the first day, complained of multiple general symptoms including nausea and pain prior to commencing the trial and experienced four adverse events (mild nausea, moderate back pain, moderate headache and moderate upper abdominal pain). These four adverse events could not be confirmed as related following the patient's withdrawal from the study. They were recorded as 'possibly related.'

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. We expect that this Phase 2b/3 study, when initiated, will be designed to replicate the REPLACE study in many aspects and to achieve a significant reduction in urinary calcium. The planned primary endpoints will be a reduction in calcium intake, reduction in active vitamin D and a serum calcium level of 7.5 – 9.5 mg/dL. A key secondary endpoint, which is relevant for the subset of patients with hypercalcemia, will be a reduction in urinary calcium. Finally, other secondary endpoints include a reduction in serum phosphate.

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 was 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 were administered during eight to 14 successive visits, each separated by at least a 48-hour washout period. The different formulations include modifications in PTH dose (0.5mg – 3.0mg) 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. The optimized formulation and the various formulations evaluated throughout the clinical trial were all based on the same components and within a predefined range.



Formulation	Participants	Cmax (pg/ml)	Tmax (min)	Coefficient of Variation (%)
EB612 Oral PTH	10	235.6 ± 36	16.5 ± 1.2	48
Injectable PTH	10	184.2 ± 26	16 ± 1.8	45

Low inter- and intra-patient variability observed in EB612 Phase 1b

Phase 1a Clinical Trial

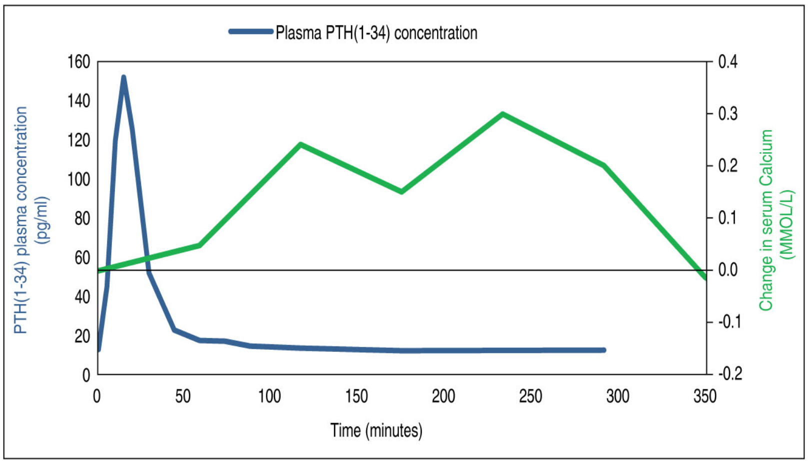
Following proof-of-concept and safety studies in various animal models, we conducted a Phase 1a clinical trial to assess the safety and pharmacokinetic profile of our oral PTH. The clinical trial was designed as a three-stage study in 42 healthy volunteers. The first stage, in which 24 subjects participated, 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. The various formulations evaluated throughout the clinical trial were all based on the same components and within a predefined range. 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 serious 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). In total across our Phase 1 clinical trials in which these 72 subjects received various oral PTH doses over 350 times, there were 11 expected, transient and minor drug-related adverse events associated with oral PTH administration. In our Phase 1b trial, there were minor drug-related adverse events such as minor hypercalcemia in two subjects, minor tachycardia in three subjects, headache in two subjects and hypothermia in one subject. There were also two possibly related mild adverse events in our Phase 1a trial: anemia in one subject and nausea in one subject. In addition, one subject in the Phase 1a trial experienced a drug-related musculoskeletal and connective tissue event of knee cramps.

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 the optimized 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.

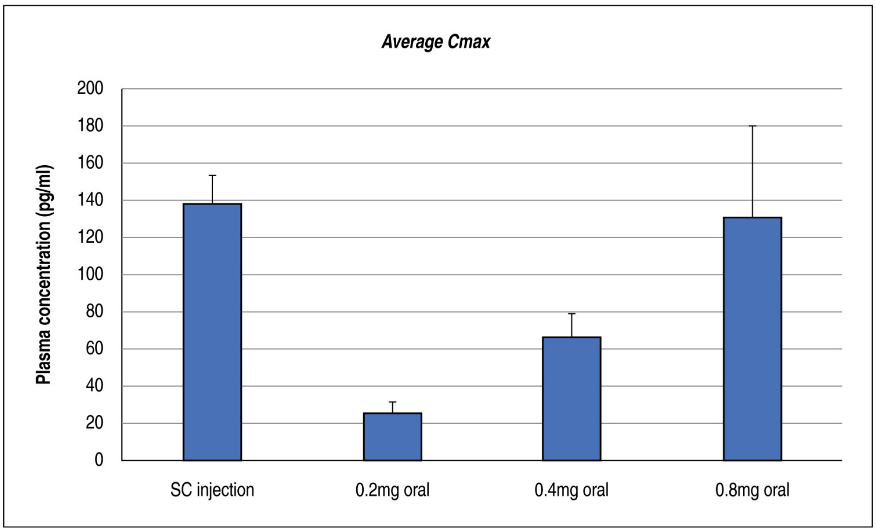
Analysis of the PD profile of our oral PTH (1-34) indicated that a biomarker of PTH activity, cyclic AMP, was activated in a similar manner to that of injectable PTH (1-34) Furthermore, analysis of serum calcium indicated that an increase can be obtained by a single dose of our oral PTH (1-34) as indicated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

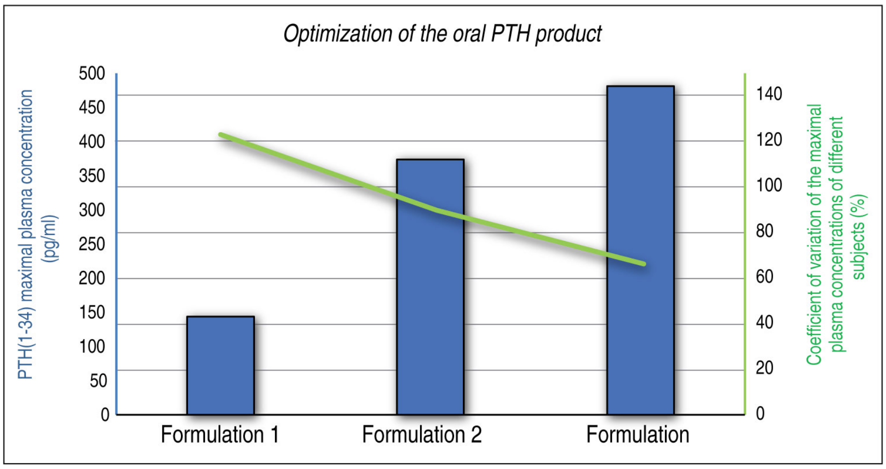
These data effectively show that oral PTH (1-34) reaches the circulation, remains intact and has biological potency similar to that observed with injectable PTH (1-34). At present, we estimate that there are at least four million patient years' experience with injectable PTH (1-34). We believe that reaching 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 no serious related adverse events and displayed compelling PK and PD properties, in particular compared to commercially available injectable PTH (1-84) Natpara and PTH (1-34) (Forteo). There were no related serious or significant adverse events reported in earlier trials; however, in our Phase 2a trial, 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. There was also one unrelated serious adverse event of hypercalcemia which occurred in one patient prior to the administration of the study drug for the first time. One subject in the Phase 2a trial, who withdrew from the trial after the first day, complained of multiple general symptoms including nausea and pain prior to commencing the trial and experienced four adverse events (mild nausea, moderate back pain, moderate headache and moderate upper abdominal pain) on the first day. These four adverse events could not be confirmed as related following the patient's withdrawal from the study. They were recorded as 'possibly related.' In our Phase 1b trial there were minor drug related adverse events such as minor hypercalcemia in two subjects, minor tachycardia in three subjects, headache in two subjects and hypothermia in one subject. There were also two possibly related mild adverse events in our Phase 1a trial: anemia in one subject and nausea in one subject. We believe these two adverse events were likely unrelated. For example, the anemia event occurred 12 days after a placebo treatment. In addition, one subject in the Phase 1a trial experienced a drug related musculoskeletal and connective tissue event of knee cramps. 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. These improvements were based on the same basic components and present a similar pharmacokinetic profile. We believe that the optimal formulation is more likely to attain regulatory approval. Once EB612 enters a Phase 2b/3 clinical trial, no further optimization would be done.

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 PK/PD study comparing various dose regimens with Natpara. This PK/PD study will include 16 to 20 hypoparathyroidism patients for a treatment and monitoring duration of around 60 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 and will allow us to better understand the relative strength and dose of our product as compared to the marketed product, Natpara. This study may also provide valuable “head to head” data that will further inform our Phase 2b/3 study design. The relevant endpoints for the PK/PD study will include levels of PTH (1-34), PTH (1-84) (Natpara), serum calcium, serum phosphate, urinary calcium and urinary phosphate.

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. 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 an additional oral PTH program, 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
Injectable abaloparatide	TYMLOS (Radius Health)	Similar to PTH, binds to PTH receptors with a higher affinity to bone formation receptors, increasing bone mineral density	Osteosarcoma, orthostatic hypotension, hypercalcemia, hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain and vertigo	N/A (launched in April 2017)
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.

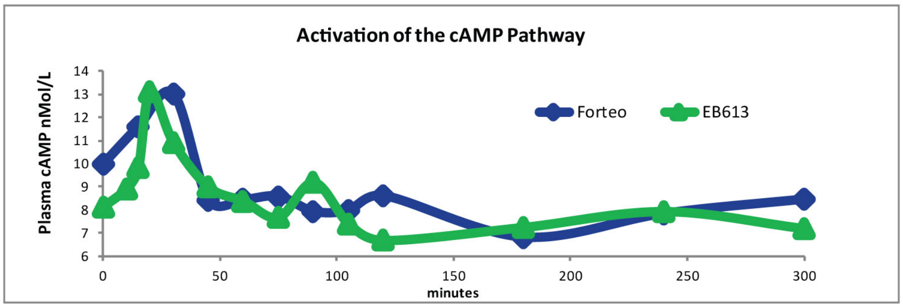
Preclinical and Clinical Development of EB613

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.

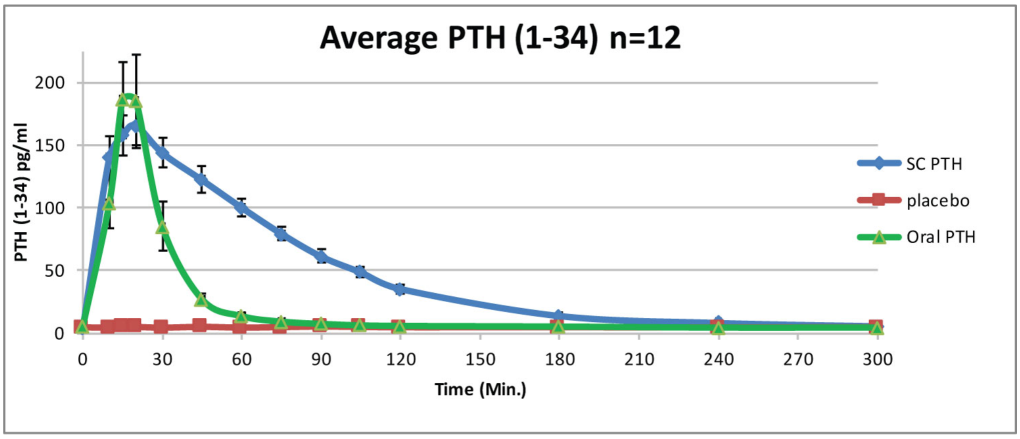
In preclinical and Phase 1 clinical development, EB613 exhibited no serious related adverse events and displayed compelling PK and PD properties, in particular compared to commercially available injectable PTH (1-34) (Forteo). There were no related serious or significant adverse events reported in earlier trials. In our Phase 1b trial, there were minor drug related adverse events such as minor hypercalcemia in two subjects, minor tachycardia in three subjects, headache in two subjects and hypothermia in one subject. There were also two possibly related mild adverse events in our Phase 1a trial: anemia in one subject and nausea in one subject. We believe these two adverse events were likely unrelated. For example, the anemia event occurred 12 days after a placebo treatment. In addition, one subject in the Phase 1a trial experienced a drug related musculoskeletal and connective tissue event of knee cramps.

EB613: Favorable Pharmacodynamic Profile

Cyclic AMP, or cAMP, is a known indicator of PTH activity. It is part of the signaling pathway activated by the PTH binding to its cellular receptors. cAMP can be measured in the plasma and used as a biological marker of PTH activity. The graph below shows a similar activation profile following dosing of both commercial Forteo and EB613.



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 with 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

Our intent is to seek FDA guidance on our proposed clinical trial design as part of a Pre-IND meeting in the second half of 2018. After we receive feedback from the FDA, we intend to conduct a Phase 2a dose finding study in osteoporosis patients in 2019.

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, including human growth hormone, and intend to commence clinical development for our next, non-PTH, product candidate in the future. For example, in initial rodent studies utilizing Entera's drug delivery technology, an oral formulation of human growth hormone obtained significant concentrations of intact human growth hormone throughout the blood stream. 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. 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.

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 costs 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.

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. For instance, we may choose to license our technology to external parties for the development of non-PTH product candidates.

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. In September 2017, Ascendis reported that it has initiated a Phase 1 trial with their drug in Australia. Ascendis expects to advance their drug directly into Phase 3 development in the first quarter of 2019

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 Grants

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

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 following any year in which we achieve sales of over $70 million.

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, 2017, the total royalty amount payable to the IIA, including accrued interest, was approximately $0.5 million. As of December 31, 2017, 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 even 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. We believe that, because production is not being done for commercial purposes, the entry into the production agreement in the U.K. will not affect the royalty rates to be paid to the IIA. Should it turn out that this position is not acceptable to the IIA, the maximum royalties to be paid to the IIA will be approximately $1.5 million, which is three times the amount of the original grants of $0.5 million. 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 cause a non-Israeli citizen or resident to become an "interested party," as defined in the Research Law (which includes any person who holds 5% or more of our outstanding shares), 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 Law. 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 and 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 March 31, 2018, 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 been 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. Specifically, in the United States Australia, Japan, China, Israel and Russia divisional or continuation patent application have been filed to specifically cover PTH (1-34). Such patents have already been granted in Australia and Japan and a notice of allowance was recently issued for the U.S. application. Applications in the remaining jurisdictions are pending. The current issued patents in the United States and China are limited to insulin. 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 applications and one Patent Cooperation Treaty (PCT) application, 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 patent applications, if issued in substantially the same form, would cover the formulations of EB612 and EB613.

- Three patent applications filed in various jurisdictions, 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 PTH 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, if granted, 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, members of our board of directors, technical review board and other advisors upon their engagement. 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.

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 we may enter into additional contracts as we see fit. 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 if 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 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 the 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 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, 2017 through September 30, 2018, the user fee for an application requiring clinical data, such as a BLA, is $2,421,495.

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 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 otherwise 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 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 10 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 trials 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 and that the trial complies with the standards set forth by the Declaration of Helsinki. 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 December 2017, the Tax Cuts and Jobs Act was enacted and signed into law, one part of which repeals the "individual mandate" introduced by the ACA starting in 2019. Considerable uncertainty remains 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 incorporated in September 2009, and commenced operations as a joint venture of D.N.A Biomedical and Oramed in June 2010 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 March 31, 2018, we had 19 employees, one consultant who provides consulting services to us on a full-time basis and two consultants who provide services to us on a part-time basis. Four of our employees have either PhDs or MDs. Eighteen of our employees are located in Israel and one in the United States. We believe that we maintain good relations with all of our employees and consultants. We are not a party to any collective labor agreements. In addition, we have entered into service agreements with three of our directors. See "Certain Relationships and Related Party Transactions — Service 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 us 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 current 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. Emisphere Technologies, Inc., or Emisphere, has notified us that it believes that it is the exclusive owner of certain U.S. and related foreign patents and patent applications we acquired from Oramed Ltd.; however, Emisphere has not initiated a legal proceeding against us regarding its claim. For more information on the risks related to Emisphere's claim, see "Risk Factors — Risks Related to Our Intellectual Property — *We may become involved in proceedings to protect or enforce our proprietary rights, which could be expensive and time consuming, and may ultimately be unsuccessful*."

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	56	Chief Executive Officer and Director
Mira Rosenzweig	46	Chief Financial Officer
Dr. Hillel Galitzer	39	Chief Operating Officer
Dr. Eric Lang	56	Chief Medical Officer
Directors		
Luke M. Beshar(1)	59	Chairman of the Board
Roger Garceau	64	Director
Gerald Lieberman(2)(3)(4)	71	Director
Zeev Bronfeld(2)(3)	66	Director
David Ben Ami	56	Director
Chaim Davis	40	Director
Yonatan Malca(2)(3)	51	Director

(1) Mr. Beshar has notified us that he intends to resign from our board of directors on the earlier of (i) immediately prior to the effectiveness of the registration statement of which this prospectus forms a part or (ii) June 30, 2018.

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

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

(4) Independent director under the rules of NASDAQ Capital Market.

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 20 years of biotech and pharmaceutical industry experience. He has also consulted privately and served 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 prior to that served as our Director of Scientific Development from July 2012. Between August 2010 and February 2014, Dr. Galitzer was an analyst and the 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 10 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. Eric Lang has served as our Chief Medical Officer since January 2018. Dr. Lang has extensive experience in designing drug development programs from early stages through phase III, including the successful filing of several recent INDs and NDAs. From 2012 to 2017, Dr. Lang worked at Covance, Inc., most recently as the Vice President and Global Head of Clinical Drug Development Strategists. From 2010 to 2011, Dr. Lang worked at Grunenthal USA Inc. where he acted as Vice President, US Clinical Development. Prior to these positions, Dr. Lang worked at both Javelin Pharmaceuticals, Novartis Consumer Health and Johnson and Johnson. He received his M.D. from Ben Gurion University of the Negev in Israel, is licensed in both the United States and Israel and is board certified as an Anesthesiologist.

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, Camberx Corporation, 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 a member of our board of directors 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 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 a B.S. in Biology from Fairfield University in Fairfield, Connecticut and an M.D. from the University of Massachusetts Medical School.

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.

Zeev Bronfeld has served as a member of our board of directors since 2010 and as chairman of our board of directors from September 2014 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 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 served as a member of its board of directors 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 also serves as a director of a number of privately-held companies, including, Contipi Medical Ltd. and as the 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 pursuant to rights granted to D.N.A Biomedical under our articles of association as in effect prior to the closing of this offering.

David Ben Ami has served as a member of our board of directors since 2014. Mr. Ben Ami is the Managing Partner of Corundum Open Innovation Fund, a life sciences venture capital fund, and the Executive Investment Director of SBI JI Innovation Advisory Ltd. Mr. Ben Ami has more than 25 years of experience with activities in management, business development, corporate strategy and investments in the life sciences industry. He served as chief executive officer of NVR Labs Ltd. from 2005 to 2010, Israeli Country Manager of Boston Scientific, Israel from 2003 to 2005, and director of business development of Teva Israel and Teva Medical from 1999 to 2002. In 2008, he founded Macrocure Ltd., and served as the chairman of the board of directors of Macrocure from 2008 until 2016. Mr. Ben Ami currently serves, and in the past served as a board member in numerous companies including: Immunobrain Checkpoint Inc., Novolog Ltd., Degania Medical Ltd., Biocell Ltd., Meytav Technology Incubator, Hairstetics Ltd., VVT Medical and Contipi Medical 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 pursuant to rights granted to Centillion Fund under our articles of association as in effect prior to the closing of this offering. For further information regarding our commitment under certain circumstances to nominate one director nominee designated by Centillion Fund following the closing of this offering, see "— Arrangements for Election of Directors." Following the consummation of this offering, Mr. Ben Ami intends to resign from our board.

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 served on the board of American Bio Medica since June 2017. 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 certain of our shareholders who are lenders under certain of our convertible financing agreements, pursuant to rights granted to these lenders under the current Articles, as in effect prior to the closing of this offering. Following the consummation of this offering, Mr. Davis intends to resign from our board.

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, Israel. Mr. Malca serves on our board of directors as a designee of D.N.A Biomedical pursuant to rights granted to D.N.A Biomedical under our articles of association as in effect prior to the closing of this offering.

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 9.96% of our issued and outstanding ordinary shares, and in the event that Centillion exercises in full all of the warrants and options to purchase our ordinary shares that we will have issued to it as of such date, Centillion will hold approximately 17.6% of our issued and outstanding ordinary shares.

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 the NASDAQ Capital Market and other applicable provisions of U.S. securities laws. As a foreign private issuer whose securities will be listed on the NASDAQ Capital Market, we have the option to follow certain Israeli corporate governance practices rather than those of the NASDAQ Capital Market, 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 NASDAQ Capital Market requirements:

- *Shareholder Approval.* Although the NASDAQ Capital Market listing requirements generally require shareholder approval of equity compensation plans and material amendments thereto, we intend to 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 NASDAQ Capital Market listing requirements requiring shareholder approval for the issuance of securities in certain circumstances, we intend to 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 NASDAQ Capital Market 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 amended Articles to be in effect 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 issued and outstanding shares and, in an adjourned meeting, subject to certain exceptions, any two shareholders.
- *Compensation Committee.* The NASDAQ Capital Market 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 NASDAQ Capital Market listing requirements. In addition, under the Companies Law, there are no specific independence evaluation requirements for outside consultants.

- *Independent Approval of Board Nominations*. The NASDAQ Capital Market listing requirements require a listed company to have independent control over the approval of board nominations, either through an independent nominating committee or through a vote by a majority of the company's independent directors. Under the Companies Law, there is no requirement to have a nominating committee or that board nominees be approved by independent directors.
- *Independent Directors.* Under the NASDAQ Capital Market listing requirements, a majority of the board of directors must be independent. Under the Companies Law, there is no requirement that a majority of the board be independent, rather only that at least two directors meet certain independence requirements and be classified as external directors for purposes of the Companies Law. See "— External Directors."
- *Executive Sessions*. The NASDAQ Capital Market listing requirements require that independent directors hold regularly scheduled executive sessions, where only independent directors are present. Under the Companies Law, our independent directors may choose to hold executive sessions at their discretion, but are not required to do so.
- *Third Party Director Compensation*. We follow Israeli law requirements with respect to disclosure of compensation for our directors and executive officers. Israeli law does not require that we disclose information regarding third party compensation of our directors or director nominees. As a result, our practice varies from the third-party compensation disclosure requirements of the Nasdaq Capital Market.

Except as stated above, we intend to substantially comply with the rules applicable to U.S. companies listed on the NASDAQ Capital Market. We may in the future decide to avail ourselves of other foreign private issuer exemptions with respect to some or all of the other NASDAQ Capital Market 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 the NASDAQ Capital Market, may provide less protection than is accorded to investors under the NASDAQ Capital Market listing requirements applicable to domestic issuers.

Board of Directors

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

Mr. Beshar intends to resign from our board on the earlier of: (i) immediately prior to the effectiveness of the registration statement or (ii) June 30, 2018. Following the consummation of this offering, Chaim Davis and David Ben-Ami intend to resign from our board. We therefore expect that our board of directors will consist of five directors. Pursuant to the three month transition period permitted under the Companies Law, within three months following our listing on the NASDAQ Capital Market, we intend to nominate two external directors whose appointment would fulfill the requirements of the Companies Law. See "— External Directors." In addition, we anticipate that these two directors would qualify as independent directors under the corporate governance standards of the NASDAQ Capital Market 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. Currently, our director Gerald Lieberman is the only member of our board of directors that satisfies these independence requirements of the NASDAQ Capital Market listing requirements and the Exchange Act.

According to our amended Articles, the number of members of our board of directors must be at least three and cannot be more than nine. Our board of directors, other than external directors, 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 shareholders in 2019, 2020 and 2021, respectively. The members of the classes at the closing of this offering will be divided as follows:

- the Class I directors are Zeev Bronfeld and Roger Garceau;
- the Class II directors are Phillip Schwartz and Yonatan Malca; and
- the Class III director is Gerald Lieberman.

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, including filling empty board seats if the number of directors is below the maximum number permitted under our amended Articles. 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 power in the Company 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 the NASDAQ Capital Market, are generally required to have at least two external directors who meet certain independence criteria to ensure that they are unaffiliated with the company and its controlling shareholder(s). Pursuant to the applicable transition period rules under the Companies Law, our external directors must be elected by our shareholders no later than three months following the completion of this offering.

An external director must also have either financial and accounting expertise or professional qualifications, as defined in regulations promulgated 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 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 Gerald Lieberman meets such qualifications.

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

Alternate Directors

Our amended Articles 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 or her 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 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 the NASDAQ Capital Market, 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 NASDAQ Capital Market 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, assessing the scope of work 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 (subject to ratification by the board of directors and shareholders), 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 initially consist of Gerald Lieberman (Chairman), Zeev Bronfeld and Yonatan Malca. Pursuant to the applicable transition period rules, we anticipate that our audit committee will satisfy 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 the NASDAQ Capital Market listing requirements within a period of three months following our listing on the NASDAQ Capital Market. After the applicable transition period of three months, all of the members will be external directors or would be eligible to qualify as independent directors as defined in the Companies Law and all of the members will also be independent as defined in SEC rules and the NASDAQ Capital Market 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 recommending 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, reviewing modifications to the compensation policy from time to time, reviewing its implementation and approving, if required by the Companies Law, the actual compensation terms of officers and directors prior to approval by the board of directors, under circumstances where board approval is required under the Companies Law.

Upon completion of this offering, we will have a compensation committee consisting Gerald Lieberman (Chairman), Zeev Bronfeld and Yonatan Malca. Pursuant to the applicable transition period of three months, our compensation committee will satisfy 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 NASDAQ Capital Market listing standards applicable to compensation committees, which the Company has chosen to opt out of as a foreign private issuer. See "— Corporate Governance Practices" above.

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 intend to 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. The duty of loyalty includes a duty to:

- refrain from any conflict of interest between the performance of his or her duties to the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the company;
- refrain from exploiting any business opportunity of the company to receive a personal gain for himself or herself or others; and

- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

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. 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 (or, in the case of compensation, indemnification or insurance of a controlling shareholder, the compensation 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. To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years and under certain conditions, five years from a company's initial public offering, approval is required at the end of such period unless, with respect to certain transactions, the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

The Companies Law generally 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.

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

Approval of Director and Officer Compensation

Under the Companies Law, we are required to adopt a compensation policy with respect to our directors and officers once every three years, provided however that a compensation policy adopted within nine months from the closing of this offering is valid for five years. The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of office holders, including compensation, benefits, exculpation, insurance and indemnification. The compensation policy must take into account certain factors, including advancement of the company's objectives, the company's business plan and its long-term strategy, and creation of appropriate incentives. It must also consider, among other things, the company's risk management, size and the nature of its operations. The compensation policy must include certain principles, such as: a link between variable compensation and long-term performance and measurable criteria; the relationship between variable and fixed compensation; and the minimum holding or vesting period for variable, equity-based compensation.

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. Even if shareholders do not approve the compensation policy, the board of directors may resolve to approve the compensation policy, subject to certain conditions. We intend to adopt a compensation policy within nine months from the consummation of this offering.

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 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, subject to certain exceptions.

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 generally do not have any agreement with directors providing for benefits upon termination of their service as directors of our company.

The aggregate compensation paid to all of the members of our directors and senior management was approximately $6.4 million in 2017. This amount includes approximately $4.7 million for share-based compensation and $92,000 set aside or accrued in the aggregate for pension or other retirement benefits for our senior management in 2017.

Summary Compensation Table

For so long as we qualify as a foreign private issuer, we are not required to comply with the proxy rules applicable to U.S. domestic companies, including the requirement to disclose the compensation of our chief executive officer, chief financial officer and other three most highly compensated executive officers on an individual basis. Nevertheless, pursuant to regulations promulgated under the Companies Law, we will be required to disclose the annual compensation of our five most highly compensated office holders, which includes our directors and officers, on an individual basis. Such disclosure will not be as extensive as that required of a U.S. domestic issuer. The following table presents all compensation we incurred for the year ended December 31, 2017 with respect to our five highest paid office holders, 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:

		Annual 2017 Compensation				
Name	**Position**	**Base Salary and Related Benefits**[1]	**Bonus**	**Retirement, Service Fees and Other Similar Benefits**	**Share Based Compensation**[2]	**Total**
Luke M. Beshar	Chairman of the board of directors	$ —	—	294,469	3,054,263	3,333,185
Dr. Roger Garceau	Chief Development Advisor	$ —	—	120,773	886,925	1,000,925
Dr. Phillip Schwartz	Chief Executive Officer and Director	$300,791	150,000	44,497	120,240	615,528
Gerald Lieberman	Director	$ —	—	17,940	482,177	500,117

		Annual 2017 Compensation				
Name	**Position**	**Base Salary and Related Benefits(1)**	**Bonus**	**Retirement, Service Fees and Other Similar Benefits**	**Share Based Compensation(2)**	**Total**
Dr. Hillel Galitzer	Chief Operating Officer	$201,749	60,000	24,808	58,211	344,768

(1) Includes base salary, social benefits and car allowances. The amounts shown in this column represent expenses recorded or to be recorded by the Company, calculated using the average monthly exchange rates of the relevant month in which the salary was recorded.

(2) The amounts shown in this column represents expenses recorded or to be recorded with respect to all options granted to such officers, calculated using the actual exchange rate on the grant date.

Share Incentive Plan

On March 17, 2013, our board of directors approved our Share Incentive Plan, or the 2013 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 service providers. As of March 31, 2018 and without giving effect to the ordinary share split described in this prospectus, a total of 651 ordinary shares remained available for issuance under the 2013 Plan. As of that date and without giving effect to the ordinary share split described in this prospectus, 24,509 ordinary shares were issuable upon the exercise of outstanding awards under the 2013 Plan, at a weighted-average exercise price of $601.54 per share. Of the foregoing outstanding awards, options to purchase 12,755 ordinary shares, in the aggregate, had vested under the 2013 Plan as of that date, with a weighted-average exercise price of $426.86 per share (and without giving effect to the ordinary share split described in this prospectus).

Awards granted under the 2013 Plan are subject to vesting schedules and generally vest over a four-year period commencing 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 12 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 2013 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 2013 Plan provides for granting awards in compliance with Section 102 of the Israeli Income Tax Ordinance, 5721-1961, or the Ordinance, which provides to employees, directors and officers, who are not controlling shareholders (as defined in the Ordinance) and are Israeli residents, favorable tax treatment for compensation in the form of shares or equity 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, any accounting expense with respect to the grant or issuance of such shares or awards which relates to gain taxed as capital gains is not allowed as a deduction for tax purposes.

The 2013 Plan addresses the treatment of vested and unvested awards upon the cessation of employment or engagement 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 2013 Plan also provides for certain lock-up arrangements upon consummation of a public offering.

The 2013 Plan is administered by our board of directors or by a committee appointed by our board of directors. Upon the completion of this offering, any remaining pool of reserved ordinary shares under the 2013 Plan will be cancelled, and the only reserved ordinary shares available for grants following the completion of this offering will be under the 2018 Plan (as defined below).

2018 Equity Incentive Plan

In connection with the completion of this offering, we intend to establish a new equity incentive plan, or the 2018 Plan, with the purpose of advancing the interests of our shareholders by enhancing our ability to attract, retain and motivate individuals to perform at the highest level. The 2018 Plan will govern issuances of equity incentive awards from and after the closing of this offering. The maximum number of ordinary shares initially available for issuance under equity incentive awards granted pursuant to the 2018 Plan will not exceed 12% of the total outstanding ordinary shares. On January 1, 2019 and on January 1 of each calendar year thereafter, an additional number of shares equal to 5% of the total outstanding ordinary shares on such date (or any lower number of shares as determined by the board of directors) will become available for issuance under the 2018 Plan.

Equity incentive awards may be granted to our employees, non-employee directors, consultants or other advisors, as well as holders of equity compensation awards granted by a company that may be acquired by us in the future. Awards under the 2018 Plan may be granted in the form of options, share appreciation rights, restricted shares, restricted share units, performance awards or other share-based awards. Options and share appreciation rights will have an exercise price determined by the administrator but that is no less than fair market value of the underlying ordinary shares on the date of grant.

The vesting conditions for grants under the 2018 Plan will be determined by the administrator and, in the case of restricted shares and restricted share units, will be set forth in the applicable award documentation.

In the event of a participant's termination of employment, the administrator may, in its discretion, determine the extent to which an equity incentive award may be exercised, settled, vested, paid or forfeited. In the event of a change in control (as defined in the 2018 Plan) of the Company, the compensation committee may, in its discretion, take a number of actions with respect to awards outstanding under the 2018 Plan, including the following: (i) continuing awards or converting such awards into an award or right with respect to shares of the successor or surviving corporation, (ii) immediately vesting and settling awards (or in the case of options and share appreciation rights, providing that such awards will become fully exercisable), (iii) cancelling unvested awards for no consideration, (iv) terminating or cancelling awards in exchange for a cash payment and (v) providing that awards may be assumed, exchanged, replaced or continued by the successor or surviving corporation with cash, securities, rights or other property. In the event of a structural change of the Company (i.e., a transaction in which the Company's shares immediately prior to the transaction are converted into or exchanged for shares that represent at least a majority of the share capital of the surviving corporation, such as a re-domestication of the Company or a share flip), outstanding awards will be exchanged or converted into awards to acquire shares of the company (if it is the surviving corporation) or the successor company in accordance with the applicable exchange ratio.

The 2018 Plan will be administered by the board of directors, provided that the board of directors may delegate its authority to the compensation committee to administer the 2018 Plan.

The 2018 Plan provides for granting awards in compliance with Section 102 of the Ordinance, which provides to employees, directors and officers of the Company, who are not controlling shareholders (as defined in the Ordinance) of the Company and are Israeli residents, potential favorable tax treatment for compensation in the form of shares or equity awards issued or granted, as applicable, to a trustee under the "capital gains track" for the benefit of the relevant employee, director or officer, subject to compliance with the terms and conditions of such tax track. Under the capital gains track, any accounting expense with respect to the grant or issuance of such shares or awards which relates to gain taxed as capital gains is not allowed as a deduction for tax purposes.

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. Ordinary share amounts referenced in this section do not reflect the ordinary share split described in this prospectus.

Convertible Debt Financing

2012 Convertible Loans

On November 8, 2012 and December 31, 2012, we entered into the 2012 Convertible Loans, with 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). In addition, under the terms of the 2012 Convertible Loans, the outstanding loan amounts will be automatically converted into our ordinary shares upon the occurrence of 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 "Shares 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, at an exercise price of 125% of the applicable price per share, 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 during 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, and as a result, the 2015 Convertible Loan agreement is no longer in force.

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 provided for a term of 18 months and bore interest at a rate of 5% per year. The 2016 Convertible Loan also granted each lender 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 in such issuance.

The 2016 Convertible Loan was to be automatically converted upon the occurrence of a 2016 Triggering Event. Following the completion of the Series B preferred shares purchase agreement, which constituted a 2016 Triggering Event, the loan amount, together with all accrued interest was converted into Series B-1 preferred shares, under the terms and conditions of the 2016 Convertible Loan. As a result, the 2016 Convertible Loan agreement is no longer in force. In addition, the Series B preferred shares purchase agreement set the price and the amounts for which the holders of the 2016 Warrants are entitled to exercise their 2016 Warrants. 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.

Our directors, Luke Beshar, Roger Garceau and Gerald Lieberman, each participated, in amounts of $50,000, $25,000 and $50,000, respectively, in our 2016 Convertible Loan. In addition, Corundum Open Innovation Fund, L.P., or Corundum, 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. Following the conversion of the 2016 Convertible Loans, Luke Beshar, Roger Garceau and Gerald Lieberman were issued 77, 38 and 156 Series B-1 preferred shares, respectively, and their 2016 Warrants relate to 31, 15 and 62 Series B preferred shares, respectively. In addition, following the conversion of the 2016 Convertible Loans, Corundum was issued 1,563 Series B-1 preferred shares and its 2016 Warrants relate to 625 Series B preferred shares.

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.

Preferred Share Purchases

Series A Private Placement

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 Series A 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 Series A 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, as amended, upon the closing of an offering of our ordinary shares on or prior to July 20, 2019, pursuant to which our ordinary shares are listed on NASDAQ, or the second milestone, Centillion was given the option to purchase from us, at its sole discretion, an additional 2,086 Series A 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 Series A preferred shares at the per share purchase price. Centillion also had the right to purchase the Series A preferred shares and warrants to be issued upon either of the milestones prior to the last milestone date.

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 purchase the Series A 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, with an option for Centillion to extend it for an additional two years, until October 1, 2017. Such option right was exercised by Centillion. 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." On July 20, 2017, the Centillion Series A preferred share purchase agreement was amended such that (i) the second milestone was extended to July 20, 2019, (ii) the second milestone was deemed to include any transaction pursuant to which our shares will be listed for trading on NASDAQ, and (iii) the investment following the occurrence of the second milestone is optional to the holders of Series A preferred shares.

During the course of 2014 and January 2015, we entered into additional preferred share purchase agreements with other purchasers of our Series A preferred shares. The additional preferred share purchase agreements also provide for the issuance of Series A 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 Series A 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. In July 2017, the additional Series A preferred share purchase agreements were amended to terms identical to those contained in the amendment to the Centillion Series A preferred share purchase agreement dated July 20, 2017, and the additional warrants terms were amended to the same terms as the additional warrants of Centillion.

If any Series A investors exercise their option to purchase Series A preferred shares pursuant to the second milestone in connection with this offering, such shares shall be converted into ordinary shares automatically and without any further action on the part of such investors, and any warrants provided in connection therewith shall be exercisable into ordinary shares.

Under the terms of the applicable agreements and pursuant to the IPO Transactions, the Series A preferred shares will be automatically converted into our ordinary shares, and the warrants to purchase Series A preferred shares will be automatically converted into warrants to purchase ordinary shares, upon the closing of this offering.

Series B Private Placement

From October to December 2017, we entered into the Series B Private Placement, with certain investors, including D.N.A Biomedical and Centillion for the sale of shares of our Series B preferred shares, at a price per share of $908.78, for an aggregate purchase price of $13.0 million. In connection with the Series B Private Placement, the Company issued and sold to the Investors 14,283 Series B preferred shares.

The Series B Private Placement constituted a 2016 Triggering Event, as defined in the 2016 Convertible Loan agreement (as discussed further under "Management's Discussion and Analysis — Contractual Obligations and Commitments — 2016 Convertible Loan"). As a result of the Series B Private Placement, the entire loan amount due to holders under the 2016 Convertible Loan agreement, together with all accrued interest, was converted to 13,229 Series B-1 preferred shares at a price per share of $681.585. The rights of the Series B-1 preferred shares are identical in all respects (other than the price per share) to the Series B preferred shares.

Under the terms of the applicable agreements and pursuant to the IPO Transactions, the Series B and B-1 preferred shares will be automatically converted into our ordinary shares, and the warrants to purchase Series B preferred shares will be automatically converted into warrants to purchase ordinary shares, upon the closing of this offering.

In addition, as a result of the Series B Private Placement, the 2016 Warrants (as discussed in "Description of Share Capital — 2016 Warrants") that the Company previously issued in connection with the 2016 Convertible Loan became warrants to purchase our Series B preferred shares at an exercise price of $908.78.

Gerald Lieberman, a member of our board of directors, participated in the Series B Private Placement and purchased 110 Series B preferred shares in an amount totaling $100,000. Revach, an entity controlled by our director Chaim Davis, participated in the Series B Private Placement and purchased 14 Series B preferred shares in an amount totaling $12,726. Dr. Phillip Schwartz, our Chief Executive Officer, participated in the Series B Private Placement and purchased 6 Series B preferred shares in an amount of $5,542.

On November 10, 2017, the Company's board of directors approved D.N.A Biomedical's request to reimburse D.N.A Biomedical for expenses incurred in relation to the Series B private placement in an amount of $300,000. The reimbursement is subject to the approval of the Company's shareholders and to the receipt of documentation supporting the amounts.

Service Agreements

In April 2017, the Company entered into a Service Agreement with our director Luke Beshar, effective as of December 2016, 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's Board and shareholders approved the Service Agreement, pursuant to which Mr. Beshar is entitled to options to purchase ordinary shares of the Company representing 6.5% of the Company's fully-diluted share capital immediately following a 2016 Triggering Event; provided that if the amount raised in such 2016 Triggering Event exceeds $10 million, then the fully-diluted share capital shall be calculated as if the amount raised in such 2016 Triggering Event was $10 million. Following the Series B Private Placement (which constituted a 2016 Triggering Event), the Company determined that the amount of ordinary shares to be granted to Mr. Beshar upon the exercise of his options will be 6,970 ordinary shares, with an exercise price of $820 per share. 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, including the occurrence of a change of control of the Company, resignation of Mr. Beshar for Good Reason and termination without Cause (as such terms are defined in the Service Agreement).

In April 2017, effective as of December 2016, 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's Board and shareholders approved the Service Agreement, pursuant to which Mr. Garceau is entitled to options to purchase ordinary shares of the Company representing 1.5% of the Company's fully-diluted share capital immediately following a 2016 Triggering Event; provided that if the amount raised in such 2016 Triggering Event exceeds $10 million, then the fully-diluted share capital shall be calculated as if the amount raised in such 2016 Triggering Event was $10 million. Following the Series B Private Placement (which constituted a 2016 Triggering Event), the Company determined that the amount of ordinary shares to be granted to Mr. Garceau upon the exercise of his options will be 1,608 ordinary shares, with an exercise price of $820 per share. 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, including the occurrence of a change of control of the Company, resignation of Mr. Garceau for Good Reason and termination without Cause (as such terms are defined in the Service Agreement).

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 paid in April 2017 and $6,500 per month. In addition, in November 2017, our board of directors and shareholders approved a bonus of $35,000, which was paid to Mr. Davis in December 2017.

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 October 4, 2017, 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.

Director Designation Rights

Pursuant to the terms of the Investors' Rights Agreement among us, Centillion and 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 9.96% 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 17.6% of our issued and outstanding ordinary shares.

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 in such financings, at the same price per equity interest paid by the new shareholders ("Centillion special pre-emptive rights"). The Centillion Special Pre-emptive Right are not exercisable in connection with this offering.

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 procedures governing the approval of related party transactions.

PRINCIPAL SHAREHOLDERS

The following table sets forth information regarding beneficial ownership of our ordinary shares as of March 31, 2018, by:

- each person or entity known by us to own beneficially 5% or more 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 10,018,320 ordinary shares outstanding, after giving effect to the 1-for-130 split of our ordinary shares that is described elsewhere in this prospectus, as of March 31, 2018, including:

- 4,905,420 ordinary shares to be issued upon the conversion of all outstanding preferred shares into ordinary shares upon the closing of this offering;
- and 622,180 ordinary shares to be issued upon the conversion into ordinary shares of our outstanding convertible loan.

The percentage of beneficial ownership of our ordinary shares after the offering is based on 11,361,654 ordinary shares outstanding after the offering which includes the ordinary shares specified above plus the ordinary shares to be sold by us in the offering plus the 10,000 ordinary shares to be issued to the representative immediately following this offering, but not including any additional shares issuable upon exercise by Centillion of the Centillion special pre-emptive rights, which rights are not exercisable in connection with this offering.

All of our shareholders, including the shareholders listed below, have the same voting rights attached to their ordinary shares. Upon the consummation of this offering, outstanding preferred shares shall be converted into ordinary shares on a one-to-one basis automatically and without any further action on the part of such investors, and any warrants that will be outstanding following the closing of this offering shall be exercisable into 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 c/o Entera Bio Ltd., 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.

Name of Beneficial Owner	Shares Beneficially Owned Prior to the Offering[1] Number	Percentage	Shares Beneficially Owned After the Offering (Assuming No Exercise of the Over-Allotment Option)[1] Number	Percentage	Shares Beneficially Owned After the Offering (Assuming Full Exercise of the Over-Allotment Option)[1] Number	Percentage
Principal Shareholders:						
D.N.A Biomedical Solutions Ltd[2]	3,978,780	39.7%	3,978,780	35.0%	3,978,780	34.4%
Centillion Fund[3]	2,192,060	19.8%	2,192,060	17.6%	2,192,060	17.4%
Pontifax (Israel), Pontifax (Cayman) IV L.P. and Pontiax (China) IV Fund L.P. (collectively, "Pontifax")[4]	853,450	8.3%	853,450	7.4%	853,450	7.2%
Capital Point Ltd.[5]	799,370	15.2%	799,370	13.4%	799,370	13.2%
Menachem Raphael[6]	540,800	6.8%	540,800	6.0%	540,800	5.9%
Executive Officers and Directors:						
Zeev Bronfeld[7]	3,978,780	39.7%	3,978,780	35.0%	3,978,780	34.4%
Yonatan Malca[8]	3,978,780	39.7%	3,978,780	35.0%	3,978,780	34.4%
Dr. Phillip Schwartz[9]	624,130	5.9%	624,130	5.2%	624,130	5.1%
Dr. Eric Lang[10]	*	*	*	*	*	*
Luke M. Beshar[11]	614,380	5.8%	614,380	5.1%	614,380	5.0%
David Ben Ami[12]	315,900	3.1%	315,900	2.8%	315,900	2.7%
Gerald Lieberman[13]	150,670	1.5%	150,670	1.3%	150,670	1.3%
Chaim Davis[14]	139,230	1.4%	139,230	1.2%	139,230	1.2%
Dr. Roger J. Garceau[15]	209,690	2.1%	209,690	1.8%	209,690	1.8%
Mira Rosenzweig[16]	*	*	*	*	*	*
Dr. Hillel Galitzer[17]	*	*	*	*	*	*
All executive officers and directors as a group (11 persons)[18]	6,161,870	52.1%	6,161,870	46.8%	6,161,870	46.1%

* 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 above, we deem shares subject to options or warrants that are currently exercisable or exercisable within 60 days of March 31, 2018, 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 3,978,780 ordinary shares. D.N.A Biomedical, whose address is at Shimon Hatarsi 43 St., Tel Aviv, Israel, is controlled by Zeev Bronfeld. 3,410,420 ordinary shares, or approximately 85.7% of the ordinary shares currently held by D.N.A Biomedical have been pledged to Capital Point, while the remaining 568,320 ordinary shares, or approximately 14.3%, have been pledged to Menachem Raphael.

(3) Consists of (i) 8,344 Series A preferred shares that will be converted to 1,084,720 ordinary shares following the closing of this offering, (ii) warrants to purchase 2,086 Series A preferred shares that will be converted to warrants to purchase 271,180 ordinary shares following the closing of this offering, which had been issued to Centillion as of March 31, 2018, (iii) 2,086 Series A preferred shares that will be converted to 271,180 ordinary shares following the closing of this offering and a warrant to purchase 521 Series A preferred shares, that will be converted to warrants to purchase 67,730 ordinary

shares following the closing of this offering, which shares can be acquired by Centillion at any time until July 20, 2019 pursuant to the terms of our Series A preferred shares purchase agreement, (iv) 427 Series A preferred shares that will be converted to 55,510 ordinary shares following the closing of this offering and a warrant to purchase 107 Series A preferred shares, that will be converted to warrants to purchase 13,910 ordinary shares following the closing of this offering, which shares can be acquired by Centillion at any time until July 20, 2019 pursuant to our current Articles, (v) 357 Series B preferred shares that will be converted to 46,410 ordinary shares following the closing of this offering, and (vi) warrants to purchase 2,934 Series B-1 preferred shares that will be converted to warrants to purchase 381,420 ordinary shares following the closing of this offering. Centillion Fund, whose address is c/o Entera Bio Ltd., Kiryat Hadassah, Minrav Building — Fifth Floor, Jerusalem 9112002, Israel, is controlled by Ariel Israilov.

(4) Consists of (i) 4,689 Series B-1 preferred shares that will be converted to 609,570 ordinary shares following the closing of this offering, and (ii) warrants to purchase 1,876 Series B preferred shares that will be converted to warrants to purchase 243,880 ordinary shares following the closing of this offering. Pontifax 4 GP L.P. (“Pontifax Management”) is the general partner of Pontifax (Israel) 4 LP, Pontifax (Cayman) IV LP and Pontifax (China) IV LP (together, the “Partnerships”). Pontifax Management 4 G.P. (2015) Ltd. (“Pontifax Management GP”) is the general partner of Pontifax Management. Mr. Tomer Kariv and Mr. Ran Nussbaum are directors of Pontifax Management GP and, as such, hold voting and/or dispositive power over the shares held by the Partnerships. The principal business address of the foregoing entities and individuals is 14 Shenkar Street, Herzeliya 46140, Israel.

(5) Consists of (i) 5,659 Series B preferred shares that will be converted to 735,760 ordinary shares following the closing of this offering (ii) 63,700 ordinary shares, transferred by D.N.A. Biomedical to Capital Point and (iii) 722,150 ordinary shares that Capital Point has the right to acquire pursuant to an option granted by D.NA Biomedical. Capital Point’s address is at Derech Menachem Begin 132 (Azrieli Center) Tel Aviv, Israel.

(6) Consists of (i) 834 Series A preferred shares that will be converted to 108,480 ordinary shares following the closing of this offering, (ii) warrants to purchase 208 Series A preferred shares that will be converted to warrants to purchase 27,040 ordinary shares, which had been issued to White Car Group, Ltd., who later transferred its shares to Menachem Raphael, as of March 31, 2018, (iii) 208 Series A preferred shares that will be converted to 27,040 ordinary shares following the closing of this offering and warrants to purchase 53 Series A preferred shares that will be converted to warrants to purchase 6,890 ordinary shares following the closing of this offering, which shares can be acquired by Menachem Raphael until July 20, 2019 pursuant to the terms of our Series A preferred shares purchase agreement, (iv) 1,099 Series B-1 preferred shares that will be converted to 142,870 ordinary shares following the closing of this offering (v) warrants to purchase 440 Series B preferred shares that will be converted to warrants to purchase 57,200 ordinary shares following the closing of this offering (vi) warrants to purchase 293 Series B-1 preferred shares that will be converted to warrants to purchase 38,090 ordinary shares following the closing of this offering, (vii) 1,126 ordinary shares that Menachem Raphael has the right to acquire pursuant to an option granted by D.N.A Biomedical and (viii) 943 Series B preferred shares that will be converted to 122,590 ordinary shares following the closing of this offering, issued to D.N.A Biomedical, who later transferred them to Menachem Raphael and (ix) 10,660 ordinary shares transferred by D.N.A. Biomedical to Menachem Raphael, whose address is at Ha’seora 12, Tel Aviv Israel.

(7) 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.

(8) Yonatan Malka is the CEO 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.

(9) Consists of (i) 623,350 ordinary shares underlying options to acquire ordinary shares, with an exercise price of NIS 0.0000769, exercisable within 60 days of March 31, 2018, expire at various periods

between May 2019 and January 2020. (ii) options to acquire 44,720 ordinary shares exercisable within 60 days of March 31, 2018, with an exercise price of $6.31 per share and expiring on November 23, 2023 and (iii) 6 Series B preferred shares that will be converted to 780 ordinary shares following the closing of this offering.

(10) Consists of 27,690 ordinary shares underlying options to acquire ordinary shares exercisable within 60 days of March 31, 2018, expiring on January 15, 2024 with an exercise price of $6.31 per share.

(11) Consists of (i) options to acquire 147,290 ordinary shares with an exercise price of $3.69 per share and expiring on December 21, 2021, (ii) 77 Series B-1 preferred shares that will be converted to 10,010 ordinary shares following the closing of this offering, (iii) warrants to purchase 31 Series B preferred shares that will be converted to warrants to purchase 4,030 ordinary shares following the closing of this offering, (iv) options to acquire 450,350 ordinary shares exercisable within 60 days of March 31, 2018, with an exercise price of $6.31 per share and expiring on December 1, 2026, granted pursuant to the Service Agreement with Mr. Beshar.

(12) Consists of (i) options to acquire 31,460 ordinary shares with an exercise price of NIS 0.0000769, exercisable within 60 days of March 31, 2018, and expiring on March 19, 2019, (ii) 1,563 Series B-1 preferred shares that will be converted to 203,190 ordinary shares following the closing of this offering, held by Corundum, of which David Ben Ami, a member of our board of directors, is the managing partner, and (iii) warrants to purchase 625 Series B preferred shares that will be converted to warrants to purchase 81,250 ordinary shares following the closing of this offering, held by Corundum.

(13) Consists of (i) options to acquire 98,280 ordinary shares with an exercise price of $7.54 per share and expiring on April 6, 2023, exercisable within 60 days of March 31, 2018, (ii) options to acquire 9,750 ordinary shares with an exercise price of $1.85 per share and expiring on March 19, 2021, exercisable within 60 days of March 31, 2018, (iii) 156 Series B-1 preferred shares that will be converted to 20,280 ordinary shares following the closing of this offering, (iv) warrants to purchase 62 Series B preferred shares that will be converted to warrants to purchase 8,060 ordinary shares following the closing of this offering and (v) 110 Series B preferred shares that will be converted to 14,300 ordinary shares following the closing of this offering.

(14) Consists of (i) 11,830 ordinary shares, (ii) options to acquire 11,050 ordinary shares exercisable within 60 days of March 31, 2018, with an exercise price of $1.85 per share and expiring on September 1, 2019 and options to acquire 13,000 ordinary shares exercisable within 60 days of March 31, 2018, with an exercise price of $6.31 per share and expiring on November 23, 2023, (iii) 47,450 ordinary shares owned by Revach Fund, L.P. ("Revach"), (iv) 54,080 ordinary shares that will be issued to Revach upon conversion of the 2012 Convertible Loan, which will be automatically converted upon the completion of this offering, and (v) 14 Series B preferred shares that will be converted to 1,820 ordinary shares following the closing of this offering. 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.

(15) Consist of (i) options to acquire 98,280 ordinary shares with an exercise price of $3.69 per share and expiring on March 29, 2022, (ii) 38 Series B-1 preferred shares that will be converted to 4,940 ordinary shares following the closing of this offering, (iii) warrants to purchase 15 Series B preferred shares that will be converted to warrants to purchase 1,950 ordinary shares following the closing of this offering, and (iv) options to acquire 104,520 ordinary shares exercisable within 60 days of March 31, 2018, with an exercise price of $6.31 per share and expiring on December 1, 2026, granted pursuant to the Service Agreement with Dr. Garceau.

(16) Consists of (i) 36,010 ordinary shares underlying options to acquire ordinary shares expiring on May 29, 2020 with an exercise price of $2.43 per share and (ii) options to acquire 11,440 ordinary shares, with an exercise price of $6.31 per share and expiring on November 15, 2023. All options are exercisable within 60 days of March 31, 2018.

(17) Consists of (i) 36,010 ordinary shares underlying options to acquire ordinary shares, of which options to acquire 16,510 ordinary shares have an exercise price of $1.85 per share, and options to acquire

19,500 ordinary shares have an exercise price of NIS 0.0000769, all expiring on September 1, 2019, (ii) options to acquire 17,940 ordinary shares, with an exercise price of $6.31 per share and expiring on November 15, 2023. All options are exercisable within 60 days of March 31, 2018.

(18) Consists of (i) 4,038,060 ordinary shares, (ii) options to acquire 1,719,720 ordinary shares (iii) 54,080 ordinary shares that will be issued upon conversion of the 2012 Convertible Loan, which will be automatically converted upon the completion of this offering, (iv) 1,834 Series B-1 preferred shares that will be converted to 238,420 ordinary shares following the closing of this offering, (v) warrants to purchase 733 Series B preferred shares that will be converted to warrants to purchase 95,290 ordinary shares following the closing of this offering, and (vi) 130 Series B preferred Shares that will be converted to 16,900 ordinary shares following the closing of this offering.

DESCRIPTION OF WARRANTS

The following description is a summary of the material provisions of the warrants being offered pursuant to this prospectus (the "warrants") and does not purport to be complete. This summary is subject to and is qualified by reference to all the provisions of the warrants, including the definitions of certain terms used in the warrants. For the complete terms of the warrants, you should refer to the form of warrant filed as an exhibit to the registration statement of which this prospectus forms a part. We urge you to read this document because it, and not this description, sets forth fully the terms of the warrants and define your rights as a holder of the warrants.

Pursuant to a warrant agency agreement between us and American Stock Transfer & Trust Company, LLC, as warrant agent, the warrants will be issued in book-entry form and will initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Exercisability, Exercise Price and Term

Each warrant represents the right to purchase 0.5 of an ordinary share. The warrants to be issued in this offering represent the rights to purchase an aggregate of up to 666,66 ordinary shares (or 766,667 ordinary shares if the underwriters were to fully exercise their over-allotment option with respect to the warrants) at an initial exercise price of $11.25 per ordinary share (which is 125% of the assumed initial public offering price per unit).

The warrants are exercisable beginning on the date of issuance, and at any time up to the five-year anniversary of the original issuance date, which we refer to as the termination date (*provided*, *however*, that if such date is not a business day, the termination date will be the immediately following business day), unless earlier repurchased by us as described below under "— Fundamental Transactions" or subject to early expiration as described below under "— Early Expiration upon Satisfaction of Sale Price Condition"; *provided*, that any single exercise must be in relation to a whole number of ordinary shares. A holder will initially be entitled to one ordinary share for every two warrants held and, as a result, will not be able to exercise warrants other than in integral multiples of two. To exercise warrants prior to the termination date, within one trading day (as defined in the warrants) of delivery of an exercise notice to the warrant agent, a warrant holder must pay to us in cash the exercise price for the aggregate number of ordinary shares to be purchased, unless such warrant holder is utilizing the "cashless" exercise provision of the warrants, which is only available prior to the termination date if, at the time of exercise, there is no effective registration statement registering with the SEC, or no prospectus contained in an effective registration is available for, the issuance of the underlying ordinary shares, or, if required, there is not an effective state law registration or exemption covering the issuance of the ordinary shares underlying the warrants. On the termination date, any warrants not previously exercised, repurchased by us or subject to early expiration will terminate and expire worthless.

If a warrant is exercised via the "cashless" exercise provision, following delivery of an exercise notice to us a holder will receive a number of ordinary shares equal to the quotient obtained by dividing (i) the difference between (x) the arithmetic average of the volume-weighted average prices, or VWAPs (as determined pursuant to the terms of the warrants) of the ordinary shares over each of the 10 consecutive trading days during the related calculation period (as defined below), and (y) the exercise price of the warrants *multiplied by* the number of ordinary shares issuable per warrant by (ii) the 10-day average VWAP determined under clause (i)(x) above. In lieu of fractional shares, we will, at our option, either (A) pay the holder an amount in cash equal to the fractional amount multiplied by the market value of an ordinary share or (B) round up to the next whole share.

The "calculation period" means the 10 consecutive trading day period beginning on, and including, the trading day immediately following the date on which a warrant is exercised (or deemed exercised) pursuant to the terms of the warrants.

A holder will not have the right to exercise any portion of its warrants if such holder (together with its affiliates, and any other persons acting as a group with the holder or any of its affiliates) would beneficially own in excess of 4.99% of the number of our ordinary shares outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. A holder may give not less than 61 days' prior notice to us to increase such beneficial ownership limit, up to

9.99%. To the extent that the limitation under this paragraph applies, the determination of a whether a warrant is exercisable, and of which portion of a warrant is exercisable, will be in the sole discretion of the holder, and the submission of an exercise notice will be deemed to be the holder's determination of whether a warrant is exercisable (in relation to other securities owned by the holder together with any affiliates, and any other persons acting as a group with the holder or any of its affiliates) and of which portion of the warrant is exercisable, in each case subject to the foregoing beneficial ownership restrictions, and we shall have no obligation to verify or confirm the accuracy of such determination and shall have no liability for exercises that are not in compliance with the beneficial ownership restrictions. The foregoing beneficial ownership restrictions will not apply to the extent a holder (together with its affiliates, and any other persons acting as a group with the holder or any of its affiliates) beneficially owned in excess of the foregoing beneficial ownership thresholds prior to the date of original issuance of the warrants.

Failure to Timely Deliver Shares

If we fail to deliver to a holder the ordinary shares otherwise deliverable by the second trading day after the receipt of a duly executed notice of exercise and the corresponding exercise price or, in the case of cashless exercise, by the second trading day after the final day of the applicable calculation period, in each case as required by the warrants (other than any such failure that is solely due to any action or inaction by the holder with respect to such exercise), and if the holder purchases the ordinary shares after that second trading day to deliver in satisfaction of a sale by the holder of the underlying warrant shares that the holder anticipated receiving from us, then, upon the holder's request, we will (A) pay in cash to the holder the amount, if any, by which (x) the holder's total purchase price (including brokerage commissions, if any) for the ordinary shares so purchased exceeds (y) the amount obtained by multiplying (1) the number of ordinary shares that we were required to deliver to the holder in connection with the relevant warrant exercise by (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the holder, either reinstate the portion of the warrant and equivalent number of warrant shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the holder the number of ordinary shares that would have been issued had we timely complied with our exercise and delivery obligations under the warrant.

Certain Adjustments

The exercise price and number of shares issuable upon exercise of each warrant are subject to appropriate adjustment in the event of certain ordinary share dividends and distributions, share splits, stock combinations or similar events affecting our ordinary shares. The exercise price is subject to reduction if, within two years of the date of original issuance of the warrants, we sell or grant any warrant or option to subscribe for or purchase, or otherwise dispose of or issue, any ordinary shares or ordinary share equivalents (as defined in the warrants) at an effective price per share less than $9.00 per share, which is the assumed initial public offering price per unit in this offering (as adjusted in proportion with any adjustments made from time to time to the exercise price), which reduction will be based on a weighted average taking into account the value of the ordinary shares outstanding immediately prior to such new issuance, determined using the exercise price then in effect, and the value of the ordinary shares to be issued or sold or deemed issued or sold in such new issuance, determined using the effective price of such new issuance; *provided* that this sentence shall not apply to certain exempt issuances (as defined in the warrants). Notwithstanding the foregoing, in no event will the exercise price per share be lower than the nominal value of an ordinary share, which is NIS 0.0000769 as of the date of this prospectus.

During such time as the warrants are outstanding, if we declare or make any dividend or other distribution of our assets (or rights to acquire our assets) to holders of ordinary shares, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin-off, corporate rearrangement, scheme of arrangement or other similar transaction, other than (x) a reclassification as to which the provisions described below under "— Fundamental Transactions" apply or (y) any issuance, deemed issuance or automatic conversion of securities in the IPO Transactions or the 2018 Plan) (a "Distribution"), a warrant holder shall be entitled to participate to the same extent that the holder would have participated in such Distribution if the holder had held the number of ordinary shares acquirable upon complete exercise of its warrants (without regard to any limitations on exercise thereof, including without limitation, the beneficial ownership restrictions described above under "— Exercisability, Exercise Price and Term") immediately before the record date for such Distribution (*provided*, *however*, to the extent that a holder's right to participate in any such Distribution would result in the holder exceeding the beneficial ownership restriction, the holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any ordinary shares as a result of such Distribution to such extent) and the portion of such Distribution will be held in abeyance for the benefit of such holder until the earlier of (i) such time, if ever, as the delivery to the holder of such position would not result in such holder exceeding the beneficial ownership restriction and (ii) such time as the holder has exercised its warrants.

Fundamental Transactions

If (i) we effect any merger or consolidation of the Company with or into another person, (ii) we effect any sale, lease or other disposition of all or substantially all of our assets (other than, for the avoidance of doubt, pursuant to a licensing arrangement so long as, after giving effect to such arrangement, our ordinary shares are listed or quoted on a designated market (as defined below)), (iii) any purchase offer, tender offer or exchange offer (whether by us or another person) is completed pursuant to which holders of ordinary shares are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding ordinary shares, (iv) we effect any reclassification, reorganization or recapitalization of the ordinary shares or any compulsory share exchange pursuant to which the ordinary shares are effectively converted into or exchanged for other securities, cash or property, or (v) we consummate a stock or share purchase agreement or other business combination with another person or group of persons whereby such other person or group acquires more than 50% of the outstanding ordinary shares (each a "Fundamental Transaction"), then following such Fundamental Transaction, the holders of the warrants will be entitled to receive upon exercise thereof the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such event. Any successor to us or surviving entity is required to assume the obligations under the warrants. Notwithstanding the foregoing, in the event of a Fundamental Transaction (other than any Fundamental Transaction that is (x) not within our control, including not approved by our board of directors, or (y) a Specified Fundamental Transaction (as defined below), in each case, as to which the right described in this sentence shall not apply), the holders will have the option, which may be exercised within 30 days after the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), to require us or the successor entity to purchase the warrants from holders by paying to them an amount of cash equal to the Black Scholes value (determined in accordance with the provisions of the warrants) of the remaining unexercised portion of the warrants on the date of the consummation of the Fundamental Transaction; *provided* that if the Fundamental Transaction is not within our control, including not approved by our board of directors, within 30 days of the date of consummation of such Fundamental Transaction, a holder will be entitled to receive from us or any successor entity the same type or form of consideration (and in the same proportion), at the Black Scholes value of the unexercised portion of the warrants, that is being offered and paid to our ordinary shareholders in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the ordinary shareholders are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction.

A "Specified Fundamental Transaction" means a Fundamental Transaction (I) described in clause (i) of the definition thereof where, immediately after giving effect thereto (x) the holders of all of our classes of common equity immediately prior to such transaction own, directly or indirectly, more than 50% of all classes of common equity of the continuing or surviving corporation or transferee or the parent thereof immediately after such transaction in substantially the same proportions as such ownership immediately prior to such transaction, or (y) we will be the surviving entity or (II) for which at least 90% of the consideration received or to be received by holders of ordinary shares (excluding cash payments for fractional shares and cash payments pursuant to dissenters' or appraisal rights) that are listed or quoted on any of the NYSE American, the NASDAQ Capital Market, the NASDAQ Global Market, the NASDAQ Global Select Market, the New York Stock Exchange, OTCQB or OTCQX (or any of their respective successors) (each, a "designated market") or will be so listed or quoted when issued or exchange in connection with such Fundamental Transaction.

Early Expiration upon Satisfaction of Sale Price Condition

We may accelerate the expiration date of the warrants upon written notice to the holders at any time if the last reported sale price (as defined in the warrants) exceeds $27.00 per share, which is 300% of the assumed initial public offering price per unit in this offering (as adjusted in proportion with any adjustments made from time to time to the exercise price) for a 10 consecutive trading day period. Any warrants not exercised by 5:00 p.m., New York City time, on the 30^{th} calendar day following the date the acceleration notice is given will terminate and expire worthless.

Transferability

Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing

We have applied to list the warrants on the NASDAQ Capital Market under the symbol “ENTXW.” However, there can be no assurance that the warrants will be approved for listing. The warrants are expected to trade separately from the ordinary shares following the effectiveness of the registration statement for this offering.

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 our ordinary shares, including any voting rights, until the holder exercises the warrant and delivers the corresponding executed exercise notice and exercise price, if any.

Governing Law

The warrants will be governed by, and construed and enforced in accordance with, the laws of the State of New York. Matters involving the rights of shareholders, the issuance of ordinary shares and the validity of ordinary shares are governed by the laws of Israel.

DESCRIPTION OF SHARE CAPITAL

The following description of our share capital and provisions of our amended Articles are summaries and are qualified by reference to our amended Articles, which have been filed with the SEC as an exhibit to the 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 Fifth Amended and Restated Articles of Association currently in effect, or the current Articles, will be further amended and restated and replaced by our Sixth 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 130,000,000 ordinary shares, par value NIS 0.0000769 per share, of which 10,018,320 ordinary shares are issued and outstanding as of date of this prospectus and 11,361,654 ordinary shares will be issued and outstanding immediately following the closing of this offering, in each case on a post-offering basis (assuming the underwriters do not exercise their option to purchase additional ordinary shares and including 10,000 ordinary shares to be issued to the representative upon the closing of this offering). All of our ordinary shares have been validly issued, fully paid and are non-assessable.

As of March 31, 2018, the number of our ordinary shares outstanding was 10,018,320, and an additional 3,186,170 ordinary shares were issuable upon the exercise of outstanding options granted to our officers, employees and certain consultants, at a weighted-average exercise price of $4.63 per share, in each case after giving effect to the 1-for-130 split of our ordinary shares that is described elsewhere in this prospectus. 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.

Existing Warrants

Series A Warrants

As of March 31, 2018, we had outstanding warrants to purchase 2,554 of our Series A preferred shares, at an exercise price of $479.38, which, upon the closing of this offering will automatically convert into warrants to purchase 322,020 of our ordinary shares, at an exercise price of $3.69.

Pursuant to the terms of the preferred share purchase agreements with Centillion and certain other preferred shareholders, upon the closing of this offering, and upon the exercise of the right to invest the second milestone amount and certain options held by Centillion, we will issue to Centillion and the other preferred shareholders warrants to purchase an additional 97,111 ordinary shares, at an exercise price of $3.69.

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 $3.69 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 March 31, 2018, we had outstanding additional warrants to purchase 3,594 Series B-1 preferred shares in an aggregate principal amount of $2.45 million, which upon the closing of this offering will become additional warrants to purchase 467,220 of our ordinary shares at an exercise price of $5.24 per share, which represents a 25% discount to the Series B preferred share purchase price per share.

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 two years 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. The Series B Private Placement constituted a 2016 Triggering Event as defined in the additional warrants, and as a result, the exercise period for such warrants is two years following October 4, 2017.

Applicable Shares. Series B-1 preferred shares, or ordinary shares if exercised upon or following the closing of this offering.

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. As a result of the Series B Private Placement, the exercise price was set at $5.24, which represents a 25% discount to the Series B preferred share purchase price per share, after giving effect to the conversion of the exercise price due to the ordinary share split described in this prospectus.

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, or the 2016 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 in to the Company's equity securities following a 2016 Triggering Event. As a result of the Series B preferred shares purchase agreement, the price at which the previously issued 2016 Warrants may be exercised was set at $908.78.

As of March 31, 2018, we had 5,292 outstanding 2016 Warrants in an aggregate principal amount of $4.8 million, which upon the closing of this offering will become warrants to purchase 687,960 of our ordinary shares at an exercise price of $6.99 per ordinary share.

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 exercisable until June 2020, and will be exercisable into ordinary shares following the completion of this offering.

Applicable Securities. Series B preferred shares, or ordinary shares if exercised upon or following the closing of this offering.

Exercise Price. $6.99 per share.

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 current Articles.

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.

Series B Warrants

In connection with the Series B Private Placement, the Company issued to GP Nurmenkari Inc., or the placement agent, a warrant to purchase up to 526 Series B preferred shares, or Series B warrants, at a price of $908.78 per share, which upon the closing of this offering will become warrants to purchase 63,380 ordinary shares at an exercise price of $6.99 per share.

The following summary of certain material terms and provisions of the Series B Warrants:

Exercisability. The Series B warrants are exercisable on or before the earlier of: (i) expiration of five years from the date of the Series B warrant, or (ii) the occurrence of a liquidation, bankruptcy, reorganization, dissolution or winding up of the Company, whether voluntary or involuntary.

Applicable Securities. The Series B warrants will be exercisable for Series B preferred shares of the Company, par value NIS 0.01 per share, or any securities issued or issuable according to the Series B warrants, including but not limited to ordinary shares, if exercised upon or following the closing of this offering.

Exercise Price. The initial exercise price will be $6.99 per share, subject to adjustments as provided in the Series B warrants.

Transferability. The Series B warrant cannot be transferred to a third party, other than an affiliate of the holder of such Series B warrant (as defined and subject to the terms and conditions of the Series B warrants) without (i) a registration under the Securities Act or (ii) an exemption from such registration and, if requested by the Company, a written opinion of legal counsel of the holder of the Series B warrant, addressed to the Company stating that the proposed transfer of the warrant may be effected without registration under the Securities Act, which opinion will be in form reasonably satisfactory to the Company.

Rights as a Shareholder. Except as otherwise provided in the Series B warrants or by virtue of such holder's ownership of our ordinary shares, the holder of a Series B warrant does not have the rights or privileges of a holder of ordinary shares, including any voting rights, until the holder exercises the Series B 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 3 of our Articles of Association, which is 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 Companies Law, and 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. Under our Articles of Association, our board of directors must consist of not less than three but no more than nine directors. Pursuant to our Articles of Association, other than the external directors, for whom special election requirements apply under the Companies Law, the vote required to appoint a director is a simple majority vote of holders of our voting shares participating and voting at the relevant meeting. In addition, our Articles of Association allow our board of directors to appoint new directors to fill vacancies on the board of directors if the number of directors is below the maximum number provided in our Articles of Association. Furthermore, under our Articles of Association, our directors other than external directors are divided into three classes with staggered three-year terms. External directors are elected for an initial term of three years, may be elected for additional terms of three years each under certain circumstances, and may be removed from office pursuant to the terms of the Companies Law. 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, 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 end of the period to which the financial statements relate is not more than six months before the distribution. Declaration of dividends requires a resolution of our Board and 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. Such amounts may be subject to Israeli withholding tax and 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 ordinary 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, holding at least 25% of our 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, subject to certain exceptions, 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. For example, resolutions with respect to certain interested party transactions, or with respect to tender offers may require a special majority.

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 items on the agenda. Under the Companies Law and regulations promulgated thereunder, one or more shareholders holding at least 1% of the voting rights at a general meeting of shareholders may request that the board of directors include a matter in the agenda of a general meeting of shareholders to be convened in the future, provided that such matter is appropriate for discussion at the general meeting.

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.

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.

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 special tender offer if, as a result of the acquisition, the purchaser would become a 25% or more shareholder of the company, unless there is already a 25% or more 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 special tender offer if as a result of the acquisition the purchaser would become a more than 45% shareholder of the company, unless there is already a more than 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 more than 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 voting rights, 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 (excluding the controlling shareholders of the offeror, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer or any of their relatives or any entity controlled by them). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer. Shares purchased in contradiction to the tender offer rules under the Israeli Companies Law will have no rights and will become dormant shares.

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 (i) the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company and (ii) more than half of the shareholders who do not have a personal interest in the offer accept the offer, then all the shares that the acquirer offered to purchase will be transferred to it. However, a full tender offer will also be accepted if the shareholders who do not accept the offer holder less than 2% of the issued and outstanding shares of the company. The Companies 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 (i) the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding shares of the company or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (ii) the shareholders who do not accept the offer hold 2% or more of the outstanding shares of the company, then the acquirer may not acquire shares that will cause his shareholdings 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, subject to certain exceptions, 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.

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.

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

In addition, certain shareholders have a duty of fairness toward the company. These shareholders include 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, taking into account the position of such shareholder in the company.

Access to Corporate Records

Under the Companies Law, shareholders are provided access to minutes of our general meetings, our shareholders register and principal shareholders register, our articles of association in effect from time to time, our financial statements and any document that we are required by law to file publicly with the Israeli Companies Registrar or the Israel Securities Authority. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

Listing

We expect to list our ordinary shares on the NASDAQ Capital Market under the symbol “ENTX”, and they are expected to trade separately from the warrants following the effectiveness of the registration statement for this offering.

Transfer Agent and Registrar

Upon listing of our ordinary shares for trading on the NASDAQ Capital Market, the transfer agent and registrar for the ordinary shares will be American Stock Transfer & Trust Company, LLC.

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 and warrants. 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 and warrants that are purchased in this 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 or warrants. 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. This discussion does not address tax consequences of a Fundamental Transaction. 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 promulgated thereunder as of the date hereof, which are subject to change. Some parts of this discussion are based on new tax legislation which has not been subject to judicial or administrative interpretation. The discussion should not be construed as legal or professional tax advice and does not cover all possible tax considerations.

General Corporate Tax Structure

Israeli companies are generally subject to corporate tax on their taxable income currently at the rate of 23%. 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), 5729-1969, 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 generally 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 tax-related 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, *inter alia*, 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); (iii) is controlled and managed from Israel; and (iv) satisfies 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, known as development zone A, in which case the rate is currently 7.5%.

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 individuals whose annual taxable income exceeds a certain threshold (NIS 641,880 for 2018).

As we have not yet generated income, 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.

Tax Benefits for Income from Preferred Technology Enterprise

An amendment to the Investment Law, or the 2017 Amendment, was enacted as part of the Economic Efficiency Law that was published on December 29, 2016, and became effective as of January 1, 2017. 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 may 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 may 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 IIA.

The 2017 Amendment further provides that a technology company satisfying certain conditions (including an annual turnover of NIS 10 billion or more of the group that the technology company is a part) will qualify as a "Special Preferred Technology Enterprise" and may 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 the IIA. 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 10 years, subject to satisfying certain conditions and obtaining 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 yet generated income, 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 or warrants of Israeli companies by non-residents of Israel, unless a specific exemption is available or unless a tax treaty between Israel and the shareholder’s country of residence provides otherwise. 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 our ordinary shares or warrants acquired pursuant to this 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”. An additional tax of 3% will be imposed on individuals whose annual taxable income exceeds a certain threshold (NIS 641,880 for 2018). Israeli companies are subject to the corporate tax rate on real capital gains derived from the sale of shares at the rate of 23%. Individual and corporate shareholders dealing in securities in Israel are taxed at the tax rates applicable to “business income”: currently, 23% for corporations and a marginal tax rate of up to 47% for individuals, plus an additional tax of 3%, which is imposed on individuals whose annual taxable income exceeds a certain threshold (NIS 641,880 for 2018).

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. The sale, exchange or other disposition of our warrants are generally exempt from capital gains tax in Israel by a non-Israeli resident holder provided, among other things, that (i) the gains were not derived from a permanent establishment of such holder in Israel; (ii) the warrants were not purchased from a related party or by way of certain tax-free reorganizations, and (iii) the warrants are not traded on an Israeli stock exchange on the date of sale. However, shareholders and holders of warrants 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 a withholding certificate issued by the Israel Tax Authority prior to the applicable payment.

Exercise and Lapse of Warrants

The following discussion relating to our warrants is not applicable to holders of warrants who are deemed “controlling members” as defined in Section 3(i) of the Ordinance, which generally means a holder who holds or is entitled to acquire, directly or indirectly, alone or together with his relative, (i) at least 5% of our issued share capital; (ii) at least 5% of our voting power; (iii) the right to receive at least 5% of our profits or assets upon winding up; or (iv) the right to appoint a director. A relative for this purpose means a spouse, brother, sister, parent, parent’s parent, descendant, the spouse’s descendant and the spouse of any of the foresaid. Such holders should consult with their own tax advisors regarding the potential tax implications to them of the receipt or exercise of our warrants.

Holders of our warrants generally will not recognize gain or loss upon the exercise of our warrants for cash. An ordinary share acquired pursuant to the exercise of a warrant for cash generally will have a tax basis equal to the holder’s tax basis in the warrant, increased by the amount paid to exercise the warrant. If a warrant is allowed to lapse unexercised, the holder generally will recognize a capital loss equal to such holder’s tax basis in the warrant.

It is possible that a cashless exercise of a warrant would be treated as a taxable exchange in which gain or loss is recognized. In such event, a holder could be deemed to have surrendered a number of warrants with a fair market value equal to the exercise price for the number of warrants deemed exercised. For this purpose, the number of warrants deemed exercised would be equal to the number of warrants that would entitle the holder to receive upon exercise the number of ordinary shares issued pursuant to the cashless exercise of the warrants. In this situation, the holder would recognize capital gain or loss in an amount equal to the difference between the fair market value of the warrants deemed surrendered to pay the exercise price and the holder’s tax basis in the warrants deemed surrendered.

Holders of warrants should consult with their own tax advisors regarding the manner in which such holders’ tax basis in each unit purchased in this offering is allocated among ordinary shares and warrants, the calculation of any tax basis adjustments and the calculation of capital gains upon the sale or other disposition of our warrants.

Withholding and Reporting

Either the purchaser, the Israeli stockbrokers or financial institutions through which the shares and warrants are held is obliged to withhold tax on the amount of consideration paid upon the sale of such securities (or on the capital gain realized on the sale, if known) at the Israeli corporate tax rate for Israeli companies (currently 23%). In case the seller is an individual, the applicable withholding tax rate would be 25% of the amount of consideration paid upon the sale of such securities (or on the capital gain realized on the sale, if known).

In some instances where our shareholders may be liable for Israeli tax on the sale of their ordinary shares or warrants, the payment of the consideration may be subject to the withholding of Israeli tax at source. Shareholders, including non-Israeli resident 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. In transactions involving a sale of all of the securities of an Israeli resident company, in the form of a merger or otherwise, the Israel Tax Authority may require non-Israeli resident 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 a non-resident of Israel, and, in the absence of such declarations or exemptions, may require the purchaser of the securities to withhold taxes at source.

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 the regulations promulgated thereunder, then the aforementioned return need not be filed and no advance payment must be made.

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). The tax rate applicable to such dividends is 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. 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 may be distributed in a way that will reduce shareholders’ tax liability.

Moreover, an additional tax of 3% will be imposed on individuals whose annual taxable income exceeds a certain threshold (NIS 641,880 for 2018).

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 a certificate for a reduced withholding tax rate is obtained in advance from the Israeli Tax Authority.

The aforementioned rates under the U.S.-Israel 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.

Eligibility to benefit from tax treaties is conditioned upon the shareholder presenting a withholding certificate issued by the Israel Tax Authority prior to the applicable dividend distribution.

Taxation of Distributions on Warrants

As discussed above under “Dividend Policy,” we do not currently expect to make distributions on our ordinary shares. However, if we make any distributions on our ordinary shares (including cash distributions), we will be required to make distributions to holders of warrants as described under “Description of Warrants — Certain Adjustments”. The gross amount of any such distributions to holders of warrants may be treated as ordinary income for Israeli income tax purposes and subject to ordinary income tax rates. Under applicable law, we will have withholding obligations and may be required to withhold from the gross amount of such distribution at rates which could be up to the highest tax rates applicable to ordinary income. Holders of our warrants should consult their own tax advisers concerning the Israeli income tax treatment of distributions on our warrants including, with respect to non-Israeli resident holders, the credibility of any Israeli taxes withheld on such distributions.

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 641,880 for 2018), which amount is 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 and warrants, 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 and warrants. This discussion applies only to a U.S. Holder that acquires our ordinary shares and warrants in this offering and holds them as capital assets for U.S. federal income tax purposes. This discussion does not address tax consequences of a Fundamental Transaction to U.S. Holders. 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 or warrants as part of a "straddle" or integrated transaction or persons entering into a constructive sale with respect to the ordinary shares or warrants;
- 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 stock by vote or value; 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 or warrants, 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 or warrants 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 or warrants.

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 warrants 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 and warrants in their particular circumstances.

In determining their tax basis for the ordinary shares and warrants purchased together, U.S. Holders are required to allocate their total purchase price between the ordinary shares and warrants on the basis of their relative fair market values at the time of issuance.

Taxation of Distributions on Ordinary Shares

As discussed above under “Dividend Policy,” we currently do not expect to make distributions on our ordinary shares. Subject to the discussion below under “Passive Foreign Investment Company Rules,” any distributions 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 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. See “— Sale or Other Disposition, Exercise or Expiration of Warrants” below for a discussion regarding a U.S. Holder’s tax basis and holding period for ordinary shares acquired pursuant to an exercise of warrants. 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.

Sale or Other Taxable Disposition, Exercise or Expiration of Warrants

Subject to the discussion below under “Passive Foreign Investment Company Rules,” gain or loss realized on the sale or other disposition of a warrant (other than by way of exercise) will be capital gain or loss and will be long-term capital gain or loss if the U.S. Holder held the warrant for more than one year at the time of the sale or disposition. The amount of the gain or loss will equal the difference between the U.S. Holder’s tax basis in the warrants disposed of and the amount realized on the disposition.

In general, a U.S. Holder will not be required to recognize income, gain or loss upon the exercise of a warrant by payment of the exercise price in cash. A U.S. Holder’s tax basis in ordinary shares received upon exercise of warrants will be equal to the sum of (1) the U.S. Holder’s tax basis in the warrant and (2) the exercise price of the warrant. A U.S. Holder’s holding period in the ordinary shares received upon exercise will commence on the day the warrants are exercised.

Although there is no direct legal authority as to the U.S. federal income tax treatment of an exercise of a warrant on a cashless basis, we believe that it is reasonable to take the position that such exercise will not be taxable (except with respect to cash received in lieu of a fractional ordinary share), either because the exercise is not a gain realization event or because it qualifies as a tax-free recapitalization. In the former case, subject to the discussion below under "— Passive Foreign Investment Company Rules," the holding period of the ordinary shares should commence on the day the warrants are exercised. In the latter case, the holding period of the ordinary shares would include the holding period of the exercised warrants. In either case, the U.S. Holder's tax basis in the ordinary shares (including any fractional ordinary share) received generally would equal the U.S. Holder's tax basis in the warrants. However, such position regarding the treatment of a cashless exercise is not binding on the Internal Revenue Service, or the IRS, and the IRS may treat a cashless exercise of a warrant as a taxable exchange. U.S. Holders are urged to consult their tax advisers as to the consequences of an exercise of a warrant on a cashless basis. The receipt of cash in lieu of a fractional ordinary share should result in a capital gain or loss equal to the difference between the cash received and the U.S. Holder's tax basis in the ordinary shares allocable to the fractional share.

If a warrant expires without being exercised, a U.S. Holder will recognize a capital loss in an amount equal to such U.S. Holder's tax basis in the warrant. This loss will be long-term capital loss if, at the time of the expiration, the U.S. Holder's holding period in the warrant is more than one year. The deductibility of capital losses is subject to limitations.

Taxation of Distributions on Warrants

As discussed above under "Dividend Policy," we do not currently expect to make distributions on our ordinary shares. However, if we make any distributions on our ordinary shares (including cash distributions), we will be required to make distributions to holders of warrants as described under "Description of Warrants — Certain Adjustments". The gross amount of any such distributions to U.S. Holders of warrants (including any amounts withheld in respect of Israeli taxes) will be treated as ordinary income for U.S. federal income tax purposes. U.S. Holders should expect that any such distributions will not qualify for the preferential tax rates applicable to qualified dividend income of non-corporate shareholders. In addition, if we are a PFIC for any taxable year, under proposed Treasury regulations any such distributions could be subject to the adverse PFIC rules described in "— Passive Foreign Investment Company Rules." U.S. Holders should consult their tax advisers concerning the U.S. federal income tax treatment of distributions on warrants, including the credibility of any Israeli taxes withheld on such distributions.

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, and on how quickly we utilize the cash in our business. Because (i) the value of our goodwill may be determined by reference to the market price of our ordinary shares, which may be volatile given the nature and early stage of our business, (ii) we expect to hold a significant amount of cash following this offering, and (iii) a company's PFIC status is determined on an annual basis 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 IRS 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 (and, under proposed Treasury regulations, warrants), an adverse tax regime would apply to the U.S. Holder’s investment in our ordinary shares (and warrants). Generally, gain recognized upon a taxable disposition (including, under certain circumstances, a pledge) of ordinary shares (or, under proposed Treasury regulations, warrants) by the U.S. Holder would be allocated ratably over the U.S. Holder’s holding period for such ordinary shares (or warrants). 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 (or, under proposed Treasury regulations, warrants) exceeded 125% of the average of the annual distributions received on such ordinary shares (or warrants) 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. Under proposed Treasury regulations, if we were a PFIC during any taxable year during which a U.S. Holder held our warrants, the holding period for the ordinary shares received upon exercise of such warrants would include the holding period of the warrants.

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 NASDAQ Capital Market, 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). Under current law, a mark-to-market election is not available with respect to the warrants. 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 (or, under proposed Treasury regulations, warrants), we generally would continue to be treated as a PFIC with respect to such U.S. Holder's ordinary shares (or warrants) 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 of our ordinary shares would not apply. In addition, if we were a PFIC for any taxable year during which a U.S. Holder owns ordinary shares (or, under proposed Treasury regulations, warrants), the U.S. Holder would be required to file annual reports with the IRS, 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 and warrants.

Information Reporting and Backup Withholding

Payments of distributions 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 IRS.

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 and warrants, unless the ordinary shares or warrants 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 and warrants.

SECURITIES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our ordinary shares or warrants. Future sales of our ordinary shares or warrants in the public market, or the availability of such securities for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of ordinary shares or warrants 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 March 31, 2018, upon completion of this offering 11,361,654 ordinary shares will be outstanding (which includes 4,905,420 ordinary shares issuable upon the conversion of our preferred shares that will be outstanding upon the closing of this offering 622,180 ordinary shares issuable upon the conversion of our convertible loans that will be outstanding upon the closing of this offering and the issuance of 10,000 ordinary shares to the representative upon the closing of this offering), after giving effect to the 1-for- 130 split of our ordinary shares that is described elsewhere in this prospectus, assuming no exercise of options or outstanding warrants or the underwriters' option to purchase additional ordinary shares from us.

Of these shares, the 1,333,334 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 10,028,320 ordinary shares outstanding after this offering will be "restricted securities" under Rule 144, and 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 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 securities offered in this offering or purchased in the open market without the prior written consent of Maxim Group LLC 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 ordinary shares may be sold subject to the restrictions under Rule 144 or 701 under the Securities Act or by means of registered public offerings. Certain securities held by our shareholders shall not be subject to any such lock-up period, other than as required by applicable law, rule or regulation. 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 any 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 the NASDAQ Capital Market 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 the Plan, 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.

Registration Rights

Upon completion of this offering, the holders of 9,273,290 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 six months following the effective date of, a previous registration statements.

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. With respect to such registration rights, we have committed to use our reasonable best efforts to include in a registration statement a prospectus relating to the resale of certain securities held by certain of our shareholders, or to file concurrently with the application of this registration statement a separate registration statement with respect to the resale under the Securities Act of such securities held by such shareholders, so as to permit their disposition (such securities held by such shareholders and the rights attached to such securities are freely transferable by such shareholders).

UNDERWRITING

We entered into an underwriting agreement with the underwriters named below on , 2018. Maxim Group LLC is acting as the representative of the underwriters. The underwriting agreement provides for the purchase of a specific number of units by each of the underwriters. The underwriters' obligations are several, which means that each underwriter is required to purchase a specified number of units, but is not responsible for the commitment of any other underwriter to purchase units. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase the number of units set forth opposite its name below:

Underwriter	Number of Units
Maxim Group LLC	
Joseph Gunnar & Co. LLC	
Total	

The underwriters have agreed to purchase all of the units offered by this prospectus (other than the additional ordinary shares and/or warrants covered by the over-allotment option described below) if any are purchased.

The units offered hereby are expected to be ready for delivery on or about , 2018 against payment in immediately available funds.

The underwriters are offering the units subject to various conditions and may reject all or part of any order. The representative of the underwriters has advised us that the underwriters propose initially to offer the units to the public at the public offering price set forth on the cover page of this prospectus and to dealers at a price less a concession not in excess of $ per units to brokers and dealers. After the ordinary shares are released for sale to the public, the representative may change the offering price, the concession, and other selling terms at various times.

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 30 days after the date of this prospectus, permits the underwriters to purchase a maximum of 200,000 additional ordinary shares and/or 200,000 additional warrants to purchase up to 100,000 ordinary shares to cover over-allotments, if any. If the underwriters exercise all or part of this option, they will purchase ordinary shares covered by the option at the public offering price that appears on the cover page of this prospectus, less the underwriting discounts and commissions. If this option is exercised in full, the total price to public will be $, and the total proceeds to us, before expenses, will be $.

The following table provides information regarding the amount of the discounts and commissions to be paid to the underwriters by us, before expenses:

	Per Unit(1)	Total Without Exercise of Over-Allotment Option	Total With Full Exercise of Over-Allotment Option
Public offering price	$	$	$
Underwriting discounts and commissions	$	$	$
Proceeds, before expenses, to us	$	$	$

(1) The public offering price and underwriting discounts and commissions correspond to a public offering price per ordinary share of $ and a public offering price per warrant of $.

We estimate that our total expenses of the offering, excluding the estimated underwriting discounts and commissions, will be approximately $1.1 million, which includes fees and expenses for which we have agreed to reimburse the underwriters, including fees and expenses incurred by underwriters' counsel of up to $100,000 and roadshow expenses incurred by the underwriters of up to $5,000.

We have also agreed to issue to the representative 10,000 ordinary shares following the closing of this offering, as well as underwriter warrants to purchase a number of ordinary shares equal to an aggregate of 5% of the ordinary shares sold as part of the units in this offering. The underwriter warrants will have an exercise price equal to 110% of the initial public offering price of the units in this offering and may be exercised on a cashless basis unless a registration statement covering the exercise of the underwriter warrants and sale of the underlying shares by the holder thereof is in effect and available. The underwriter warrants will be exercisable 180 days following the date on which the registration statement of which this prospectus forms a part becomes effective until the fifth anniversary of the such effective date. The underwriter warrants are not redeemable by us. The underwriter warrants also provide for unlimited "piggyback" registration rights at our expense with respect to the underlying ordinary shares during the seven-year period commencing on the closing date of the units offering and for one demand registration right at our expense and an additional demand registration right at the underwriter warrant holder's expense during the five-year period commencing on the closing date of the units offering. The underwriter warrants will provide for adjustment of the exercise price of such warrants (and the ordinary shares underlying such warrants) for dilutive events such as a stock dividend or stock split and for recapitalizations, mergers and other fundamental transactions. The underwriter warrants and the ordinary shares issuable upon the exercise of the underwriter warrants have been deemed underwriting compensation by FINRA and are therefore subject to a 180 day lock up pursuant to FINRA Rule 5110(g)(1). Except as otherwise permitted by FINRA rules, for a period of 180 days following the effective date of the registration statement of which this prospectus forms a part, such underwriters warrants shall not be (A) sold, transferred, assigned, pledged or hypothecated or (B) the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person. We have also agreed, subject to certain conditions and exceptions, to provide Maxim Group, LLC with a right of first refusal to act, for a period of 12 months following the closing of this offering, as (i) sole lead managing underwriter and book runner in any subsequent financing equal to or less than $25 million, and (ii) joint book runner in any subsequent financing of more than $25 million.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

We and our executive officers, directors and certain of our shareholders have agreed to a 180-day "lock-up" with respect to our ordinary shares and other of our securities that they beneficially own, including securities that are convertible into ordinary shares and securities that are exchangeable or exercisable ordinary shares. This means that, subject to certain exceptions, for a period of 180 days following the date of this prospectus, we and such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of Maxim Group LLC.

Rules of the Securities and Exchange Commission may limit the ability of the underwriters to bid for or purchase ordinary shares before the distribution of the ordinary shares is completed. However, the underwriters may engage in the following activities in accordance with the rules:

- Stabilizing transactions — The representative may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the ordinary shares, so long as stabilizing bids do not exceed a specified maximum.
- Over-allotments and syndicate covering transactions — The underwriters may sell more ordinary shares in connection with this offering than the number of ordinary shares that they have committed to purchase. This over-allotment creates a short position for the underwriters. This short sales position may involve either "covered" short sales or "naked" short sales. Covered short sales are short sales made in an amount not greater than the underwriters' over-allotment option to purchase additional ordinary shares in this offering described above. The underwriters may close out any covered short position either by exercising its over-allotment option or by purchasing ordinary shares in the open market. To determine how they will close the covered short position, the underwriters will consider, among other things, the price of ordinary shares available for purchase in the open market, as compared to the price at which they may purchase ordinary shares through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. 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, in the open market after pricing, there may be downward pressure on the price of the ordinary shares that could adversely affect investors who purchase ordinary shares in this offering.

- Penalty bids — If the representative purchases ordinary shares in the open market in a stabilizing transaction or syndicate covering transaction, it may reclaim a selling concession from the underwriters and selling group members who sold those ordinary shares as part of this offering.
- Passive market making — Market makers in the ordinary shares who are underwriters or prospective underwriters may make bids for or purchases of ordinary shares, subject to limitations, until the time, if ever, at which a stabilizing bid is made.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales or to stabilize the market price of our ordinary shares may have the effect of raising or maintaining the market price of our ordinary shares or preventing or mitigating a decline in the market price of our ordinary shares. As a result, the price of the ordinary shares of our common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the ordinary shares if it discourages resales of the ordinary shares.

Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the ordinary shares or the warrants. These transactions may occur on The NASDAQ Capital Market or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

Certain of our existing shareholders and parties affiliated with our existing shareholders have indicated an interest in purchasing an aggregate of up to approximately $5.0 million of the units in this offering at the initial public offering price per unit. However, indications of interest are not binding agreements or commitments to purchase, and these entities may determine to purchase a greater or lesser number of units than they have indicated an interest in purchasing or to not purchase any units in this offering. In addition, we and the underwriters could determine to sell a greater or lesser number of units to any of these entities than the entities have indicated an interest in purchasing or to not sell any units to these entities.

Electronic Delivery of Preliminary Prospectus

A prospectus in electronic format may be delivered to potential investors by one or more of the underwriters participating in this offering. The prospectus in electronic format will be identical to the paper version of such prospectus. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part.

Notice to Non-U.S. Investors

Belgium

The offering is exclusively conducted under applicable private placement exemptions and therefore it has not been and will not be notified to, and this document or any other offering material relating to the securities offered hereby has not been and will not be approved by, the Belgian Banking, Finance and Insurance Commission ("Commission bancaire, financière et des assurances/Commissie voor het Bank, Financie en Assurantiewezen"). Any representation to the contrary is unlawful.

Each underwriter has undertaken not to offer sell, resell, transfer or deliver directly or indirectly, any ordinary shares, or to take any steps relating/ancillary thereto, and not to distribute or publish this document or any other material relating to the ordinary shares or to the offering in a manner which would be construed as: (a) a public offering under the Belgian Royal Decree of 7 July 1999 on the public character of financial transactions; or (b) an offering of securities to the public under Directive 2003/71/EC which triggers an obligation to publish a prospectus in Belgium. Any action contrary to these restrictions will cause the recipient and the company to be in violation of the Belgian securities laws.

Canada

This document constitutes an "exempt offering document" as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the securities described herein (the "Securities"). No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this document or on the merits of the Securities and any representation to the contrary is an offence.

Canadian investors are advised that this document has been prepared in reliance on section 3A.3 of National Instrument 33-105 Underwriting Conflicts (“NI 33-105”). Pursuant to section 3A.3 of NI 33-105, this document is exempt from the requirement to provide investors with certain conflicts of interest disclosure pertaining to “connected issuer” and/or “related issuer” relationships as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

Resale Restrictions

The offer and sale of the securities in Canada is being made on a private placement basis only and is exempt from the requirement to prepare and file a prospectus under applicable Canadian securities laws. Any resale of Securities acquired by a Canadian investor in this offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the securities outside of Canada.

Representations of Purchasers

Each Canadian investor who purchases the securities will be deemed to have represented to the issuer and to each dealer from whom a purchase confirmation is received, as applicable, that the investor (i) is purchasing as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) is an “accredited investor” as such term is defined in section 1.1 of National Instrument 45-106 *Prospectus Exemptions* (“NI 45-106”) or, in Ontario, as such term is defined in section 73.3(1) of the *Securities Act* (Ontario); and (iii) is a “permitted client” as such term is defined in section 1.1 of National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*.

Taxation and Eligibility for Investment

Any discussion of taxation and related matters contained in this document does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the securities and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the securities or with respect to the eligibility of the securities for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

Rights of Action for Damages or Rescission

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum, including where the distribution involves an “eligible foreign security” as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration Exemptions* and in Multilateral Instrument 45-107 *Listing Representation and Statutory Rights of Action Disclosure Exemptions*, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a “misrepresentation” as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defences under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

Language of Documents

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

France

Neither this prospectus nor any other offering material relating to the ordinary shares has been submitted to the clearance procedures of the Autorité des marchés financiers in France. The ordinary shares have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the ordinary shares has been or will be: (a) released, issued, distributed or caused to be released, issued or distributed to the public in France; or (b) used in connection with any offer for subscription or sale of the ordinary shares to the public in France. Such offers, sales and distributions will be made in France only: (i) to qualified investors (investisseurs qualifiés) and/or to a restricted circle of investors (cercle restreint d'investisseurs), in each case investing for their own account, all as defined in and in accordance with Articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code monétaire et financier; (ii) to investment services providers authorised to engage in portfolio management on behalf of third parties; or (iii) in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French Code monétaire et financier and article 211-2 of the General Regulations (Règlement Général) of the Autorité des marchés financiers, does not constitute a public offer (appel public à l'épargne). Such ordinary shares may be resold only in compliance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code monétaire et financier.

Israel

This prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the "Securities Law"), and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the securities offered hereby is directed only at, investors listed in the first addendum to the Israeli Securities Law (the "Addendum"), consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, 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 (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Italy

The offering of the ordinary shares offered hereby in Italy has not been registered with the Commissione Nazionale per la Società e la Borsa ("CONSOB") pursuant to Italian securities legislation and, accordingly, the ordinary shares offered hereby cannot be offered, sold or delivered in the Republic of Italy ("Italy") nor may any copy of this prospectus or any other document relating to the ordinary shares offered hereby be distributed in Italy other than to professional investors (operatori qualificati) as defined in Article 31, second paragraph, of CONSOB Regulation No. 11522 of 1 July, 1998 as subsequently amended. Any offer, sale or delivery of the ordinary shares offered hereby or distribution of copies of this prospectus or any other document relating to the ordinary shares offered hereby in Italy must be made:

(a) by an investment firm, bank or intermediary permitted to conduct such activities in Italy in accordance with Legislative Decree No. 58 of 24 February 1998 and Legislative Decree No. 385 of 1 September 1993 (the "Banking Act");

(b) in compliance with Article 129 of the Banking Act and the implementing guidelines of the Bank of Italy; and

(c) in compliance with any other applicable laws and regulations and other possible requirements or limitations which may be imposed by Italian authorities.

Sweden

This prospectus has not been nor will it be registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this prospectus may not be made available, nor may the ordinary shares offered hereunder be marketed and offered for sale in Sweden, other than under circumstances which are deemed not to require a prospectus under the Financial Instruments Trading Act (1991: 980).

Switzerland

The ordinary shares offered pursuant to this prospectus will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to art. 652a or art. 1156 of the Swiss Federal Code of Obligations. The company has not applied for a listing of the ordinary shares being offered pursuant to this prospectus on the SWX Swiss Exchange or on any other regulated securities market, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the relevant listing rules. The ordinary shares being offered pursuant to this prospectus have not been registered with the Swiss Federal Banking Commission as foreign investment funds, and the investor protection afforded to acquirers of investment fund certificates does not extend to acquirers of ordinary shares.

Investors are advised to contact their legal, financial or tax advisers to obtain an independent assessment of the financial and tax consequences of an investment in ordinary shares.

United Kingdom/Germany/Norway/The Netherlands

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relevant Member State”) an offer to the public of any ordinary shares which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State other than the offers contemplated in this prospectus in name(s) of Member State(s) where prospectus will be approved or passported for the purposes of a non-exempt offer once this prospectus has been approved
by the competent authority in such Member State and published and passported in accordance with the Prospectus Directive as implemented in name(s) of relevant Member State(s) except that an offer to the public in that Relevant Member State of any 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:

(a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

(b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;

(c) by the representative to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or

(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of ordinary shares shall result in a requirement for the publication by the company 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 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 ordinary shares to be offered so as to enable an investor to decide to purchase any ordinary shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression “Prospectus Directive” means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Each underwriter has represented, warranted and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (the FSMA)) received by it in connection with the issue or sale of any ordinary shares in circumstances in which section 21(1) of the FSMA does not apply to the company; and

(b) it has complied with and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the ordinary shares in, from or otherwise involving the United Kingdom.

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	$ 10,062
NASDAQ Capital Market listing fee	$ 50,000
FINRA filing fee	$ 12,622
Printing expenses	$ 100,000
Legal fees and expenses	$ 450,000
Accounting fees and expenses	$ 300,000
Transfer agent's fees	$ 33,000
Miscellaneous	$ 144,316
Total	$1,000,000

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. Certain legal matters in connection with this offering will be passed upon for the underwriters by Gornitzky & Co., Tel Aviv, Israel, with respect to Israeli law, and by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York, with respect to U.S. law.

EXPERTS

The financial statements as of December 31, 2017 and 2016 and for each of the two years in the period ended December 31, 2017 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 1a.2 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 which, subject to certain exceptions, is non-appealable, 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, among other things, the following conditions are met:

- the judgment is enforceable under the laws of State of Israel and under the laws of 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 and present his or her evidence;
- 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 units. 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 intend to 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 to 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.

Opinion on the Financial Statements

We have audited the accompanying statements of financial position of Entera Bio Ltd. as of December 31, 2017 and 2016, and the related statements of comprehensive loss, changes in capital deficiency and cash flows for each of the two years in the period ended December 31, 2017, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Explanatory Paragraph — Going Concern

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 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.

Basis for Opinion

These financial statements are the responsibility of the Company's management and Board of Directors. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/S/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member of PricewaterhouseCoopers International Limited
Tel-Aviv, Israel
March 30, 2018

We have served as the Company's auditor since 2010.

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 2017	December 31 2016
		U.S. dollars in thousands	
Assets			
CURRENT ASSETS:			
Cash and cash equivalents	5	11,746	4,163
Restricted deposits	7a2	—	1,075
Other current assets	12a	671	195
TOTAL CURRENT ASSETS		12,417	5,433
NON-CURRENT ASSETS:			
Property and equipment		207	199
Intangible assets	6	654	654
TOTAL NON-CURRENT ASSETS		861	853
TOTAL ASSETS		13,278	6,286
Liabilities net of capital deficiency			
CURRENT LIABILITIES:			
Accounts payable:			
Trade		596	53
Other	12b	1,424	604
Convertible loans	7	—	9,885
TOTAL CURRENT LIABILITIES		2,020	10,542
NON-CURRENT LIABILITIES:			
Convertible loan	7	3,893	4,835
Preferred shares	8	33,455	11,031
Warrants to purchase preferred shares and shares	7,8	5,398	4,800
Liability to issue preferred shares and warrants	8	—	273
Severance pay obligations, net		70	51
TOTAL NON-CURRENT LIABILITIES		42,816	20,990
TOTAL LIABILITIES		44,836	31,532
COMMITMENTS AND CONTINGENCIES	9		
CAPITAL DEFICIENCY:	10		
Ordinary Shares, NIS 0.01 par value:			
Authorized – as of December 31, 2017 and 2016, 1,000,000 shares; issued and outstanding as of December 31, 2017 and 2016 – 34,544 shares		*	*
Accumulated other comprehensive income		41	41
Other reserves		7,361	2,844
Additional paid in capital		2,853	2,485
Accumulated deficit		(41,813)	(30,616)
TOTAL CAPITAL DEFICIENCY		(31,558)	(25,246)
TOTAL LIABILITIES NET OF CAPITAL DEFICIENCY		13,278	6,286

* Represents an amount less than one thousand.

Mr. Luke M. Beshar **Chairman of the Board**	**Mr. Philip Schwartz** **Chief Executive Officer**	**Mrs. Mira Rosenzweig** **Chief Financial Officer**

Date of approval of the financial statements: March 30, 2018.

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

ENTERA BIO LTD.

STATEMENTS OF COMPREHENSIVE LOSS

	Note	Year ended December 31 2017	2016
		U.S. dollars in thousands	
RESEARCH AND DEVELOPMENT EXPENSES		2,768	2,648
GENERAL AND ADMINISTRATIVE EXPENSES		8,575	2,719
OPERATING LOSS		11,343	5,367
FINANCIAL INCOME:	7,8		
Income from change in fair value of financial liabilities at fair value		(251)	(4,311)
Other financial expenses, net		105	143
FINANCIAL EXPENSES (INCOME), net		(146)	(4,168)
NET COMPREHENSIVE LOSS		11,197	1,199
		U.S. dollars (except for share numbers)	
LOSS PER ORDINARY SHARE –	13		
Basic		324	35
Diluted		324	102
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES –			
Basic		34,544	34,409
Diluted		34,544	51,972

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, 2016	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)
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2017:							
Loss for the year	—	—	—	—	—	(11,197)	(11,197)
Share based compensation	—	—	—	4,885	—	—	4,885
Reclassification of capital contribution from controlling shareholder (note 7a)	—	—	—	(333)	333	—	—
Reclassification due to share-based compensation forfeited	—	—	—	(35)	35	—	—
BALANCE AT DECEMBER 31, 2017	34,544	*	41	7,361	2,853	(41,813)	(31,558)

* 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	
	2017	2016
	U.S. dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Loss for the year	(11,197)	(1,199)
Adjustments required to reflect net cash used in operating activities (see appendix A)	6,671	(1,943)
Net cash used in operating activities	(4,526)	(3,142)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Decrease (increase) in restricted deposits	1,053	(1,075)
Purchase of property and equipment	(51)	(41)
Net cash provided by (used in) investing activities	1,002	(1,116)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of preferred shares and warrants, net	12,087	—
Proceeds from convertible loan and warrants, net	—	7,216
Payment for maturity of Convertible loans	(980)	
Net cash generated from financing activities	11,107	7,216
NET INCREASE IN CASH AND CASH EQUIVALENTS	7,583	2,958
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR	4,163	1,205
CASH AND CASH EQUIVALENTS AT END OF THE YEAR	11,746	4,163

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

ENTERA BIO LTD.

STATEMENTS OF CASH FLOWS – (continued)

	Year ended December 31	
	2017	2016
	U.S. dollars in thousands	
APPENDIX A:		
Adjustments required to reflect net cash used in operating activities:		
Depreciation	43	35
Income from change in fair value of financial liabilities at fair value	(251)	(4,311)
Issuance costs related to preferred shares, convertible loan and warrants	1,091	363
Financial expenses	48	105
Net changes in severance pay	19	22
Share-based compensation	4,885	1,490
	5,835	(2,296)
Changes in working capital:		
(Increase) decrease in other current assets	(454)	500
Increase (decrease) in accounts payable:		
Trade	543	(298)
Other	820	151
	909	353
Cash used for operating activities –		
Interest paid	(73)	—
	6,671	(1,943)

SUPPLEMENTARY INFORMATION ON FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:

As to extinguishment and conversion of convertible loans see note 7a2 and 7a3, respectively.
As to change in conditions of the liability to issue preferred shares and warrants to warrants see note 8a.

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

ENTERA BIO LTD.

NOTES TO 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. On January 8, 2018, the Company incorporated Entera Bio Inc. a fully owned subsidiary based in the US.

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, 2017, accumulated losses in the amount of $41,813 thousand. The Company has cash outflows from operating activities. The Company’s management is of the opinion that its available funds as of December 31, 2017 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 March 30, 2018.

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, 2017 and 2016 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.

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

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 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.

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;

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

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

- 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, 2017 and 2016, 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, 2017 and 2016, 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.

i. Financial Liabilities:

1) Financial liabilities at fair value through profit or loss

This category includes the Company's 2016 Convertible Loan, 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". Transactional costs recorded as an expense when they occur.

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.

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

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

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.

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 when the performance condition is probable. The vesting period 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

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

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.

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: 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, 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 implementation of this standard is expected to have no material impact on the 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

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

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

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.

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.

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 4 — FINANCIAL INSTRUMENTS: (continued)

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.

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, 2017, and 2016, the fair value of certain financial instruments (cash and cash equivalents, restricted deposits, other receivables and accounts payable) approximates their carrying value.

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 4 — FINANCIAL INSTRUMENTS: (continued)

d. Classification of financial instruments by groups:

	Loans and receivables
	U.S. dollars in thousands
As of December 31, 2017:	
Cash and cash equivalents	11,746
Receivables (excluding prepaid expenses)	182
	11,928
As of December 31, 2016:	
Cash and cash equivalents	4,163
Restricted deposits	1,075
Receivables (excluding prepaid expenses)	157
	5,395

	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, 2017:			
Trade and other payable	—	2,020	2,020
Convertible loan	3,893	—	3,893
Preferred shares	33,455	—	33,455
Warrants to purchase preferred shares and shares	5,398	—	5,398
	42,746	2,020	44,766
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

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 5 — CASH AND CASH EQUIVALENTS

	December 31,	
	2017	2016
	U.S. dollars in thousands	
Cash in bank	11,741	4,159
Short-term bank deposits	5	4
	11,746	4,163

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, 2017 the Company applied the market approach and used a price per share of $908.78 per Series B preferred share from the Company's preferred share issuance in October and December 2017 as a basis for fair market value. 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.

Main assumptions used for the assessment of recoverable amount in 2016 were: weighted average cost of capital (WACC) of 22%, commencement of sales in 2021 – 2025 and probability of reaching sales of 20.1% – 37.9%.

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

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 7 — CONVERTIBLE LOANS: (continued)

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 certain events. 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 additional shares equal to 40% of the shares issued upon conversion of the loan.

The Company measured 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 (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 as a finance expenses.

According to the 2016 Convertible Loan agreement, the Company deposited at the trustee an amount of $1,053 thousand.

On the maturity date, February 5, 2017, the Company repaid the amount of $1,053 thousand using the cash deposited at the trustee.

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

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 7 — CONVERTIBLE LOANS: (continued)

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 (“2016 Warrants”) 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.

As described in note 8, as part of the Series B preferred share purchase agreement the 2016 convertible loan together with the accrued interest was converted in to 13,299 series B-1 preferred shares at a price per share of $681.585. Also, the 2016 Warrants became warrant to purchase Series B preferred shares at an exercise price of $908.78.

b. The Company prepared a valuation of the 2012 Convertible loan and the 2016 convertible loan 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,	
	2017	**2016**
Preferred B price per share*	$908.78	—
Value of equity**	$78 million	$71 million
Volatility	55%	77%
Probability of entering Phase 2b/3	70%	70%
Probability for IPO	85%	50%

* According to agreement as described in note 8b.

** The value of equity as of December 31, 2017 was based on market approach as described in note 6. The value of equity as of December 31, 2016 was based on a valuation performed by the Company as detailed in note 6. The value of equity includes ordinary shares, preferred shares, warrants and options to preferred shares and shares.

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 7 — CONVERTIBLE LOANS: (continued)

c.

	Convertible loans
	U.S. dollars in thousands
Balance as of January 1, 2016	8,053
Additions during 2016	6,110
Financial expenses	105
Changes in fair value	452
Balance as of December 31, 2016	14,720
Maturity during period	(1,053)
Conversion to Series B-1 preferred shares	(11,695)
Financial expenses	48
Changes in fair value	1,873
Balance as of December 31, 2017	3,893

	Warrants to purchase preferred shares and shares
	U.S. dollars in thousands
Balance as of January 1, 2016	215
Additions during 2016	1,319
Changes in fair value	103
Balance as of December 31, 2016	1,637
Conversion to warrants to purchase Series B preferred shares	(1,988)
Changes in fair value	351
Balance as of December 31, 2017	—

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

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 8 — PREFERRED SHARES AND WARRANTS TO PREFERED SHARES: (continued)

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.

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.

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 8 — PREFERRED SHARES AND WARRANTS TO PREFERED SHARES: (continued)

On July 20, 2017, the Company approved the amendment to the preferred share A purchase agreement with the preferred shareholders (the “Investors”). Pursuant to the amendment the date for the second milestone was extended from October 1, 2017 to July 20, 2019 and following the occurrence of the second milestone and until July 20, 2019, the Investors shall have the option, at their sole discretion, to invest any or all of the milestone investment amount. In addition, the exercise terms of the additional warrants granted to the Investors in 2015 were changed to a period of two year following the event of 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.

Following the completion of the Preferred B Financing as defined in note 8b, the additional warrants that the Company previously issued 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 certain other preferred A shareholders became warrants to purchase Series B-1 preferred shares at an exercise price of $681.585.

b. In October and December 2017, the Company entered into a Series B preferred share purchase agreement (the “Preferred B Financing”), with certain investors, including D.N.A and Centillion (together, the “Investors”). Pursuant to the terms of the Series B preferred share purchase agreement, the Company issued and sold to the Investors 14,283 Series B preferred shares at a price per share of $908.78, for an aggregate purchase price of $12.98 million. The total consideration net of issuance costs which paid in cash was $12.087 million.

In addition, the Company issued to a broker dealer, a warrant to purchase 526 Series B preferred shares, at a price of $908.78 per share therefore, the Company recorded additional issuance costs of $198 thousand.

Of the Investors, few related parties participated in the Preferred B Financing and purchased 7,089 Series B preferred shares, in the amount of $6,442 thousand.

The Preferred B Financing constitutes a Triggering Event as defined in the 2016 Convertible Loan and as a result, the entire loan amount under the 2016 Convertible Loan, together with accrued interest in the amount of $9.0 million, was automatically converted into 13,229 Series B-1 preferred shares at a price per share of $681.585.

In addition, as a result of the Preferred B Financing, the 2016 Warrants became warrants to purchase Series B preferred shares at an exercise price of $908.78.

As part of the automatic conversion of the 2016 Convertible Loans, the Company issued to four of its related parties 1,834 Series B-1 preferred shares, and their 2016 warrants became warrants to purchase 733 Series B preferred shares. The fair value of the preferred shares and warrants was $1,621 thousand and $264 thousand, respectively.

The rights of the Series B-1 preferred shares are identical in all respects (other than the price per share) to the Series B preferred shares.

Following the completion of the Preferred B Financing the Company determined the amount of options to purchase ordinary shares of the Company, to be granted to Mr. Beshar and Dr. Garceau of 6,970 and 1,608, respectively. See also note 10(g).

c. 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.

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 8 — PREFERRED SHARES AND WARRANTS TO PREFERED SHARES: (continued)

ii. In any liquidation, bankruptcy, reorganization, dissolution or winding up of the Company as defined in Article 66(d) of the Company's Fifth 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.

d. 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, Series B preferred shares and Series B-1 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, Series B preferred shares and the Series B-1 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.

Before the change in condition in July 2017, the liability for future issuances of preferred shares and warrants upon fulfillment of the second milestones as described in a) above, constituted contingent forward contracts, and therefore accounted for at fair value through profit or loss at each balance sheet date.

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 8 — PREFERRED SHARES AND WARRANTS TO PREFERED SHARES: (continued)

e. The table below presents the movements in the three components during 2017 and 2016:

	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, 2016	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
Issuance of Series B preferred shares and warrants to purchase Series B preferred shares	12,980	198	—	13,178
Conversion of 2016 Convertible Loan and warrants to series B-1 preferred shares and warrant to purchase Series B preferred shares	11,695	1,988	—	13,683
Change of conditions of the liability to issue preferred shares and warrants to warrants	—	1,160	(1,160)	—
Changes in fair value	(2,251)	(1,111)	887	(2,475)
Balance as of December 31, 2017	33,455	5,398	—	38,853

f. The Company prepared valuations of the fair value of the instruments 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,	
	2017	2016
Preferred B price per share*	$908.78	—
Value of equity**	$78 million	$71 million
Volatility	55%	77%
Probability of entering Phase 2b/3	70%	70%
Probability for IPO	85%	50%

* According to agreement as described in note 8b.

** The value of equity as of December 31, 2017 was based on market approach as described in note 6. The value of equity as of December 31, 2016 was based on a valuation performed by the Company as detailed in note 6. The value of equity includes ordinary shares, preferred shares, warrants and options to preferred shares and shares.

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.

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 will expire 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.

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 9 — COMMITMENTS: (continued)

b. In 2015 and 2017, the Company entered into operating lease agreements for three vehicles. The leases will expire during the years 2018 and 2020. In January 2018 the agreement for one vehicle renewed and will expire in 2020. The projected annual lease payments are approximately $29 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, 2017, the total royalty amount that would be payable by the Company, before the additional Libor interest, is approximately $460 thousand.

e. Emisphere Technologies, Inc., or Emisphere, has notified the Company that it believes that it is the exclusive owner of certain U.S. and related foreign patents and patent applications the Company acquired from Oramed Ltd. Emisphere has not initiated a legal proceeding as of the date of the approval of this financial statements. The matter is still in its early stages. If Emisphere were to initiate a legal proceeding, we would vigorously defend against such claim and believe that Emisphere's notification is without merit.

NOTE 10 — SHARE CAPITAL:

a. Composed of ordinary shares of NIS 0.01 par value, as follows:

	Number of ordinary shares	
	December 31	
	2017	2016
Authorized	1,000,000	1,000,000
Issued	34,544	34,544

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.

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 10 — SHARE CAPITAL: (continued)

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.

2) Options grants:

a) 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.

b) 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.

c) 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.

d) In March 2017, the Company granted options to purchase 12 ordinary shares to a certain consultant, with an exercise price of par value (0.01 NIS). The options shall vest immediately. The fair value of the options at the date of grant was $12 thousand.

e) On March 27, 2017, the board of directors approved the nomination of Mr. Luke Beshar as Executive chairman of the board and Dr. Roger Garceau 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, 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 the date of service provision, and are subject to acceleration under certain circumstances as described in the service agreement. Following the completion of the Preferred B Financing the Company determined the amount of options to purchase ordinary shares

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 10 — SHARE CAPITAL: (continued)

of the Company, to be granted to Mr. Beshar and Dr. Garceau of 6,970 and 1,608, respectively. The exercise price of the options is $820 determined based on an external valuation and approved by the board of directors of the company on November 10, 2017.

The Company treated the awards as performance-based awards, the performance condition was achieved during 2017.

The fair value of the options at the date of grant is $4,814 thousand.

f) 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.

g) On November 15, 2017, the Company granted options to purchase 4,550 ordinary shares to the CEO, COO and the CFO of the Company, with an exercise price of $820. The options will vest in 4 years in sixteen equal quarterly instalments. The fair value of the options at the date of grant is $2,338 thousand. The options granted to the CEO were approved by the shareholders of the Company on November 23, 2017.

h) On November 23, 2017, the Company granted options to purchase 100 ordinary shares to a certain consultant, with an exercise price $820. The options shall vest immediately. The fair value of the options at the date of grant was $38 thousand.

i) On December 27, 2017, the Company granted options to purchase 586 ordinary shares to certain employees, with an exercise price of $820. 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 $295 thousand.

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:

	2017	2016
Ordinary share price	$ 773	$1,018
Exercise price	$ 773	$ 479
Dividend yield	—	—
Expected volatility	73.77%	76%
Risk-free interest rate	1.67%	1.05%
Expected life – in years	7.94	4.11

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.

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 10 — SHARE CAPITAL: (continued)

4) Changes in the number of options and weighted average exercise prices are as follows:

	Year ended December 31,			
	2017		2016	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of year	8,743	$ 186.3	7,092	$119.7
Forfeited	(279)	295.2	—	—
Granted	14,959	$ 831.5	1,651	$472.3
Outstanding at end of year	23,423	$ 597.1	8,743	$186.3
Exercisable at end of year	11,006	$379.62	6,426	$93.73

5) The following is information about the exercise price and remaining contractual life of outstanding options at year-end:

December 31, 2017			December 31, 2016		
Number of options outstanding at end of year	Exercise price	Weighted average of remaining contractual life	Number of options outstanding at end of year	Exercise price	Weighted average of remaining contractual life
4,879	*	2.48	4,867	*	3.29
254	$240.26	1.7	254	$240.26	2.7
277	$ 316	2.42	277	$ 316	3.42
250	$273.88	2.05	500	$273.88	1.54
85	$ 240	3.21	85	$ 240	4.21
2,731	$479.38	4.2	2,266	$479.38	5.11
13,814	$ 820	7.77	494	$ 479	5.65
1,133	$ 980	5.26			

* Par value

6) The remaining unrecognized compensation expense as of December 31, 2017 is $4,083 thousand. This amount will be expensed in full by December 2021.

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 24% for 2017 and 25% for 2016.

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 11 — TAXES ON INCOME: (continued)

In December 2016, the Economic Efficiency Law (Legislative Amendments for Implementing the Economic Policy for the 2017 and 2018 Budget Years), 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 was 24% in 2017 and will be 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, 2017 and 2016 are approximately $15.3 million and $9.9 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, 2017, all of the Company's tax assessments through tax year 2012 are considered final.

NOTE 12 — SUPPLEMENTARY FINANCIAL INFORMATION:

	December 31,	
	2017	2016
	U.S. dollars in thousands	
a. Other current assets:		
Prepaid expenses	489	38
Restricted deposits	23	—
Other	159	157
	671	195

	Year ended December 31,	
	2017	2016
	U.S. dollars in thousands	
b. Accounts payable – other:		
Employees and employees related	215	139
Provision for vacation	214	155
Accrued expenses and other	995	310
	1,424	604

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

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 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 were not taken into account in the diluted loss per share calculation for the year ended December 31, 2016, as the conversion terms depend on future events.

All outstanding options, 2012 Convertible Loan, 2016 Convertible loan, preferred shares and warrants to issue preferred shares have been excluded from the calculation of the diluted loss per share for the year ended December 31, 2017 since their effect was anti-dilutive. The total number of ordinary shares related to the 2012 Convertible Loan, 2016 Convertible Loan, preferred shares and warrants to issue preferred shares excluded from the calculation of diluted loss per share was 59,131 for the year ended December 31, 2017.

The 2015 Convertible Loan, warrants and liability to issue preferred shares were not taken into account in the diluted loss per share calculation for the year ended December 31, 2017, as the conversion terms depend on future events.

	Year ended December 31,	
	2017	2016
	U.S. dollars (except for share numbers)	
Loss attributable to equity holders of the Company	11,197,000	1,199,000
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	11,197,000	5,324,000
Weighted average number of Ordinary Shares used in the computation of basic loss per share	34,544	34,409
Add:		
Weighted average number of additional shares issuable upon the assumed conversion/exercise 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	34,544	51,972
Basic loss per Ordinary Share	324	35
Diluted loss per Ordinary Share	324	102

ENTERA BIO LTD.

NOTES TO THE FINANCIAL STATEMENTS

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) On March 27, 2017, the board of directors approved the nomination of Mr. Luke Beshar as Executive chairman of the board and Dr. Roger Garceau 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 fee in the amount of $21,500 and $6,500, respectively.

3) During 2017 and 2016, the Company granted stock options to certain key management personnel and directors, see note 10b.

4) During 2017, certain related parties was participated in the Preferred B Financing. Concurrently with the Preferred B Financing the 2016 Convertible loan converted and as a result a few of the Company's related parties received Series B-1 preferred shares, see note 8(b).

	Year ended December 31,	
	2017	2016
	U.S. dollars in thousands	
5) Key management compensation:		
Labor cost and related expenses	1,048	830
Share-based compensation	4,694	1,351
Directors fee and services	577	73
Others	109	25
	6,428	2,279

b. Balances with related parties:

	December 31,	
	2017	2016
	U.S. dollars in thousands	
Key management:		
Payables and accrued expenses	93	57
Severance pay obligations	70	51
Provision for vacation	186	138
Directors fee and services	76	28

NOTE 15 — SUBSEQUENT EVENTS

On January 10, 2018, the Company appointed Dr. Eric Lang as the Company's Chief Medical Officer, effective January 15, 2018. Mr. Lang will replace Dr. Miriam Blum, who has served as the Company's Chief Medical Officer since January 2015. In connection with Dr. Lang's appointment as the Company's new Chief Medical Officer, the Company's Board of Directors approved an increase to the available pool of ordinary shares reserved under the Company's current share incentive plan and granted Dr. Lang options to purchase 850 ordinary shares at an exercise price of $820 per share.

PROSPECTUS

Sole Bookrunning Manager

Maxim Group LLC

Co-Manager

Joseph Gunnar & Co.

, 2018

Until , 2018 (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 amended Articles 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 in each case, to the fullest extent permitted by our amended Articles and applicable law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance.

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 or her in consequence of an act done in his or her capacity as such, in any of the following cases:

- a breach of the duty of care toward us or a third party, to the extent such a breach arises out of the negligent conduct of the office holder;
- 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 or her in favor of a third party;
- a payment imposed on him or her 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 or her in connection with a proceeding under Chapters H’3, H’4 or I’l of the Israeli Securities Law or under Article D of the Fourth Chapter, Ninth Part of the Companies Law, if applicable, including reasonable legal expenses, which term includes attorney fees.

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 or her in consequence of an action taken by him in his capacity as such, as follows:

- a financial obligation or liability imposed on or incurred in favor of another person and/or legal entity, including by any government office, or expended as a result of a court judgment, including in a settlement or an arbitrator’s decision approved by a court of law, in respect of any act or omission taken or made by him or her in his or her capacity as a director or an officer of the Company of any of its subsidiaries;
- reasonable legal expenses, including attorney’s fees, expended by him or her as a result of an investigation or proceeding instituted against him or her by a competent authority, provided that such investigation or proceeding concluded without the filing of an indictment against him or her and without any financial liability imposed on him or her in lieu of criminal proceedings, or that is 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 imposed on him or her in his or her capacity as a director or an officer of the Company or of any of its subsidiaries;
- reasonable legal expenses, including attorney’s fees, and all other costs, expenses and obligations incurred in connection with investigating, defending, being a witness in or participating in (including on appeal), or preparing to defend in or participate, in any action, suit, proceeding, alternative dispute resolution mechanism, hearing, inquiry or investigation brought against him or her by the Company or on its behalf or by another person or in any criminal prosecution in which

he or she was acquitted, or in a criminal prosecution of a crime which does not require proof of criminal intent, in which he or she was convicted, all in respect of actions taken by him or her in his or her capacity as a director or an officer of the Company or of any of its subsidiaries;

- a payment he or she was obligated to make to an injured party as set forth in Section 52(54)(a)(1)(a) of the Israeli Securities Law;
- reasonable litigation expenses, including attorney fees, incurred by the director or officer in connection with a proceeding under Chapters H'3, H'4 or I'1 of the Israeli Securities Law; or
- any other circumstances arising under the law in respect of which the Company may indemnify a director or an officer of the Company (including, without limitation, Section 50P(b)(2) of the Israeli Restrictive Trade Practices Law, 5758-1988).

Exemption. We are entitled to exempt a director or officer in advance from any or all of his or her liability for damage caused by a breach of his or her duty of care toward us, to the fullest extent permitted by law.

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 to the Company or any of its subsidiaries, except to the extent permitted by the Companies Law, with respect to insurance coverage or indemnification for a breach of the duty of loyalty to the Company or any of its subsidiaries while acting in good faith and having reasonable cause to assume that such act would not prejudice the interest of the Company or any of its subsidiaries, as applicable;
- a willful or reckless breach of the duty of care, other than a breach committed solely by negligence;
- an action taken or not taken with the intent of unlawfully realizing personal gain; or
- a fine or penalty imposed upon the director or the officer for an offense.

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 closing 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) Series A preferred shares prior to

the consummation of this offering and (ii) ordinary shares upon the closing 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 closing 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 closing 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 two years 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. The Series B preferred shares purchase agreement has set the price in which, and the amounts for which, the holders of the additional warrants are entitled to exercise their additional warrants.
- 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 closing 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 (and for a period of two years thereafter) upon 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 $450,000 of the type of shares issued in such triggering event at a 25% discount to the applicable price per share. The Series B preferred shares purchase agreement has set the price in which, and the amounts for which, the holders of the additional warrants are entitled to exercise their additional warrants.
- 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 at an exercise price of 125% of the applicable price per share. 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 was given for a term of 18 months and bore interest at a rate of 5% per year. The 2016 Convertible Loan also granted each lender 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. The 2016 Convertible Loan was to be automatically converted upon the occurrence of a 2016 Triggering Event. Following the completion of the Series B Private Placement, which constituted a 2016 Triggering Event, the loan amount, together with all accrued interest was converted into Series B-1 preferred shares, under the terms and conditions of the 2016 Convertible Loan. In addition, the Series B preferred shares purchase agreement has set the price in which, and the amounts for which, the holders of the 2016 Warrants are entitled to exercise their 2016 Warrants.

- Through May and during November 2016, a certain consultant received options to purchase 24 ordinary shares, exercisable within 60 days of March 31, 2018 at an exercise price of NIS 0.01 (par value) and expiring in 2022.

- Pursuant to the Series B Preferred Share Purchase Agreements the company entered into from October to December 2017 with the other parties identified therein, such parties purchased from us an aggregate of 14,283 Series B preferred shares (which can be converted into 14,283 of our ordinary shares at the current conversion rate of one ordinary share for one Series B preferred share and will be automatically converted into our ordinary shares at the then-current conversion rate upon the closing of this offering) for an aggregate purchase price of $13 million, and we issued to GP Nurmenkari Inc. representatives warrants to purchase up to 526 of the applicable shares.

- In March 2017, a certain consultant received options to purchase 12 ordinary shares, exercisable within 60 days of March 31, 2018 at an exercise price of NIS 0.01 (par value) and expiring in March 2023.

- Pursuant to the applicable Service Agreements entered into in April 2017, our directors Luke Beshar and Roger Garceau received options to acquire 6,970 and 1,608 ordinary shares, respectively, of which 3,485 and 804 ordinary shares, respectively, were exercisable within 60 days of March 31, 2018, with an exercise price of $820 per share and expiring on December 1, 2026.

- In November 2017, certain directors and officers received options to acquire 4,650 ordinary shares, of which 670 ordinary shares were exercisable within 60 days of March 31, 2018 at an exercise price of $820 per share and expiring on November 15, 2023.

- In January 2018, an officer received options to acquire 850 ordinary shares, of which 210 ordinary shares were exercisable within 60 days of March 31, 2018 at an exercise price of $820 per share and expiring on January 15, 2024.

- In January 2018, a certain consultant received options to acquire 250 ordinary shares, exercisable within 60 days of March 31, 2018 at an exercise price of $273.88 per share and expiring on January 15, 2020.

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**	Fifth Amended and Restated Articles of Association of the Registrant (currently in effect).
3.2**	Form of Sixth 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 pursuant to this offering.
4.3**	Form of Underwriter Warrant issued by the Registrant to Maxim Group LLC.
4.4**	Form of Warrant issued by the Registrant to Centillion Fund on each of January 29, 2014 and January 21, 2015.
4.5**	Form of additional Warrant issued by the Registrant to Centillion Fund on January 21, 2015.
4.6**	Form of Warrant issued by the Registrant to the lenders on June 24, 2016.
4.7**	Form of Warrant issued by the Registrant to GP Nurmenkari Inc.
5.1	Opinion of Herzog Fox & Neeman, Israeli counsel to the Registrant, as to the validity of the ordinary shares and warrants.
8.1	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 8, 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.
10.7**	Second Amendment to Series A Preferred Share Purchase Agreement, dated as of January 21, 2015, between the Registrant and Centillion Fund.
10.8**	Third Amendment to Series A Preferred Share Purchase Agreement, dated as of November 2015, between the Registrant and Centillion Fund.
10.9**	Fourth Amendment to Series A Preferred Share Purchase Agreement, dated as of July 20, 2017, between the Registrant and Centillion Fund.
10.10**	Series B Preferred Share Purchase Agreement, dated as of October 4, 2017, October 25, 2017 and December 18, 2017, between the Registrant and the other parties thereto.
10.11**	Amended and Restated Investors' Rights Agreement, dated as of October 4, 2017, between the Registrant and the other parties thereto.
10.12**	Form of indemnification agreement between the Registrant and its directors and executive officers.
10.13**	Form of Convertible Financing Agreement, dated as of June 14, 2016, among the Registrant and the lenders thereto.
10.14**	Service Agreement, dated April 6, 2017, between Roger Garceau and the Company.
10.15**	Service Agreement, dated April 6, 2017, between Luke Beshar and the Company.

Exhibit No.	Description
10.16	Form of 2018 Equity Incentive Plan and forms of agreements thereunder (to be in effect upon the closing of this offering).
10.17**	Amendment No. 1 to the Series B Preferred Share Purchase Agreement, dated December 18, 2017, between the Registrant and the other parties thereto.
10.18	Form of Warrant Agency Agreement
21.1**	List of subsidiaries.
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).
23.3	Consent of Davis Polk & Wardwell LLP (included in Exhibit 8.1)
24.1	Powers of Attorney (included on signature page).

* To be filed by amendment.

** Previously filed.

(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.

EXHIBIT INDEX

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Exhibit No.	Description
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10.18	Form of Warrant Agency Agreement
21.1**	List of subsidiaries.
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).
23.3	Consent of Davis Polk & Wardwell LLP (included in Exhibit 8.1)
24.1	Powers of Attorney (included on signature page).

* To be filed by amendment.

** Previously filed.

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 June 15, 2018.

ENTERA BIO LTD.

By: /s/ Dr. Phillip Schwartz

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
/s/ Dr. Phillip Schwartz Dr. Phillip Schwartz	Chief Executive Officer (Principal Executive Officer) and Director	June 15, 2018
/s/ Mira Rosenzweig Mira Rosenzweig	Chief Financial Officer (Principal Financial and Accounting Officer)	June 15, 2018
* David Ben Ami	Chairman of the Board	June 15, 2018
* Chaim Davis	Director	June 15, 2018
* Roger Garceau	Director	June 15, 2018
* Gerald Lieberman	Director	June 15, 2018
* Yonatan Malca	Director	June 15, 2018
* Zeev Bronfeld	Director	June 15, 2018

By: /s/ Phillip Schwartz

Phillip Schwartz, *Attorney-in-Fact*

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 the United States on June 15, 2018.

By: /s/ Colleen A. DeVries

Name: Colleen A. DeVries
Title: SVP on behalf of Cogency Global

Exhibit 1.1

______________ Ordinary Shares

and

Warrants to Purchase ______________ Ordinary Shares

ENTERA BIO LTD.

FORM OF UNDERWRITING AGREEMENT

________, 2018

Maxim Group LLC
as Representative of the several
Underwriters named in Schedule I hereto
405 Lexington Avenue, 2nd Floor
New York, New York 10174

Ladies and Gentlemen:

Entera Bio Ltd., an Israeli company (the "Company"), proposes, subject to the terms and conditions contained herein, to sell to you and the other underwriters (the "Underwriters") named on Schedule I to this Underwriting Agreement (the "Agreement"), for whom you are acting as Representative (the "Representative"), (i) an aggregate of ________ ordinary shares (the "Firm Shares") of the Company, NIS par value per share (the "Ordinary Shares") and (ii) warrants (each whole warrant, a "Warrant") to purchase up to an aggregate of ________ Ordinary Shares (the "Firm Warrants"). The respective amounts of the Firm Shares and Firm Warrants to be purchased by each of the several Underwriters are set forth opposite their names on Schedule I hereto. In the event only one underwriter is listed in Schedule I hereto, any references in this Agreement to the "Underwriters" shall be deemed to refer to the sole underwriter in the singular form, as listed in such Schedule I. The Firm Shares and Firm Warrants will be sold as units (the "Units"), with each Unit consisting of one Ordinary Share and ______ of one Warrant, with each whole Warrant initially exercisable to purchase one Ordinary Share. In addition, the Company proposes to grant to the Underwriters an option to purchase up to an additional ______ Ordinary Shares (the "Option Shares") and/or Warrants to purchase up to an additional ______ Ordinary Shares (the "Option Warrants" and, collectively with the Option Shares, the "Option Securities") from the Company for the sole purpose of covering over-allotments in connection with the sale of the Firm Shares and the Firm Warrants. The Ordinary Shares underlying the Firm Warrants and the Option Warrants are collectively called the "Warrant Shares." The Firm Shares, the Option Shares and the Warrant Shares are collectively called the "Shares." The Units (including the Firms Shares and the Firm Warrants), the Option Securities and the Warrant Shares are collectively called the "Securities."

The Company has prepared and filed in conformity with the requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the published rules and regulations thereunder (the "Rules") adopted by the Securities and Exchange Commission (the "Commission") a Registration Statement (as hereinafter defined) on Form F-1 (No. 333-_____), including a preliminary prospectus relating to the Securities, and such amendments thereof as may have been required to the date of this Agreement. Copies of such Registration Statement (including all amendments thereof) and of the related Preliminary Prospectus (as hereinafter defined) have heretofore been delivered by the Company to you. The term "Preliminary Prospectus" means any preliminary prospectus included at any time as a part of the Registration Statement or filed with the Commission by the Company pursuant to Rule 424(a) of the Rules. The term "Registration Statement" as used in this Agreement means the initial registration statement (including all exhibits and financial schedules), as amended at the time and on the date it becomes effective (the "Effective Date"), including the information (if any) contained in the form of final prospectus filed with the Commission pursuant to Rule 424(b) of the Rules and deemed to be part thereof at the time of effectiveness pursuant to Rule 430A of the Rules. If the Company has filed an abbreviated registration statement to register additional Securities pursuant to Rule 462(b) under the Rules (the "462(b) Registration Statement"), then any reference herein to the Registration Statement shall also be deemed to include such 462(b) Registration Statement. The term "Prospectus" as used in this Agreement means the prospectus in the form included in the Registration Statement at the time of effectiveness or, if Rule 430A of the Rules is relied on, the term Prospectus shall also include the final prospectus filed with the Commission pursuant to and within the time limits described in Rule 424(b) of the Rules.

The Company hereby also agrees (i) to issue and sell to the Representative (and / or its designated affiliates) on the Closing Date (as defined below) a warrant (the “Representative’s Warrant”) for the purchase of an aggregate of _____ Ordinary Shares, representing 5% of the Firm Shares and the Option Shares, and (ii) to issue to the Representative (and / or its designees) on the Closing Date 10,000 Ordinary Shares (the “Representative’s Shares”). The Representative Warrant, the Ordinary Shares issuable upon exercise thereof, and the Representative’s Shares are hereinafter referred to together as the “Representative’s Securities.”

The Company understands that the Underwriters propose to make a public offering of the Securities, as set forth in and pursuant to the Statutory Prospectus (as hereinafter defined) and the Prospectus, as soon after the Effective Date and the date of this Agreement as the Representative deems advisable. The Company hereby confirms that the Underwriters and dealers have been authorized to distribute or cause to be distributed each Preliminary Prospectus, and each Issuer Free Writing Prospectus (as hereinafter defined) and are authorized to distribute the Prospectus (as from time to time amended or supplemented if the Company furnishes amendments or supplements thereto to the Underwriters).

1. Sale, Purchase, Delivery and Payment for the Securities. On the basis of the representations, warranties and agreements contained in, and subject to the terms and conditions of, this Agreement:

(a) The Company agrees to issue and sell to each of the Underwriters, and each of the Underwriters agrees, severally and not jointly, to purchase from the Company, at a purchase price of $_____ per Unit, the number of Firm Shares and Firm Warrants set forth opposite the name of such Underwriter under the columns "Number of Firm Shares to be Purchased " and "Number of Firm Warrants to be Purchased," respectively on Schedule I to this Agreement, subject to adjustment in accordance with Section 8 hereof.

(b) The Company hereby grants to the several Underwriters an option to purchase, severally and not jointly, all or any part of the Option Shares at a purchase price of $_____ per Option Share and/or all or any part of the Option Warrants at a purchase price of $______ per Option Warrant. The number of Option Shares and/or Option Warrants to be purchased by each Underwriter shall be the same percentage (adjusted by the Representative to eliminate fractions) of the total number of Option Shares and/or Option Warrants to be purchased by the Underwriters as such Underwriter is purchasing of the Units. Such option may be exercised only to cover over-allotments in the sales of the Units by the Underwriters and may be exercised in whole or in part at any time on or before 12:00 noon, New York City time, on the business day before the Firm Securities Closing Date (as defined below), and from time to time thereafter within 30 days after the date of this Agreement, in each case upon written, facsimile or telegraphic notice, or verbal or telephonic notice confirmed by written, facsimile or telegraphic notice, by the Representative to the Company no later than 12:00 noon, New York City time, on the business day before the Firm Securities Closing Date or at least two business days before the Option Securities Closing Date (as defined below), as the case may be, setting forth the number of Option Shares and/or Option Warrants to be purchased and the time and date (if other than the Firm Securities Closing Date) of such purchase.

(c) Payment of the purchase price for, and delivery of the Firm Shares and the Firm Warrants shall be made at the offices of Maxim Group LLC, 405 Lexington Avenue, New York, New York 10174, at 10:00 a.m., New York City time, on the second business day following the date of this Agreement or at such time on such other date, not later than ten (10) business days after the date of this Agreement, as shall be agreed upon by the Company and the Representative (such time and date of delivery and payment are called the "Firm Securities Closing Date"). In addition, in the event that any or all of the Option Securities are purchased by the Underwriters, payment of the purchase price, and delivery of the certificates, for such Option Securities shall be made at the above-mentioned offices, or at such other place as shall be agreed upon by the Representative and the Company, on each date of delivery as specified in the notice from the Representative to the Company (such time and date of delivery and payment are called the "Option Securities Closing Date"). The Firm Securities Closing Date and any Option Securities Closing Date are called, individually, a "Closing Date" and, together, the "Closing Dates."

(d) Payment shall be made to the Company by wire transfer of immediately available funds or by certified or official bank check or checks payable in New York Clearing House (same day) funds drawn to the order of the Company, against delivery to the Representative for the respective accounts of the Underwriters of the Firm Shares and Firm Warrants comprising the Units and/or the Option Securities, as the case may be, to be purchased by them on the relevant Closing Date.

(e) The Firm Shares and the Firm Warrants shall be registered in such names and shall be in such denominations as the Representative shall request at least two full business days before the Firm Securities Closing Date or, in the case of Option Securities, on the day of notice of exercise of the option as described in Section 1(b), and shall be delivered by or on behalf of the Company to the Representative through the facilities of the Depository Trust Company ("DTC") for the account of such Underwriter.

(f) The Company hereby agrees (i) to issue and sell to the Representative (and / or its designees) on the Closing Date the Representative's Warrant and (ii) to issue to the Representative (and / or its designated affiliates) on the Closing Date the Representative's Shares. The Representative's Warrant shall be exercisable, in whole or in part, commencing a date which is one hundred eighty (180) days after the date hereof and expiring on the five-year anniversary of the date hereof at an exercise price equal to 110% of the price at which the Units are sold to the public, provided that such exercise period shall not exceed five (5) years from the effective date of this offering pursuant to FINRA Rule 5110(f)(2)(G)(i). The Representative understands and agrees that there are significant restrictions pursuant to FINRA Rule 5110 against transferring the Representative's Warrant and the underlying Ordinary Shares and the Representative's Shares during the one hundred eighty (180) days after the date hereof and by its acceptance thereof agrees that it will not sell, transfer, assign, pledge or hypothecate the Representative's Warrant or the Representative's Shares or any portion thereof, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of such securities for a period of one hundred eighty (180) days following the date hereof to anyone other than (i) an Underwriter or a selected dealer in connection with this offering, or (ii) a bona fide officer or partner of the Representative or of any such Underwriter or selected dealer, in each case, only if any such transferee agrees to the foregoing lock-up restrictions.

(g) Delivery of the Representative's Warrant and the Representative's Shares shall be made on the Closing Date and shall be issued into the name or names and in such authorized denominations as the Representative may request.

2. <u>Representations and Warranties of the Company</u>. The Company represents and warrants to each Underwriter as of the date hereof, as of the Firm Securities Closing Date and as of each Option Securities Closing Date (if any), as follows:

(a) On the Effective Date, the Registration Statement complied, and on the date of the Prospectus, the date any post-effective amendment to the Registration Statement becomes effective, the date any supplement or amendment to the Prospectus is filed with the Commission and each Closing Date, the Registration Statement and the Prospectus (and any amendment thereof or supplement thereto) will comply, in all material respects, with the requirements of the Securities Act and the Rules and the Securities and Exchange Act of 1934, as amended (the "Exchange Act") and the rules and regulations of the Commission thereunder. The Registration Statement did not, as of the Effective Date, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading; and on the Effective Date and the other dates referred to above neither the Registration Statement nor the Prospectus, nor any amendment thereof or supplement thereto, will contain any untrue statement of a material fact or will omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading. When any Preliminary Prospectus was first filed with the Commission (whether filed as part of the Registration Statement or any amendment thereto or pursuant to Rule 424(a) of the Rules) and when any amendment thereof or supplement thereto was first filed with the Commission, such Preliminary Prospectus as amended or supplemented complied in all material respects with the applicable provisions of the Securities Act and the Rules and did not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading. If applicable, each Preliminary Prospectus and the Prospectus delivered to the Underwriters for use in connection with this offering was identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T. Notwithstanding the foregoing, none of the representations and warranties in this paragraph 2(a) shall apply to statements in, or omissions from, the Registration Statement, any Preliminary Prospectus or the Prospectus made in reliance upon, and in conformity with, information herein or otherwise furnished in writing by the Representative on behalf of the several Underwriters specifically for use in the Registration Statement, any Preliminary Prospectus or the Prospectus, as the case may be. With respect to the preceding sentence, the Company acknowledges that the only information furnished in writing by the Representative on behalf of the several Underwriters for use in the Registration Statement, any Preliminary Prospectus or the Prospectus consists of the statements contained in the [ ] and [ ] paragraphs under the caption "Underwriting" in the Prospectus (collectively, the "Underwriter Information").

(b) As of the Applicable Time (as hereinafter defined), none of (i) the price to the public and the number of Units offered and sold, as indicated on the cover page of the Prospectus and the Statutory Prospectus (as hereinafter defined), all considered together (collectively, the "General Disclosure Package"), (ii) any individual Issuer Free Writing Prospectus when considered together with the General Disclosure Package, and (iii) any individual Written Testing-the Waters Communication (as defined herein), when considered together with the General Disclosure Package, included, includes or will include any untrue statement of a material fact or omitted, omits or will omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were or will be made, not misleading; provided, however, that this representation and warranty shall not apply to statements in or omissions in the General Disclosure Package made in reliance upon and in conformity with the Underwriter Information.

Each Issuer Free Writing Prospectus (as hereinafter defined), including any electronic road show (including without limitation any "bona fide electronic road show" as defined in Rule 433(h)(5) under the Securities Act) (each, a "Road Show") (i) is identified in Schedule III hereto and (ii) complied when issued, and complies, in all material respects with the requirements of the Securities Act and the Rules and the Exchange Act and the rules and regulations of the Commission thereunder. The Company has made at least one version of the Road Show available without restriction by means of graphic communication to any person, including any potential investor in the Securities (and if there is more than one version of a Road Show for the Offering that is a written communication, the version available without restriction was made available no later than the other versions).

As used in this Section and elsewhere in this Agreement:

"Applicable Time" means [ ]:00 [a.m.]/[p.m.] (Eastern time) on the date of this Agreement.

"Statutory Prospectus" as of any time means the Preliminary Prospectus relating to the Securities that is included in the Registration Statement immediately prior to the Applicable Time.

"Issuer Free Writing Prospectus" means each "free writing prospectus" (as defined in Rule 405 of the Rules) prepared by or on behalf of the Company or used or referred to by the Company in connection with the offering of the Securities, including, without limitation, each Road Show.

(c) The Registration Statement is effective under the Securities Act and no stop order preventing or suspending the effectiveness of the Registration Statement or suspending or preventing the use of any Preliminary Prospectus, the Prospectus or any "free writing prospectus", as defined in Rule 405 under the Rules, has been issued by the Commission and no proceedings for that purpose have been instituted or are threatened under the Securities Act. Any required filing of any Preliminary Prospectus and/or the Prospectus and any supplement thereto pursuant to Rule 424(b) of the Rules has been or will be made in the manner and within the time period required by such Rule 424(b). Any material required to be filed by the Company pursuant to Rule 433(d) of the Rules has been or will be made in the manner and within the time period required by such Rules.

(d) Each Issuer Free Writing Prospectus, if any, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Securities or until any earlier date that the Company notified or notifies the Representative as described in the next sentence, did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, the Statutory Prospectus or the Prospectus.

If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement, the Statutory Prospectus or the Prospectus or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances prevailing at the subsequent time, not misleading, the Company has promptly notified or will promptly notify the Representative and has promptly amended or will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(e) The financial statements of the Company (including all notes and schedules thereto) included in the Registration Statement, the Statutory Prospectus and Prospectus present fairly the financial position of the Company at the dates indicated and the statement of operations, stockholders' equity and cash flows of the Company for the periods specified; and such financial statements and related schedules and notes thereto, and the unaudited financial information filed with the Commission as part of the Registration Statement, have been prepared in conformity with International Financial Reporting Standards ("IFRS"), consistently applied throughout the periods involved. The summary and selected financial data included in the Statutory Prospectus and Prospectus present fairly the information shown therein as at the respective dates and for the respective periods specified and have been presented on a basis consistent with the consolidated financial statements set forth in the Prospectus.

(f) Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited (the "Auditor"), whose reports are filed with the Commission as a part of the Registration Statement, are and, during the periods covered by their reports, were independent public accountants as required by the Securities Act and the Rules.

(g) The Company is duly organized and validly existing under the laws of Israel and has all requisite power and authority to carry on its business as is currently being conducted as described in the Statutory Prospectus and the Prospectus, and to own, lease and operate its properties. The Company is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the nature of the business conducted by it or location of the assets or properties owned, leased or licensed by it requires such qualification, except for such jurisdictions where the failure to so qualify individually or in the aggregate would not have a material adverse effect on the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company (a "Material Adverse Effect"); and to the Company's knowledge, no proceeding has been instituted revoking, limiting, or curtailing, or seeking to revoke, limit or curtail, such power and authority or qualification. The Company is not designated as a "breaching company" (within the meaning of the Israeli Companies Law, 5759-1999, the "Companies Law") by the Registrar of Companies of the State of Israel (the "Israeli Registrar"). The certificate of incorporation, charter, articles of incorporation, by-laws, articles of association and other organizational documents of the Company comply with the requirements of applicable law of its jurisdiction of incorporation and are in full force and effect. Except for Entera Bio, Inc., the Company has no subsidiaries and does not control, directly or indirectly, any entity, including any corporation, partnership, joint venture, association or other business organization.

(h) (i) At the time of filing the Registration Statement and (ii) at the date hereof**,** the Company was not and is not an "ineligible issuer," as defined in Rule 405 of the Rules.

(i) Except as would not, singly or in the aggregate, have a Material Adverse Effect, and except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus (i) the Company owns or possesses legally enforceable rights to use all patents, patent rights, inventions, trademarks, trademark applications, trade names, service marks, copyrights, copyright applications, licenses, know-how and other similar intellectual property rights and proprietary knowledge (collectively, "Intangibles") necessary for the conduct of its business and (ii) the Company has not received any written notice of, or is otherwise aware of, any infringement of or conflict with asserted rights of others with respect to any Intangibles.

(j) The Company has good and marketable title in fee simple to all real property, and good and marketable title to all other property owned by it, in each case free and clear of all liens, encumbrances, claims, security interests and defects, except such as do not materially affect the value of such property and do not materially interfere with the use made or proposed to be made of such property by the Company. All real property held under lease by the Company is held by them under valid, existing and enforceable leases, free and clear of all liens, encumbrances, claims, security interests and defects, except such as are not material and do not materially interfere with the use made or proposed to be made of such property by the Company.

(k) Subsequent to the respective dates as of which information is given in the Registration Statement, the Statutory Prospectus and the Prospectus, (i) there has not been any event which would have a Material Adverse Effect; (ii) the Company has not sustained any loss or interference with its assets, businesses or properties (whether owned or leased) from fire, explosion, earthquake, flood or other calamity, whether or not covered by insurance, or from any labor dispute or any court or legislative or other governmental action, order or decree which would have a Material Adverse Effect; and (iii) except as otherwise disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, since the date of the latest balance sheet included in the Registration Statement and the Prospectus, the Company has not (A) issued any securities or incurred any liability or obligation, direct or contingent, for borrowed money, except such liabilities or obligations incurred in the ordinary course of business, (B) entered into any transaction not in the ordinary course of business or (C) declared or paid any dividend or made any distribution on any shares of its stock or redeemed, purchased or otherwise acquired or agreed to redeem, purchase or otherwise acquire any shares of its capital stock.

(l) There is no document, contract or other agreement required to be described in the Registration Statement, the Statutory Prospectus or the Prospectus or to be filed as an exhibit to the Registration Statement which is not described or filed as required by the Securities Act or Rules. Each description of a contract, document or other agreement in the Registration Statement, the Statutory Prospectus or the Prospectus accurately reflects in all material respects the terms of the underlying contract, document or other agreement. Except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, each contract, document or other agreement described in the Registration Statement, the Statutory Prospectus or the Prospectus or listed in the exhibits to the Registration Statement as being in full force and effect is in full force and effect and is valid and enforceable by and against the Company or its subsidiary, as the case may be, in accordance with its terms. Neither the Company, nor to the Company's knowledge, any other party, is in default in the observance or performance of any term or obligation to be performed by it under any such agreement, and no event has occurred which with notice or lapse of time or both would constitute such a default, in any such case which default or event, individually or in the aggregate, would have a Material Adverse Effect. No default exists, and no event has occurred which with notice or lapse of time or both would constitute a default, in the due performance and observance of any term, covenant or condition by the Company, of any other agreement or instrument to which the Company is a party or by which the Company or its properties or business may be bound or effected, which default or event, individually or in the aggregate, would have a Material Adverse Effect.

(m) The statistical and market related data included in the Registration Statement, the Statutory Prospectus or the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate.

(n) The Company is not (i) in violation of articles of association or other organizational documents of the Company, (ii) in default under, and no event has occurred which, with notice or lapse of time, or both, would constitute a default under, or result in the creation or imposition of any lien, charge, mortgage, pledge, security interest, claim, limitation on voting rights, equity, trust or other encumbrance, preferential arrangement, defect or restriction of any kind whatsoever, upon, any property or assets of the Company pursuant to any bond, debenture, note, indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which it is a party or by which it is bound or to which any of its properties or assets is subject, including any instrument or approval granted to any of them by the Israel Innovation Authority (formerly the Office of the Chief Scientist) of the Israeli Ministry of the Economy and Industry (the "IAA"), or (iii) in violation of any statute, law, rule, regulation, ordinance, directive, judgment, decree or order of any judicial, regulatory or other legal or governmental agency or body, foreign or domestic, except (in the case of clauses (ii) and (iii) above) for violations or defaults that would not (individually or in the aggregate) reasonably be expected to have a Material Adverse Effect.

(o) This Agreement has been duly authorized, executed and delivered by the Company.

(p) Neither the execution, delivery and performance of this Agreement, the Warrant Agreement (as hereinafter defined), the Firm Warrants, the Option Warrants, the Representative’s Warrant or the Representative’s Shares by the Company nor the consummation of any of the transactions contemplated hereby (including, without limitation, the issuance and sale by the Company of the Securities or the Representative’s Securities) will (i) give rise to a right to terminate or accelerate the due date of any payment due under, or conflict with or result in the breach of any term or provision of, or constitute a default (or an event which with notice or lapse of time or both would constitute a default) under, or require any consent or waiver under, or result in the execution or imposition of any lien, charge or encumbrance upon any properties or assets of the Company pursuant to the terms of, any indenture, mortgage, deed of trust or other agreement or instrument to which the Company is a party or by which either the Company or any of its properties or businesses is bound, or any franchise, license, permit, judgment, decree, order, statute, rule or regulation applicable to the Company, except, in each case, as would not (individually or in the aggregate) reasonably be expected to have a Material Adverse Effect or (ii) violate any provision of the articles of association, charter or by-laws or other organizational documents of the Company.

(q) The Company has authorized and outstanding capital stock as set forth under the caption "Capitalization" in the Statutory Prospectus and the Prospectus. The Securities and the Representative's Securities have been duly authorized for issuance by the Company. All of the issued and outstanding shares of capital stock of the Company have been duly and validly issued and are fully paid and nonassessable and have been issued in compliance with all federal, state and local, including Israeli, securities laws. Except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, there are no statutory preemptive or other similar statutory rights to subscribe for or to purchase or acquire any shares of capital stock of the Company, including Ordinary Shares, or any such rights pursuant to its article of association, charter, certificate of incorporation or by-laws or any other applicable organizational documents or any agreement or instrument to or by which the Company is a party or bound. The Company has reserved and kept available for issuance upon the exercise of the Firm Warrants, the Option Warrants and the Representative's Warrant such number of authorized but unissued Ordinary Shares as are sufficient to permit the exercise in full of the Firm Warrants, the Option Warrants and the Representative's Warrant. The Firm Shares and the Option Shares, when issued and sold pursuant to this Agreement, and the Warrant Shares and the Ordinary Shares underlying the Representative's Warrant, when issued and sold in accordance with the terms of the Warrants and the Representative's Warrant, respectively, after the issuance and sale of the Firm Warrants and any Option Warrants and the Representative's Warrant pursuant to this Agreement, and the Representative's Shares, when issued pursuant to this Agreement, have been duly authorized for issuance and sale and, when so issued and sold, will be duly and validly issued, fully paid and nonassessable and none of them will be issued in violation of any preemptive or other similar right. Except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, there is no outstanding option, warrant or other right calling for the issuance of, and there is no commitment, plan or arrangement to issue, any share of capital stock of the Company or any security convertible into, or exercisable or exchangeable for, such shares. Except as disclosed in the registration statement, the exercise price of each option to acquire Ordinary Shares (each, a "Company Stock Option") is no less than the fair market value of an Ordinary Share as determined on the date of grant of such Company Stock Option. All grants of Company Stock Options were validly issued and properly approved by the Board of Directors of the Company (and, if required, by a committee of the Board of Directors of the Company and/or the shareholders of the Company) in material compliance with all applicable laws and the terms of the plans under which such Company Stock Options were issued and were recorded on the Company financial statements, in accordance with IFRS as issued by the International Accounting Standards Board, and no such grants involved any "back dating," "forward dating," "spring loading" or similar practices with respect to the effective date of grant. The Ordinary Shares and the Securities conform in all material respects to all statements in relation thereto contained in the Registration Statement and the Statutory Prospectus and the Prospectus.

(r) Except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, no holder of any security of the Company has any right, which has not been waived, to have any security owned by such holder included in the Registration Statement or to demand registration of any security owned by such holder for a period of 180 days after the date of this Agreement. Each director and executive officer of the Company and each stockholder of the Company listed on Schedule II hereto has delivered to the Representative his or her enforceable written lock-up agreement in the form attached to this Agreement as Exhibit A hereto (the "Lock-Up Agreement").

(s) Except as disclosed in the Registration Statement, there are no legal or governmental proceedings pending to which the Company is a party or of which any property of the Company is the subject which, if determined adversely to the Company, would individually or in the aggregate have a Material Adverse Effect; and, to the knowledge of the Company, no such proceedings are threatened or contemplated by governmental authorities or threatened by others.

(t) All necessary corporate action has been duly and validly taken by the Company to authorize the execution, delivery and performance of this Agreement by the Company and the issuance and sale of the Securities and the Representative’s Securities by the Company, including Chapter 5 of the Part VI of the Companies Law. The Firm Warrants and the Representative’s Warrant on the Firm Securities Closing Date and the Option Warrants on each Option Securities Closing Date (if any) will be duly and validly authorized, executed and delivered by the Company and will constitute legal, valid and binding obligations of the Company enforceable against the Company in accordance with their respective terms.

(u) The Company is not involved in any labor dispute nor, to the knowledge of the Company, is any such dispute threatened, which dispute would have a Material Adverse Effect. To the Company's knowledge, there is no existing or imminent labor disturbance by the employees of any of its principal suppliers or contractors which would have a Material Adverse Effect. To the Company's knowledge, there is no threatened or pending litigation between the Company and any of its executive officers which, if adversely determined, would have a Material Adverse Effect and has no reason to believe that such officers will not remain in the employment of the Company.

(v) No transaction has occurred between or among the Company and any of its officers or directors, shareholders or any affiliate or affiliates of any such officer or director or shareholder that is required to be described in and is not so described in the Registration Statement, the Statutory Prospectus and the Prospectus.

(w) The Company has not taken, nor will it take, directly or indirectly, any action designed to, or which might reasonably be expected to cause or result in, or which has constituted or which might reasonably be expected to constitute, the stabilization or manipulation of the price of the Ordinary Shares or any security of the Company to facilitate the sale or resale of any of the Securities. The Company has not engaged and will not engage in any form of solicitation, advertising or other action constituting an offer or a sale under the Israeli Securities Law, 5728-1968, as amended (the "Israeli Securities Law"), and the regulations promulgated thereunder in connection with the transactions contemplated hereby which would require the publication of a prospectus in the State of Israel under the laws of the State of Israel.

(x) Except as would not, in each case, individually or in the aggregate, have a Material Adverse Effect, the Company (i) has filed all federal, state, local and foreign tax returns which are required to be filed through the date hereof or has received timely extensions thereof, (ii) such returns are true and correct in all respects, and (iii) the Company has paid all taxes shown on such returns and all assessments received by it to the extent that the same have become due. There are no tax audits or investigations pending, which if adversely determined would have a Material Adverse Effect; nor is the Company aware of any proposed additional tax assessments against the Company, except as would not individually or in the aggregate have a Material Adverse Effect.

(y) The Shares and the Warrants have been approved for listing on the NASDAQ Capital Market. A registration statement has been filed on Form 8-A pursuant to Section 12 of the Exchange Act, which registration statement complies in all material respects with the Exchange Act.

(z) The books, records and accounts of the Company accurately and fairly reflect, in all material respects, the transactions in, and dispositions of, the assets of, and the results of operations of, the Company. The Company maintains a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in accordance with IFRS and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(aa) The Company has established and maintains disclosure controls and procedures (as such term is defined in Rule 13a-15 under the Exchange Act) that are designed to comply with the requirements of the Exchange Act applicable to the Company and that: (i) are designed to ensure that material information relating to the Company is made known to the Company's principal executive officer and its principal financial officer by others within the Company, particularly during the periods in which the periodic reports required under the Exchange Act are required to be prepared; (ii) provide for the periodic evaluation of the effectiveness of such disclosure controls and procedures at the end of the periods in which the periodic reports are required to be prepared; and (iii) are effective in all material respects to perform the functions for which they were established.

(bb) Based on the evaluation of its disclosure controls and procedures, to the Company's knowledge, there is no (i) material weakness or significant deficiency in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize and report financial data or any material weaknesses in internal controls; or (ii) fraud, whether or not material, that involves management or other employees who have a role in the Company's internal controls.

(cc) Except as described in the Registration Statement, the Statutory Prospectus and the Prospectus, there are no material off-balance sheet arrangements (as defined in Item 303 of Regulation S-K) that have or are reasonably likely to have a material current or future effect on the Company's financial condition, revenues or expenses, changes in financial condition, results of operations, liquidity, capital expenditures or capital resources.

(dd) The Company's Board of Directors has validly appointed an audit committee whose composition satisfies the requirements of Rule 5605 of the Nasdaq Stock Market and the Board of Directors and/or the audit committee has adopted a charter that satisfies the requirements of Rule 5605 of the Nasdaq Stock Market. The audit committee has reviewed the adequacy of its charter within the past twelve months.

(ee) The Company is in compliance with all other applicable provisions of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), any related applicable rules and regulations promulgated by the Commission and corporate governance requirements under applicable Nasdaq regulations upon the effectiveness of such provisions and has no reason to believe that it will not be able to comply with such provisions at the time of effectiveness. There has been no failure on the part of the Company or any of its directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act, including, without limitation, Section 402 related to loans and Sections 302 and 906 related to certifications.

(ff) The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are customary in the businesses in which they are engaged or propose to engage after giving effect to the transactions described in the Statutory Prospectus and the Prospectus; all policies of insurance and fidelity or surety bonds insuring the Company or the Company's respective businesses, assets, employees, officers and directors are in full force and effect; the Company is in compliance with the terms of such policies and instruments in all material respects; and the Company has no any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that is not materially greater than the current cost. The Company has not been denied any insurance coverage which it has sought or for which it has applied, which would reasonably be expected to have a Material Adverse Effect.

(gg) Each approval, consent, order, authorization, designation, declaration or filing of, by or with any regulatory, administrative or other governmental body necessary in connection with the execution and delivery by the Company of this Agreement and the consummation of the transactions herein contemplated required to be obtained or performed by the Company (except such additional steps as may be required by the Financial Industry Regulatory Authority ("FINRA") or may be necessary to qualify the Securities for public offering by the Underwriters under the state securities or Blue Sky laws) has been obtained or made and is in full force and effect, except for, following the Firm Securities Closing Date and each Option Securities Closing Date (if any), (i) certain filings and notices with the Israeli Registrar regarding the issuance of the Securities and the Company becoming a "public company" (within the meaning of the Companies Law) and (ii) providing certain information to the IIA.

(hh) To the Company's knowledge, there are no affiliations with FINRA among the Company's officers, directors or, to the best of the knowledge of the Company, any five percent or greater shareholder of the Company, except as set forth in the Registration Statement or otherwise disclosed in writing to the Representative.

(ii) (i) Except as would not reasonably be expected to have a Material Adverse Effect, the Company is in compliance with all rules, laws and regulations relating to the use, treatment, storage and disposal of toxic substances and protection of health or the environment ("Environmental Law") which are applicable to its business; (ii) the Company has not received any notice from any governmental authority or third party of an asserted claim under Environmental Laws; (iii) the Company has received all permits, licenses or other approvals required of it under applicable Environmental Laws to conduct its business and is in compliance with all terms and conditions of any such permit, license or approval; (iv) to the Company's knowledge, no facts currently exist that will require the Company to make future material capital expenditures to comply with Environmental Laws; and (v) no property which is or has been owned, leased or occupied by the Company has been designated as a Superfund site pursuant to the Comprehensive Environmental Response, Compensation of Liability Act of 1980, as amended (42 U.S.C. Section 9601, et. seq.) or otherwise designated as a contaminated site under other applicable Environmental Laws. The Company has not been named as a "potentially responsible party" under the CERCLA 1980.

(jj) In the ordinary course of its business, the Company periodically reviews the effect of Environmental Laws on the business, operations and properties of the Company, in the course of which the Company identifies and evaluates associated costs and liabilities (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws, or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties). On the basis of such review, the Company has reasonably concluded that such associated costs and liabilities would not, singly or in the aggregate, have a Material Adverse Effect.

(kk) The Company is not and, after giving effect to the offering and sale of the Securities and the application of proceeds thereof as described in the Statutory Prospectus and the Prospectus, will not be required to register as an "investment company" within the meaning of the Investment Company Act of 1940, as amended (the "Investment Company Act").

(ll) Neither the Company, nor, to the Company's knowledge, any director, officer, agent or employee of the Company or any other person acting on behalf of the Company, has, directly or indirectly, while acting on behalf of the Company (i) used any corporate funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity; (ii) made any unlawful payment to foreign or domestic government officials or employees or to foreign or domestic political parties or campaigns from corporate funds; (iii) violated any provision of the Foreign Corrupt Practices Act of 1977, as amended or any provision of any applicable non-U.S. anti-bribery or anti-corruption law or regulation; or (iv) made any other unlawful payment.

(mm) The operations of the Company are and have been conducted at all times in material compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the applicable money laundering statutes of any jurisdiction where the Company conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending, or to the best knowledge of the Company, threatened.

(nn) Neither the Company, nor, to the knowledge of the Company, any director, officer, agent or employee of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and the Company will not directly or indirectly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(oo) Except as described in the Statutory Prospectus and the Prospectus, the Company has not sold or issued any shares of capital stock during the six-month period preceding the date of the Prospectus, including any sales pursuant to Rule 144A under, or Regulations D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, qualified stock options plans or other employee compensation plans or pursuant to outstanding options, rights or warrants.

(pp) None of the Company, its directors or its officers has distributed nor will distribute prior to the later of (i) the Firm Securities Closing Date, or the Option Securities Closing Date, and (ii) completion of the distribution of the Securities, any offering material in connection with the offering and sale of the Securities other than any Preliminary Prospectus, the Prospectus, the Registration Statement and other materials, if any, permitted by the Securities Act and consistent with the terms of this Agreement.

(qq) Since the date of the preliminary prospectus included in the Registration Statement filed with the Commission on _________ (or, if earlier, the first date on which the Company engaged directly or through any Person authorized to act on its behalf in any Testing-the-Waters Communication (as defined herein)) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "Emerging Growth Company"). "Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.

(rr) The Company (a) has not alone engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representative with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act, and (b) has not authorized anyone other than the Representative to engage in Testing-the-Waters Communications. The Company reconfirms that the Representative has been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications (as defined herein) other than those listed on Schedule IV hereto. "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.

(ss) The Company has the power to submit, and pursuant to Section 9 of this Agreement, has legally, validly, effectively and irrevocably submitted, to the personal jurisdiction of each Specified Court (as defined below), and the Company has the power to designate, appoint and authorize, and pursuant to Section 9 of this Agreement, has legally, validly, effectively and irrevocably designated, appointed and authorized an agent for service of process in any action arising out of or relating to this Agreement in any Specified Court, and service of process effected on such authorized agent will be effective to confer valid personal jurisdiction over the Company as provided in Section 9 hereof.

(tt) The Company is a "foreign private issuer" within the meaning of Rule 405 under the Securities Act.

(uu) The Company has all requisite corporate power and authority, and all necessary authorizations, approvals, consents, orders, licenses, certificates and permits of and from all governmental or regulatory bodies or any other person or entity (collectively, the "Permits"), to own, lease and license its assets and properties and conduct its business, all of which are valid and in full force and effect, except where the lack of such Permits, individually or in the aggregate, would not have a Material Adverse Effect. The Company has fulfilled and performed in all respects all of its obligations with respect to such Permits and no event has occurred that allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other impairment of the rights of the Company thereunder, except, in each case, as would not reasonably be expected to have a Material Adverse Effect. The Company has not received any written notice denying, revoking or modifying any grants or benefits from the IIA (including, in all such cases, notice of proceedings or investigations related thereto). All information supplied by the Company with respect to the applications or notifications relating to grants and benefits from the IIA was true, correct and complete in all material respects when supplied to the appropriate authorities.

3. Conditions of the Underwriters' Obligations. The obligations of the Underwriters under this Agreement are several and not joint. The respective obligations of the Underwriters to purchase the Securities are subject to each of the following terms and conditions:

(a) Notification that the Registration Statement has become effective shall have been received by the Representative and the Prospectus shall have been timely filed with the Commission in accordance with Section 4(a) of this Agreement and any material required to be filed by the Company pursuant to Rule 433(d) of the Rules shall have been timely filed with the Commission in accordance with such rule.

(b) No order preventing or suspending the use of any Preliminary Prospectus, the Prospectus or any Issuer Free Writing Prospectus, shall have been or shall be in effect and no order suspending the effectiveness of the Registration Statement shall be in effect and no proceedings for such purpose shall be pending before or threatened by the Commission, and any requests for additional information on the part of the Commission (to be included in the Registration Statement or the Prospectus or otherwise) shall have been complied with to the satisfaction of the Commission and the Representative. If the Company has elected to rely upon Rule 430A, Rule 430A information previously omitted from the effective Registration Statement pursuant to Rule 430A shall have been transmitted to the Commission for filing pursuant to Rule 424(b) within the prescribed time period and the Company shall have provided evidence satisfactory to the Underwriters of such timely filing, or a post-effective amendment providing such information shall have been promptly filed and declared effective in accordance with the requirements of Rule 430A.

(c) The representations and warranties of the Company contained in this Agreement and in the certificates delivered pursuant to Section 3(d) shall be true and correct when made and on and as of each Closing Date as if made on such date. The Company shall have performed all covenants and agreements and satisfied all the conditions contained in this Agreement required to be performed or satisfied by it at or before such Closing Date.

(d) The Representative shall have received on each Closing Date a certificate, addressed to the Representative and dated such Closing Date, of the chief executive and the chief financial officer or chief accounting officer of the Company in such capacity to the effect that: (i) the representations, warranties and agreements of the Company in this Agreement were true and correct when made and are true and correct as of such Closing Date; (ii) the Company has performed all covenants and agreements and satisfied all conditions contained herein; (iii) they have carefully examined the Registration Statement, the Prospectus, the General Disclosure Package, and any individual Issuer Free Writing Prospectus and, in their opinion (A) as of the Effective Date the Registration Statement and Prospectus did not include, and as of the Applicable Time, neither (i) the General Disclosure Package, nor (ii) any individual Issuer Free Writing Prospectus, when considered together with the General Disclosure Package, included, any untrue statement of a material fact and did not omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, and (B) since the Effective Date, no event has occurred which should have been set forth in a supplement or otherwise required an amendment to the Registration Statement, the Statutory Prospectus or the Prospectus; (iv) no stop order suspending the effectiveness of the Registration Statement has been issued and, to their knowledge, no proceedings for that purpose have been instituted or are pending under the Securities Act and (v) there has not occurred any material adverse change in the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company.

(e) The Representative shall have received: (i) simultaneously with the execution of this Agreement, a signed letter from the Auditor addressed to the Representative and dated the date of this Agreement, in form and substance reasonably satisfactory to the Representative, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement and the Disclosure Package, and (ii) on each Closing Date, a signed bring-down letter from the Auditor addressed to the Representative and dated the date of such Closing Date(s), in form and substance reasonably satisfactory to the Representative containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement and the Prospectus.

(f) The Representative shall have received on each Closing Date from Davis Polk & Wardwell LLP, U.S. counsel for the Company, an opinion and negative assurance statement, addressed to the Representative and dated such Closing Date, in form and substance reasonably satisfactory to the Representative.

(g) The Representative shall have received on each Closing Date from Herzog Fox & Neeman, Israeli counsel for the Company, an opinion, addressed to the Representative and dated such Closing Date, in form and substance reasonably satisfactory to the Representative.

(h) The Representative shall have received on each Closing Date from Erlich & Fenster, intellectual property counsel for the Company, an opinion and written negative assurances statement, addressed to the Representative and dated such Closing Date, in form and substance satisfactory to the Representative.

(i) The Representative shall have received on the Closing Date from Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., as U.S. counsel for the Representative, a negative assurance statement, addressed to the Representative and dated as of such Closing Date, with respect to such matters as the Representative may reasonably require, and the Company shall have furnished or provided access to such counsel of such documents as they request for enabling them to pass upon such matters.

(j) All proceedings taken in connection with the sale of the Securities as herein contemplated shall be reasonably satisfactory in form and substance to the Representative and its counsel.

(k) The Representative shall have received copies of the Lock-up Agreements executed by each entity or person listed on Schedule II hereto. In the event that Maxim Group LLC, in its sole discretion, agrees to release or waive any restriction set forth in a Lock-Up Agreement for an officer or director of the Company, and provides the Company with notice of the impending release or waiver at least three business days before the effective date of such release or waiver (which release or waiver shall be substantially in the Form found at Exhibit A-1 hereto), the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit A-2 hereto through a major news service at least two business days before the effective date of the release or waiver.

(l) The Shares and the Warrants shall have been approved for quotation on the Nasdaq Capital Market, subject only to official notice of issuance.

(m) The Representative shall be reasonably satisfied that since the respective dates as of which information is given in the Registration Statement, the Statutory Prospectus, the General Disclosure Package and the Prospectus, (i) there shall not have been any material change in the capital stock of the Company or any material change in the indebtedness (other than in the ordinary course of business) of the Company, (ii) except as set forth or contemplated by the Registration Statement, the Statutory Prospectus, the General Disclosure Package or the Prospectus, no material oral or written agreement or other transaction shall have been entered into by the Company that is not in the ordinary course of business or that would reasonably be expected to result in a material reduction in the future earnings of the Company, (iii) no loss or damage (whether or not insured) to the property of the Company shall have been sustained that had or would reasonably be expected to have a Material Adverse Effect, (iv) no legal or governmental action, suit or proceeding affecting the Company or any of its properties that is material to the Company or that affects or would reasonably be expected to affect the transactions contemplated by this Agreement shall have been instituted or threatened and (v) there shall not have been any material change in the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company that makes it impractical or inadvisable in the Representative's judgment to proceed with the purchase or offering of the Securities as contemplated hereby.

(n) FINRA shall have confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and agreements in connection with the offering of the Securities and receipt by the Representative of the Representative’s Securities.

(o) The Company shall have duly and validly executed and delivered the Warrant Agreement in respect of the Warrants, which shall have been countersigned by American Stock Transfer & Trust Company, LLC, and delivered to the Representative in a form reasonably acceptable to the Representative (the "Warrant Agreement").

(p) On the Closing Date, the Company shall have issued the Representative's Shares and delivered to the Representative the Representative's Warrant.

(q) The Company shall have furnished or caused to be furnished to the Representative such customary certificates or documents as the Representative shall have reasonably requested.

4. Covenants and other Agreements of the Company and the Underwriters.

(a) The Company covenants and agrees as follows:

(i) The Company will use its best efforts to cause the Registration Statement, if not effective at the time of execution of this Agreement, and any amendments thereto, to become effective as promptly as possible. The Company shall prepare the Prospectus in a form approved by the Representative and file such Prospectus pursuant to Rule 424(b) under the Securities Act not later than the Commission's close of business on the second business day following the execution and delivery of this Agreement, or, if applicable, such earlier time as may be required by the Rules. The Company will file with the Commission all Issuer Free Writing Prospectuses in the time and manner required under Rules 433(d) or 163(b)(2), as the case may be.

(ii) The Company shall promptly advise the Representative in writing (A) when any post-effective amendment to the Registration Statement shall have become effective or any supplement to the Prospectus shall have been filed, (B) of any request by the Commission for any amendment of the Registration Statement or the Prospectus or for any additional information, (C) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any order preventing or suspending the use of any preliminary prospectus or any "free writing prospectus", as defined in Rule 405 of the Rules, or the institution or threatening of any proceeding for that purpose and (D) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Securities for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose. The Company shall not file any amendment of the Registration Statement or supplement to the Prospectus or any Issuer Free Writing Prospectus unless the Company has furnished the Representative a copy for its review prior to filing and shall not file any such proposed amendment or supplement to which the Representative reasonably objects. The Company shall use its best efforts to prevent the issuance of any such stop order and, if issued, to obtain as soon as possible the withdrawal thereof.

(iii) If, at any time when a prospectus relating to the Securities (or, in lieu thereof, the notice referred to in Rule 173(a) of the Rules) is required to be delivered under the Securities Act, any event occurs as a result of which the Prospectus as then amended or supplemented would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made not misleading, or if it shall be necessary to amend or supplement the Prospectus to comply with the Securities Act or the Rules, the Company promptly shall prepare and file with the Commission, subject to the second sentence of paragraph (ii) of this Section 4(a), an amendment or supplement which shall correct such statement or omission or an amendment which shall effect such compliance.

(iv) If at any time following issuance of an Issuer Free Writing Prospectus there occurs an event or development as a result of which such Issuer Free Writing Prospectus would conflict with the information contained in the Registration Statement or would include an untrue statement of a material fact or would omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances prevailing at the subsequent time, not misleading, the Company will promptly notify the Representative and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(v) The Company shall make generally available to its security holders and to the Representative as soon as practicable, but not later than 45 days after the end of the 12-month period beginning at the end of the fiscal quarter of the Company during which the Effective Date occurs (or 90 days if such 12-month period coincides with the Company's fiscal year), an earnings statement (which need not be audited) of the Company, covering such 12-month period, which shall satisfy the provisions of Section 11(a) of the Securities Act or Rule 158 of the Rules.

(vi) Upon request, the Company shall furnish to the Representative and counsel for the Underwriters, without charge, two signed copies of the Registration Statement (including all exhibits thereto and amendments thereof) and to each other Underwriter a copy of the Registration Statement (without exhibits thereto) and all amendments thereof and, so long as delivery of a prospectus by an Underwriter or dealer may be required by the Securities Act or the Rules, as many copies of any Preliminary Prospectus, any Issuer Free Writing Prospectus and the Prospectus and any amendments thereof and supplements thereto as the Representative may reasonably request. If applicable, the copies of the Registration Statement, preliminary prospectus, any Issuer Free Writing Prospectus and Prospectus and each amendment and supplement thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(vii) The Company shall cooperate with the Representative and its counsel to use commercially reasonable efforts to qualify the Securities for offer and sale in connection with the offering under the laws of such jurisdictions in the United States as the Representative may reasonably designate and shall maintain such qualifications in effect so long as required for the distribution of the Securities pursuant to this Agreement; provided, however, that the Company shall not be required in connection therewith, as a condition thereof, to qualify as a foreign corporation or to execute a general consent to service of process in any jurisdiction or subject itself to taxation as doing business in any jurisdiction.

(viii) The Company, during the period when the Prospectus (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules) is required to be delivered under the Securities Act and the Rules or the Exchange Act, will file all reports and other documents required to be filed with the Commission pursuant to Section 13, 14 or 15 of the Exchange Act within the time periods required by the Exchange Act and the regulations promulgated thereunder.

(ix) Without the prior written consent of Maxim Group LLC, for a period of 180 days after the date of this Agreement (the "Restricted Period"), the Company shall not issue, sell or register with the Commission (other than on Form S-8 or on any successor form), or otherwise dispose of, directly or indirectly, any equity securities of the Company (or any securities convertible into, exercisable for or exchangeable for equity securities of the Company), except for (A) the issuance and sale of the Securities and Representative’s Securities pursuant hereto and, in the case of the Securities, pursuant to the Registration Statement, (B) the issuance of Ordinary Shares upon the exercise of an option or warrant or grants pursuant to the Company's existing stock option plan or bonus plan as described in the Registration Statement and the Prospectus or the filing by the Company of a registration statement with the Commission on Form S-8 in connection therewith, (C) the issuance of any Ordinary Shares to holders of preferred shares of the Company pursuant to the conversion of the Company's Series A or Series B preferred shares into Ordinary Shares as described in the Registration Statement, the Statutory Prospectus and the Prospectus, (D) the issuance of any Ordinary Shares to lenders under the Company's convertible loan agreements pursuant to the conversion of outstanding convertible loans into Ordinary Shares as described in the Registration Statement, the Statutory Prospectus and the Prospectus, (E) the entrance into an agreement providing for the issuance by the Company of Ordinary Shares or any security convertible into or exercisable for Ordinary Shares in connection with the acquisition by the Company of the securities, business, or other assets of another person or entity or pursuant to an employee benefit plan assumed by the Company in connection with such acquisition, and the issuance of any such securities pursuant to any such agreement, (F) the entry into an agreement providing for the issuance of Ordinary Shares or any security convertible into or exercisable for Ordinary Shares in connection with joint ventures, commercial relationships or other strategic transactions, and the issuance of any such securities pursuant to any such agreement; provided that in the case of clauses (E) and (F), any such issuances shall be approved by a majority of the independent members of the Company's Board of Directors, and the aggregate number of Ordinary Shares that the Company may sell or issue or agree to sell or issue pursuant to clauses (E) and (F) shall not exceed 5.0% of the total number of Ordinary Shares issued and outstanding immediately following the completion of the transactions contemplated by this Agreement; and provided further, that each recipient of securities issued pursuant to clauses (C) through (F) shall execute a lock-up letter substantially in the form of Exhibit A hereto, (G) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Ordinary Shares, provided that (i) such plan does not provide for the transfer of Ordinary Shares during the Restricted Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Ordinary Shares may be made under such plan during the Restricted Period, or (H) the issuance of any Warrant Shares in accordance with the terms of the Warrants or Ordinary Shares in accordance with the Representative’s Warrant.

(x) On or before completion of this offering, the Company shall make all filings required under applicable securities laws and by the Nasdaq Capital Market (including any required registration under the Exchange Act).

(xi) The Company will apply the net proceeds from the offering of the Securities substantially in the manner set forth under "Use of Proceeds" in the Prospectus.

(xii) The Company will promptly notify the Representative if the Company ceases to be an Emerging Growth Company at any time prior to the later of (a) completion of the distribution of the Securities within the meaning of the Securities Act and (b) completion of the 180-day restricted period referred to in Section 4(a)(ix) hereof.

(xiii) If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representative and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

(b) The Company agrees to pay, or reimburse if paid by the Representative, whether or not the transactions contemplated hereby are consummated or this Agreement is terminated, all costs and expenses incident to the public offering of the Securities and the performance of the obligations of the Company under this Agreement including those relating to: (i) the preparation, printing, reproduction filing and distribution of the Registration Statement, including all exhibits thereto, each Preliminary Prospectus, the Prospectus, any Issuer Free Writing Prospectus, all amendments and supplements thereto, and the printing, filing and distribution of this Agreement, (ii) the preparation and delivery of certificates for the Securities and the Representative's Securities to the Underwriters, (iii) the registration or qualification of the Securities for offer and sale under the securities or Blue Sky laws of the various jurisdictions referred to in Section 4(a)(vii), including the reasonable and documented fees and disbursements of counsel for the Underwriters in connection with such registration and qualification and the preparation, printing, distribution and shipment of preliminary and supplementary Blue Sky memoranda (up to a maximum amount, when taken together with the fees and disbursements of counsel for the Underwriters incurred in connection with clause (v) of this Section 4(b), of $10,000 and subject to the Overall Fee Cap (defined below)); (iv) the furnishing (including costs of shipping and mailing) to the Representative and to the Underwriters of copies of each Preliminary Prospectus, the Prospectus and all amendments or supplements to the Prospectus, any Issuer Free Writing Prospectus, and of the several documents required by this Section to be so furnished, as may be reasonably requested for use in connection with the offering and sale of the Securities by the Underwriters or by dealers to whom Securities may be sold; (v) the filing fees of FINRA in connection with its review of the terms of the public offering and reasonable and documented fees and disbursements of counsel for the Underwriters (including the Representative's Securities) in connection with such review (up to a maximum amount, when taken together with the fees and disbursements of counsel for the Underwriters incurred in connection with clause (iii) of this Section 4(b), of $10,000 and subject to the Overall Fee Cap (defined below)); (vi) any additional reasonable and documented fees of counsel for the Underwriters incurred in connection with the offering, including the fees and disbursements of counsel for the Underwriters incurred in connection with clause (iii) and (v) of this Section 4(b), up to a maximum of $100,000 (the "Overall Fee Cap"); (vii) inclusion of the Shares and the Warrants for quotation on the NASDAQ Global Market, Capital Market, NYSE MKT or NYSE; (viii) all transfer taxes, if any, with respect to the sale and delivery of the Securities and the Representative's Securities by the Company to the Underwriters; and (ix) all costs and expenses incident to any "road show" marketing efforts undertaken by the Representative in connection with the Offering up to a maximum of $5,000. In addition to the payments set forth in this Section, the Company agrees that, for a period of twelve (12) months from the Closing Date: (A) the Company grants to the Representative the right of first refusal to act as sole lead managing underwriter and sole book runner in a Subsequent Financing (as defined below) during such 12-month period if the gross proceeds to the Company in such Subsequent Financing are equal to or less than $25 million, and the Representative shall reserve 20% of the placement fee (or gross spread if an underwritten offering) to be allocated to potential co-placement agents or manager(s), as the case may be, in such future offerings in such twelve (12) month period, provided that notwithstanding the above, the Company may, with the Representative's consent (such consent not to be unreasonably withheld) appoint additional underwriters, book runners, co-placement agents or managers, with respect to such Subsequent Financing, and the Representative shall, upon such appointment, commence good faith negotiations with such additional underwriters and/or book runners to reach an agreement with respect to the fees to be paid on the Subsequent Financing; and (B) for any Subsequent Financing with gross proceeds to the Company during such 12-month period of more than $25 million, the Representative shall be entitled to join the follow-on offering by the Company at a minimum as a "right" joint book-runner with economics of no less than 35% of the underwriter fees attributed to the gross proceeds received by the Company in such Subsequent Financing. The term "Subsequent Financing" shall mean any future public and private equity or debt financings or follow-on offerings of the Company, during the period of twelve (12) months from the Closing the Offering, provided that, for the avoidance of doubt, any M&A transactions, or any transactions or partnerships with strategic partners or pharmaceutical companies, shall not be deemed a Subsequent Financing. The Representative shall receive a fee in line with standard industry practice in connection with any such Subsequent Financing, the precise terms and conditions to be determined at such time.

(c) The Company acknowledges and agrees that each of the Underwriters has acted and is acting solely in the capacity of a principal in an arm's length transaction between the Company, on the one hand, and the Underwriters, on the other hand, with respect to the offering of Securities contemplated hereby (including in connection with determining the terms of the offering) and not as a financial advisor, agent or fiduciary to the Company or any other person. Additionally, the Company acknowledges and agrees that the Underwriters have not and will not advise the Company or any other person as to any legal, tax, investment, accounting or regulatory matters in any jurisdiction. The Company has consulted with its own advisors concerning such matters and shall be responsible for making its own independent investigation and appraisal of the transactions contemplated hereby, and the Underwriters shall have no responsibility or liability to the Company or any other person with respect thereto, whether arising prior to or after the date hereof. Any review by the Underwriters of the Company, the transactions contemplated hereby or other matters relating to such transactions have been and will be performed solely for the benefit of the Underwriters and shall not be on behalf of the Company. The Company agrees that it will not claim that the Underwriters, or any of them, has rendered advisory services of any nature or respect, or owes a fiduciary duty to the Company or any other person in connection with any such transaction or the process leading thereto.

(d) The Company represents and agrees that, unless it obtains the prior consent of the Representative, and each Underwriter represents and agrees that, unless it obtains the prior consent of the Company and the Representative, it has not made and will not make any offer relating to the Securities that would constitute an "issuer free writing prospectus," as defined in Rule 433, or that would otherwise constitute a "free writing prospectus," as defined in Rule 405, required to be filed with the Commission. The Company has complied and will comply with the requirements of Rule 433 under the Securities Act applicable to any Issuer Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping. The Company represents that is has satisfied and agrees that it will satisfy the conditions set forth in Rule 433 of the Rules to avoid a requirement to file with the Commission any Road Show.

(e) The Company acknowledges, understands and agrees that the Securities may be offered and sold in Israel only by the Underwriters and only to such Israeli investors listed in the First Addendum to the Israeli Securities Law (the "Addendum") who submit written confirmation to the Underwriters and the Company that such investor (i) falls within the scope of the Addendum, is aware of the meaning of same and agrees to it and (ii) is acquiring the Securities for investment for its own account or, if applicable, for investment for clients who are investors listed in the Addendum and in any event not as a nominee, market maker or agent and not with a view to, or for the resale in connection with, any distribution thereof ("Israeli Accredited Investors").

(f) The Underwriters acknowledge, understand and agree that the Securities may be offered and sold in Israel only by the Underwriters and only to Israeli Accredited Investors.

5. Indemnification.

(a) The Company agrees to indemnify and hold harmless each Underwriter, its officers and employees and each person, if any, who controls any Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all losses, claims, damages and liabilities, joint or several (including any reasonable investigation, legal and other expenses incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted), to which they, or any of them, may become subject under the Securities Act, the Exchange Act or other federal or state law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, the Registration Statement, the Statutory Prospectus, the Prospectus, any Issuer Free Writing Prospectus or any "issuer-information" filed or required to be filed pursuant to Rule 433(d) of the Rules, any amendment thereof or supplement thereto, any Written Testing-the-Waters Communication, or arise out of or are based upon any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; provided, however, that such indemnity shall not inure to the benefit of any Underwriter (or any person controlling such Underwriter) on account of any losses, claims, damages or liabilities arising from the sale of the Securities to any person by such Underwriter if such untrue statement or omission or alleged untrue statement or omission was made in such preliminary prospectus, the Registration Statement, the Prospectus, the Statutory Prospectus, any Issuer Free Writing Prospectus or such amendment or supplement thereto, any Written Testing-the-Waters Communication, in reliance upon and in conformity with the Underwriter Information. This indemnity agreement will be in addition to any liability which the Company may otherwise have.

(b) Each Underwriter, severally and not jointly, agrees to indemnify and hold harmless the Company, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, each director of the Company, and each officer of the Company who signs the Registration Statement, against any losses, claims, damages or liabilities to which such party may become subject, under the Securities Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, the Registration Statement or the Prospectus, or any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in any Preliminary Prospectus, the Registration Statement, the Statutory Prospectus or the Prospectus or any such amendment or supplement in reliance upon and in conformity with the Underwriter Information; provided, however, that the obligation of each Underwriter to indemnify the Company (including any controlling person, director or officer thereof) shall be limited to the amount of the underwriting discount and commissions applicable to the Securities to be purchased by such Underwriter hereunder.

(c) Any party that proposes to assert the right to be indemnified under this Section 5 will, promptly after receipt of notice of commencement of any action, suit or proceeding against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 5, notify each such indemnifying party of the commencement of such action, suit or proceeding, enclosing a copy of all papers served. No indemnification provided for in Section 5(a) or 5(b) shall be available to any party who shall fail to give notice as provided in this Section 5(c) if the party to whom notice was not given was unaware of the proceeding to which such notice would have related and was prejudiced by the failure to give such notice but the omission so to notify such indemnifying party of any such action, suit or proceeding shall not relieve it from any liability that it may have to any indemnified party for contribution or otherwise than under this Section 5. In case any such action, suit or proceeding shall be brought against any indemnified party and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in, and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof and the approval by the indemnified party of such counsel, the indemnifying party shall not be liable to such indemnified party for any legal or other expenses, except as provided below and except for the reasonable costs of investigation subsequently incurred by such indemnified party in connection with the defense thereof. The indemnified party shall have the right to employ its counsel in any such action, but the reasonably incurred fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the employment of counsel by such indemnified party has been authorized in writing by the indemnifying parties, (ii) the indemnified party shall have been advised by counsel that there may be one or more legal defenses available to it which are different from or in addition to those available to the indemnifying party (in which case the indemnifying parties shall not have the right to direct the defense of such action on behalf of the indemnified party) or (iii) the indemnifying parties shall not have employed counsel to assume the defense of such action within a reasonable time after notice of the commencement thereof, in each of which cases the reasonably incurred fees and expenses of counsel shall be at the expense of the indemnifying parties. An indemnifying party shall not be liable for any settlement of any action, suit, and proceeding or claim effected without its written consent, which consent shall not be unreasonably withheld or delayed.

6. Contribution. In order to provide for a just and equitable contribution in circumstances in which the indemnification provided for in Section 5(a) or 5(b) is due in accordance with its terms but for any reason is unavailable to or insufficient to hold harmless an indemnified party in respect to any losses, liabilities, claims, damages or expenses referred to therein, each indemnifying party shall contribute to the aggregate losses, liabilities, claims, damages and expenses (including any investigation, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claims asserted, but after deducting any contribution received by any person entitled hereunder to contribution from any person who may be liable for contribution) incurred by such indemnified party, as incurred, in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other hand from the offering of the Securities pursuant to this Agreement or, if such allocation is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to above but also the relative fault of the Company on the one hand and the Underwriters on the other hand in connection with the statements or omissions which resulted in such losses, liabilities, claims, damages or expenses, as well as any other relevant equitable considerations. The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 6 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above. The aggregate amount of losses, liabilities, claims, damages and expenses incurred by an indemnified party and referred to above shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission. Notwithstanding the provisions of this Section 6, no Underwriter (except as may be provided in the Agreement Among Underwriters) shall be required to contribute any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by such Underwriter. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 6, each person, if any, who controls an Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act shall have the same rights to contribution as such Underwriter, and each director of the Company, including any person who, with his or her consent, is named in the Registration Statement as about to become a director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Section 15 of the Securities Act or Section 20 of the Exchange Act, shall have the same rights to contribution as the Company. Any party entitled to contribution will, promptly after receipt of notice of commencement of any action, suit or proceeding against such party in respect of which a claim for contribution may be made against another party or parties under this Section 6, notify such party or parties from whom contribution may be sought, but the omission to so notify such party or parties from whom contribution may be sought shall not relieve the party or parties from whom contribution may be sought from any other obligation it or they may have hereunder or otherwise than under this Section 6. No party shall be liable for contribution with respect to any action, suit, proceeding or claim settled without its written consent. The Underwriter's obligations to contribute pursuant to this Section 6 are several in proportion to their respective underwriting commitments and not joint.

7. Termination.

(a) This Agreement may be terminated with respect to the Securities to be purchased on a Closing Date by the Representative by notifying the Company at any time at or before a Closing Date in the absolute discretion of the Representative if: (i) there has occurred any material adverse change in the securities markets or any event, act or occurrence that has materially disrupted, or in the opinion of the Representative, will in the future materially disrupt, the securities markets or there shall be such a material adverse change in general financial, political or economic conditions or the effect of international conditions on the financial markets in the United States is such as to make it, in the judgment of the Representative, inadvisable or impracticable to market the Securities or enforce contracts for the sale of the Securities, (ii) there has occurred any outbreak or material escalation of hostilities or acts of terrorism or other calamity or crisis the effect of which on the financial markets of the United States is such as to make it, in the judgment of the Representative, inadvisable or impracticable to market the Securities or enforce contracts for the sale of the Securities, (iii) trading in the Shares or any securities of the Company has been suspended or materially limited by the Commission or trading generally on the New York Stock Exchange, Inc. or the Nasdaq Stock Market has been suspended or materially limited, or minimum or maximum ranges for prices for securities shall have been fixed, or maximum ranges for prices for securities have been required, by any of said exchanges or by such system or by order of the Commission, FINRA, or any other governmental or regulatory authority, (iv) a banking moratorium has been declared by any state or federal authority or (v) in the judgment of the Representative, there has been, since the time of execution of this Agreement or since the respective dates as of which information is given in the Prospectus, any material adverse change in the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company, whether or not arising in the ordinary course of business.

(b) If this Agreement is terminated pursuant to any of its provisions, the Company shall not be under any liability to any Underwriter, and no Underwriter shall be under any liability to the Company, except that (i) if this Agreement is terminated by the Representative or the Underwriters because of any failure, refusal or inability on the part of the Company to comply with the terms or to fulfill any of the conditions of this Agreement, the Company will reimburse the Underwriters for all out-of-pocket expenses (including the reasonably incurred fees and disbursements of their counsel) incurred by them in connection with the proposed purchase and sale of the Securities or in contemplation of performing their obligations hereunder and (ii) no Underwriter who shall have failed or refused to purchase the Securities agreed to be purchased by it under this Agreement, without some reason sufficient hereunder to justify cancellation or termination of its obligations under this Agreement, shall be relieved of liability to the Company or to the other Underwriters for damages occasioned by its failure or refusal.

8. Substitution of Underwriters. If any Underwriter shall default in its obligation to purchase on any Closing Date the Securities agreed to be purchased hereunder on such Closing Date, the Representative shall have the right, within 36 hours thereafter, to make arrangements for one or more of the non-defaulting Underwriters, or any other Underwriters, to purchase such Securities on the terms contained herein. If, however, the Representative shall not have completed such arrangements within such 36-hour period, then the Company shall be entitled to a further period of 36 hours within which to procure another party or other parties satisfactory to the Underwriters to purchase such Securities on such terms. If, after giving effect to any arrangements for the purchase of the Securities of a defaulting Underwriter or Underwriters by the Representative and the Company as provided above, the aggregate number of Securities which remains unpurchased on such Closing Date does not exceed one-eleventh of the aggregate number of all the Securities that all the Underwriters are obligated to purchase on such date, then the Company shall have the right to require each non-defaulting Underwriter to purchase the number of Securities which such Underwriter agreed to purchase hereunder at such date and, in addition, to require each non-defaulting Underwriter to purchase its pro rata share (based on the number of Securities which such Underwriter agreed to purchase hereunder) of the Securities of such defaulting Underwriter or Underwriters for which such arrangements have not been made; but nothing herein shall relieve a defaulting Underwriter from liability for its default. In any such case, either the Representative or the Company shall have the right to postpone the applicable Closing Date for a period of not more than seven days in order to effect any necessary changes and arrangements (including any necessary amendments or supplements to the Registration Statement or Prospectus or any other documents), and the Company agrees to file promptly any amendments to the Registration Statement or the Prospectus which in the opinion of the Company and the Underwriters and their counsel may thereby be made necessary.

If, after giving effect to any arrangements for the purchase of the Securities of a defaulting Underwriter or Underwriters by the Representative and the Company as provided above, the aggregate number of such Securities which remains unpurchased exceeds 10% of the aggregate number of all the Securities to be purchased at such date, then this Agreement, or, with respect to a Closing Date which occurs after the Firm Securities Closing Date, the obligations of the Underwriters to purchase and of the Company to sell the Option Securities to be purchased and sold on such date, shall terminate, without liability on the part of any non-defaulting Underwriter to the Company, and without liability on the part of the Company, except as provided in Sections 4(b), 5, 6 and 7. The provisions of this Section 8 shall not in any way affect the liability of any defaulting Underwriter to the Company or the nondefaulting Underwriters arising out of such default. The term "Underwriter" as used in this Agreement shall include any person substituted under this Section 8 with like effect as if such person had originally been a party to this Agreement with respect to such Securities.

9. Miscellaneous. The respective agreements, representations, warranties, indemnities and other statements of the Company and the several Underwriters, as set forth in this Agreement or made by or on behalf of them pursuant to this Agreement, shall remain in full force and effect, regardless of any investigation (or any statement as to the results thereof) made by or on behalf of any Underwriter or the Company or any of their respective officers, directors or controlling persons referred to in Sections 5 and 6 hereof, and shall survive delivery of and payment for the Securities. In addition, the provisions of Sections 4(b), 5, 6 and 7 shall survive the termination or cancellation of this Agreement.

This Agreement has been and is made for the benefit of the Underwriters, the Company, and their respective successors and assigns, and, to the extent expressed herein, for the benefit of persons controlling any of the Underwriters, or the Company, and directors and officers of the Company, and their respective successors and assigns, and no other person shall acquire or have any right under or by virtue of this Agreement. The term "successors and assigns" shall not include any purchaser of Securities from any Underwriter merely because of such purchase.

All notices and communications hereunder shall be in writing and mailed or delivered or by telephone or facsimile if subsequently confirmed in writing, (a) if to the Representative, c/o Maxim Group LLC, 405 Lexington Avenue, New York, New York 10174 Attention: Legal Department, Facsimile: (212) 895-3555, with a copy to Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., 666 Third Avenue, New York, New York 10017, Attention: Ivan K. Blumenthal, Esq., Facsimile: 212-983-3115, and (b) if to the Company, to its agent for service as such agent's address appears on the cover page of the Registration Statement, with a copy to Davis Polk & Wardwell LLP, 450 Lexington Avenue, New York, New York 10017, Attention: Michael Kaplan and Sophia Hudson.

This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby ("Related Proceedings") may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the "Specified Courts"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court (a "Related Judgment"), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum. The Company has irrevocably appointed Cogency Global Inc., which currently maintains an office at 10 E 40th Street, 10th Floor, New York, New York 10016, United States of America, as its agent to receive service of process or other legal summons for purposes of any such suit, action or proceeding that may be instituted in any state or federal court in the Borough of Manhattan in the City of New York, United States of America.

With respect to any Related Proceeding, each party irrevocably waives, to the fullest extent permitted by applicable law, all immunity (whether on the basis of sovereignty or otherwise) from jurisdiction, service of process, attachment (both before and after judgment) and execution to which it might otherwise be entitled in the Specified Courts, and with respect to any Related Judgment, each party waives any such immunity in the Specified Courts or any other court of competent jurisdiction, and will not raise or claim or cause to be pleaded any such immunity at or in respect of any such Related Proceeding or Related Judgment, including, without limitation, any immunity pursuant to the United States Foreign Sovereign Immunities Act of 1976, as amended.

The obligations of the Company pursuant to this Agreement in respect of any sum due to the Underwriters shall, notwithstanding any judgment in a currency other than United States dollars, not be discharged until the first business day, following receipt by the Underwriters of any sum adjudged to be so due in such other currency, on which the Underwriters may in accordance with normal banking procedures purchase United States dollars with such other currency. If the United States dollars so purchased are less than the sum originally due to the Underwriters in United States dollars hereunder, the Company agrees as a separate obligation and notwithstanding any such judgment, to indemnify the Underwriters against such loss. If the United States dollars so purchased are greater than the sum originally due to the Underwriters hereunder, the Underwriters agree to pay to the Company an amount equal to the excess of the dollars so purchased over the sum originally due to the Underwriters hereunder.

Each Underwriter shall be solely responsible for the payment of all income and similar taxes which apply to it under applicable law, on account of the provision of services provided hereunder, provided, however, that the Company may, only if required under applicable law and subject thereto, withhold, deduct or set-off any amounts as required by applicable law from payments hereunder or in connection with this Agreement. Should any payment required to be made to any Underwriter in accordance with the provisions of this Agreement be subject to withholding of any applicable taxes assessable upon such Underwriter, Company shall inform such Underwriter of such withholding requirement in advance of the first payment to be made by Company to such Underwriter hereunder, so as to allow such Underwriter to obtain and provide Company with an appropriate certificate of exemption or such other valid tax certificate in accordance with the applicable law. No withholding (or reduced withholding) shall be made if a valid exemption or tax certificate provided in accordance with the applicable law is timely obtained, and for as long as such exemption or tax certificate is valid.

[Remainder of Page Intentionally Left Blank. Signature Page Follows.]

This Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

Please confirm that the foregoing correctly sets forth the agreement among us.

Very truly yours,

ENTERA BIO LTD.

By ______________________________

Title:

Confirmed:

MAXIM GROUP LLC

____

Acting severally on behalf of itself
and as representative of the several
Underwriters named in Schedule I annexed
hereto.

[Signature Page to Underwriting Agreement]

SCHEDULE I

Name	Number of Firm Shares to be Purchased	Number of Firm Warrants to be Purchased
Maxim Group LLC		
Total		

SCHEDULE II

Lock-up Signatories

SCHEDULE III

Issuer Free Writing Prospectuses

[None]

SCHEDULE IV

Testing-the-Waters Communications

Exhibit A

FORM OF LOCK-UP AGREEMENT

___, 2018

Maxim Group LLC
as Representative of the Several Underwriters
405 Lexington Avenue, 2nd Floor
New York, New York 10174

Re: Initial Public Offering of Entera Bio Ltd.

Ladies and Gentlemen:

The undersigned, a holder of ordinary shares, NIS 0.01 (“**Ordinary Shares**”), or securities convertible into or rights to acquire Ordinary Shares, of Entera Bio Ltd. (the “**Company**”), understands that Maxim Group LLC (the “**Representative**”), as Representative of the several Underwriters, proposes to enter into an Underwriting Agreement (the “**Underwriting Agreement**”) with the Company, providing for the initial public offering (the “**Offering**”) by the several underwriters named in Schedule I to the Underwriting Agreement (the “**Underwriters**”), of Ordinary Shares (the “**Securities**”) pursuant to a registration statement on Form F-1.

In consideration of the Underwriters' agreement to enter into the Underwriting Agreement and to proceed with the Offering, and for other good and valuable consideration, receipt of which is hereby acknowledged, the undersigned hereby agrees for the benefit of the Company, you and the other Underwriters that, without the prior written consent of the Representative on behalf of the Underwriters, in accordance with the terms of the Underwriting Agreement, the undersigned will not, from the date hereof through the period ending 180 days (the "**Lock-Up Period**") following the date of the Underwriting Agreement, directly or indirectly, unless otherwise provided herein, (1) offer, pledge, assign, encumber, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, any Ordinary Shares or any securities convertible into or exercisable or exchangeable for Ordinary Shares either owned of record or beneficially owned (as defined in the Securities Exchange Act of 1934, as amended (the "**Exchange Act**")) by the undersigned on the date hereof or hereafter acquired (the "**Lock-Up Securities**") or (2) enter into any swap, hedge or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Lock-Up Securities, whether any such transaction described in clauses (1) or (2) above is to be settled by delivery of Ordinary Shares or such other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing. In addition, the undersigned agrees that, without the prior written consent of the Representative, it will not, during the Lock-Up Period, make any demand for or exercise any right with respect to, the registration of any Ordinary Shares or any security convertible into or exercisable or exchangeable for Ordinary Shares. The foregoing shall not apply to (a) the Lock-Up Securities to be transferred as a bona fide gift or gifts (provided that any donee thereof agrees in writing to be bound by the terms hereof), (b) the transfer of the Lock-Up Securities (1) to any immediate family member (provided that any such recipient agrees in writing to be bound by the terms hereof) or to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned, (2) if the undersigned is a corporation, partnership, limited liability company, trust or other business entity (A) to another corporation, partnership, limited liability company, trust or other business entity that is a direct or indirect affiliate (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended (the "**Securities Act**")) of the undersigned or any investment fund or other entity controlled or managed by the undersigned or (B) to limited partners, limited liability company members or stockholders of the undersigned (provided that any such transfer in this clause (2) shall not involve a disposition for value), (3) if the undersigned is a trust, to the beneficiary of such trust, (4) by testate succession or intestate succession, (5) by operation of law or by an order of a court or regulatory agency, such as pursuant to a qualified domestic order or in connection with a divorce settlement, (6) pursuant to any contract, instruction or plan that satisfies all of the requirements of Rule 10b5-1 under the Exchange Act established prior to the date of this agreement (the "**Letter Agreement**"), (7) through the exercise of an option to purchase any Ordinary Shares (including by way of "net" or "cashless" exercise of stock options) or the vesting, conversion, exchange, settlement or delivery of Ordinary Shares in connection with any stock incentive plan of the Company, *provided* that any Ordinary Shares received by the undersigned upon such exercise, vesting, conversion, exchange, settlement or delivery shall be subject to the restrictions on transfer set forth herein, (8) through the exercise of a warrant to purchase Ordinary Shares (including by way of "net" or "cashless" exercise of warrants), *provided* that any Ordinary Shares received by the undersigned upon such exercise shall be subject to the restrictions on transfer set forth herein, (9) through the exercise of an optional conversion right pursuant to the Company's convertible loan agreements or Series A or Series B preferred share purchase agreements to convert outstanding convertible loan amounts or preferred shares into the Company's Ordinary Shares, *provided* that any Ordinary Shares received by the undersigned upon such conversion shall be subject to the restrictions on transfer set forth herein, (10) through transfers or dispositions of Ordinary Shares prior to the first filing of a prospectus for the Public Offering with a "price range" set forth on the cover of such prospectus, (11) through the acquisition of Ordinary Shares by the undersigned in the Offering or in open market transactions subsequent to the closing of the Offering or (12) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (1)-(10) above; *provided*, in the case of clauses (1)-(3) and (10) that the transferee agrees in writing with the Representative to be bound by the terms of this Letter Agreement, (c) transfers of Ordinary Shares, warrants or Company stock options to the Company (including by way of "net" or "cashless" exercise of stock options or warrants), (d) with the prior written consent of the Representative on behalf of the Underwriters, and (e) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Ordinary Shares, *provided* that such plan does not provide for the transfer of Ordinary Shares during the Lock-Up Period, and to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Ordinary Shares may be made under such plan during the Lock-Up Period.

Notwithstanding the foregoing, and subject to the conditions in this paragraph, the undersigned may also transfer the Lock-Up Securities during the Lock-Up Period without the prior written consent of the Representative if any such transfers are made by the undersigned: (i) to satisfy tax withholding obligations of the undersigned in connection with the vesting or exercise of equity awards outstanding as of the date of the preliminary prospectus by the undersigned pursuant to the Company's equity compensation plans and arrangements; or (ii) pursuant to the conversion or sale of, or an offer to purchase, outstanding Ordinary Shares involving a change of control for the Company, whether pursuant to a merger, tender offer or otherwise; provided, however, that in the case of any transfer described in clause (i) of this paragraph, it shall be a condition to the transfer that if the undersigned is required to file a report under Section 16(a), the undersigned shall include a statement in such report to the effect that such transfer is being made for tax withholding obligations; and provided further that in the case of any conversion or sale described in clause (ii) of this paragraph, in the event that such transaction is abandoned, the Lock-Up Securities shall remain subject to the restrictions hereunder. Furthermore, the undersigned may sell Ordinary Shares of the Company purchased by the undersigned on the open market following the Offering during the Lock-Up Period if and only if (i) such sales are not required to be reported in any public report or filing with the Securities and Exchange Commission, or otherwise and (ii) the undersigned does not otherwise voluntarily effect any public filing or report regarding such sales.

In furtherance of the foregoing, the Company, and any duly appointed transfer agent for the registration or transfer of the Lock-Up Securities described herein, are hereby authorized to decline to make any transfer of securities if such transfer would constitute a violation or breach of this Letter Agreement.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Letter Agreement. All authority herein conferred or agreed to be conferred and any obligations of the undersigned shall be binding upon the successors, assigns, heirs or personal representatives of the undersigned.

The undersigned understands that, if the Underwriting Agreement does not become effective by September 3, 2018, or if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Securities to be sold thereunder, the undersigned shall be released from all obligations under this Letter Agreement.

The undersigned, whether or not participating in the Offering, understands that the Underwriters are entering into the Underwriting Agreement and proceeding with the Offering in reliance upon this Letter Agreement.

[Signature page follows.]

This Letter Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflict of laws principles thereof (other than New York General Obligations Law § 5-1401).

Very truly yours,

By: ______________________________

Name:

Title:

Exhibit A-1

[Form of Waiver of Lock-up]

[Maxim Letterhead]

[corporation]
Public Offering of Ordinary Shares and Warrants

[ ], 20[ ]

[Name and Address of
Officer or Director
Requesting Waiver]

Dear Mr./Ms. [Name]:

This letter is being delivered to you in connection with the offering by [Corporation] (the "Company") of [ ] ordinary shares of the Company, NIS [ ] par value per share (the "Ordinary Shares") and warrants to purchase up to an aggregate of [ ] Ordinary Shares, and the lock-up agreement dated [ ], 20[ ] (the "Lock-up Agreement"), executed by you in connection with such offering, and your request for a [waiver] [release] dated [ ], 20[ ], with respect to [ ] Ordinary Shares (the "Shares").

Maxim Group LLC hereby agrees to [waive] [release] the transfer restrictions set forth in the Lock-up Letter, but only with respect to the Shares, effective [ ], 20[ ][date to be 3 business days from date of letter]; provided, however, that such [waiver] [release] is conditioned on the Company announcing the impending [waiver] [release] by press release through a major news service at least two business days before effectiveness of such [waiver] [release]. This letter will serve as notice to the Company of the impending [waiver] [release].

Except as expressly [waived] [released] hereby, the Lock-up Agreement shall remain in full force and effect.

Yours very truly,

MAXIM GROUP LLC

By: ______________________________

Name:

Title:

cc: [Company contact]

Exhibit A-2

[Form of Lock Up Waiver/Release Company Press Release]

[Company]
[Date]

("[Company]") announced today that Maxim Group LLC, the [lead book-running] manager in the Company's recent public sale of [ ] ordinary shares and warrants, is [waiving] [releasing] a lock-up restriction with respect to [ ] ordinary shares of the Company held by [ ], an [officer/director] of the Company. The [waiver] [release] will take effect on [ ], 20[ ], and the related shares may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

HERZOG FOX & NEEMAN
LAW OFFICE

June 15, 2018
File No: 49050

EXHIBIT 5.1

Entera Bio Ltd.
Hadassah Medical Center
Kiryat Hadassah
Jerusalem 9112002
Israel

Re: Registration Statement on Form F-1

Ladies and Gentlemen:

We have acted as Israeli counsel to Entera Bio Ltd. (the "**Company**"), a company organized under the laws of the State of Israel, in connection with an underwritten public offering (the "**Offering**") contemplating the issuance and sale by the Company of up to 1,333,334 units (the "**Units**"), each consists of one ordinary share, par value NIS 0.0000769 per share of the Company (the "**Ordinary Shares**"), and one warrant to purchase Ordinary Shares of the Company (the "**Warrants**"), including Units issuable upon exercise of an option granted to the Underwriters (as defined below) to purchase additional Units for overallotment purposes.

In connection herewith, we have examined originals or copies of (i) the registration statement on Form F-1, (File No. 333-221472), publicly filed by the Company with the U.S. Securities and Exchange Commission (the "**SEC**") on May 17, 2018 (as amended through the date hereof, the "**Registration Statement**") including the prospectus of the Company (the "**Prospectus**"), with respect to the offering of the Units included therein, (ii) a copy of the Articles of Association of the Company, as currently in effect, (iii) a draft of the amended and restated Articles of Association of the Company to become effective concurrently with the Offering, (iv) resolutions of the board of directors of the Company (the "**Board**"), the shareholders of the Company, and draft resolutions of the pricing committee appointed by the Board (the "**Pricing Committee**"), in each case, relating to the Registration Statement, the Prospectus and the actions to be taken in connection with the Offering, (v) the draft Underwriting Agreement to be entered into in connection with the Offering (the "**Underwriting Agreement**"), between the Company and Maxim Group LLC, as representatives of the several underwriters named therein (collectively, the "**Underwriters**"), (vi) a printout of the Israeli Companies Registrar report with respect to the Company, dated June 15, 2018, and (vii) such other documents, corporate records, agreements, certificates and other instruments, and have made inquiries with such officers and representatives of the Company, as we have deemed necessary or advisable for the purpose of rendering this opinion.

Asia House, 4 Weizmann St., Tel-Aviv 6423904, Israel, Tel: (972)-3-692-2020, Fax: (972)-3-696-6464, e-mail: hfn@hfn.co.il www.hfn.co.il

In our examination, we have assumed the genuineness of all signatures, the legal capacity of all natural persons executing documents upon which we have relied, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as certified, photostatic or facsimile copies and the authenticity of the originals of such copies. As to all questions of fact required for rendering this opinion that have not been independently established, we have relied upon certificates or comparable documents of officers and representatives of the Company.

Based upon and subject to the foregoing, we are of the opinion that (i) upon payment to the Company for the Units of the consideration per Unit in such amount and form as shall be determined by the Board, and subject to the approval of the Board or the Pricing Committee, the Units, the Ordinary Shares and the Warrants included therein, when issued and sold in the Offering as described in the Registration Statement, will be duly authorized, validly issued, fully paid and non-assessable, and (ii) the Ordinary Shares underlying the Warrants, when issued and sold by the Company and delivered by the Company against receipt of the exercise price therefor, in accordance with and in the manner described in the Registration Statement and pursuant to the terms of the Warrants, will be duly authorized and validly issued, fully paid and non-assessable.

We consent to the filing of this opinion as an exhibit to the Registration Statement and to the references to our name under the caption “Legal Matters” in the Prospectus. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the U.S. Securities Act of 1933 (the “**Securities Act**”), the rules and regulations promulgated thereunder or Item 509 of Regulation S-K under the Securities Act.

The opinion expressed herein is limited to Israeli law, and we do not express any opinion as to the laws of any other jurisdiction. In addition, this opinion is limited to the matters stated herein and no opinion is implied or may be inferred beyond the matters expressly stated.

This opinion letter is rendered as of the date hereof and we disclaim any obligation to advise you of facts, circumstances, events or developments that may be brought to our attention after the date hereof that may alter, affect or modify the opinions expressed herein.

Very truly yours,

Herzog Fox & Neeman

Herzog, Fox & Neeman

New York	**Paris**
Northern California	**Madrid**
Washington DC	**Tokyo**
São Paulo	**Beijing**
London	**Hong Kong**

Davis Polk & Wardwell LLP 212 450 4000 tel
450 Lexington Avenue 212 701 5800 fax
New York, NY 10017

June 15, 2018

Entera Bio Ltd.
Kiryat Hadassah, Minrav Building – Fifth Floor
Jerusalem, Israel

Ladies and Gentlemen:

We are acting as United States counsel to Entera Bio Ltd. (the "**Company**") in connection with the preparation of the Registration Statement on Form F-1 (the "**Registration Statement**") and the related Prospectus (the "**Prospectus**") filed with the United States Securities and Exchange Commission (File No. 333-221472) by the Company for the purpose of registering under the United States Securities Act of 1933 (the "**Act**") the Company's ordinary shares and warrants.

We, as your counsel, have examined originals or copies of such documents, corporate records, certificates of public officials and other instruments as we have deemed necessary or advisable for the purpose of rendering this opinion.

We hereby confirm that our opinion as to the material U.S. federal income tax consequences to U.S. Holders of an investment in ordinary shares and warrants is set forth in full under the caption "Taxation and Government Programs – Material U.S. Federal Income Tax Considerations for U.S. Holders" in the Prospectus.

We are members of the Bar of the State of New York and the foregoing opinion is limited to the laws of the State of New York and the federal laws of the United States.

We hereby consent to the use of our name under the captions "Taxation and Government Programs" and "Legal Matters" in the Prospectus included in the Registration Statement and to the filing, as an exhibit to the Registration, of this letter. In giving this consent we do not admit that we come within the category of persons whose consent is required under Section 7 of the Act.

Very truly yours,

/s/ Davis Polk & Wardwell LLP

Exhibit 10.16

ENTERA BIO LTD.
2018 EQUITY INCENTIVE PLAN

Section 1. *Purpose*. The purpose of the Entera Bio Ltd. 2018 Equity Incentive Plan (the "**Plan**") is to motivate and reward those employees, directors, consultants and advisors of Entera Bio Ltd. (the "**Company**") and its Affiliates to perform at the highest level and to further the best interests of the Company and its shareholders. Capitalized terms not otherwise defined herein are defined in Section 21.

Section 2. *Eligibility.*

(a) Any employee, Non-Employee Director, consultant or other advisor of the Company or any subsidiary shall be eligible to be selected to receive an Award under the Plan.

(b) Holders of equity compensation awards granted by a company acquired by the Company (or whose business is acquired by the Company) or with which the Company combines are eligible for grants of Replacement Awards under the Plan.

Section 3. *Administration.*

(a) The Plan shall be administered by the Board, provided that the Board may delegate authority to administer the Plan, as allowed under Applicable Law and the Articles of Association of the Company, to the Committee (the Board and the Committee shall be referred to herein as the "**Administrator**" as applicable) . The Committee shall be appointed by the Board and shall consist of not less than two directors of the Board. The Board may designate one or more directors as a subcommittee who may act for the Committee if necessary to satisfy the requirements of this Section. The Board may issue rules and regulations for administration of the Plan.

(b) Subject to the terms of the Plan and Applicable Law, the Administrator shall have full power and authority to: (i) designate Participants; (ii) determine the type or types of Awards (including Replacement Awards) to be granted to each Participant under the Plan; (iii) determine the number of Shares to be covered by (or with respect to which payments, rights or other matters are to be calculated in connection with) Awards; (iv) determine the terms and conditions of any Award; (v) determine whether, to what extent and under what circumstances Awards may be settled or exercised in cash, Shares, other Awards, other property, net settlement (including broker-assisted cashless exercise) or any combination thereof, or canceled, forfeited or suspended, and the method or methods by which Awards may be settled, exercised, canceled, forfeited or suspended (including as the result of any change to the scope of engagement of a Participant on previously granted Awards) ; (vi) determine whether, to what extent and under what circumstances cash, Shares, other Awards, other property and other amounts payable with respect to an Award under the Plan shall be deferred either automatically or at the election of the holder thereof or of the Administrator; (vii) interpret and administer the Plan and any instrument or agreement relating to, or Award made under, the Plan; (viii) establish, amend, suspend or waive such rules and regulations and appoint such agents as it shall deem appropriate for the proper administration of the Plan; (ix) authorize conversion or substitution under the Plan of any or all Awards or Shares and to cancel or suspend Awards, as necessary, provided that, if such action is not specifically allowed under the terms of this Plan, any material harm to the interests of the Participants shall be subject to consent from the Participants;; (ix) authorize any person to execute on behalf of the Company any instrument required to effectuate the grant of an Award previously granted by the Board; and (x) make any other determination and take any other action that the Administrator deems necessary or desirable for the administration of the Plan.

(c) All decisions of the Administrator shall be final, conclusive and binding upon all parties, including the Company, its shareholders and Participants and any Beneficiaries thereof.

Section 4. *Shares Available for Awards.*

(a) Subject to adjustment as provided in Section 4(c), the maximum number of Shares available for issuance under the Plan shall not exceed 12% of the Company's issued and outstanding share capital; *provided* that, starting on January 1, 2019, on January 1 of each year, the total number of Shares available for issuance under the Plan will be increased by an amount equal to the lesser of (i) 5% of the Company's outstanding Shares on December 31 of the immediately preceding year or (ii) such number of Shares as determined by the Board in its discretion. Shares underlying Replacement Awards and Shares remaining available for grant under a plan of an acquired company or of a company with which the Company combines, appropriately adjusted to reflect the acquisition or combination transaction, shall not reduce the number of Shares remaining available for grant hereunder.

(b) Any Shares subject to an Award or to an equity-based award granted under a prior plan of the Company (other than a Replacement Award and any Award granted out of the authorized shares of an acquired plan), that expires, is canceled, forfeited or otherwise terminates without the delivery of such Shares, including any Shares subject to such Award or award to the extent that such Award or award is settled without the issuance of Shares, shall again be, or shall become, available for issuance under the Plan. Any Shares surrendered or withheld in payment of any grant, acquisition or exercise price of such Award or award or taxes related to such Award or award shall not become available for issuance under the Plan.

(c) In the event that, as a result of any dividend or other distribution (whether in the form of cash, Shares or other securities), recapitalization, share split, reverse share split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange of Shares or other securities of the Company, issuance of warrants or other rights to acquire Shares or other securities of the Company, issuance of Shares pursuant to the anti-dilution provisions of securities of the Company, or other similar corporate transaction or event affecting the Shares, or of changes in Applicable Law, regulations or accounting principles, an adjustment is necessary in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan, then the Administrator shall, subject to Section 18, adjust equitably any or all of:

(i) the number and type of Shares (or other securities) which thereafter may be made the subject of Awards, including the aggregate and individual limits specified in Section 4(a);

(ii) the number and type of Shares (or other securities) subject to outstanding Awards; and

(iii) the grant, acquisition, exercise price with respect to any Award or, if deemed appropriate, make provision for a cash payment to the holder of an outstanding Award;

provided, *however*, that the number of Shares subject to any Award denominated in Shares shall always be a whole number (and to the extent required by law or tax regulations, fractional Shares shall be rounded down).

(d) Any Shares delivered pursuant to an Award may consist, in whole or in part, of authorized and unissued Shares or Shares acquired by the Company.

Section 5. *Options.* The Administrator is authorized to grant Options to Participants with the following terms and conditions and with such additional terms and conditions, in either case not inconsistent with the provisions of the Plan, as the Administrator shall determine.

(a) The exercise price per Share under an Option shall be determined by the Administrator; *provided*, *however*, that, except in the case of Replacement Awards, such exercise price shall not be less than the Fair Market Value of a Share on the date of grant of such Option.

(b) The term of each Option shall be fixed by the Administrator but shall not exceed 10 years from the date of grant of such Option.

(c) The Administrator shall determine the time or times at which an Option may be exercised in whole or in part.

(d) The Administrator shall determine the methods by which, and the forms in which payment of the exercise price with respect thereto may be made or deemed to have been made, including cash, Shares, other Awards, other property, net settlement (including broker-assisted cashless exercise) or any combination thereof, having a Fair Market Value on the exercise date equal to the relevant exercise price.

Section 6. *Share Appreciation Rights.* The Administrator is authorized to grant SARs to Participants with the following terms and conditions and with such additional terms and conditions, in either case not inconsistent with the provisions of the Plan, as the Administrator shall determine.

(a) SARs may be granted under the Plan to Participants either alone (“freestanding”) or in addition to other Awards granted under the Plan (“tandem”).

(b) The exercise price per Share under a SAR shall be determined by the Administrator; *provided, however*, that, except in the case of Replacement Awards, such exercise price shall not be less than the Fair Market Value of a Share on the date of grant of such SAR (or if granted in connection with an Option, on the grant date of such Option).

(c) The term of each SAR shall be fixed by the Administrator but shall not exceed 10 years from the date of grant of such SAR.

(d) The Administrator shall determine the time or times at which a SAR may be exercised or settled in whole or in part.

(e) Upon the exercise of a SAR, the Company shall pay to the Participant an amount equal to the number of Shares subject to the SAR multiplied by the excess, if any, of the Fair Market Value of one Share on the exercise date over the exercise price of such SAR. The Company shall pay such excess in cash, in Shares valued at Fair Market Value, or any combination thereof, as determined by the Administrator.

Section 7. *Restricted Shares and RSUs.* The Administrator is authorized to grant Awards of Restricted Shares and RSUs to Participants with the following terms and conditions and with such additional terms and conditions, in either case not inconsistent with the provisions of the Plan, as the Administrator shall determine.

(a) The applicable Award Document shall specify the vesting schedule and, with respect to RSUs, the delivery schedule (which may include deferred delivery later than the vesting date) and whether the Award of Restricted Shares or RSUs is entitled to dividends or dividend equivalents, voting rights or any other rights.

(b) Restricted Shares and RSUs shall be subject to such restrictions as the Administrator may impose (including any limitation on the right to vote a Restricted Share or the right to receive any dividend, dividend equivalent or other right), which restrictions may lapse separately or in combination at such time or times, in such installments or otherwise, as the Administrator may deem appropriate. Without limiting the generality of the foregoing, if the Award relates to Shares on which dividends are declared during the period that the Award is outstanding, the Award shall not provide for the payment of such dividend (or a dividend equivalent) to the Participant prior to the time at which such Award, or applicable portion thereof, becomes nonforfeitable, unless otherwise provided in the applicable Award Document.

(c) Restricted Shares granted under the Plan may be evidenced in such manner as the Administrator may deem appropriate, including book-entry registration or issuance of a share certificate or certificates. In the event that any share certificate is issued in respect Restricted Shares granted under the Plan, such certificate shall be registered in the name of the Participant and shall bear an appropriate legend referring to the terms, conditions and restrictions applicable to such Restricted Share.

(d) The Administrator may determine the form or forms (including cash, Shares, other Awards, other property or any combination thereof) in which payment of the amount owing upon settlement of any RSU Award may be made.

Section 8. *Performance Awards.* The Administrator is authorized to grant Performance Awards to Participants with the following terms and conditions and with such additional terms and conditions, in either case not inconsistent with the provisions of the Plan, as the Administrator shall determine.

(a) Performance Awards may be denominated as a cash amount, a number of Shares or a combination thereof and are Awards which may be earned upon achievement or satisfaction of performance conditions specified by the Administrator. In addition, the Administrator may specify that any other Award shall constitute a Performance Award by conditioning the right of a Participant to exercise the Award or have it settled, and the timing thereof, upon achievement or satisfaction of such performance conditions as may be specified by the Administrator. The Administrator may use such business criteria and other measures of performance as it may deem appropriate in establishing any performance conditions. Subject to the terms of the Plan, the performance goals to be achieved during any Performance Period, the length of any Performance Period, the amount of any Performance Award granted and the amount of any payment or transfer to be made pursuant to any Performance Award shall be determined by the Administrator. If the Performance Award relates to Shares on which dividends are declared during the Performance Period, the Performance Award shall not provide for the payment of such dividend (or dividend equivalent) to the Participant prior to the time at which such Performance Award, or the applicable portion thereof, is earned.

(b) Performance criteria may be measured on an absolute (*e.g.*, plan or budget) or relative basis, and may be established on a corporate-wide basis or with respect to one or more business units, divisions, subsidiaries or business segments. Relative performance may be measured against a group of peer companies, a financial market index or other acceptable objective and quantifiable indices. If the Administrator determines that a change in the business, operations, corporate structure or capital structure of the Company, or the manner in which the Company conducts its business, or other events or circumstances render the performance objectives unsuitable, the Administrator may modify the minimum acceptable level of achievement, in whole or in part, as the Administrator deems appropriate and equitable. Performance objectives shall be adjusted for material items not originally contemplated in establishing the performance target for items resulting from discontinued operations, extraordinary gains and losses, the effect of changes in accounting standards or principles, acquisitions or divestitures, changes in tax rules or regulations, capital transactions, restructuring, nonrecurring gains or losses or unusual items. Performance measures may vary from Performance Award to Performance Award, and from Participant to Participant, and may be established on a stand-alone basis, in tandem or in the alternative. The Administrator shall have the power to impose such other restrictions on Awards subject to this Section 8(b) as it may deem necessary or appropriate to ensure that such Awards satisfy all requirements of any Applicable Law, stock market or exchange rules and regulations or accounting or tax rules and regulations.

(c) *Settlement of Performance Awards; Other Terms.* Settlement of Performance Awards shall be in cash, Shares, other Awards, other property, net settlement or any combination thereof, as determined in the discretion of the Administrator. Performance Awards will be settled only after the end of the relevant Performance Period. The Administrator may, in its discretion, increase or reduce the amount of a settlement otherwise to be made in connection with a Performance Award.

Section 9. *Other Share-Based Awards.* The Administrator is authorized, subject to limitations under Applicable Law, to grant to Participants such other Awards that may be denominated or payable in, valued in whole or in part by reference to, or otherwise based on, or related to, Shares or factors that may influence the value of Shares, including convertible or exchangeable debt securities, other rights convertible or exchangeable into Shares, acquisition rights for Shares, Awards with value and payment contingent upon performance of the Company or business units thereof or any other factors designated by the Administrator. The Administrator shall determine the terms and conditions of such Awards.

Section 10. *Minimum Vesting.* Notwithstanding any provisions of this Plan to the contrary and except as provided in this Section 10 or pursuant to Section 11, Awards (other than Replacement Awards) shall not vest in full prior to the one-year anniversary of the applicable grant date; *provided, however*, that no more than five percent (5%) of the Shares available for issuance under the Plan may be granted subject to Awards with such other vesting requirements, if any, as the Administrator may establish in its sole discretion (which number of Shares shall not include any Shares subject to Awards granted pursuant to Section 8).

Section 11. *Effect of Termination of Service, Change in Control or Structural Change on Awards.*

(a) The Administrator may provide, by rule or regulation or in any Award Document, or may determine in any individual case, the circumstances in which, and the extent to which, an Award may be exercised, settled, vested, paid or forfeited in the event of a Participant's Termination of Service prior to the vesting, exercise or settlement of such Award or the end of a Performance Period.

(b) In the event of a Change in Control, to the extent not inconsistent with the provisions of Section 11(a) above or the applicable Award Document, the Committee, in its sole discretion, and on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such Change in Control, may take any one or more of the following actions whenever the Committee determines that such action is appropriate or desirable in order to prevent the dilution or enlargement of the benefits intended to be made available under the Plan or to facilitate the Change in Control transaction:

(i) Awards may be continued in effect or converted into an award or right with respect to shares of the successor or surviving corporation (or a parent or subsidiary thereof) (in the case of Options and SARs awarded to a Participant to whom Section 18 applies, in a manner that complies with Sections 424 and 409A of the Code) in accordance with the terms of such Change of Control;

(ii) Awards may immediately vest and settle and, in the case of Options and SARs, become fully exercisable;

(iii) Unvested Awards may be cancelled for no consideration;

(iv) Awards may be terminated or cancelled in exchange for a cash payment (and, for the avoidance of doubt, if as of the date of the Change in Control, the Board determines that no amount would have been realized upon the exercise of the Award or other realization of the Participant's rights, then the Award may be cancelled by the Company without payment of consideration); and

(v) Awards may be assumed, exchanged, replaced or continued by the successor or surviving corporation (or a parent or subsidiary thereof) with cash, securities, rights or other property to be paid or issued, as the case may be, by the successor or surviving corporation (or a parent or subsidiary thereof).

For purposes of subsections (i) and (ii) above, no Option, SAR, Restricted Share or RSU shall be treated as "continued or converted" on a basis consistent with the requirements of subsection (i) or (ii), as applicable, unless the shares underlying such award after such continuation or conversion consists of securities of a class that is widely held and publicly traded on a U.S. national securities exchange.

Under any of subsections (i) through (iv) above, appropriate adjustments will be made with respect to the number and type of securities (or other consideration) of the successor or surviving corporation (or a parent or subsidiary thereof), subject to any replacement awards, the terms and conditions of the replacement awards (including, without limitation, any applicable performance targets or criteria with respect thereto) and the grant, exercise or purchase price per share for the replacement awards.

(c) *Adjustment Due to a Structural Change*. In the event of a Structural Change, Awards shall be exchanged or converted into awards to acquire shares of the Company (if it is the surviving corporation) or the successor company in accordance with the applicable exchange ratio, and the Exercise Price and quantity of shares underlying the Awards shall be adjusted in accordance with the terms of the Structural Change. The adjustments required shall be determined in good faith solely by the Board in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available in respect of the Awards, and shall be subject to the receipt of any approval required, including any tax ruling, if necessary.

Section 12. *General Provisions Applicable to Awards.*

(a) Awards shall be granted for no cash consideration or for such minimal cash consideration as may be required by Applicable Law.

(b) Awards may, in the discretion of the Administrator, be granted either alone or in addition to or in tandem with any other Award or any award granted under any other plan of the Company. Awards granted in addition to or in tandem with other Awards, or in addition to or in tandem with awards granted under any other plan of the Company, may be granted either at the same time as or at a different time from the grant of such other Awards or awards.

(c) Subject to the terms of the Plan and Section 18, payments or transfers to be made by the Company upon the grant, exercise or settlement of an Award may be made in the form of cash, Shares, other Awards, other property, net settlement or any combination thereof, as determined by the Administrator in its discretion, and may be made in a single payment or transfer, in installments or on a deferred basis, in each case in accordance with rules and procedures established by the Administrator. Such rules and procedures may include provisions for the payment or crediting of reasonable interest on installment or deferred payments or the grant or crediting of dividend equivalents in respect of installment or deferred payments.

(d) Except as may be permitted by the Board or as specifically provided in an Award Document, (i) no Award and no right under any Award shall be assignable, alienable, saleable or transferable by a Participant otherwise than by will or pursuant to Section 12(e) and (ii) during a Participant's lifetime, each Award, and each right under any Award, shall be exercisable only by the Participant or, if permissible under Applicable Law, by the Participant's guardian or legal representative. The provisions of this Section 12(d) shall not apply to any Award that has been fully exercised or settled, as the case may be, and shall not preclude forfeiture of an Award in accordance with the terms thereof.

(e) A Participant may designate a Beneficiary or change a previous Beneficiary designation at such times prescribed by the Board by using forms and following procedures approved or accepted by the Board for that purpose.

(f) All certificates for Shares and/or other securities delivered under the Plan pursuant to any Award or the exercise thereof shall be subject to such stop transfer orders and other restrictions as the Administrator may deem advisable under the Plan or the rules, regulations and other requirements of the Securities and Exchange Commission, any stock market or exchange upon which such Shares or other securities are then quoted, traded or listed, and any applicable securities laws, and the Administrator may cause a legend or legends to be put on any such certificates to make appropriate reference to such restrictions.

(g) Without limiting the generality of Section 12(h), the Administrator may impose restrictions on any Award with respect to noncompetition, confidentiality and other restrictive covenants, or requirements to comply with minimum share ownership requirements, as it deems necessary or appropriate in its sole discretion.

(h) The Administrator may specify in an Award Document that the Participant's rights, payments and benefits with respect to an Award shall be subject to reduction, cancellation, forfeiture or recoupment upon the occurrence of certain specified events, in addition to any otherwise applicable vesting or performance conditions of an Award. Such events may include a Termination of Service with or without Cause (and, in the case of any Cause that is resulting from an indictment or other non-final determination, the Administrator may provide for such Award to be held in escrow or abeyance until a final resolution of the matters related to such event occurs, at which time the Award shall either be reduced, cancelled or forfeited (as provided in such Award Document) or remain in effect, depending on the outcome), violation of material policies, breach of noncompetition, confidentiality or other restrictive covenants that may apply to the Participant, or other conduct by the Participant that is detrimental to the business or reputation of the Company and/or its Affiliates.

(i) Rights, payments and benefits under any Award shall be subject to repayment to or recoupment ("clawback") by the Company in accordance with such policies and procedures as the Committee or Board may adopt from time to time, including policies and procedures to implement Applicable Law, stock market or exchange rules and regulations or accounting or tax rules and regulations.

Section 13. *Amendments and Termination.*

(a) Except to the extent prohibited by Applicable Law and unless otherwise expressly provided in an Award Document or in the Plan, the Board may amend, alter, suspend, discontinue or terminate the Plan or any portion thereof at any time; *provided, however*, that no such amendment, alteration, suspension, discontinuation or termination shall be made without (i) shareholder approval, if such approval is required by Applicable Law or the rules of the stock market or exchange, if any, on which the Shares are principally quoted or traded or (ii) the consent of the affected Participant, if such action would materially adversely affect the rights of such Participant under any outstanding Award, except to the extent any such amendment, alteration, suspension, discontinuance or termination is made to cause the Plan to comply with Applicable Law, stock market or exchange rules and regulations or accounting or tax rules and regulations, or to impose any recoupment provisions on any Awards in accordance with Section 12(i). Notwithstanding anything to the contrary in the Plan, the Board may amend the Plan in such manner as may be necessary to enable the Plan to achieve its stated purposes in any jurisdiction in a tax-efficient manner and in compliance with local laws, rules and regulations.

(b) The Board may waive any conditions or rights under, amend any terms of, or amend, alter, suspend, discontinue or terminate any Award theretofore granted, prospectively or retroactively, without the consent of any relevant Participant or holder or Beneficiary of an Award; *provided, however*, that, subject to Section 4(c) and Section 11(b), no such action shall materially adversely affect the rights of any affected Participant or holder or Beneficiary under any Award theretofore granted under the Plan, except to the extent any such action is made to cause the Plan to comply with Applicable Law, stock market or exchange rules and regulations or accounting or tax rules and regulations, or to impose any recoupment provisions on any Awards in accordance with Section 12(i); *provided further* that, except as provided in Section 4(c), the Board shall not without the approval of the Company's shareholders (a) lower the exercise price per Share of an Option or SAR after it is granted or take any other action that would be treated as a repricing of such Award under the rules of the principal stock market or exchange on which the Company's Shares are quoted or traded, or (b) cancel an Option or SAR when the exercise price per Share exceeds the Fair Market Value in exchange for cash or another Award (other than in connection with a Change in Control).

(c) Except as provided in Section 8(b), the Administrator shall be authorized to make adjustments in the terms and conditions of, and the criteria included in, Awards in recognition of events (including the events described in Section 4(c)) affecting the Company, or the financial statements of the Company, or of changes in Applicable Law, stock market or exchange rules and regulations or accounting or tax rules and regulations, whenever the Administrator determines that such adjustments are appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan.

(d) The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem desirable to carry the Plan into effect.

Section 14. *Prohibition on Option and SAR Repricing.* Except as provided in Section 4(c), the Board may not, without prior approval of the Company's shareholders, seek to effect any re-pricing of any previously granted "underwater" Option or SAR by: (i) amending or modifying the terms of the Option or SAR to lower the exercise price; (ii) cancelling the underwater Option or SAR and granting either (A) replacement Options or SARs having a lower exercise price or (B) Restricted Share, RSU, Performance Award or Other Share-Based Award in exchange; or (iii) cancelling or repurchasing the underwater Options or SARs for cash or other securities. An Option or SAR will be deemed to be "underwater" at any time when the Fair Market Value of the Shares covered by such Award is less than the exercise price of the Award.

Section 15. *Miscellaneous.*

(a) No employee, Participant or other person shall have any claim to be granted any Award under the Plan, and there is no obligation for uniformity of treatment of employees, Participants or holders or Beneficiaries of Awards under the Plan. The terms and conditions of Awards need not be the same with respect to each recipient. Any Award granted under the Plan shall be a one-time Award that does not constitute a promise of future grants. The Company, in its sole discretion, maintains the right to make available future grants under the Plan.

(b) The grant of an Award shall not be construed as giving a Participant the right to be retained in the employ of, or to continue to provide services to, the Company or any Affiliate. Further, the Company or the applicable Affiliate may at any time dismiss a Participant, free from any liability, or any claim under the Plan, unless otherwise expressly provided in the Plan or in any Award Document or in any other agreement binding the parties. The receipt of any Award under the Plan is not intended to confer any rights on the receiving Participant except as set forth in the applicable Award Document.

(c) Nothing contained in the Plan shall prevent the Company from adopting or continuing in effect other or additional compensation arrangements, and such arrangements may be either generally applicable or applicable only in specific cases.

(d) Any taxes recognized by a Participant in respect of his or her Awards and/or Shares, including, but not limited to, in respect of the grant of an Award, and/or the vesting, exercise or settlement of the Award, and/or the sale of Shares underlying an Award, shall be borne solely by such Participant and his or her heirs or transferees. Except as provided in Section 15(e) below, neither the Company nor any of its Affiliates shall be required to bear the aforementioned taxes, directly or indirectly, nor shall they be required to gross up such tax in the Participants' salaries or remuneration.

(e) The Company shall be authorized to withhold from any Award granted or any payment due or transfer made under any Award or under the Plan or from any compensation or other amount owing to a Participant the amount (in cash, Shares, other Awards, other property, net settlement or any combination thereof) of applicable withholding taxes due in respect of an Award, its exercise or settlement or any payment or transfer under such Award or under the Plan and to take such other action (including providing for elective payment of such amounts in cash or Shares by the Participant) as may be necessary in the opinion of the Company to satisfy all obligations for the payment of such taxes. Without limiting the foregoing, the Administrator, in its sole discretion and pursuant to such procedures as it may specify from time to time, may permit a Participant to satisfy such tax withholding obligation, in whole or in part by (without limitation) (i) paying cash, (ii) electing to have the Company withhold otherwise deliverable cash or Shares having a fair market value not in excess of the maximum statutory amount required to be withheld, or (iii) delivering to the Company already-owned Shares having a fair market value not in excess of the maximum statutory amount required to be withheld. The fair market value of the Shares to be withheld or delivered will be determined as of the date that the taxes are required to be withheld.

(f) For avoidance of doubt, it is clarified that the tax treatment of any Award granted under this Plan is not guaranteed and although Awards may be granted under a certain tax route, they may become subject to a different tax route in the future.

(g) If any provision of the Plan or any Award Document is or becomes or is deemed to be invalid, illegal or unenforceable in any jurisdiction, or as to any person or Award, or would disqualify the Plan or any Award under any law deemed applicable by the Administrator, such provision shall be construed or deemed amended to conform to Applicable Laws, or if it cannot be so construed or deemed amended without, in the determination of the Administrator, materially altering the intent of the Plan or the Award Document, such provision shall be stricken as to such jurisdiction, person or Award, and the remainder of the Plan and any such Award Document shall remain in full force and effect.

(h) Neither the Plan nor any Award shall create or be construed to create a trust or separate fund of any kind or a fiduciary relationship between the Company and a Participant or any other person. To the extent that any person acquires a right to receive payments from the Company pursuant to an Award, such right shall be no greater than the right of any unsecured general creditor of the Company.

(i) No fractional Shares shall be issued or delivered pursuant to the Plan or any Award, and the Board shall determine whether cash or other securities shall be paid or transferred in lieu of any fractional Shares, or whether such fractional Shares or any rights thereto shall be canceled, terminated or otherwise eliminated.

(j) Awards may be granted to Participants who are non-Israeli nationals or employed or providing services outside Israel, or both, on such terms and conditions different from those applicable to Awards to Participants who are employed or providing services in Israel as may, in the judgment of the Board, be necessary or desirable to recognize differences in local law, tax policy or custom. The Board also may impose conditions on the exercise or vesting of Awards in order to minimize the Company's obligation with respect to tax equalization for Participants on assignments outside their home country.

Section 16. *Effective Date of the Plan.* The Plan is effective as of (the "**Effective Date**").

Section 17. *Term of the Plan.* No Award shall be granted under the Plan after the earliest to occur of (i) the ten-year anniversary of the Effective Date; *provided* that to the extent permitted by the listing rules of any stock exchanges on which the Company is listed, such ten-year term may be extended indefinitely so long as the maximum number of Shares available for issuance under the Plan have not been issued, (ii) the maximum number of Shares available for issuance under the Plan have been issued or (iii) the Board terminates the Plan in accordance with Section 13(a). However, unless otherwise expressly provided in the Plan or in an applicable Award Document, any Award theretofore granted may extend beyond such date, and the authority of the Board to amend, alter, adjust, suspend, discontinue or terminate any such Award, or to waive any conditions or rights under any such Award, and the authority of the Board to amend the Plan, shall extend beyond such date.

Section 18. *Section 409A of the Code*. With respect to Awards subject to Section 409A of the Code, the Plan is intended to comply with the requirements of Section 409A of the Code, and the provisions of the Plan and any Award Document shall be interpreted in a manner that satisfies the requirements of Section 409A of the Code, and the Plan shall be operated accordingly. If any provision of the Plan or any term or condition of any Award would otherwise frustrate or conflict with this intent, the provision, term or condition will be interpreted and deemed amended so as to avoid this conflict. If an amount payable under an Award as a result of the Participant's Termination of Service (other than due to death) occurring while the Participant is a "specified employee" under Section 409A of the Code constitutes a deferral of compensation subject to Section 409A of the Code, then payment of such amount shall not occur until six months and one day after the date of the Participant's Termination of Service, except as permitted under Section 409A of the Code. If the Award includes a "series of installment payments" (within the meaning of Section 1.409A-2(b)(2)(iii) of the Treasury Regulations), the Participant's right to the series of installment payments shall be treated as a right to a series of separate payments and not as a right to a single payment, and if the Award includes "dividend equivalents" (within the meaning of Section 1.409A-3(e) of the Treasury Regulations), the Participant's right to the dividend equivalents shall be treated separately from the right to other amounts under the Award. Notwithstanding the foregoing, the tax treatment of the benefits provided under the Plan or any Award Document is not warranted or guaranteed, and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by the Participant on account of non-compliance with Section 409A of the Code.

Section 19. *Data Protection*. By participating in the Plan, the Participant consents to the holding and processing of personal information provided by the Participant to the Company or any Affiliate, trustee or third party service provider, for all purposes relating to the operation of the Plan. These include, but are not limited to:

(i) administering and maintaining Participant records;

(ii) providing information to the Company, Affiliates, trustees of any employee benefit trust, registrars, brokers or third party administrators of the Plan;

(iii) providing information to future purchasers or merger partners of the Company or any Affiliate, or the business in which the Participant works; and

(iv) transferring information about the Participant to any country or territory that may not provide the same protection for the information as the Participant's home country.

Section 20. *Governing Law*. The Plan and each Award Document shall be governed by the laws of the State of Israel. The Company, its Affiliates and each Participant (by acceptance of an Award) irrevocably submit, in respect of any suit, action or proceeding related to the implementation or enforcement of the Plan, to the exclusive jurisdiction of the competent courts in Tel-Aviv-Jaffe.

Section 21. *Definitions*. As used in the Plan, the following terms shall have the meanings set forth below:

(a) "**Affiliate**" means (i) any entity that, directly or indirectly, is controlled by the Company, (ii) any entity in which the Company, directly or indirectly, has a significant equity interest, in each case as determined by the Committee and (iii) any other entity which the Committee determines should be treated as an "Affiliate."

(b) "**Applicable Law**" means the legal requirements applicable to the administration of equity incentive plans, any applicable laws, rules and regulations of any country or jurisdiction where Awards are granted under the Plan or in which Participants pay are subject to taxation, as such laws, rules, regulations and requirements shall be in place from time to time, and any applicable stock exchange rules or regulations.

(c) "**Award**" means any Option, SAR, Restricted Share, RSU, Performance Award or Other Share-Based Award granted under the Plan.

(d) "**Award Document**" means any agreement, contract or other instrument or document, which may be in electronic format, evidencing any Award granted under the Plan, which may, but need not, be executed or acknowledged by a Participant.

(e) "**Beneficiary**" means a person entitled to receive payments or other benefits or exercise rights that are available under the Plan in the event of the Participant's death. If no such person is named by a Participant, or if no Beneficiary designated by the Participant is eligible to receive payments or other benefits or exercise rights that are available under the Plan at the Participant's death, such Participant's Beneficiary shall be such Participant's estate.

(f) "**Board**" means the board of directors of the Company.

(g) "**Cause**" means, with respect to any Participant, "cause" as defined in such Participant's employment agreement with the Company, if any, or if not so defined, except as otherwise provided in such Participant's Award Document, such Participant's:

(i) indictment for any crime (A) constituting a felony, or (B) that has, or could reasonably be expected to result in, an adverse impact on the performance of a Participant's duties to the Company or any of its subsidiaries, or otherwise has, or could reasonably be expected to result in, an adverse impact to the business or reputation of the Company or any of its subsidiaries;

(ii) having been the subject of any order, judicial or administrative, obtained or issued by the Securities and Exchange Commission for any securities violation involving fraud, including, for example, any such order consented to by the Participant in which findings of facts or any legal conclusions establishing liability are neither admitted nor denied;

(iii) conduct, in connection with his or her employment or service, which is not taken in good faith and has, or could reasonably be expected to result in, material injury to the business or reputation of the Company or any of its subsidiaries;

(iv) willful violation of the Company's code of conduct or other material policies set forth in the manuals or statements of policy of the Company or any of its subsidiaries;

(v) willful neglect in the performance of a Participant's duties for the Company or any of its subsidiaries or willful or repeated failure or refusal to perform such duties;

(vi) material breach of any applicable employment agreement or other agreement with the Company; or

(vii) conduct, in connection with his or her employment or service.

The occurrence of any such event described in clauses (ii) through (v) that is susceptible to cure or remedy shall not constitute Cause if such Participant cures or remedies such event within 30 (thirty) days after the Company provides notice to such Participant.

(h) "**Change in Control**" means the occurrence of any one or more of the following events:

(i) a direct or indirect change in ownership or control of the Company effected through one transaction or a series of related transactions within a 12-month period, whereby any Person other than the Company, directly or indirectly acquires or maintains beneficial ownership of securities of the Company constituting more than 50% of the total combined voting power of the Company's equity securities outstanding immediately after such acquisition;

(ii) at any time during a period of 12 consecutive months, individuals who at the beginning of such period constituted the Board cease for any reason to constitute a majority of members of the Board; *provided, however,* that any new member of the Board whose election or nomination for election was approved by a vote of at least a majority of the directors then still in office who either were directors at the beginning of such period or whose election or nomination for election was so approved, shall be considered as though such individual were a member of the Board at the beginning of the period, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a Person other than the Board;

(iii) the consummation of a merger or consolidation of the Company or any of its subsidiaries with any other corporation or entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or being converted into voting securities of the surviving entity or, if applicable, the ultimate parent thereof) at least 50% of the combined voting power and total fair market value of the securities of the Company or such surviving entity or parent outstanding immediately after such merger or consolidation; or

(iv) the consummation of any sale, lease, exchange or other transfer to any Person (other than an Affiliate of the Company), in one transaction or a series of related transactions within a 12-month period, of all or substantially all of the assets of the Company and its subsidiaries.

Notwithstanding the foregoing or any provision of any Award Document to the contrary, for any Award to which Section 18 applies that provides for accelerated distribution on a Change in Control of amounts that constitute "deferred compensation" (as defined in Section 409A of the Code), if the event that constitutes such Change in Control does not also constitute a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company's assets (in either case, as defined in Section 409A of the Code), such amount shall not be distributed on such Change in Control but instead shall vest as of the date of such Change in Control and shall be paid on the scheduled payment date specified in the applicable Award Document, except to the extent that earlier distribution would not result in the Participant who holds such Award incurring any additional tax, penalty, interest or other expense under Section 409A of the Code.

(a) "**Code**" means the United States Internal Revenue Code of 1986, as amended from time to time, and the rules, regulations and guidance thereunder. Any reference to a provision in the Code shall include any successor provision thereto.

(b) "**Committee**" means the Compensation Committee of the Board or such other committee as may be designated by the Board.

(c) "**Exchange Act**" means the United States Securities Exchange Act of 1934, as amended from time to time, and the rules, regulations and guidance thereunder. Any reference to a provision in the Exchange Act shall include any successor provision thereto.

(d) "**Fair Market Value**" means (i) with respect to a Share, the closing price of a Share on the date in question (or, if there is no reported sale on such date, on the last preceding date on which any reported sale occurred) on the principal stock market or exchange on which the Shares are quoted or traded, or if Shares are not so quoted or traded, the fair market value of a Share as determined by the Board, and (ii) with respect to any property other than Shares, the fair market value of such property determined by such methods or procedures as shall be established from time to time by the Board.

(e) "**Non-Employee Director**" means a member of the Board who is not an employee of the Company or an Affiliate.

(f) "**Option**" means an option representing the right to acquire Shares from the Company, granted in accordance with the provisions of Section 5.

(g) "**Other Share-Based Award**" means an Award granted in accordance with the provisions of Section 9.

(h) "**Participant**" means the recipient of an Award granted under the Plan.

(i) "**Performance Award**" means an Award granted in accordance with the provisions of Section 8.

(j) "**Performance Period**" means the period established by the Administrator at the time any Performance Award is granted or at any time thereafter during which any performance goals specified by the Administrator with respect to such Award are measured.

(k) "**Person**" means a natural person or a partnership, company, association, cooperative, mutual insurance society, foundation or any other body which operates externally as an independent unit or organisation.

(l) "**Replacement Award**" means an Award granted in assumption of, or in substitution for, an outstanding award previously granted by a company or business acquired by the Company or with which the Company, directly or indirectly, combines.

(m) "**Restricted Share**" means any Share granted in accordance with the provisions of Section 7.

(n) "**RSU**" means a contractual right granted in accordance with the provisions of Section 7 that is denominated in Shares. Each RSU represents a right to receive the value of one Share. Awards of RSUs may include the right to receive dividend equivalents.

(o) "**SAR**" means any right granted in accordance with the provisions of Section 6 to receive upon exercise by a Participant or settlement the excess of (i) the Fair Market Value of one Share on the date of exercise or settlement over (ii) the exercise price of the right on the date of grant, or if granted in connection with an Option, on the date of grant of the Option.

(p) "**Shares**" means ordinary shares of the Company.[1]

[1] **Note to HFN Corporate**: Please confirm there is only one class of ordinary shares.

(q) "**Structural Change**" means any re-domestication of the Company, share flip, creation of a holding company for the Company which will hold substantially all of the Shares of the Company or any other transaction involving the Company in which the Shares of the Company outstanding immediately prior to such transaction continue to represent, or are converted into or exchanged for shares that represent, immediately following such transaction, at least a majority, by voting power, of the share capital of the surviving, acquiring or resulting corporation;

(r) "**Termination of Service**" means:

(i) in the case of a Participant who is an employee of the Company or an Affiliate, cessation of the employment relationship such that the Participant is no longer an employee of the Company or Subsidiary;

(ii) in the case of a Participant who is a director of the Board, the date that the Participant ceases to be a member of the Board for any reason; or

(iii) in the case of a Participant who is a consultant or other advisor, the effective date of the cessation of the performance of services for the Company or an Subsidiary;

provided, *however*, that in the case of an employee, the transfer of employment from the Company to an Affiliate, from an Affiliate to the Company, from one Affiliate to another Affiliate or, unless the Administrator determines otherwise, the cessation of employee status but the continuation of the performance of services for the Company or an Affiliate as a member of the Board or a consultant or other advisor shall not be deemed a cessation of service that would constitute a Termination of Service; and *provided further*, that a Termination of Service will be deemed to occur for a Participant employed by an Affiliate when an Affiliate ceases to be an Affiliate, unless such Participant's employment continues with the Company or another Affiliate.

ENTERA BIO LTD.

2018 EQUITY INCENTIVE PLAN

ISRAELI SUB PLAN

1. GENERAL

1.1 This sub-plan (the "**Sub-plan**") shall apply only to Participants who are residents of the State of Israel upon the date of grant of the Award, as defined below in Section 2, or who are deemed Israeli tax residents (collectively, "**Israeli Participants**"). The provisions specified hereunder shall form an integral part of the Entera Bio Ltd. 2018 Equity Incentive Plan (hereinafter the **"Plan"**).

1.2 This Sub-plan is adopted pursuant to Sections Section 3(a) and Section 13(a) of the Plan and is to be read as a continuation of the Plan and modifies Awards granted to Israeli Participants only to the extent necessary to comply with the requirements set by the Israeli law in general, and in particular, with the provisions of the Israeli Income Tax Ordinance [New Version] 1961, as may be amended or replaced from time to time. This Sub-plan does not add to or modify the Plan in respect of any other category of Participants.

1.3 The Plan and this Sub-plan are complimentary to each other and shall be deemed as one. In the event of any conflict, whether explicit or implied, between the provisions of this Sub-plan and the Plan, the provisions set out in the Sub-plan shall prevail.

1.4 Any capitalized term not specifically defined in this Sub-plan shall be construed according to the interpretation given to it in the Plan.

1.5 This Sub-plan does not apply to any Award which is settled in cash.

2. DEFINITIONS

2.1 "**102 Award**" means any Award, provided it is settled in Shares, granted to an Approved Israeli Participant pursuant to Section 102 of the Ordinance.

2.2 "**Approved Israeli Participant**" means an Israeli Participant who is an employee, director or an officer of the Company or any an Israeli resident Affiliate, excluding any Controlling Share Holder of the Company.

2.**3** **"Capital Gain Award" or "CGA"** means a Trustee 102 Award elected and designated by the Company to qualify under the capital gain tax treatment in accordance with the provisions of Section 102(b)(2) and Section 102(b)(3) of the Ordinance.

2.4 “**Controlling Share Holder**” shall have the meaning ascribed to it in Section 32(9) of the Ordinance.

2.5 “**ITA”** means the Israeli Tax Authority.

2.6 **“Israeli Award Agreement”** means the Award Agreement between the Company and an Israeli Participant that sets out the terms and conditions of an Award.

2.7 “**Non-Trustee 102 Award**” means a 102 Award granted pursuant to Section 102(c) of the Ordinance and not held in trust by a Trustee.

2.8 “**Ordinary Income Award” or “OIA**” means a Trustee 102 Award elected and designated by the Company to qualify under the ordinary income tax treatment in accordance with the provisions of Section 102(b)(1) of the Ordinance.

2.9 **“Ordinance”** means the Israeli Income Tax Ordinance [New Version] – 1961, as now in effect or as hereafter amended.

2.10 **“Section 102”** means Section 102 of the Ordinance and any regulations, rules, orders or procedures promulgated thereunder as now in effect or as hereafter amended.

2.11 “**Tax**” means any applicable tax and other compulsory payments such as social security and health tax contributions under any Applicable Law.

2.12 “**Trustee**” means any person or entity appointed by the Company or the Subsidiary to serve as a trustee and approved by the ITA, all in accordance with the provisions of Section 102(a) of the Ordinance, as may be replaced from time to time.

2.13 **"Trustee 102 Award**” means a 102 Award granted to an Approved Israeli Participant pursuant to Section 102(b) of the Ordinance and held in trust by a Trustee for the benefit of an Approved Israeli Participant.

2.14 **"Unapproved Israeli Participant**” means an Israeli Participant who is not an Approved Israeli Participant, including a consultant or a Controlling Share Holder of the Company.

3. ISSUANCE OF AWARDS

3.1 The persons eligible for participation in the Plan as Israeli Participants shall include Approved Israeli Participants and Unapproved Israeli Participants, provided, however, that only Approved Israeli Participants may be granted 102 Awards.

3.2 The Company may designate Awards granted to Approved Israeli Participants pursuant to Section 102 as Trustee 102 Awards or Non-Trustee 102 Awards.

3.3 The grant of Trustee 102 Awards shall be made under this Sub-plan and shall not be made until 30 days from the date the Plan has been submitted for approval by the ITA and shall be conditioned upon the approval of the Plan and this Sub-plan by the ITA.

3.4 Trustee 102 Awards may either be classified as Capital Gain Awards (CGAs) or Ordinary Income Awards (OIAs).

3.5 No Trustee 102 Award may be granted under this Sub-plan to any Approved Israeli Participant, unless and until the Company has filed with the ITA its election regarding the type of Trustee 102 Awards, whether CGAs or OIAs, that will be granted under the Plan and this Sub-plan (the "**Election**"). Such Election shall become effective beginning the first date of grant of a Trustee 102 Award under this Sub-plan and shall remain in effect at least until the end of the year following the year during which the Company first granted Trustee 102 Awards. The Election shall obligate the Company to grant *only* the type of Trustee 102 Award it has elected, and shall apply to all Israeli Participants who are granted Trustee 102 Awards during the period indicated herein, all in accordance with the provisions of Section 102(g) of the Ordinance. For the avoidance of doubt, the Election shall not prevent the Company from granting Non-Trustee 102 Awards simultaneously.

3.6 All Trustee 102 Awards must be held in trust by, or subject to the approval of the ITA, under the control or supervision of a Trustee, as described in Section 4 below.

3.7 The designation of Non-Trustee 102 Awards and Trustee 102 Awards shall be subject to the terms and conditions set forth in Section 102.

3.8 Awards granted to Unapproved Israeli Participants shall be subject to tax according to the provisions of the Ordinance and shall not be subject to the Trustee arrangement detailed herein.

4. TRUSTEE

4.1 Trustee 102 Awards which shall be granted under this Sub-plan and/or any Shares allocated or issued upon grant, vesting or exercise of a Trustee 102 Award and/or other Shares received following any realization of rights under the Plan, shall be allocated or issued to the Trustee or controlled by the Trustee, for the benefit of the Approved Israeli Participants, in accordance with the provisions of Section 102. In the event that the requirements for Trustee 102 Awards are not met, the Trustee 102 Awards may be regarded as Non-Trustee 102 Awards or as Awards which are not subject to Section 102, all in accordance with the provisions of Section 102.

4.2 With respect to any Trustee 102 Award, subject to the provisions of Section 102, an Approved Israeli Participant shall not sell or release from trust any Shares received upon the grant, vesting or exercise of a Trustee 102 Award and/or any Shares received following any realization of rights, including, without limitation, stock dividends, under the Plan at least until the lapse of the period of time required under Section 102 or any shorter period of time determined by the ITA (the "**Holding Period**"). Notwithstanding the above, if any such sale or release occurs during the Holding Period, the sanctions under Section 102 shall apply to and shall be borne by such Approved Israeli Participant.

4.3 Notwithstanding anything to the contrary, the Trustee shall not release or sell any Shares allocated or issued upon grant, vesting or exercise of a Trustee 102 Award unless the Company, its Israeli Subsidiary and the Trustee are satisfied that the full amounts of Tax due have been paid or will be paid.

4.4 Upon receipt of any Trustee 102 Award, the Approved Israeli Participant will consent to the grant of the Award under Section 102 and undertake to comply with the terms of Section 102 and the trust arrangement between the Company and the Trustee.

5. THE AWARDS

The terms and conditions upon which the Awards shall be issued and exercised or vest, shall be specified in the Israeli Award Agreement to be executed pursuant to the Plan and to this Sub-plan. Each Israeli Award Agreement shall state, *inter alia*, the number of Shares to which the Award relates, the type of Award granted thereunder (*i.e.*, a CGA, OIA or Non-Trustee 102 Award or any Award granted to Unapproved Israeli Participant), and any applicable vesting provisions and exercise price that may be payable. For the avoidance of doubt it is clarified that there is no obligation for uniformity of treatment of Israeli Participants and that the terms and conditions of Awards need not be the same with respect to each Israeli Participant (whether or not such Israeli Participants are similarly situated).

6. EXERCISE AND VESTING OF AWARDS

The grant, vesting and exercise of Awards granted to Israeli Participants shall be subject to the terms and conditions and, with respect to exercise, the method, as may be determined by the Company (including the provisions of the Plan) and, when applicable, by the Trustee, in accordance with the requirements of Section 102.

7. ASSIGNABILITY, DESIGNATION AND SALE OF AWARDS

7.1. Notwithstanding any other provision of the Plan (including sections 5(e) and 6(a)(iv) of the Plan), no Award or any right with respect thereto, or purchasable hereunder, whether fully paid or not, shall be assignable, transferable or given as collateral, or any right with respect to any Award given to any third party whatsoever, and during the lifetime of the Israeli Participant, each and all of such Israeli Participant's rights with respect to an Award shall belong only to the Israeli Participant. Any such action made directly or indirectly, for an immediate or future validation, shall be void.

7.2 As long as Awards or Shares issued or purchased hereunder are held by the Trustee on behalf of the Israeli Participant, all rights of the Israeli Participant over the Shares cannot be transferred, assigned, pledged or mortgaged, other than by will or laws of descent and distribution.

8. INTEGRATION OF SECTION 102 AND TAX ASSESSING OFFICER'S APPROVAL

8.1. With regard to Trustee 102 Awards, the provisions of the Plan and/or the Sub-plan and/or the Israeli Award Agreement shall be subject to the provisions of Section 102 and any approval issued by the ITA and the said provisions shall be deemed an integral part of the Plan, the Sub-plan and the Israeli Award Agreement.

8.2. Any provision of Section 102 and/or said approval issued by the ITA which must be complied with in order to receive and/or to maintain any tax Award pursuant to Section 102, which is not expressly specified in the Plan, the Sub-plan or the Israeli Award Agreement, shall be considered binding upon the Company, any Israeli Subsidiary and the Israeli Participants.

9. TAX CONSEQUENCES

9.1 Any tax consequences arising from the grant, exercise, vesting or sale of any Award, from the payment for or sale of Shares covered thereby or from any other event or act (of the Company, and/or its Subsidiaries, and the Trustee or the Israeli Participant), hereunder, shall be borne solely by the Israeli Participant. The Company and/or its Subsidiaries, and/or the Trustee shall withhold Tax according to the requirements under the applicable laws, rules, and regulations, including withholding taxes at source. Furthermore, the Israeli Participant agrees to indemnify the Company and/or its Subsidiaries and/or the Trustee and hold them harmless against and from any and all liability for any such Tax or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such Tax from any payment made to the Israeli Participant.

9.2 The Company and/or, when applicable, the Trustee shall not be required to release any Award or Shares to an Israeli Participant until all required Tax payments have been fully made.

9.3 Approved Awards that do not comply with the requirements of Section 102 shall be considered Non-Approved 102 Awards or Awards subject to tax under Section 3(i) or 2 of the Ordinance.

9.4 With respect to Non-Trustee 102 Awards, if the Israeli Participant ceases to be employed by the Company or any Subsidiary, or otherwise if so requested by the Company or the Subsidiary, the Israeli Participant shall extend to the Company and/or the Subsidiary a security or guarantee for the payment of Tax due at the time of sale of Shares, in accordance with the provisions of Section 102.

9.5 For avoidance of doubt, it is clarified that the tax treatment of any Award granted under this Sub-plan is not guaranteed and, although Awards may be granted under a certain tax route, they may become subject to a different tax route in the future.

10. ONE TIME AWARD

The Awards and underlying Shares are extraordinary, one-time awards granted to the Participants, and are not and shall not be deemed a salary component for any purpose whatsoever, including in connection with calculating severance compensation under Applicable Law, nor shall receipt of an award entitle a Participant to any future Awards.

Exhibit 10.18

Entera Bio Ltd.

and

American Stock Transfer & Trust Company, LLC, as
Warrant Agent

Warrant Agency Agreement

Dated as of [ ], 2018

WARRANT AGENCY AGREEMENT

WARRANT AGENCY AGREEMENT, dated as of [ ], 2018 ("**Agreement**"), between Entera Bio Ltd., a company limited by shares incorporated under the laws of Israel (the "**Company**"), and American Stock Transfer & Trust Company, LLC, a New York limited liability trust company (the "**Warrant Agent**").

WITNESSETH

WHEREAS, pursuant to a registered offering by the Company of ordinary shares of the Company, nominal value NIS [ ] per share (the "**Ordinary Shares**") and warrants (the "**Warrants**") to purchase Ordinary Shares pursuant to an effective registration statement on Form F-1 (File No. 333-221472), as amended (the "**Registration Statement**"), the Company wishes to issue Warrants in book-entry form entitling the respective holders of the Warrants (the "**Holders**", which term shall include a Holder's transferees, successors and assigns and "**Holder**" shall include, if the Warrants are held in "street name", a Participant (as defined below) or a designee appointed by such Participant) to purchase an aggregate of up to [ ] Ordinary Shares upon the terms and subject to the conditions hereinafter set forth (the "**Offering**");

WHEREAS, the Ordinary Shares and Warrants to be issued in connection with the Offering shall be immediately separable and will be issued separately; and

WHEREAS, the Company wishes the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing so to act, in connection with the issuance, registration, transfer, exchange, exercise and replacement of the Warrants and, in the Warrant Agent's capacity as the Company's transfer agent, the delivery of the Warrant Shares.

NOW, THEREFORE, in consideration of the premises and the mutual agreements herein set forth, the parties hereby agree as follows:

Section 1. *Certain Definitions*. For purposes of this Agreement, the following terms have the meanings indicated:

(a) "**Business Day**" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or Israel or any day on banking institutions in the State of New York or Israel are authorized or required by law or other governmental action to close.

(b) "**Close of Business**" on any given date means 5:00 p.m., New York City time, on such date.

(c) "**Person**" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

(d) "**Warrant Certificate**" means a certificate in substantially the form attached as Exhibit 1 hereto, representing such number of Warrant Shares as is indicated therein, *provided* that any reference to the delivery of a Warrant Certificate in this Agreement shall include delivery of notice from the Depositary or a Participant (each as defined below) of the transfer or exercise of Warrant in the form of a Global Warrant (as defined below).

(d) "**Warrant Shares**" means the Ordinary Shares underlying the Warrants and issuable upon exercise of the Warrants.

All other capitalized terms used but not otherwise defined herein shall have the meaning ascribed to such terms in the Warrant Certificate.

Section 2. *Appointment of Warrant Agent*. The Company hereby appoints the Warrant Agent to act as agent for the Company in accordance with the terms and conditions hereof, and the Warrant Agent hereby accepts such appointment. The Company may from time to time appoint a co-Warrant Agent as it may, in its sole discretion, deem necessary or desirable. The Warrant Agent shall have no duty to supervise, and will in no event be liable for the acts or omissions of, any co-Warrant Agent.

Section 3. *Global Warrants*.

(a) The Warrants shall be issuable in book-entry form (the "**Global Warrants**"). All of the Warrants shall initially be represented by one or more Global Warrants deposited with the Warrant Agent and registered in the name of Cede & Co., a nominee of The Depository Trust Company (the "**Depositary**"), or as otherwise directed by the Depositary. Ownership of beneficial interests in the Global Warrants shall be shown on, and the transfer of such ownership shall be effected through, records maintained by (i) the Depositary or its nominee for each Global Warrant or (ii) institutions that have accounts with the Depositary (each such institution, with respect to a Warrant in its account, a "**Participant**"), in each case, in accordance with the applicable procedures of the Depositary. All notices and communications to be given to the Holders and all deliveries to be made to Holders in respect of the Warrants shall be given or made only to, or upon the order of, the registered Holder(s) (which shall be the Depositary or its nominee in the case of the Global Warrants), and the Company shall not have any responsibility or liability for the delivery of Warrant Shares or other property to owners of beneficial interests in a Global Warrant, for any aspect of the records relating to or payments or deliveries made on account of those interests by or to the Depositary, for maintaining, supervising or reviewing any records of the Depositary relating to such beneficial ownership of those interests or for any act or omission of the Depositary.

(b) If the Depositary subsequently ceases to make its book-entry settlement system available for the Warrants or if required by applicable law, the Company may instruct the Warrant Agent regarding other arrangements for book-entry settlement. In the event that the Warrants are not eligible for, or it is no longer necessary or permitted under applicable law to have the Warrants available in, book-entry form, the Warrant Agent shall provide written instructions to the Depositary to deliver to the Warrant Agent for cancellation each Global Warrant, and the Company shall instruct the Warrant Agent to deliver to each Holder a Warrant Certificate.

(c) A Holder has the right to elect at any time or from time to time a Warrant Exchange (as defined below) pursuant to a Warrant Certificate Request Notice (as defined below). Upon written notice by a Holder to the Warrant Agent for the exchange of some or all of such Holder's Global Warrants for a Warrant Certificate evidencing the same number of Warrants, which request shall be in the form attached hereto as Annex A (a "**Warrant Certificate Request Notice**" and the date of delivery of such Warrant Certificate Request Notice by the Holder, the "**Warrant Certificate Request Notice Date**" and the deemed surrender upon delivery by the Holder of a number of Global Warrants for the same number of Warrants evidenced by a Warrant Certificate, a "**Warrant Exchange**"), the Warrant Agent shall provide a written copy of such Warrant Certificate Request Notice to the Company, upon receipt of which the Company shall promptly effect the Warrant Exchange by issuing and delivering to the Holder a Warrant Certificate for the number of Warrants subject to such Warrant Exchange in the name set forth in the Warrant Certificate Request Notice. Such Warrant Certificate shall be signed in the name and on behalf of the Company by the manual or facsimile signature of an authorized signatory of the Company and shall be in substantially the form attached hereto as Exhibit 1. The Company covenants and agrees that, upon a Holder's submission of a completed Warrant Certificate Request Notice, such Holder (or such other Person as such Holder may have specified in the applicable Warrant Certificate Request Notice) shall be deemed to be the holder of a Warrant Certificate representing the number of Warrants subject to such Warrant Certificate Request Notice as of the Warrant Certificate Request Notice Date and, notwithstanding anything to the contrary set forth herein, the Warrant Certificate shall be deemed for all purposes to contain all of the terms and conditions of the Warrants evidenced by such Warrant Certificate and the terms of this Agreement, other than Sections 3(c) and 9 hereof, which shall not apply to the Warrants evidenced by the Warrant Certificate.

Section 4. *Form of Warrant Certificates*. The Warrant Certificate, together with the form of election to purchase Ordinary Shares ("**Notice of Exercise**") and the form of assignment to be printed on the reverse thereof, shall be in substantially the form of Exhibit 1 hereto. Any Warrant Certificate may have such letters, numbers or other marks of identification and such notations, legends or endorsements as the officer executing the same on behalf of the Company may approve (execution thereof to be conclusive evidence of such approval) and as are not inconsistent with the provisions of this Agreement and the Warrants, or as may be required to comply with any law or with any rule or regulation made pursuant thereto or with any rule or regulation of any securities exchange or automated quotation system on which the Warrants may be listed or designated for issuance, or to conform to usage or to indicate any special limitations or restrictions to which any particular Warrants are subject.

Section 5. *Countersignature and Registration*. The Warrant Certificates shall be executed on behalf of the Company by its Chief Executive Officer, Chief Financial Officer, Treasurer, Secretary or any President or Vice President, either manually or by facsimile signature. The Warrant Certificates shall be countersigned by the Warrant Agent either manually or by facsimile signature and shall not be valid for any purpose unless so countersigned. In case any officer of the Company who shall have signed any of the Warrant Certificates shall cease to be such officer of the Company before countersignature by the Warrant Agent and issuance and delivery by the Company, such Warrant Certificates, nevertheless, may be countersigned by the Warrant Agent, issued and delivered with the same force and effect as though the person who signed such Warrant Certificate had not ceased to be such officer of the Company; and any Warrant Certificate may be signed on behalf of the Company by any person who, at the actual date of the execution of such Warrant Certificate, shall be a proper officer of the Company to sign such Warrant Certificate, although at the date of the execution of this Agreement any such person was not such an officer.

The Warrant Agent will keep or cause to be kept, at one of its offices, or at the office of one of its agents, books for registration and transfer of the Warrant Certificates issued hereunder. Such books shall show the names and addresses of the respective Holders of the Warrant Certificates, the number of Warrants evidenced on the face of each of such Warrant Certificate and the date of each of such Warrant Certificate. The Warrant Agent will create a special account for the issuance of Warrant Certificates.

Section 6. *Transfer, Split Up, Combination and Exchange of Warrant Certificates; Mutilated, Destroyed, Lost or Stolen Warrant Certificates*. With respect to the Global Warrant, subject to the provisions of the Warrant Certificate and the last sentence of this first paragraph of Section 6 and subject to applicable law, rules or regulations or any “stop transfer” instructions the Company may give to the Warrant Agent, at any time after their original issuance, and at or prior to the Close of Business on the Termination Date (as such term is defined in the Warrant Certificate), any Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants may be transferred, split up, combined or exchanged for another Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants, as the case may be, entitling the Holder to purchase a like number of Ordinary Shares as the Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants surrendered then entitled such Holder to purchase. Any Holder desiring to transfer, split up, combine or exchange any Warrant Certificate or Global Warrant shall make such request in writing delivered to the Warrant Agent, and shall surrender the Warrant Certificate or Warrant Certificates to be transferred, split up, combined or exchanged at the principal office of the Warrant Agent, *provided* that no such surrender shall be required by the Holder of a Global Warrant deposited with the Warrant Agent in accordance with Section 3(a). Any requested transfer of Warrants, whether in book-entry form or certificate form, shall be accompanied by reasonable evidence of authority of the party making such request that may be required by the Warrant Agent. Thereupon the Warrant Agent shall, subject to the last sentence of this first paragraph of Section 6, countersign and deliver to the Person entitled thereto a Warrant Certificate or Warrant Certificates, as the case may be, as so requested. The Company may require payment from the Holder of a sum sufficient to cover any tax or governmental charge that may be imposed in connection with any transfer, split up, combination or exchange of Warrant Certificates.

Upon receipt by the Warrant Agent of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of a Warrant Certificate, which evidence shall include an affidavit of loss, or in the case of mutilated certificates, the certificate or portion thereof remaining, and, in case of loss, theft or destruction, of indemnity in customary form and amount, and satisfaction of any other reasonable requirements established by Section 8-405 of the Uniform Commercial Code as in effect in the State of New York, and reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto, and upon surrender to the Warrant Agent and cancellation of the Warrant Certificate if mutilated, the Company will make and deliver a new Warrant Certificate of like tenor to the Warrant Agent for delivery to the Holder in lieu of the Warrant Certificate so lost, stolen, destroyed or mutilated.

Section 7. *Exercise of Warrants; Exercise Price; Termination Date*.

(a) The Warrants shall be exercisable commencing on the Initial Exercise Date (as such term is defined in the Warrant Certificate). The Warrants shall cease to be exercisable and shall terminate and become void, and all rights thereunder and under this Agreement shall cease, at or prior to the Close of Business on the Termination Date. Subject to Section 7(b) below, the Holder of a Warrant may exercise the Warrant in accordance with Section 2(a) and, if applicable, Section 2(c) of the Warrant Certificate. Notwithstanding any other provision in this Agreement, a holder whose interest in a Global Warrant is a beneficial interest in a Global Warrant held in book-entry form through the Depositary (or another established clearing corporation performing similar functions) shall effect exercises by delivering to the Depositary (or such other clearing corporation, as applicable) the appropriate instruction form for exercise and complying with the applicable procedures to effect exercise that are then required by the Depositary (or such other clearing corporation, as applicable).

(b) Upon receipt by the Company of a Notice of Exercise for a “cashless” exercise pursuant to Section 2(c) of the Warrant Certificate (a “**Cashless Exercise**”) and following the conclusion of the applicable Calculation Period, the Company will promptly calculate and notify the Warrant Agent of the number of Warrant Shares issuable in connection with such Cashless Exercise and deliver (x) a copy of the Notice of Exercise and (y) instruction to issue such number of Warrant Shares, in each case, to the Warrant Agent (the date on which such notice and instruction are delivered by the Company under this Section 7(b), a “**Cashless Exercise Notice Delivery Date**”), which shall issue such number of Warrant Shares in accordance with Section 7(c) below (it being understood that the notices provided for in this paragraph may be delivered by electronic transmission (including by way of email attachment)). The Company shall be responsible for making all calculations in respect of each Cashless Exercise, and the Warrant Agent shall have no liability for making any such calculations.

(c) Upon the Warrant Agent's receipt of (x) (i) an executed Notice of Exercise, which shall have the Warrant Certificate attached if the Warrants represented thereby are being exercised in full, and (ii) solely in respect of a Cashless Exercise, the instruction described in Section 7(b) above, in each case, at or prior to the Close of Business on the Termination Date or, if applicable, the Cashless Exercise Notice Delivery Date and (y) confirmation by the Company of its timely receipt of the Exercise Price for the Warrant Shares to be purchased (other than in the case of a Cashless Exercise) and an amount equal to any applicable tax, governmental charge or expense reimbursement referred to in Section 6 in cash, or by certified check or bank draft payable to the order of the Company (or, in the case of the Holder of a Global Warrant, the delivery of the executed Notice of Exercise and the payment of the Exercise Price (other than in the case of a Cashless Exercise) and any other applicable amounts as set forth herein), the Warrant Agent shall cause the Warrant Shares to which the Holder is entitled as a result of such exercise to be delivered to or upon the order of such Holder, registered in such name or names as may be designated by such Holder, no later than the applicable Warrant Share Delivery Date (as such term is defined in the Warrant Certificate). If the Company is then a participant in the DWAC system of the Depositary and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to the Holder or (B) the Warrant is being exercised via Cashless Exercise, then the relevant Warrant Shares shall be transmitted by the Warrant Agent to the Holder by crediting the account of the Holder's broker with the Depositary through its DWAC system. For the avoidance of doubt, if the Company becomes obligated to pay any amounts to any Holders pursuant to Section 2(d)(i) or 2(d)(iv) of the Warrant Certificate, such obligation to Holders shall be solely that of the Company and not that of the Warrant Agent. Notwithstanding anything else to the contrary in this Agreement, except in the case of a Cashless Exercise, if any Holder fails to timely deliver valid payment to the Company of an amount equal to the aggregate Exercise Price of the Warrant Shares to be purchased upon exercise of such Holder's Warrants as set forth in Section 7(a) hereof, the Warrant Agent will not obligated to deliver certificates representing any such Warrant Shares (via DWAC or otherwise).

(d) In case the Holder of any Warrants shall exercise fewer than all Warrants evidenced by such Holder's Warrant Certificate, a new Warrant Certificate evidencing the number of Warrants equivalent to the number of Warrants remaining unexercised may be issued by the Warrant Agent to the Holder of such Warrants or to its duly authorized assigns in accordance with Section 2(d)(ii) of the Warrant Certificate, subject to the provisions of Section 6 hereof.

Section 8. *Cancellation and Destruction of Warrant Certificates*. All Warrant Certificates surrendered for the purpose of exercise, transfer, split up, combination or exchange shall, if surrendered to the Company or to any of its agents, be delivered to the Warrant Agent for cancellation or in canceled form, or, if surrendered to the Warrant Agent, shall be canceled by it, and no Warrant Certificates shall be issued in lieu thereof except as expressly permitted by any of the provisions of this Agreement. The Company shall deliver to the Warrant Agent for cancellation and retirement, and the Warrant Agent shall so cancel and retire, any other Warrant Certificate purchased or acquired by the Company otherwise than upon the exercise thereof. The Warrant Agent shall deliver all canceled Warrant Certificates to the Company, or shall, at the written request of the Company, destroy such canceled Warrant Certificates, and in such case shall deliver a certificate of destruction thereof to the Company, subject to any applicable law, rule or regulation requiring the Warrant Agent to retain such canceled certificates.

Section 9. *Certain Representations; Reservation and Availability of Ordinary Shares*.

(a) This Agreement has been duly authorized, executed and delivered by the Company and, assuming due authorization, execution and delivery hereof by the Warrant Agent, constitutes a valid and legally binding obligation of the Company enforceable against the Company in accordance with its terms, and the Warrants have been duly authorized, executed and issued by the Company and, assuming due authentication thereof by the Warrant Agent pursuant hereto and payment therefor by the Holders as provided in the Registration Statement, constitute valid and legally binding obligations of the Company enforceable against the Company in accordance with their terms and entitled to the benefits hereof; in each case except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium and other similar laws relating to or affecting creditors' rights generally or by general equitable principles (regardless of whether such enforceability is considered in a proceeding in equity or at law).

(b) The Company covenants and agrees that it will cause to be reserved and kept available out of its authorized and unissued Ordinary Shares or its authorized and issued Ordinary Shares held in its treasury, free from preemptive rights, the number of Ordinary Shares that will be sufficient to permit the exercise in full of all outstanding Warrants.

(c) The Warrant Agent will create a special reserve for the issuance of Ordinary Shares upon the exercise of Warrants.

(d) The Company further covenants and agrees that it will pay when due and payable any and all federal and state transfer taxes and charges which may be payable in respect of the original issuance or delivery of Warrant Certificates or certificates evidencing Ordinary Shares upon exercise of the Warrants. The Company shall not, however, be required to pay any tax or governmental charge which may be payable in respect of any transfer involved in the transfer or delivery of Warrant Certificates or the issuance or delivery of certificates for Ordinary Shares in a name other than that of the Holder of the Warrants evidenced by the Warrant Certificate surrendered for exercise or to issue or deliver any certificate for Ordinary Shares upon the exercise of any Warrants until any such tax or governmental charge shall have been paid (any such tax or governmental charge being payable by the Holder of such Warrants at the time of surrender) or until it has been established to the Company's reasonable satisfaction that no such tax or governmental charge is due.

Section 10. *Ordinary Shares Record Date*. Each Person in whose name any certificate for Ordinary Shares is issued (or whose broker's account is credited with Ordinary Shares through the DWAC system) upon the exercise of Warrants shall for all purposes be deemed to have become the holder of record for the Ordinary Shares represented thereby on, and such certificate shall be dated (i) in the case of any exercise other than a Cashless Exercise, the date of delivery of the Notice of Exercise in accordance with Section 2(a) of the Warrant Certificate or (ii) in the case of a Cashless Exercise, the final day of the related Calculation Period (as such term is defined in the Warrant Certificate), as applicable; *provided*, *however*, that payment to the Company of the aggregate Exercise Price (other than in the case of a Cashless Exercise) and any applicable transfer taxes shall have been timely made prior to the issuance of such Ordinary Shares; *provided*, *further*, that if the date of such payment and submission, or such final day of the Calculation Period, as the case may be, is a date upon which the Ordinary Share transfer books of the Company are closed, such Person shall be deemed to have become the record holder of such shares on, and such certificate shall be dated, the next succeeding day on which the Ordinary Share transfer books of the Company are open.

Section 11. *Adjustment of Exercise Price or Number of Ordinary Shares*. The Exercise Price and the number of Ordinary Shares covered by each Warrant are subject to adjustment from time to time as provided in Section 3 of the Warrant Certificate. In the event that at any time, as a result of an adjustment made pursuant to Section 3 of the Warrant Certificate, the Holder of any Warrant thereafter exercised shall become entitled to receive any shares of capital stock of the Company other than Ordinary Shares, thereafter the number of such other shares so receivable upon exercise of any Warrant shall be subject to adjustment from time to time in a manner and on terms as nearly equivalent as practicable to the provisions with respect to the Ordinary Shares contained in Section 3 of the Warrant Certificate, and the provisions of Sections 7, 9(b) through (d) and 13 of this Agreement with respect to the Ordinary Shares shall apply on like terms to any such other shares. All Warrants originally issued by the Company subsequent to any adjustment made to the Exercise Price pursuant to the Warrant Certificate shall evidence the right to purchase, at the adjusted Exercise Price, the number of Ordinary Shares purchasable from time to time hereunder upon exercise of the Warrants, all subject to further adjustment as provided herein.

Section 12. *Certification of Adjusted Exercise Price or Number of Ordinary Shares*. Whenever the Exercise Price or the number of Ordinary Shares issuable upon the exercise of each Warrant is adjusted as provided in Section 11 or 13, the Company shall (a) promptly prepare a certificate setting forth the Exercise Price and the number of Ordinary Shares covered by each Warrant, in each case, as so adjusted, and a brief statement of the facts accounting for such adjustment(s), (b) promptly file with the Warrant Agent and with each transfer agent for the Ordinary Shares a copy of such certificate and (c) instruct the Warrant Agent to send a brief summary thereof to each Holder of Warrants.

Section 13. *Fractional Interests*.

(a) The Company shall not issue fractions of Warrants or distribute Warrant Certificates which evidence fractional Warrants. Whenever any fractional Warrant would otherwise be required to be issued or distributed, the actual issuance or distribution shall reflect a rounding of such fraction to the nearest whole Warrant (rounded down).

(b) The Company shall not issue fractions of Ordinary Shares upon exercise of Warrants or distribute stock certificates which evidence fractional Ordinary Shares. Whenever any fraction of an Ordinary Share would otherwise be required to be issued or distributed, the actual issuance or distribution in respect thereof shall be made in accordance with Section 2(d)(v) of the Warrant Certificate.

Section 14. *Conditions of the Warrant Agent's Obligations*. The Warrant Agent accepts its obligations herein set forth upon the terms and conditions hereof, including the following, to all of which the Company agrees and to all of which the rights hereunder of the Holders from time to time of the Warrants shall be subject:

(a) *Compensation and Indemnification*. The Company agrees promptly to pay the Warrant Agent the compensation as separately agreed with the Warrant Agent for all services rendered by the Warrant Agent and to reimburse the Warrant Agent for reasonable and documented out-of-pocket expenses (including reasonable counsel fees) incurred without gross negligence, bad faith or willful misconduct by the Warrant Agent in connection with the services rendered hereunder by the Warrant Agent. The Company also agrees to indemnify the Warrant Agent for, and to hold it harmless against, any loss, liability or expense incurred without gross negligence, bad faith or willful misconduct on the part of the Warrant Agent, arising out of or in connection with its acting as Warrant Agent hereunder, including the reasonable and documented costs and expenses of defending against any claim of such liability.

(b) *Agent for the Company*. In acting under this Agreement and in connection with the Warrants, the Warrant Agent is acting solely as agent of the Company and does not assume any obligations or relationship of agency or trust for or with any of the Holders of Warrants or beneficial owners of Warrants.

(c) *Counsel*. The Warrant Agent may consult with counsel satisfactory to it, which may include counsel for the Company, and the written advice of such counsel shall be full and complete authorization and protection in respect of any action taken, suffered or omitted by it hereunder in good faith and in accordance with the advice of such counsel.

(d) *Documents*. The Warrant Agent shall be protected and shall incur no liability for or in respect of any action taken or omitted by it in reliance upon any Warrant Certificate, notice, direction, consent, certificate, affidavit, statement or other paper or document reasonably believed by it to be genuine and to have been presented or signed by the proper parties.

(e) *Certain Transactions*. The Warrant Agent, and its officers, directors and employees, may become the owner of, or acquire any interest in, Warrants, with the same rights that it or they would have if it were not the Warrant Agent hereunder, and, to the extent permitted by applicable law, it or they may engage or be interested in any financial or other transaction with the Company and may act on, or as depositary, trustee or agent for, any committee or body of Holders of Warrant Securities or other obligations of the Company as freely as if it were not the Warrant Agent hereunder. Nothing in this Agreement shall be deemed to prevent the Warrant Agent from acting as trustee under any indenture to which the Company is a party.

(f) *No Liability for Interest*. Unless otherwise agreed with the Company, the Warrant Agent shall have no liability for interest on any monies at any time received by it pursuant to any of the provisions of this Agreement or of the Warrant Certificates.

(g) *No Liability for Invalidity*. The Warrant Agent shall have no liability with respect to any invalidity of this Agreement or any of the Warrant Certificates (except as to the Warrant Agent's countersignature thereon).

(h) *No Responsibility for Representations*. The Warrant Agent shall not be responsible for any of the recitals or representations herein or in the Warrant Certificates (except as to the Warrant Agent's countersignature thereon), all of which are made solely by the Company.

(i) *No Implied Obligations*. The Warrant Agent shall be obligated to perform only such duties as are herein and in the Warrant Certificates specifically set forth and no implied duties or obligations shall be read into this Agreement or the Warrant Certificates against the Warrant Agent. The Warrant Agent shall not be under any obligation to take any action hereunder which may tend to involve it in any expense or liability, the payment of which within a reasonable time is not, in its reasonable opinion, assured to it. The Warrant Agent shall not be accountable or under any duty or responsibility for the use by the Company of any of the Warrant Certificates authenticated by the Warrant Agent and delivered by it to the Company pursuant to this Agreement or for the application by the Company of the proceeds of the Warrants. The Warrant Agent shall have no duty or responsibility in case of any default by the Company in the performance of its covenants or agreements contained herein or in the Warrant Certificates or in the case of the receipt of any written demand from a Holder of a Warrant with respect to such default, including, without limiting the generality of the foregoing, any duty or responsibility to initiate or attempt to initiate any proceedings at law.

Section 15. *Purchase or Consolidation or Change of Name of Warrant Agent*. Any corporation into which the Warrant Agent or any successor Warrant Agent may be merged or with which it may be consolidated, or any corporation resulting from any merger or consolidation to which the Warrant Agent or any successor Warrant Agent shall be party, or any corporation succeeding to the corporate trust business of the Warrant Agent or any successor Warrant Agent, shall be the successor to the Warrant Agent under this Agreement without the execution or filing of any paper or any further act on the part of any of the parties hereto, *provided* that such corporation would be eligible for appointment as a successor Warrant Agent under the provisions of Section 17. In case at the time such successor Warrant Agent shall succeed to the agency created by this Agreement any of the Warrant Certificates shall have been countersigned but not delivered, any such successor Warrant Agent may adopt the countersignature of the predecessor Warrant Agent and deliver such Warrant Certificates so countersigned; and in case at that time any of the Warrant Certificates shall not have been countersigned, any successor Warrant Agent may countersign such Warrant Certificates either in the name of the predecessor Warrant Agent or in the name of the successor Warrant Agent; and in all such cases such Warrant Certificates shall have the full force provided in the Warrant Certificates and in this Agreement.

In case at any time the name of the Warrant Agent shall be changed and at such time any of the Warrant Certificates shall have been countersigned but not delivered, the Warrant Agent may adopt the countersignature under its prior name and deliver Warrant Certificates so countersigned; and in case at that time any of the Warrant Certificates shall not have been countersigned, the Warrant Agent may countersign such Warrant Certificates either in its prior name or in its changed name; and in all such cases such Warrant Certificates shall have the full force provided in the Warrant Certificates and in this Agreement.

Section 16. *Duties of Warrant Agent*. The Warrant Agent undertakes the duties and obligations imposed by this Agreement upon the following terms and conditions, by all of which the Company, by its acceptance hereof, shall be bound:

(a) The Warrant Agent may consult with legal counsel reasonably acceptable to the Company (who may be legal counsel for the Company), and the opinion of such counsel shall be full and complete authorization and protection to the Warrant Agent as to any action taken or omitted by it in good faith and in accordance with such opinion.

(b) Whenever in the performance of its duties under this Agreement the Warrant Agent shall deem it necessary or desirable that any fact or matter be proved or established by the Company prior to taking or suffering any action hereunder, such fact or matter (unless other evidence in respect thereof be herein specifically prescribed) may be deemed to be conclusively proved and established by a certificate signed by the Chief Executive Officer, Chief Financial Officer, Treasurer, Secretary or any President or Vice President of the Company; and such certificate shall be full authentication to the Warrant Agent for any action taken or suffered in good faith by it under the provisions of this Agreement in reliance upon such certificate.

(c) Subject to the limitation set forth in Section 14, the Warrant Agent shall be liable hereunder only for its own gross negligence, bad faith or willful misconduct, or for a breach by it of this Agreement.

(d) The Warrant Agent shall not be liable for or by reason of any of the statements of fact or recitals contained in this Agreement or in the Warrant Certificates (except its countersignature thereof) by the Company or be required to verify the same, but all such statements and recitals are and shall be deemed to have been made by the Company only.

(e) The Warrant Agent shall not be under any responsibility in respect of the validity of this Agreement or the execution and delivery hereof (except the due execution and delivery hereof by the Warrant Agent) or in respect of the validity or execution of any Warrant Certificate (except its countersignature thereof); nor shall it be responsible for any breach by the Company of any covenant or condition contained in this Agreement or in any Warrant Certificate; nor shall it be responsible for the adjustment of the Exercise Price (other than, for the avoidance of doubt, providing notice to Holders as provided in Section 12(c)) or the making of any change in the number of Ordinary Shares required under the provisions of Section 11 or 13 or responsible for the manner, method or amount of any such change or the ascertaining of the existence of facts that would require any such adjustment or change (except with respect to the exercise of Warrants evidenced by Warrant Certificates after actual notice of any adjustment of the Exercise Price); nor shall it by any act hereunder be deemed to make any representation or warranty as to the authorization or reservation of any Ordinary Shares to be issued pursuant to this Agreement or any Warrant Certificate or as to whether any Ordinary Shares will, when issued, be duly authorized, validly issued, fully paid and nonassessable.

(f) Each party hereto agrees that it will perform, execute, acknowledge and deliver or cause to be performed, executed, acknowledged and delivered all such further and other acts, instruments and assurances as may reasonably be required by the other party hereto for the carrying out or performing by any party of the provisions of this Agreement.

(g) The Warrant Agent is hereby authorized to accept instructions with respect to the performance of its duties hereunder from the Chief Executive Officer, Chief Financial Officer, Treasurer, Secretary or any President or Vice President of the Company, and to apply to such officers for advice or instructions in connection with its duties, and it shall not be liable and shall be indemnified and held harmless for any action taken or suffered to be taken by it in good faith in accordance with instructions of any such officer, provided Warrant Agent carries out such instructions without gross negligence, bad faith or willful misconduct.

(h) The Warrant Agent and any shareholder, director, officer or employee of the Warrant Agent may buy, sell or deal in any of the Warrants or other securities of the Company or become pecuniarily interested in any transaction in which the Company may be interested, or contract with or lend money to the Company or otherwise act as fully and freely as though it were not Warrant Agent under this Agreement. Nothing herein shall preclude the Warrant Agent from acting in any other capacity for the Company or for any other legal entity.

(i) The Warrant Agent may execute and exercise any of the rights or powers hereby vested in it or perform any duty hereunder either itself or by or through its attorney or agents, and the Warrant Agent shall not be answerable or accountable for any act, default, neglect or misconduct of any such attorney or agents or for any loss to the Company resulting from any such act, default, neglect or misconduct, provided reasonable care was exercised in the selection and continued employment thereof.

Section 17. *Change of Warrant Agent*. The Warrant Agent may resign and be discharged from its duties under this Agreement upon 30 days' notice in writing sent to the Company and to each transfer agent for the Ordinary Shares, and to the Holders of the Warrants. The Company may remove the Warrant Agent or any successor Warrant Agent upon 30 days' notice in writing, sent to the Warrant Agent or successor Warrant Agent, as the case may be, and to each transfer agent for the Ordinary Shares, and to the Holders of the Warrants. If the Warrant Agent shall resign or be removed or shall otherwise become incapable of acting, the Company shall appoint a successor to the Warrant Agent. If the Company shall fail to make such appointment within a period of 30 days after such removal or after it has been notified in writing of such resignation or incapacity by the resigning or incapacitated Warrant Agent or by a Holder of Warrants (which shall, with such notice, submit its Warrant Certificate for inspection by the Company), then the Holder of any Warrants may apply to any court of competent jurisdiction for the appointment of a new Warrant Agent, *provided* that, for purposes of this Agreement, the Company shall be deemed to be the Warrant Agent until a new warrant agent is appointed. Any successor Warrant Agent, whether appointed by the Company or by such a court, shall be a corporation organized and doing business under the laws of the United States or of a state thereof, in good standing, which is authorized under such laws to exercise corporate trust powers and is subject to supervision or examination by federal or state authority and which has at the time of its appointment as Warrant Agent a combined capital and surplus of at least $50,000,000. After appointment, the successor Warrant Agent shall be vested with the same powers, rights, duties and responsibilities as if it had been originally named as Warrant Agent without further act or deed; but the predecessor Warrant Agent shall deliver and transfer to the successor Warrant Agent any property at the time held by it hereunder, and execute and deliver any further assurance, conveyance, act or deed necessary for the purpose. Not later than the effective date of any such appointment, the Company shall file notice thereof in writing with the predecessor Warrant Agent and each transfer agent for the Ordinary Shares, and mail a notice thereof in writing to the Holders of the Warrants. However, failure to give any notice provided for in this Section 17, or any defect therein, shall not affect the legality or validity of the resignation or removal of the Warrant Agent or the appointment of the successor Warrant Agent, as the case may be.

Section 18. *Issuance of New Warrant Certificates*. Notwithstanding any of the provisions of this Agreement or of the Warrants to the contrary, the Company may, at its option, issue new Warrant Certificates evidencing Warrants in such form as may be approved by its Board of Directors to reflect any adjustment or change in the Exercise Price per share and the number or kind or class of shares of stock or other securities or property purchasable under the several Warrant Certificates made in accordance with the provisions of this Agreement, the Warrants and the Warrant Certificates.

Section 19. *Notices*. Notices or demands authorized by this Agreement to be given or made (i) by the Warrant Agent or by the Holder of any Warrants to or on the Company, (ii) subject to the provisions of Section 17, by the Company or by the Holder of any Warrants to or on the Warrant Agent or (iii) by the Company or the Warrant Agent to the Holder of any Warrants, shall be deemed given (a) upon receipt, if delivered personally; (b) when sent, if sent by facsimile (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party); (c) when sent, if sent by e-mail (provided that such sent e-mail is kept on file (whether electronically or otherwise) by the sending party and the sending party does not receive an automatically generated message from the recipient's e-mail server that such e-mail could not be delivered to such recipient) and (d) if sent by overnight courier service, one (1) Business Day after deposit with an overnight courier service with next day delivery specified, in each case, properly addressed to the party to receive the same. If notice is given by facsimile or email, a copy of such notice shall be dispatched no later than the next Business Day by first class mail, postage prepaid. The addresses, facsimile numbers and e-mail addresses for such communications shall be:

(a) If to the Company, to its agent for service:

Cogency Global Inc.
10 E 40th Street, 40th Floor
New York, New York 10016
Reference: Entera Bio Ltd.

With a copy to:

Email: Notice@enterabio.com

And with a copy (for informational purposes only) to:

Michael P. Kaplan, Esq.
Sophia Hudson, Esq.
Davis Polk & Wardwell LLP
450 Lexington Avenue
New York, New York 10017
(212) 450-4000

and

Yair Geva, Adv.
Ron Ben Menachem, Adv.
Tomer Farkash, Adv.
Herzog Fox & Neeman
4 Weizmann Street
Tel Aviv 6423904, Israel
+972 (3) 692-2020

(b) If to the Warrant Agent, to:

American Stock Transfer & Trust Company, LLC
6201 15th Avenue
Brooklyn, New York 11219
Email: [_______]

(c) If to the Holder of any Warrants, to the address of such Holder as shown on the registry books of the Company. Any notice required to be delivered by the Company to the Holder of any Warrant may be given by the Warrant Agent on behalf of the Company. Notwithstanding any other provision of this Agreement, where this Agreement provides for notice of any event to a Holder of any Global Warrant, such notice shall be sufficiently given if given to the Depositary (or its designee) pursuant to the procedures of the Depositary or its designee.

Or, in each of the above instances, to such other address, facsimile number or e-mail address and/or to the attention of such other Person as the recipient party has specified by written notice given to each other party at least five (5) days prior to the effectiveness of such change.

Section 20. *Supplements and Amendments*.

(a) The Company and the Warrant Agent may from time to time supplement or amend this Agreement without the approval of any Holders of Warrants in order to add to the covenants and agreements of the Company for the benefit of the Holders of the Warrants or to surrender any rights or power reserved to or conferred upon the Company in this Agreement, *provided* that such addition or surrender shall not adversely affect the interests of the Holders of the Warrants in any material respect.

(b) In addition to the foregoing, with the consent of Holders of Warrants entitled, upon exercise thereof, to receive not less than a majority of the Ordinary Shares issuable thereunder, the Company and the Warrant Agent may modify this Agreement for the purpose of adding any provisions to or changing in any manner or eliminating any of the provisions of this Agreement or modifying in any manner the rights of the Holders of the Warrants; *provided*, *however*, that no modification of the terms (including but not limited to the adjustments described in Section 11) upon which the Warrants are exercisable or reducing the percentage required for consent to modification of this Agreement may be made without the consent of the Holder of each outstanding Warrant affected thereby. As a condition precedent to the Warrant Agent's execution of any amendment, the Company shall deliver to the Warrant Agent a certificate from a duly authorized officer of the Company that states that the proposed amendment complies with the terms of this Section 20.

Section 21. *Successors*. All covenants and provisions of this Agreement by or for the benefit of the Company or the Warrant Agent shall bind and inure to the benefit of their respective successors and assigns hereunder.

Section 22. *Benefits of this Agreement*. Nothing in this Agreement shall be construed to give any Person other than the Company, the Holders of Warrants and the Warrant Agent any legal or equitable right, remedy or claim under this Agreement. This Agreement shall be for the sole and exclusive benefit of the Company, the Warrant Agent and the Holders of the Warrants.

Section 23. *Governing Law*. This Agreement and each Warrant Certificate issued hereunder shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to the conflicts of law principles thereof.

Section 24. *Counterparts*. This Agreement may be executed in any number of counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

Section 25. *Captions*. The captions of the sections of this Agreement have been inserted for convenience only and shall not control or affect the meaning or construction of any of the provisions hereof.

Section 26. *Information*. The Company agrees to promptly provide to the Holders of the Warrants any information it provides to the holders of the Ordinary Shares, except to the extent any such information is publicly available on the EDGAR system (or any successor thereof) of the Securities and Exchange Commission.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

ENTERA BIO LTD.

By: ______________________________

Name:
Title:

AMERICAN STOCK TRANSFER & TRUST COMPANY, LLC

By: ______________________________

Name:
Title:

Annex A: Form of Warrant Certificate Request Notice

WARRANT CERTIFICATE REQUEST NOTICE

To: American Stock Transfer & Trust Company, LLC, as Warrant Agent for Entera Bio Ltd. (the "**Company**")

The undersigned Holder of Ordinary Share Purchase Warrants ("**Warrants**") in the form of Global Warrants issued by the Company hereby elects to receive a Warrant Certificate evidencing the Warrants held by the Holder as specified below:

1. Name of Holder of Warrants in form of Global Warrants: ______________________

2. Name of Holder in Warrant Certificate (if different from name of Holder of Warrants in form of Global Warrants): ________________________________

3. Number of Warrants in name of Holder in form of Global Warrants: _____________

4. Number of Warrants for which Warrant Certificate shall be issued: _______________

5. Number of Warrants in name of Holder in form of Global Warrants after issuance of Warrant Certificate, if any: ___________

6. Warrant Certificate shall be delivered to the following address:

____

____

____

____

The undersigned hereby acknowledges and agrees that, in connection with this Warrant Exchange and the issuance of the Warrant Certificate, the Holder is deemed to have surrendered the number of Warrants in form of Global Warrants in the name of the Holder equal to the number of Warrants evidenced by the Warrant Certificate.

[SIGNATURE OF HOLDER]

Name of Investing Entity: ____

Signature of Authorized Signatory of Investing Entity: ___________________________

Name of Authorized Signatory: ____

Title of Authorized Signatory: ____

Date: ____

Exhibit 1: Form of Warrant Certificate

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Amendment No. 5 to the Registration Statement on Form F-1 of Entera Bio Ltd. of our report dated March 30, 2018 relating to the financial statements of Entera Bio Ltd., which appears in this Registration Statement. We also consent to the reference to us under the heading “Experts" in such Registration Statement.

Tel-Aviv, Israel
June 15, 2018

/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