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

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2018

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from ___ to ___ .

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Date of event requiring this shell company report ___

Commission file number: 001-38556

ENTERA BIO LTD.

(Exact name of Registrant as specified in its charter)

State of Israel
(Jurisdiction of incorporation or organization)

Kiryat Hadassah
Minrav Building - Fifth Floor
Jerusalem, Israel
Tel: +972-2-532-7151
(Address of principal executive offices)

Dr. Phillip Schwartz, Chief Executive Officer
Kiryat Hadassah
Minrav Building - Fifth Floor
Jerusalem, Israel
Tel: +972-2-532-7151
(Name, Telephone E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Ordinary Shares, par value of NIS 0.0000769	NASDAQ Capital Market
Warrants, each warrant exercisable for 0.5 shares of Ordinary Shares at an exercise price of $8.4 per Ordinary Share.	NASDAQ Capital Market

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

11,459,780 Ordinary Shares, par value NIS 0.0000769 per share.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company (as defined in Rule 12b-2 of the Act).

Large Accelerated Filer ☐	Accelerated Filer ☐	Non-Accelerated Filer ☒ Emerging growth company ☒

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐	International Financial Reporting Standards as issued by the International Accounting Standards Board ☒	Other ☐

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

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DEFINITIONS

Unless otherwise indicated, all references to the "Company," "we," "us," "our" and "Entera" refer to Entera Bio Ltd. and its wholly owned subsidiary, Entera Bio Inc., a Delaware corporation, unless the context otherwise requires.

References to the "Companies Law" are to Israel's Companies Law, 5759-1999, as currently amended;

References to the "Exchange Act" are to the Securities Exchange Act of 1934, as amended;

References to the "FDA" are to the United States Food and Drug Administration;

References to "Nasdaq" are to the Nasdaq Capital Market;

References to "Ordinary Shares" are to our ordinary shares, par value of NIS 0.0000769 per share;

References to "Warrants" are to our warrants listed on the Nasdaq under the symbol ENTXW;

References to the "SEC" are to the United States Securities and Exchange Commission;

References to the "Securities Act" are to the Securities Act of 1933, as amended; and

References to "U.S. dollars" and "$" are to currency of the United States of America, "euro" or "€" are to the Euro, the legal currency of certain countries of the European Union and references to "NIS" are to new Israeli shekels.

We do not endorse or adopt any third-party research or forecast firms' statements or reports referred to in this annual report and assume no responsibility for the contents or opinions represented in such statements or reports, nor for the updating of any information contained therein.

PRESENTATION OF FINANCIAL INFORMATION

We report under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or 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 annual report. 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, or the Functional Currency. Our financial statements and other financial information included in this annual report are presented in U.S. dollars unless otherwise noted. See Note 2 of our audited consolidated financial statements for the year ended December 31, 2018, included elsewhere in this annual report.

USE OF TRADEMARKS

"Entera Bio," "Enterabio," "Entera," the EnteraBio logo and other trademarks, trade names or service marks of Entera appearing in this annual report are the property of Entera. This Form 20-F also contains trade names, trademarks and service marks of others, which are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies. Solely for the convenience of the reader, we only use the ® symbol the first time any federal or trade name is mentioned. Each trademark or tradename of any other company appears in this annual report, to our knowledge, owned by such company.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains expressed or implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. Such forward-looking statements 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. In addition, historic results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not be different, and historic results referred to in this annual report may be interpreted differently in light of additional research and clinical and preclinical trials results. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terminology such as “may,” “believe,” “expect,” “anticipate,” “predict,” “estimate,” “intend,” “plan,” “potential,” “targets,” “likely,” “will,” “would,” “could,” “should,” “continue,” and similar expressions or phrases, or the negative of these terms or other comparable terminology. 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 regarding the following matters:

- our estimates and expectations regarding anticipated expenses, capital requirements and needs for additional financing;
- our expectations regarding licensing, business transactions and strategic operations;
- 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;
- the commercial launch of current or future product candidates, and the timing, cost or other aspects of the commercialization of our product candidates;
- our expectations regarding the commercial supply of our product candidates;
- our ability to manage our relationships with licensing agreement partners for the future development of our product candidates;
- our ability to receive FDA approval of, or other regulatory action in the U.S. and elsewhere with respect to our product candidates, 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 interpretation of comments made by the FDA and how this may impact our clinical development plans;
- our competitive position, especially with respect to Natpara, our key competitor for hypoparathyroidism treatment;
- 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;
- the patient market size of any diseases and market adoption of our products by physicians and patients;
- 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 ability to manage growth; and
- other risk factors discussed under “Item 3.D.–Risk Factors.”

All forward-looking statements involve known and unknown 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. The forward-looking statements contained in this annual report are subject to risks and uncertainties, including those discussed under "Item–3.D. Risk Factors" and "Item 5. –Operating and Financial Review and Prospects" and in our other filings with the SEC. 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 annual report are based on information available to us on the date of this annual report. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we are under no duty, and expressly disclaim any obligation, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this annual report.

PART ONE

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

3.A. Selected Financial Data

Our historical consolidated financial statements are prepared in accordance with IFRS and are presented in U.S. dollars. The selected historical consolidated financial information for the years ended December 31, 2018, 2017 and 2016 and the selected statements of financial position data as of December 31, 2018 and 2017 have been derived from, and should be read in conjunction with, the audited consolidated financial statements of Entera Bio Ltd. and notes thereto appearing elsewhere in this annual report. The selected historical consolidated financial information as of December 31, 2016 has been derived from our audited consolidated financial statements not included in this annual report.

The information presented below is qualified by the more detailed historical consolidated financial statements set forth in this annual report, and should be read in conjunction with those consolidated financial statements, the notes thereto and the discussion under "Item 5.–Operating and Financial Review and Prospects"–included elsewhere in this annual report.

We have not included selected historical consolidated financial data for the years ended December 31, 2015 and 2014 in the table below as we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act ("Emerging Growth Company"), and we make use of an accommodation for reduced reporting.

Consolidated Statements of Comprehensive Loss Data

	Year Ended December 31,		
	2018	2017	2016
	(In thousands, except shares and per share data)		
Consolidated statements of comprehensive loss:			
Revenue	500	-	-
Research and development expenses, net	$ 8,518	$ 2,768	$ 2,648
General and administrative expenses	2,843	8,575	2,719
Total operating loss	10,861	11,343	5,367
Financial income:			
Income from change in fair value of financial liabilities at fair value through profit or loss	(523)	(251)	(4,311)
Other financial expenses (income), net	(34)	105	143
Financial income, net	(557)	(146)	(4,168)
Net comprehensive loss	$ 10,304	$ 11,197	$ 1,199
Loss per ordinary share(1)			
Basic	$ 1.30	$ 2.49	$ 0.27
Diluted	$ 1.31	$ 2.49	$ 0.78
Weighted average number of Ordinary Shares used in computing basic loss per ordinary share[(1)]	7,955,447	4,490,720	4,473,170
Weighted average number of Ordinary Shares used in computing diluted loss per ordinary share[(1)]	7,983,402	4,490,720	6, 756,360

(1) Basic and diluted loss per ordinary share and basic and diluted weighted average number of Ordinary Shares in 2017 and 2016 were retroactively adjusted due to Ordinary Shares split of 1 for 130. 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 14 of our consolidated financial statements for the year ended December 31, 2018, included elsewhere in this annual report for further details on the calculation of basic and diluted loss per ordinary share.

Consolidated Statements of Financial Position Data:

	As of December 31,		
	2018	2017	2016
		(In thousands)	
Consolidated statements of financial position data:			
Cash and cash equivalents	7,506	11,746	4,163
Short-term bank deposits	4,015	-	-
Restricted deposits	-	-	1,075
Accounts receivable	725	-	-
Other current assets	220	671	195
Total current assets	12,466	12,417	5,433
Property and equipment	224	207	199
Intangible assets	651	654	654
Total assets	$ 13,341	$ 13,278	$ 6,286
Accounts payable-Trade and other	1,563	2,020	657
Contract liabilities	225	-	-
Convertible Loans	-	-	9,885
Total current liabilities	1,788	2,020	10,542
Convertible loans	-	3,893	4,835
Preferred shares	-	33,455	11,031
Warrants to purchase Ordinary Shares and preferred shares	1,372	5,398	4,800
Liability to issue preferred shares and warrants	-	-	273
Severance pay obligations, net	65	70	51
Total non-current liabilities	1,437	42,816	20,990
Total liabilities	$ 3,225	$ 44,836	$ 31,532
Shareholders' equity (Capital deficiency)	$ 10,116	$ (31,558)	$ (25,246)
Working capital[(1)]	$ 10,678	$ 10,397	$ (5,109)

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

3.B. Capitalization and Indebtedness

Not applicable.

3.C. Reasons For the Offer and Use of Proceeds

Not applicable.

3.D. Risk Factors

Any investment in our securities involves a high degree of risk. You should consider carefully the following factors and all other information contained in this annual report before you make a decision to invest in our Ordinary Shares and Warrants. If any of the negative events referred to below occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. In any such case, the trading price of our Ordinary Shares could decline, and you could lose all or part of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

Management has performed an analysis of our ability to continue as a going concern. In addition, our independent registered public accounting firm has raised substantial doubt as to our ability to continue as a going concern.

Based on its assessment, management has raised substantial doubt about our ability to continue as a going concern. In addition, our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern in their report accompanying our audited consolidated financial statements. As of March 15, 2019, we had cash and cash equivalents of approximately $9.6 million. Our ability to continue as a going concern will depend on our ability to obtain additional financing. Management is in the process of evaluating various financing alternatives in the public or private equity markets, debt financings, government grants or through license of the company's technology to additional external parties through partnerships or research collaborations as the Company will need to finance future research and development activities and general and administrative expenses through fund raising. A going concern opinion could impair our ability to finance our operations through public or private equity offerings or debt financings, or a combination of one or more of these funding sources. Any additional equity or debt financing could be extremely dilutive to our current shareholders. Additional capital may not be available on reasonable terms, or at all, and we may be required to terminate or significantly curtail our operations, or enter into arrangements with collaborative partners or others that may require us to relinquish rights to certain aspects of our product candidates, or potential markets that we would not otherwise relinquish. If we are unable to obtain capital, our business, including our ability to conduct studies and develop our product candidates, including a planned completion of a phase 2 study in PTH I-34, would be jeopardized and we may not be able to continue operations.

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 significant 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 $11.3 million and $10.9 million for the years ended December 31, 2017 and 2018. As of December 31, 2018, we have an accumulated deficit of $52.1 million. As a result of our recurring losses from operations and negative cash flows, management has concerns about our ability to continue as a going concern and our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of, and for the year ended, December 31, 2018, expressing substantial doubt about our ability to continue as a going concern.

Our audited consolidated financial statements for the year ended December 31, 2018 included elsewhere in this annual report, 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. Additionally, in July 2018 we completed our initial public offering and raised an additional $11.2 million ($9.6 million net of offering expenses). In order to fund further operations, we will need to raise additional capital. 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 revenues from sales of products 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. 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 would lose all or a part of their investment.

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.

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.

We estimate that our existing cash and cash equivalents will not enable us to fund our research and development expenses, general and administrative expenses and working capital requirements for the next 12 months. 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 EB613 dose-ranging study, our several nonclinical safety assessment studies and our Phase 3 study comparing Oral PTH with Forteo® over a 12-month treatment period, 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 current 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 entered or 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, and these financings, or disputes with pre-IPO shareholders or 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. We will need to raise additional capital. 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.

Shareholders who invested prior to the Company's initial public offering or lenders which indebtedness converted upon consummation of the IPO into our Ordinary Shares, 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.

As a public company, we are required to comply with various regulatory and reporting requirements, including those required by the SEC. Complying with these reporting and regulatory requirements are 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 are subject to the reporting requirements of 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 are implementing procedures and processes for the purpose of addressing the standards and requirements applicable to public companies. Complying with these requirements is costly and time consuming. In the event that we are unable to demonstrate compliance with our obligations as a public company in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or Nasdaq, and investors may lose confidence in our operating results and the price of our Ordinary Shares could decline. 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, 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 our initial public offering, specifically, December 31, 2023; (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, or Large Accelerated Filer, under the Exchange Act with at least $700 million of equity securities held by non-affiliates. We cannot predict or estimate the amount of additional costs we may incur as a result of no longer being an Emerging Growth Company or the timing of such costs.

Our Ordinary Shares and Warrants are listed on Nasdaq. As a public company listed on Nasdaq, we incur significant legal, accounting and other expenses that we did not incur prior to the listing of our Ordinary Shares on Nasdaq.

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. Being a publicly traded company in the United States and being subject to U.S. rules and regulations makes 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 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. 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 Nasdaq rules and in accordance with the applicable transition rules, we have appointed additional independent directors, which may result in a change in the company's direction over time, as discussed in further detail in "Item 6.C.—Board practices—Board of Directors."

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

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 FDA, European Union, or EU, and EU Member State legislators and agencies, such as the European Medicines Agency, or EMA, and other non-U.S. regulatory authorities, which enforce regulations that differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval of a biologics license application, or BLA, from the FDA or in any other country until we receive marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in drug development. We have not submitted a marketing 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 EB613, our oral human PTH (1-34) tablet (oral PTH), is under development for the treatment of Osteoporosis. We are also developing EB612, an additional oral PTH (1-34) product candidate, with significant modifications to dose and potentially to formulation, for the treatment of hypoparathyroidism. Each of our oral PTH product candidates, including EB613 and EB612, 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 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 investigators or 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 Osteoporosis, there is no guarantee that we will successfully develop and commercialize it for other indications, including hypoparathyroidism and delayed union 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.

For our EB613 product candidate in osteoporosis, a Pre-IND meeting with the FDA was held in November 2018. Following FDA guidance on our proposed preclinical and clinical development plans, we intend to further develop EB613 and conduct the required nonclinical studies and clinical trials in order to attain regulatory approval. In addition, upon the completion and evaluation of our pharmacokinetic/pharmacodynamic, or PK/PD, clinical trial in EB612 for the treatment of hypoparathyroidism 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. We also plan in the future, inter alia, to conduct clinical trials of a formulation of oral PTH for the treatment of delayed union of fracture.

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 who withdraw from the study, resulting in incomplete data;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- varying interpretations of data by the FDA and foreign regulatory agencies; and
- inaccurate interpretations by us of the FDA's guidance for the clinical and regulatory path.

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 (for trials in the US), other regulatory authorities (for trials conducted outside the U.S.), the IRB /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 are 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 the investigator's conduct 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 non-clinical 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 non-clinical 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 obtain 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 non-clinical 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 casually-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 an adequate number of volunteers or 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 enough volunteers in early studies, or patients with a specific disease in later trials. 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 in the US 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 EB613, we may be unsuccessful in leveraging our oral drug delivery technology for use with other APIs. In addition, we may significantly modify the formulation of oral PTH to develop new formulations for applications in hypoparathyroidism 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 produced by the parathyroid glands. 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 product 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 be recognized either during clinical development or, if such side effects are 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 non-clinical 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 based on non-clinical studies.

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 EB613 and EB612 for the treatment of osteoporosis and hypoparathyroidism, 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 current or 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.

The results of the United Kingdom's referendum on withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business.

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the EU, commonly referred to as Brexit. On March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The U.K.'s withdrawal is currently scheduled to take place on March 29, 2019, unless an extension is agreed to; however, ongoing uncertainty remains as to what kind of post-Brexit agreement between the U.K. and the EU, if any, may be approved by the U.K. parliament. Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, the withdrawal of the United Kingdom from the EU could materially impact the regulatory regime with respect to our activities in the United Kingdom and could affect our activities in other countries. Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the UK from the EU would have and how such withdrawal would affect our activities.

European data collection is governed by restrictive regulations governing the collection, use, processing and cross-border transfer of personal information.

We may collect, process, use or transfer personal information from individuals located in the European Union in connection with our business, including in connection with conducting clinical trials in the European Union. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the European Union. The collection and use of personal health data in the European Union is governed by the provisions of the General Data Protection Regulation ((EU) 2016/679), or the GDPR. This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside of the European Economic Area, including to the United States, and other countries providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Union may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

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 non-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 non-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 agree that a synthesized molecule like the synthesized PTH molecule that is used in our oral PTH formulation, has the same biological activity as recombinant PTH (1-34) utilized by Eli Lilly in its Forteo product;
- the data collected from non-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 non-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, or REMS, 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 in hypoparathyroidism. 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 of absorption of 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 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 may 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, specifically human PTH (1-34), 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 oral PTH product candidates for the treatment of other diseases. 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 (recently acquired by Takeda Pharmaceutical Company Ltd.), whose product Natpara, an injectable bioengineered recombinant form of PTH (1-84), was approved by the FDA in January 2015, and conditionally approved by the EMA in April 2017. 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, 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. 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 payers. 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 payers 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 payers.

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 ACA, 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 ACA 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 2027, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, 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.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal and replace certain aspects of the ACA, and we expect such challenges to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been enacted. The Tax Cuts and Jobs Act of 2017, or 2017 Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans. In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation, regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a federal judge in Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the 2017 Tax Act. While the judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA, will impact our business.

Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products. There have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. The Trump administration's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients.

Additionally, in May 2018, the Trump administration released a blueprint to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in August 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019. In October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors, which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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 payers 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 payers 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 ACA 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 payer, 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 "Item 3.D. —Risk Factors—Risks Related to Regulatory Approval of Our Product Candidates." In order to obtain FDA approval for EB612 prior to the expiration of Natpara's orphan drug exclusivity in 2022, we need to show that EB612 is clinically superior to Natpara 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. In addition, Ascendis Pharma has reported that it is developing a long-acting, oral prodrug formulation of PTH for the treatment of hypoparathyroidism. In February 2019, Ascendis reported that it had filled an IND application with the FDA for initiation of a global Phase 2 trial with their drug. Ascendis anticipates top line results in the fourth 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 payers 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 rare but potentially 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 payers to justify a higher price compared to generic products. In many cases, insurers or other third-party payers, 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 payers, 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 payers;
- 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 payers, 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 payers 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 payers 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 payers. To manage healthcare costs, many governments and third-party payers 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.

Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. In addition, third-party payers are likely to impose strict requirements for reimbursement in order to limit off-label use of a higher priced drug. Reimbursement by a third-party payer may depend upon a number of factors including the third-party payer's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Third party payers 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.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payer is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payer. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for our product candidates, if approved. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only to limited levels, we may not be able to commercialize our product candidates, profitably or at all, even if approved.

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. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our product candidates or products we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation, which may be only partially recoverable even in the event of successful defense;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues; and
- the inability to commercialize any products we develop.

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 have recently entered into a research collaboration and license agreement with Amgen Inc., or Amgen. Under the agreement, the parties will collaborate for the development and discovery of clinical candidates in the field of inflammatory disease and other serious illnesses. Further, under the terms of the agreement, we will engage in preclinical development at Amgen’s expense. Amgen will be responsible for research, clinical development, manufacturing and commercialization of any of the resulting programs, at its expense. We also 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, inter alia, 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 or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property. For example, Amgen has the first right to enforce or defend certain of our intellectual property rights under our research collaboration and license agreement, and although we may have the right to assume the enforcement and defense of such intellectual property rights if Amgen does not, our ability to do so may be compromised by Amgen's actions;

- Collaborators may own or co-own intellectual property covering our product candidates or research programs that results from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates or research programs;

- 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 may suffer from negative publicity and we may find it more difficult to attract new collaborators. For example, at any point in the research and development process, subject to certain conditions, Amgen can terminate our research collaboration and license agreement in its entirety or with respect to a specific development program.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elects not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations and company culture. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of such product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this annual report also apply to the activities of any of our future program collaborators.

Exclusivity and other governance provisions within our research collaboration and license agreement with Amgen may prevent us from pursuing certain alternative product candidates and exercising complete control over our product candidates' development.

During certain periods under our research collaboration and license agreement with Amgen, we may not, alone or with a third party, research, develop, manufacture or commercialize certain products primarily interacting with the targets of the applicable collaboration programs. Further, our collaboration with Amgen is governed by a joint research committee, or JRC, made up of equal representatives of us and Amgen. The JRC may establish additional subcommittees to oversee particular projects or activities. Subject to limitations specified in the agreement, if the JRC is unable to make a decision by consensus, the disagreement is to be resolved through escalation to specified senior executive officers of the parties, although Amgen has the final decision-making ability with respect to certain specified issues. These exclusivity and governance provisions may inhibit our development efforts and could have a material adverse effect on our business, prospects, financial condition and results of operations.

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.

If the third parties or consultants that assist us in conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we may not be able to obtain, or may be delayed in obtaining, regulatory approval for the product candidates being tested in such trials, and will not be able to, or may be delayed in our efforts to, successfully commercialize these product candidates.

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.

Our failure or the failure of our third party subcontractors and suppliers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates that we may develop.

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 that the supply is inadequate or delayed;

- the risk that the third party may enter the field and seek to compete and may no longer be willing to continue supplying;

- 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, Canada, Japan, New Zealand, China, Israel and Russia. Related patent applications are pending in the United States, the European Union, Hong Kong, Brazil, China and India. 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 be issued 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 additional 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.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our Ordinary Shares could be significantly harmed.

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 to 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. Litigation may be necessary to defend against these claims and, even if we are successful in defending ourselves, could result in substantial costs to us or be distracting to our management. If we do not succeed with respect to any such claims, in addition to paying monetary damages and possible ongoing royalties, we may lose valuable intellectual property rights or personnel. For example, as described above, 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.

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. Any unauthorized use of these trademarks could harm our reputation or commercial interests. In addition, our enforcement against third-party infringers or violators may be unduly expensive and time-consuming, and the outcome may be an inadequate remedy. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

Risks Related to Our Ordinary Shares, and Warrants

The price of our Ordinary Shares and Warrants may be volatile, and holders of our Ordinary Shares and Warrants could lose all or part of their investment

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. The market price of our Ordinary Shares and Warrants on Nasdaq may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated fluctuations in our and our competitors' results of operations and financial condition;
- 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;
- success or failure of our research and development projects or those of our competitors;
- our entering into or terminating strategic relationships;
- changes in laws or government regulation;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;
- 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;
- market acceptance of our products;
- the mix of products that we sell and related services that we provide;
- the success or failure of our licensees to develop, obtain approval for and commercialize our licensed products, for which we are entitled to contingent payments and royalties;
- publication of the results of preclinical or clinical trials for EB612, EB613 or our other product candidates;
- failure by us to achieve a publicly announced milestone;
- delays between our expenditures to develop and market new or enhanced products and the generation of sales from those products;
- changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;
- changes in our expenditures to promote our products;
- 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, including factors unrelated to our operating performance.

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.

We do not know whether a market for our Ordinary Shares or Warrants will be sustained and as a result, it may be difficult for holders of our Ordinary Shares to sell their shares.

Although our Ordinary Shares and Warrants are listed on Nasdaq, an active trading market for our Ordinary Shares and Warrants may not be sustained. The lack of an active market may impair the ability of holders of our Ordinary Shares or Warrants to sell their Ordinary Shares or Warrants at the time they wish to sell them or at a price that they consider reasonable. The lack of an active market may also reduce the value of our Ordinary Shares or Warrants, and may cause the trading price of our Ordinary Shares or Warrants to be more volatile. An inactive market may also impair our ability to raise capital by selling Ordinary Shares or Warrants and may impair our ability to acquire other companies by using our Ordinary Shares or Warrants as consideration**.**

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 or other factors as detailed above 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 "Outstanding Warrants–Tradable and Others–The Tradable 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 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 not be restricted from resale. 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.

The significant share ownership position of D.N.A Biomedical that beneficially owns approximately 34.7% of our Ordinary Shares may significantly influence the outcome of matters requiring shareholder approval.

D.N.A Biomedical Solutions Ltd., or D.N.A Biomedical, beneficially owns approximately 34.7% of our outstanding shares, as of December 31, 2018. 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. D.N.A Biomedical's interests may not be consistent with those of our other shareholders. In addition, this significant interest in us may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of our Ordinary Shares.

The market price of our Ordinary Shares and Warrants could be negatively affected by future sales of our securities.

If our shareholders, particularly our directors and their affiliates of our executive officers, that in aggregate, beneficially own approximately 41.8% of our Ordinary Shares as of March 15, 2019, sell substantial amounts of our Ordinary Shares or Warrants in the public market, 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. The perception in the public market that our shareholders might sell our Ordinary Shares or Warrants could also depress the market price of our Ordinary Shares or Warrants and could impair our future ability to obtain capital, especially through an offering of equity securities. In addition, our sale of additional Ordinary Shares or Warrants or other similar securities in order to raise capital might have a similar negative impact on the share price of our Ordinary Shares or Warrants. A decline in the price of our Ordinary Shares may impede our ability to raise capital through the issuance of additional Ordinary Shares, Warrants or other equity securities, and may cause holders of our Ordinary Shares or Warrants to lose part or all of their investment.

We have never paid, and we currently do not intend to pay dividends.

We have never declared or paid any cash dividends on our Ordinary Shares. 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. As a result, capital appreciation, if any, of our Ordinary Shares will be investors' sole source of gain for the foreseeable future. In addition, Israeli law may limit our declaration or payment of dividends, and may subject our dividends to Israeli withholding taxes.

We are currently a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are 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.

We 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 Nasdaq rules, we follow certain home country governance practices rather than the corporate governance requirements of Nasdaq.

As a foreign private issuer, we have the option to follow certain Israeli corporate governance practices rather than those of Nasdaq, 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, or Foreign Private Issuer Exemption, with respect to Nasdaq 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 Nasdaq 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 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, 2019, the end of our second fiscal quarter in our current fiscal year, 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, 2020. We will not maintain our current status as a foreign private issuer, if as of June 30, 2019 (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 Nasdaq 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, 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. investors.

We believe we were not a passive foreign investment company, or PFIC, for 2018, but there can be no assurance that we will not be a PFIC for the 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, 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 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 hold, and expect to continue to hold, a significant amount of cash, and (iii) a company's annual PFIC status can be determined only after the end of each taxable year, we cannot express a view as to whether we will be a PFIC for the current or any future taxable year. In addition, it is not clear how to apply the income test to a company such as our company, whose overall losses from research activities significantly exceed the amount of its income (including passive income). 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 "Item 10.E.—Taxation—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, 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 as 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 can qualify as an Emerging Growth Company for up to five years, although circumstances could cause us to lose that status earlier, including, inter alia, 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 following our initial public 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 depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have control over these analysts and we do not have commitments from them to write research reports about us. If securities or industry analysts do not commence coverage of our company, the trading price for our shares may 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 and the IIA regulations, 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 and the 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. For additional information, see "Item 4.B.—Business Overview—The Israeli Innovation Authority Grant."

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) in or outside of the State of Israel, except under limited circumstances and only with the approval of 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 transfer of such technology to a non-Israeli entity up to 600% of the grant amounts and the 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 that would make a non-Israeli citizen or resident an interested party, as defined in the Israeli Securities Law, 5728-1968, as amended, 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 and the interest. If we fail to satisfy the conditions of the Research Law, we may be required to refund grants previously received together with interest and penalties, to make other payments to the IIA or 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. In addition, part of our key employees, officers and directors are residents of 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. We cannot predict any future trends in the rate of inflation or deflation in Israel or the rate of devaluation or appreciation of the shekel against the dollar. For example, in 2018, the value of the NIS devaluated in relation to the U.S. dollar by 8.1%, the effect of which was offset by inflation in Israel at a rate of approximately 0.8%. In 2017, the value of the NIS appreciated in relation to the U.S. dollar by approximately 9.8%, the effect of which was potentially compounded by inflation in Israel at the rate of approximately 1.5%. If the dollar cost of our operations in Israel increases, our dollar-measured results of operations will be adversely affected.

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 annual report, 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 in our Registration Statement on Form F-1 filed under the Securities Act with the SEC on June 27, 2018, entitled “Enforceability of Civil Liabilities.” As a result of the difficulty associated with enforcing a judgment against us in Israel, holders of our Ordinary Shares may not be able to collect any damages awarded by either a U.S. or foreign court.

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 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. Additionally, a tender offer for all of a company's issued and outstanding shares can only be completed if the acquirer receives positive responses from the holders of at least 95% of the issued share capital. Completion of the tender offer also requires approval of a majority of the offerees that do not have a personal interest in the tender offer unless, following consummation of the tender offer, the acquirer would hold more than 98% of the company's outstanding shares. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition, unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek such appraisal rights. For additional information regarding the regulation of mergers and tender offers under the Israeli Companies Law, see "Item 16.G.–Corporate Governance— Anti-Takeover Measures under Israeli Law; Acquisitions under Israeli Law."

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 of Association, or 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.

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 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 and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at 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 with regard to such vote or appointment. 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.

ITEM 4. INFORMATION ON THE COMPANY

4.A. History and Development

Our legal and commercial name is Entera Bio Ltd. We were incorporated as a limited liability company under the laws of the State of Israel on September 30, 2009. We 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. 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.

We are registered with the Israeli Registrar of Companies. Our registration number is 51-433060-4. Article 3 of our Articles generally provides that our objectives are to engage in any lawful activity.

Our principal executive offices are located at Kiryat Hadassah Minrav Building, 5th Floor, Jerusalem 9122002, Israel, and our telephone number is +972 (2) 532-7151. Our website is https://www.enterabio.com/. The information contained on, or that can be accessed through, our website does not constitute a part of this form and is not incorporated by reference herein. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The address of this website is http://www.sec.gov.

Entera Bio, Inc., our wholly-owned subsidiary, was incorporated on January 8, 2018 under the laws of the State of Delaware. The registered office of Entera Bio, Inc. is located at 1209 Orange St., Wilmington New Castle, Delaware 19801.

We are an Emerging Growth Company. As such, we are eligible to, and intend to, take advantage, for up to five years, of certain exemptions from various reporting requirements applicable to other public companies that are not Emerging Growth Companies, such as not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

Further, under the JOBS act, emerging growth companies 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. However, 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.

We will remain an emerging growth company until the earliest of: (i) the last day of our fiscal year during which we have total annual gross revenues of at least $1.07 billion; (ii) the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; (iv) the date on which we are deemed to be a Large Accelerated Filer under the Exchange Act, with at least $700 million of equity securities held by non-affiliates.

For information regarding our capital expenditures, see “Item 5.B.–Liquidity and Capital Resources.”

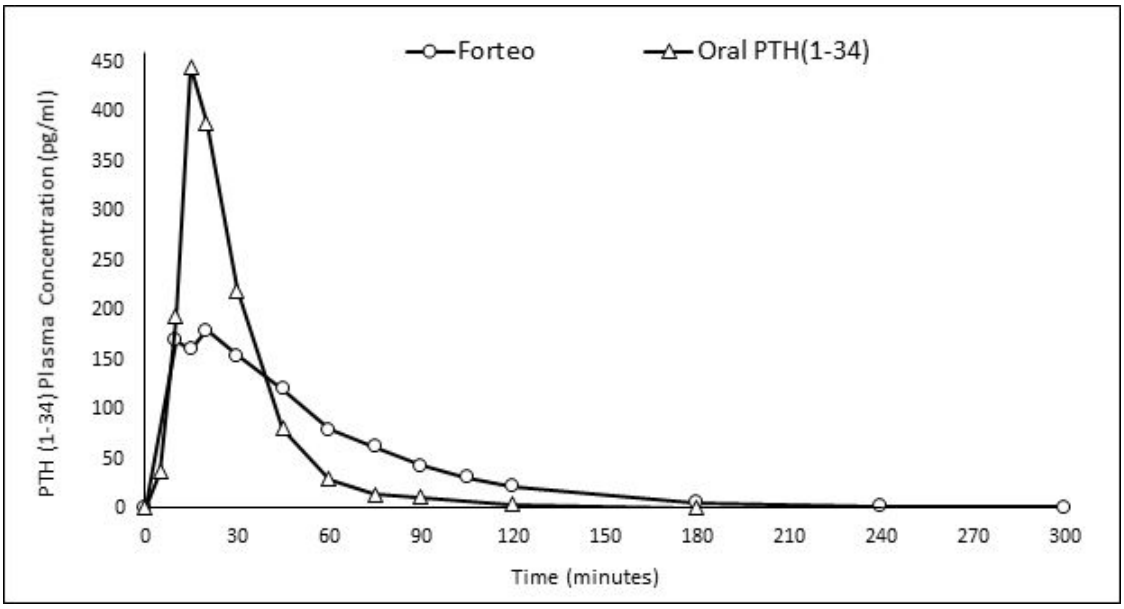
4.B. Business Overview

Who We Are

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. Our current main focus is applying our technology to develop an oral formulation of human parathyroid hormone (1-34), or PTH, which has been approved in the United States in injectable form for over a decade. Our lead oral PTH product candidates are EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism.

Osteoporosis is a systemic skeletal disease characterized by low bone mass, deterioration of bone tissue and increased bone fragility and susceptibility to fracture. Forteoâ, an Eli Lilly product, is a once-daily injectable form of PTH, that has been approved in 2002 for the treatment of osteoporosis in the United States 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. In two separate Phase 1, open label, crossover design pharmacokinetic studies conducted at the Hadassah Clinical Research Center, 9 to 10 healthy male volunteers, in each cohort, received commercial subcutaneous (SC) PTH (1-34) injection (20 micrograms) or EB613. The pharmacokinetic profile of EB613 was characterized by rapid absorption and disappearance rates, which lead to the short pharmacokinetic exposure to the drug (see graph below). In total, more than 100 healthy volunteers and patients, have received multiple doses of various formulations of Oral PTH (1-34).

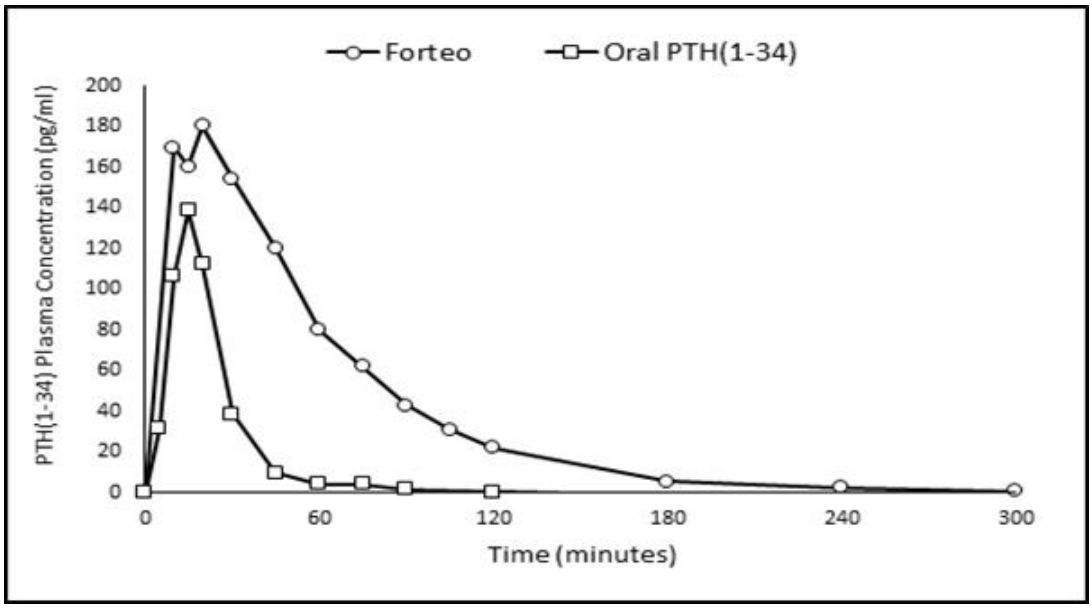
Pharmacokinetic profiles following the administration of an oral formulation of PTH (1-34) versus the commercial SC PTH (1-34) injection Forteoâ. *Each data point represents the mean of* observations in *9 - 10 volunteers.*



The total systemic exposure (AUC) following the administration of oral EB613 was similar to the AUC of the subcutaneous (SC) drug, while the maximal plasma concentrations (Cmax) of the oral PTH (1-34) formulation was approximately two-fold higher than Cmax of the injection. The duration of the exposure above the upper limit of the reference range of endogenous parathyroid hormone, (equivalent to ≥28 pg/mL PTH(1-34), if adjusted on a molar basis), was two-fold shorter following the administration of oral EB613 in comparison to the SC injection (1 hour for oral PTH (1-34) formulation in comparison to more than two hours for SC injection of the drug). The extended exposure is believed to be associated with the calcemic effect, which may lead to an increased incidence of hypercalcemia, an undesired side effect, observed in some patients treated with subcutaneous injections of PTH. The sharper-shorter duration of exposure, thus may be preferable for the treatment of osteoporosis.

In an additional treatment arm of the above study, a lower dose was used to achieve a Cmax similar to the Cmax following an SC injection with a lower AUC (see graph below titled “Pharmacokinetic profiles following the administration of an oral formulation of PTH (1-34) versus the commercial SC PTH (1-34) injection Forteoâ. Each data point represents the mean of observations in 9 - 10 volunteers.”). The activation of the various biological pathways is believed to be triggered by PTH levels above a specific threshold. It is possible that a similar Cmax associated with a lower AUC and shorter exposure time may not only be sufficient to activate the anabolic pathways, but may also reduce the risk of hypercalcemia adverse events.

Pharmacokinetic profiles following the administration of an oral formulation of PTH (1-34) versus the commercial SC PTH (1-34) injection Forteoâ. Each data point represents the mean of observations in 9 - 10 volunteers.



Oral EB613 appeared to be safe and well tolerated with no drug related adverse events reported. In a single volunteer, two mild unrelated adverse events (cough and dyspepsia) were reported one day after the oral drug administration. In contrast, three cases of transient increases in serum calcium above the upper limit of normal, and a single case of vomiting, were observed following the SC injectable administration of PTH (1-34).

A planned phase 2 multi-center 'dose ranging' clinical trial in osteoporosis patients will evaluate the efficacy of various doses of oral PTH, enabling selection of the most efficacious dose to take forward into a phase 3 study.

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 a biologics license application (BLA) submission for EB613 without a placebo-controlled fracture endpoint trial. Instead, we believe that the clinical development program will include one or two pivotal Phase 3 studies, conducted with approximately 600 - 800 osteoporosis patients, that will evaluate the effects of oral PTH on bone mineral density and biochemical markers of bone formation and resorption. These studies would include a comparison to the currently marketed injectable human PTH (1-34) drug, Forteo. Following FDA guidance on our proposed preclinical and clinical development plans, which were presented at a Pre-IND meeting in November 2018, we intend to further develop EB613 and conduct the required clinical trials in order to attain regulatory approval. In addition to discussing various aspects of the nonclinical and clinical development plan, the meeting focused on the 505 b(2) regulatory pathway and the use of bone mineral density (BMD) rather than fracture incidence as the primary endpoint to support a BLA. Based on the FDA's response, we believe that the Phase 3 study may use BMD as the primary efficacy endpoint and that a fracture endpoint study will not be required. We have begun planning for the dose ranging Phase 2 multi-center study in approximately 160 postmenopausal women with osteoporosis or patients with low BMD. We plan to begin the study in the first half of 2019. Following analysis of the data from this study, we intend to design and execute Phase 3 pivotal trial(s) in osteoporosis patients guided by the abovementioned feedback of the FDA. We therefore believe that the BMD endpoint of the alternative pathway, as discussed with the FDA, will be significantly shorter than a pathway that utilizes placebo-controlled bone fracture endpoint studies in significantly larger numbers of patients over greater periods of time.

Hypoparathyroidism is a rare condition in which the body fails to produce sufficient amounts of PTH or the PTH produced lacks biologic activity. Historically, the treatments for hypoparathyroidism have been calcium supplements, active vitamin D analogs (calcitriol or similar drugs) and occasionally phosphate binders, the chronic use of which results in serious side effects with significant costs to patients and the healthcare system. Natpara®, a once-daily injectable form of PTH (1-84), has been approved for the treatment of hypoparathyroidism. Our lead product candidate for hypoparathyroidism, EB612, is delivered orally and can be administered in customized doses several times a day. Studies performed by researchers at the NIH have shown that dosing PTH multiple times per day significantly increases the efficacy of therapy and may 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 doses several times during the day may be clinically superior to existing daily therapy 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. 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. We have recently completed the treatment phase of a clinical trial to evaluate the pharmacokinetic/pharmacodynamics, or PK/PD profile of various EB612 dose regimens. No serious adverse events were reported, and analysis of the data will be presented once all data analyses are completed. In the future, after the completion and evaluation of our PK/PD clinical trial and subject to available funds, we expect to initiate a Phase 2b/3 clinical trial of EB612 for the treatment of hypoparathyroidism, which will further evaluate the dosage, effectiveness and safety profile of EB612 in an expanded population of patients with hypoparathyroidism conducted at multiple trial sites. 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, a Phase 2b/3 trial may be successful, and 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 phase 2b/3 clinical trial of EB612 in hypoparathyroidism 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.

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 a favorable clinical profile as compared to daily subcutaneous Natpara, and may potentially have with an additional positive effect to reduce the elevated urinary calcium that characterizes hyperparathyroidism treated with calcium and calcitriol. If our preliminary results are borne out in additional trials, we believe this combination of advantages and long term clinical benefits could be very compelling to both patients and physicians.

In addition to the utilization of our technology to develop our own internal drug candidates, 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. Our proprietary technology for the oral delivery of large molecules has potential advantages over alternative delivery options, creating a potential pipeline of products across a range of conditions to drive future growth.

We have recently entered into a research collaboration and license agreement with Amgen. Under the agreement, the parties will collaborate for the development and discovery of clinical candidates in the field of inflammatory disease and other serious illnesses. We and Amgen will use our proprietary drug delivery platform to help Amgen develop oral formulations for up to three large molecule biological drug candidates within Amgen's pipeline. Further, under the terms of the agreement, we will engage in preclinical development, at Amgen’s expense. Amgen will be responsible for research, clinical development, manufacturing and commercialization of any of the resulting programs, at its expense. Furthermore, pursuant to the agreement, in January 2019 Entera has received a non-refundable and non-creditable initial modest technology access fee of $725,000 from Amgen. We will be eligible to receive from Amgen aggregate payments of up to $270 million upon achievement of various clinical and commercial milestones, or Amgen’s exercise of options to select an additional program to include in the collaboration, as well as tiered royalty payments ranging from the low to mid single digits based on the level of Amgen’s net sales of the applicable products. We will retain all intellectual property rights to our drug delivery technology, which under this collaboration will be licensed to Amgen exclusively for Amgen’s nominated drug targets. Amgen will retain all rights to its certain large molecules and any subsequent improvements.

Our Pipeline

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 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 have initially focused on the development of products, which are 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.

We commenced operations in 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 have begun 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 the current stage of development of each of our current product candidates, as well as their indications.

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 needs. The key elements of our strategy to achieve this goal are to:

- *Produce supportive clinical data for our lead product candidate, EB613, for the treatment of osteoporosis, before advancing into late-stage clinical trials*: Following FDA guidance on our proposed preclinical and clinical development plans, which were presented at a Pre-IND meeting in November 2018, we intend to further develop EB613 and conduct the required non-clinical and clinical trials in order to attain regulatory approval, including to conduct a Phase 2a multi-center dose-ranging study in patients with osteoporosis or low BMD, planned to start in the first half of 2019, and a single Phase 3, multicenter study BMD endpoint study comparing Oral PTH with Forteo over a 12-month treatment period, to begin in 2020, based on a successful outcome of the Phase 2a study and adequate resources.

- *Advance our hypoparathyroid drug 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 currently completing the data collection from a clinical trial to evaluate the PK/PD profile of various EB612 dose regimens. Upon the completion and evaluation of our 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. The FDA and the EMA have granted EB612 orphan drug designation for the treatment of hypoparathyroidism.

- *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 the anabolic effects of pulsatile PTH to stimulate bone formation may play a key pharmacologic role, including delayed union of fractures, one indication within the field of bone healing after a fracture. 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. As noted, treatment of osteoporosis with EB613 and treatment of hypoparathyroidism with EB612 remain the top priorities and additional resources would be required to pursue additional development programs.

- *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 while in the gastrointestinal tract.

- *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 indications with significant unmet medical need. Between 1993 and 2017, large-molecule clinical approval success rates have outpaced small molecules by more than two-to-one and there are a wide range of large-molecules candidates 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 efficiently 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. We have recently entered into a research collaboration and license agreement with Amgen. Under the agreement, the parties will collaborate for the development and discovery of clinical candidates in the field of inflammatory disease and other serious illnesses. We and Amgen will use our proprietary drug delivery platform to help develop oral formulations for drug candidates that Amgen has selected and will select. We will retain all intellectual property rights to our drug delivery technology, which under this collaboration will be licensed to Amgen, exclusively for Amgen's nominated drug targets. Amgen will retain all rights to its certain large molecules and any subsequent improvements.

- *Initially develop products based on FDA-approved injectable 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. In recent years, 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 agents, 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, we chose to focus initially on product candidates related to oral delivery of PTH molecules, which has the potential for therapeutic use in a number of indications including hypoparathyroidism, osteoporosis and non-union fractures.

In addition, as described herein, we have recently entered into a research collaboration and license agreement with Amgen, under which, the parties will collaborate for the development and discovery of up to three clinical candidates in the field of inflammatory disease and other serious illnesses that Amgen has and will select. We will retain all intellectual property rights to our drug delivery technology, which under this collaboration will be licensed to Amgen, exclusively for Amgen's nominated drug targets. Amgen will retain all rights to its certain large molecules and any subsequent improvements.

Our Product Candidates

The following table 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
EB613	Osteoporosis	Oral PTH (1-34)	Starting Phase 2	Pre-IND meeting conducted in Q4 2018 Phase 2a initiation expected in the first half of 2019 Phase 3 initiation expected in 2020
EB612	Hypoparathyroidism	Oral PTH (1-34)	Phase 2	Phase 2a successfully completed; results reported Q3 2015 Phase 2b PK/PD study head to head with Natpara in hypoparathyroid patients completed treatment in Q4 2018

Oral PTH Therapeutics

PTH is a hormone that regulates the levels of calcium and phosphorus in the blood. The naturally occurring form of PTH that is found in the human body is composed of 84 amino acids, although only the first 34 amino acids are believed to be responsible for its biological effects. A recombinant form of PTH that is comprised of only the first 34 amino acids, or PTH (1-34), can be used as a treatment for a number of indications, including hypoparathyroidism, osteoporosis and non-union fractures. An injectable form of human PTH (1-34), marketed under the name Forteo, has been approved in the United States since 2002 and has been used by more than 1 million patients for the treatment of osteoporosis. An injectable form of full length human 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 levels that produce a blood concentration 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 65 pg/mL. The changes in PTH secretion are in response to ionized calcium concentration in blood plasma that result from entry of calcium from nutrients in the intestine and resorption of calcium from bone. 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. In the absence of adequate parathyroid function producing these pulses in response to decreasing blood calcium, it is difficult for the body to regulate normal homeostatic processes.

EB613 for Osteoporosis

Osteoporosis

We are also developing an oral PTH program, EB613, for the treatment of osteoporosis. Osteoporosis is a systemic skeletal disease characterized by low bone mass, deterioration of the microarchitecture 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. In healthy individuals, bone resorption is matched by new bone formation. 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. Moreover, in many types of osteoporosis, the overall rate of bone turnover is accelerated, increasing the rate of bone loss. These weak and brittle bones become susceptible to fractures caused by fall, mild stress or even a cough, that would cause no harm to normal bones. The complications of fractures and treatment in frail elderly individuals can even be fatal (for example, due to pulmonary embolism, pneumonia or urosepsis).

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 due to the aging of populations in developed countries, 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 deprivation therapies used for prostate cancer.

Market opportunity

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.

Limitations of current treatments for osteoporosis

The goal of pharmacological treatment of osteoporosis is to maintain or increase bone strength, to prevent factures and to minimize osteoporosis-related morbidity and mortality caused by fractures throughout the patient's life. Current treatments for osteoporosis generally fall into two categories: antiresorptive medications that prevent bone loss but do not restore normal bone mass and anabolic medications to increase the rate of bone formation, and at least in part, restore lost bone. The global osteoporosis drug market was dominated for many years by bisphosphonates that inhibit bone resorption, although bisphosphonates' market share in the United States has declined over recent years due to fear of the occurrence of rare but potentially serious side effects, as well as the introduction of newly developed pharmacological treatments that also inhibit bone resorption, including the RANK-ligand inhibitor denosumab (Prolia®). In recent years, anabolic drugs like Forteo (human PTH (1-34), and the most recent new drug abaloparatide (Tymlos®) which is a synthetic PTH receptor agonist, have become more frequently used. Both anabolic drugs require subcutaneous injection and are used for limited 1 to 2 year periods, followed by an anti-resorptive drug.

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

Class of Drug	Name (Producer)	Method of Action	Known Side Effects	2017 Branded Sales (in millions)
Injectable PTH	Forteo (Eli Lilly)	Increases bone mineral density by increasing bone formation.	Decrease in blood pressure, increase in serum calcium in the blood; nausea, joint aches, pain, leg cramps, injection site reactions	$1,750
Monoclonal antibody	Prolia (Amgen)	Blocks bone resorption by osteoclasts by binding RANK-L a protein that is essential to activate osteoclasts	Hypocalcemia, serious infections, dermatologic adverse reactions, osteonecrosis of the jaw, Atypical Femoral Fractures, back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis	$1,970
Selective estrogen receptor modulators (SERMs)	Evista (Eli Lilly)	Binds to estrogen receptors at a selective tissue, with an agonist effects on bone tissue and antagonist in breast	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 and results in bone formation and increased bone mineral density	Osteosarcoma, orthostatic hypotension, hypercalcemia, hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain and vertigo	$12.1 (launched in April 2017)
Bisphosphonate	Fosamax (Merck) Actonel, Boniva, (oral) Zometa (IV) (Novartis)	Prevent bone loss by inhibiting osteoclasts. Effects reversible at low doses but high intravenous causes apoptosis.	Irritation of the gastrointestinal mucosa, hypocalcemia, severe musculoskeletal pain, osteonecrosis of the jaw, atypical femoral fractures	N/A (Generic) N/A (Generic)

In osteoporosis patients, who have normal basal levels of PTH, therapeutic administration of PTH initially activates osteoblasts, but eventually activates osteoclasts after several months of treatment. While both types of cells are activated when PTH is administered, osteoblasts are activated to a greater extent, increasing net 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 in reducing the risk of spine fractures than bisphosphonates. No adequate head-to-head comparisons on the risk of non-vertebral fracture risk have been conducted. Forteo is particularly advantageous in glucocorticoid-induced osteoporosis produced by drugs like prednisone. 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 glucocorticoid-induced osteoporosis treated with Forteo increased twice as much as that in the group treated with a bisphosphonate.

Unlike our oral delivery system, Forteo is administered by subcutaneous 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 antibodies to the drug in approximately 3% of the patient population. We believe an oral form of PTH (1-34) would significantly improve patient and physician acceptance. Eli Lilly has evaluated several collaborations with developers of alternative transdermal 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.

EB613 for the treatment of osteoporosis

We also believe that our oral delivery technology is superior to other oral peptide delivery 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. 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.

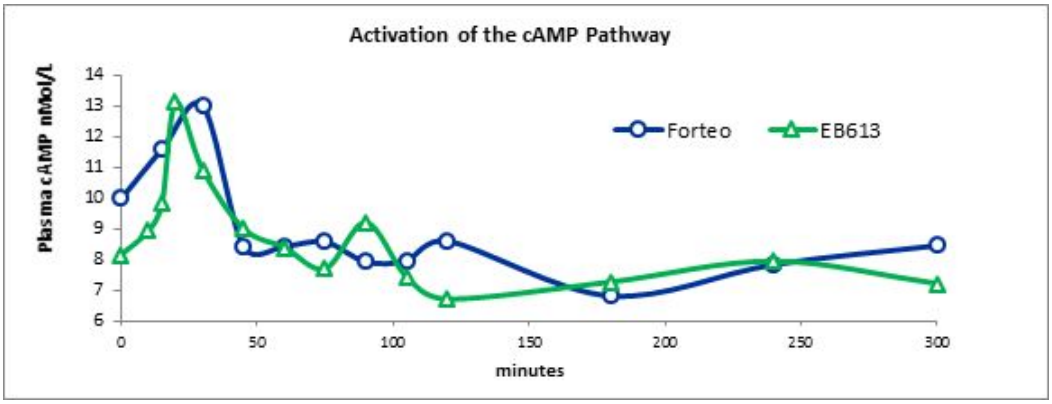
Preclinical and Clinical Development of EB613

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.

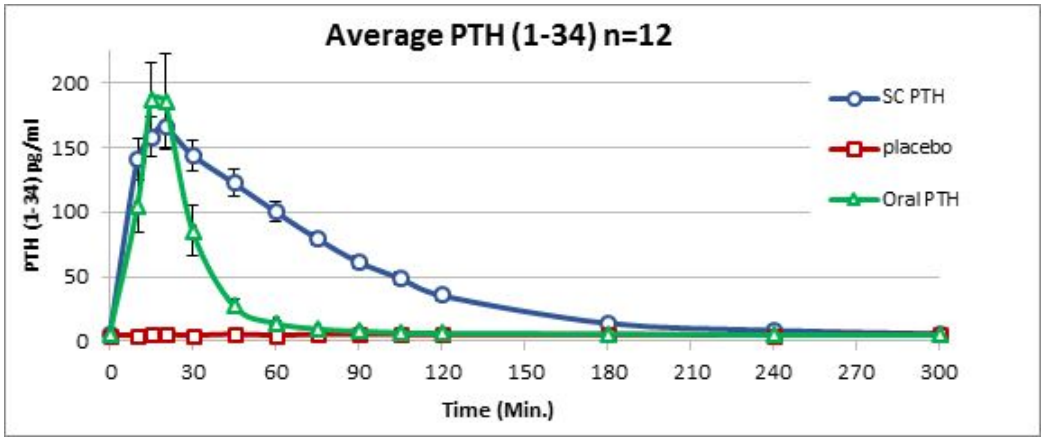
In preclinical and Phase 1 clinical development, EB613 exhibited no serious related adverse events and displayed compelling PK and PD properties, in particular compared to commercially available injectable PTH (1-34) (Forteo). There were no related serious or significant adverse events reported in earlier trials. In our Phase 1b trial, in which we administered doses significantly higher than the current planned dose for EB613 for the treatment of osteoporosis, there were minor drug related adverse events such as minor hypercalcemia in two volunteers, minor tachycardia in three volunteers and a headache in two volunteers. There were also two possibly related mild adverse events in our Phase 1a trial: anemia in one volunteer and nausea in one volunteer. We believe these two adverse events were likely unrelated. For example, the anemia event occurred 12 days after a placebo treatment. In addition, one volunteer in the Phase 1a trial experienced a drug related musculoskeletal and connective tissue event of knee cramps, but also complained of these symptoms on other occasions, when he was not dosed.

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

In November 2018, a pre-IND meeting was held with the FDA to discuss our development plan for Oral PTH for the treatment of osteoporosis. In addition to discussing various aspects of the nonclinical and clinical development plan, the meeting focused on the 505 b(2) regulatory pathway and the use of bone mineral density (BMD) rather than fracture incidence as the primary endpoint to support a BLA.

Entera Bio's Oral PTH (1-34) has been shown to produce a blood level profile similar to Forteo (teriparatide), which was approved by the FDA in 2002 for the treatment of osteoporosis in men and postmenopausal women who are at high risk for fractures. Developers of osteoporosis drugs that contain new chemical entities are required to conduct extensive clinical studies that employ an endpoint which measures the reduction in fractures. These trials often require thousands of patients over a multi-year period, and typically cost hundreds of millions of dollars. Once fracture risk reduction has been demonstrated, the FDA and other regulatory agencies have allowed new formulations or treatment regimens of the same active ingredient to be approved using BMD as the primary efficacy endpoint.

Based on the FDA's response, we believe that in the Phase 3 study, BMD may be used as the primary efficacy endpoint and that a fracture endpoint study will not be required.

Post FDA feedback, we are proceeding with the development of EB613 for osteoporosis. The next step in this clinical development program will be to conduct a Phase 2a multi-center dose-ranging study in approximately 160 osteoporosis patients, at 4 leading osteoporosis centers in Israel, in order to study both safety and the optimal dose to advance into a Phase 3 pivotal study. This dose ranging study will commence in the first half of 2019, and will include a treatment period of 6 months. Multiple bone markers, such as P1NP – a bone formation marker, CTX – a bone resorption marker, BMD, and various additional safety endpoints will be evaluated. The Company will be conducting several nonclinical safety assessment studies in parallel. Assuming a favorable outcome of these studies, the Company is planning a single Phase 3, multicenter study comparing Oral PTH with Forteo over a 12-month treatment period, to begin in 2020. Although still at the early stages of planning, such a study would likely be conducted in the U.S. and Europe, and potentially enroll between 600 and 800 patients in total, depending on statistical powering assumptions.

EB612 for Hypoparathyroidism

Hypoparathyroidism

Our lead product candidate for hypoparathyroidism, EB612, is an oral formulation of PTH (1-34). We believe that EB612, if approved, 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. There are rare genetic diseases where mutations in the PTH gene results in PTH that 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 where mutations in the PTH gene results in PTH that lacks biologic activity.

Market opportunity

The prevalence of hypoparathyroidism is estimated to be 37 per 100,000 in the United States, with 70% of cases caused by surgery, 8% due to genetic disorder and 7% 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.

Limitations of current treatments for 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 serum calcium near the lower limit of the normal range. Moreover, ordinary vitamin D is generally insufficient as the body cannot produce adequate quantities of 1,25-dihydroxyvitamin D, the active hormone derived from vitamin D. Drugs like calcitriol and alfacalcitol must be prescribed to stimulate calcium absorption. If excess calcium is absorbed, it then falls upon the kidneys to dispose of excess calcium. Endogenous PTH normally regulates renal calcium excretion, but this regulation is defective in patients with hypoparathyroidism. Over potentially years of treatment, kidney stones may develop, and ultimately kidney failure may occur due to either kidney stones or deposition of calcium phosphate in kidney tissue (called nephrocalcinosis). Even with the use of calcium and vitamin D supplements and other medications, many patients with hypoparathyroidism continue to experience 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.

EB612 for the treatment of hypoparathyroidism

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 fewer adverse events of hypercalcemia.* Our planned treatment regimen would be increased gradually and in parallel as serum calcium increases slightly. As a result, calcium supplements active vitamin D metabolites (e.g., calcitriol) 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. Moreover, the target serum calcium level would be the lower end of the normal range. If serum calcium were at, or greater than, the middle of the normal range, calcium supplements, active vitamin D metabolites and oral PTH dose would be reduced.

- *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, and then administered by subcutaneous injection. 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 (based on the number of tablets per dose) and could therefore more precisely regulate calcium and phosphate levels throughout the day without the side effects associated with a high once-daily injection. We believe this would alleviate the symptoms of hypocalcemia while reducing the need for calcium supplements and active vitamin D metabolite drug therapy, thus also lessening the frequency of 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 patients with hypoparathyroidism.

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 showed positive PK profiles and PD properties, in particular compared to commercially available injectable PTH (1-34) (Forteo).

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 compelling to both patients and physicians.

EB612 Clinical Trials

The following summarizes our clinical development of EB612 to date:

We completed 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 completed an extended Phase 1b clinical trial in additional 30 volunteers 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 successfully met, and 17 patients 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 have recently completed a clinical trial to evaluate the PK/PD profile of various EB612 dose regimens. In November 2018, we announced the successful results of the first part of our PK/PD study in patients with hypoparathyroidism. In this partial crossover study, ten patients completed two three-day in-patient visits. An initial analysis of the Part 1 data suggests that the four times a day regimen provided a greater effect on all of the parameters measured as compared to the twice a day regimen. The four times a day regimen had a positive impact on serum calcium, phosphate and active vitamin D levels, and was associated with a significant decrease in 24-hour urinary calcium levels as compared to baseline. No serious adverse events were reported in the study.

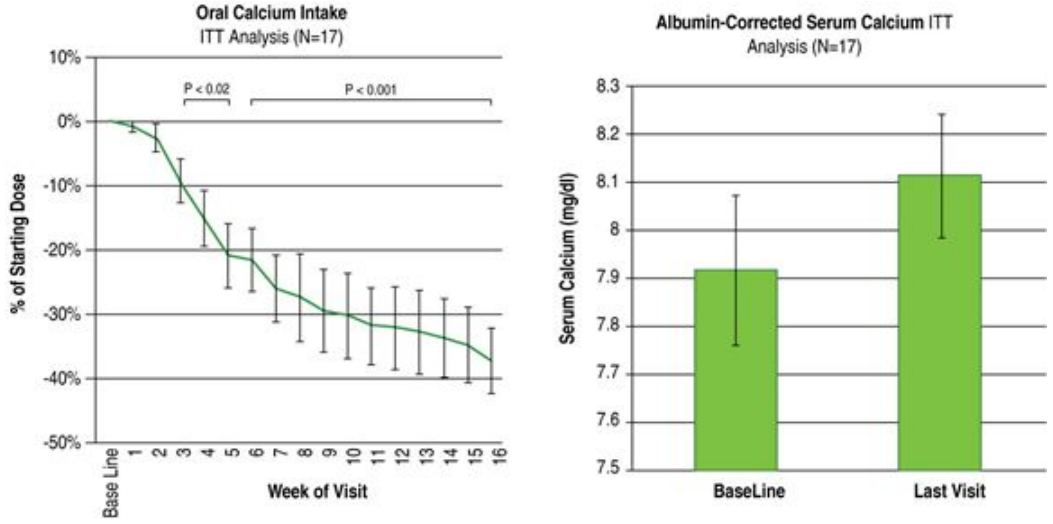
The second and final part of this PK/PD study evaluates a three times per day treatment regimen with a high and low dose of Oral PTH (1-34), as well as Natpara. Part 2 treatment visits were completed in December 2018, and data collection has commenced. The results from the completed Phase 2 PK/PD trial will provide input for the design of our anticipated pivotal clinical trials. Details of the complete data set of this PK/PD study will be presented at scientific meetings and in publications in 2019.

Phase 2a Clinical Trial

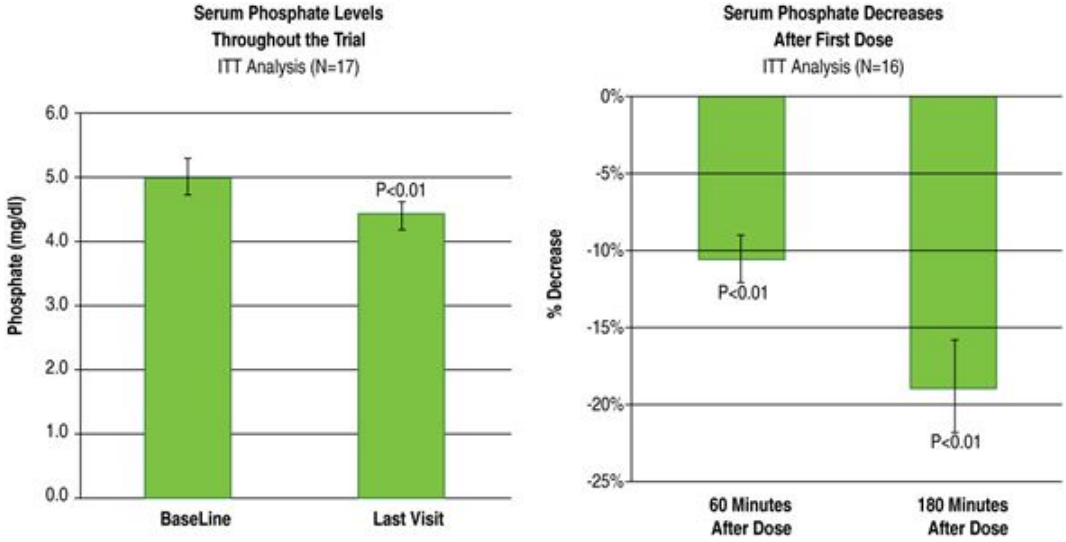
In 2015, we successfully completed a multicenter Phase 2a clinical trial of EB612 in hypoparathyroidism patients. The end points in the trial were met, and 17 patients completed the four-month trial and reported no related serious adverse events.

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 patients (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 patient, 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'.

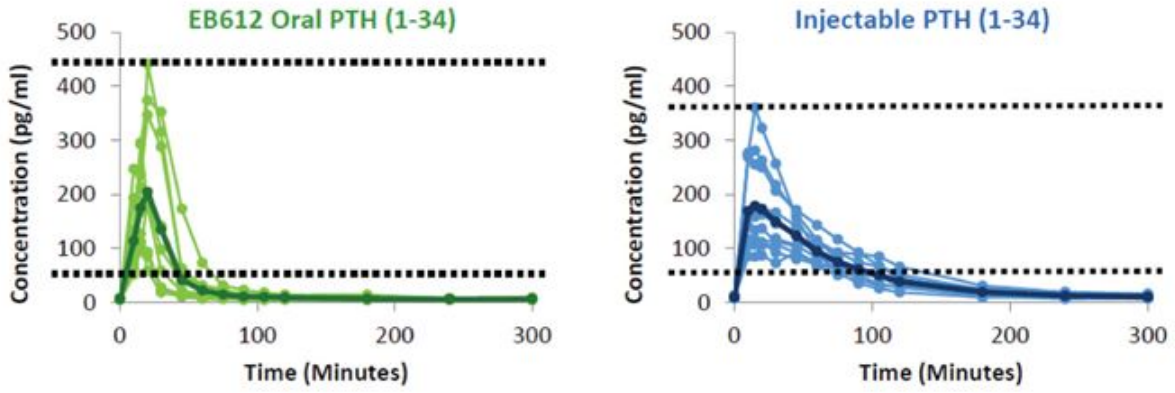
Based on consultations with key opinion leaders in the hypoparathyroidism field who have reviewed our Phase 2a results and are familiar with the REPLACE study, we are planning for a Phase 2b/3 trial, designed to be a pivotal study for registration. We expect that this Phase 2b/3 study, when initiated, will be designed to replicate the REPLACE study in many aspects and to achieve a significant reduction in urinary calcium. The trial would be placebo controlled with a "rescue" provision for patients who have substantial persistent symptoms, hyperphosphatemia, hypocalcemia or hypercalciuria. The planned primary endpoints will be the proportion of patients obtaining a serum calcium and phosphate within a "target" range, reducing hypercalciuria and from a safety perspective, the incidence of clinically important hypercalcemia and decreased renal function adverse events. The study will also compare the reduction in calcium intake, reduction in active vitamin D in each treatment group. Secondary endpoints include mean absolute levels of serum calcium and 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 subcutaneous 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.

Low inter-patient variability observed in EB612 Phase 1b



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

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 healthy volunteers 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 volunteers 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 volunteers. 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.

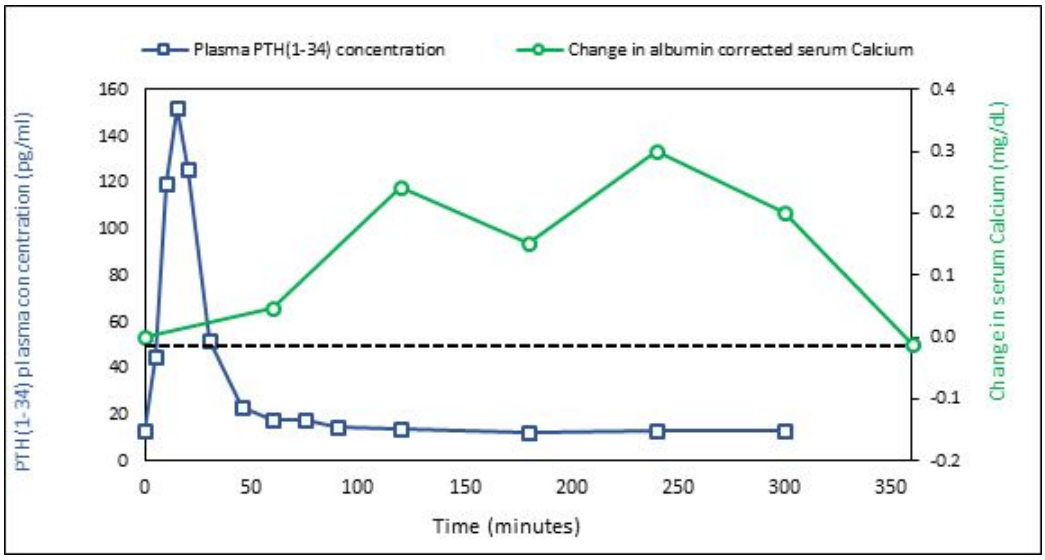
The clinical trial began in August 2011 and was completed in early 2013. This clinical trial was conducted over an extended period of time as multiple formulations of oral PTH (1-34) were tested. In typical Phase 1 clinical trials, one formulation is tested for safety and, in certain cases, PK and PD 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 volunteers 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 volunteers 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 possibly drug-related adverse events such as minor possibly hypercalcemia in two volunteers, minor tachycardia in three volunteers and a headache in two volunteers. There were also two possibly related mild adverse events in our Phase 1a trial: anemia in one volunteer and nausea in one volunteer. In addition, one volunteer in the Phase 1a trial experienced a possibly drug-related musculoskeletal and connective tissue event of knee cramps. We believe the adverse events of anemia and cramps were likely unrelated, since the anemia event occurred 12 days after a placebo treatment and the subject with the cramps also complained of these symptoms on other occasions when he was not dosed.

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.

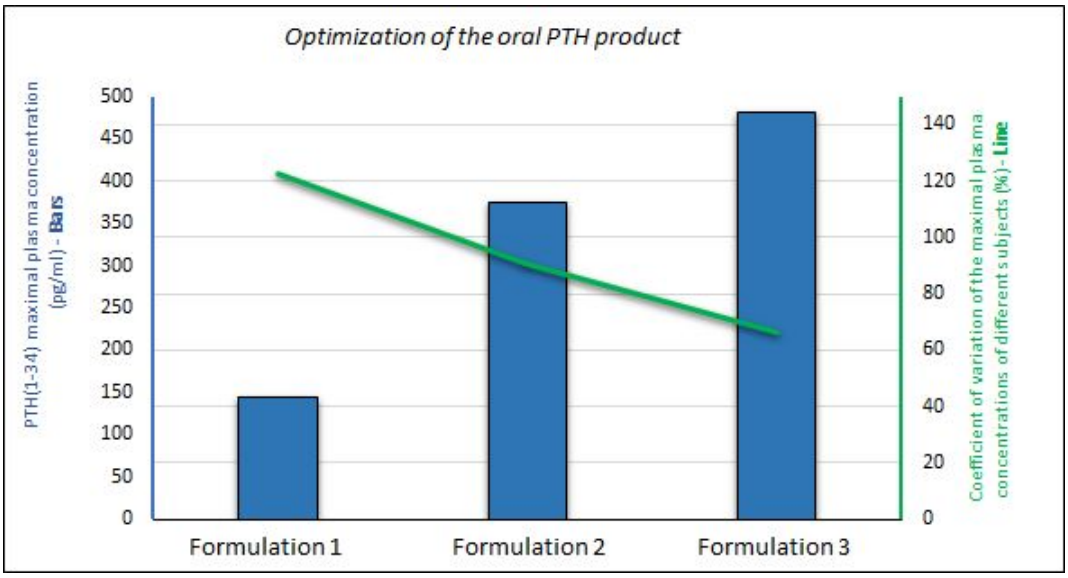
Analysis of the PD profile of our oral PTH (1-34) indicated that a biomarker of PTH activity, cyclic AMP, was activated in a similar manner to that of injectable PTH (1-34). Furthermore, analysis of serum calcium indicated that an increase can be obtained by a single dose of our oral PTH (1-34) as indicated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



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. One volunteer 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 volunteers, minor tachycardia in three volunteers and a headache in two volunteers. There were also two possibly related mild adverse events in our Phase 1a trial: anemia in one volunteer and nausea in one volunteer. We believe the anemia event was likely unrelated as it occurred 12 days after a placebo treatment. In addition, one volunteer in the Phase 1a trial experienced a drug related musculoskeletal and connective tissue event of knee cramps. This volunteer also complained of these symptoms on other occasions when he was not dosed.

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. These improvements were based on the same basic components and present a similar pharmacokinetic profile. In part I of our Phase 2 PK/PD study, we have further evaluated the PK/PD profile of various EB612 dose regimens. An initial analysis of the Part 1 data suggests that the four times a day regimen provided a greater effect on all of the parameters measured as compared to the twice a day regimen. No serious adverse events were reported in the study. 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.

Phase 2 PK/PD Clinical Trial

In November 2018 we announced the completion of part I of our clinical trial known as our Phase 2 PK/PD study or PK/PD study, to evaluate the PK/PD profile of various EB612 dose regimens, while comparing such various dose regimens with Natpara.

This study was 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 to also 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 include levels of PTH (1-34), PTH (1-84) (Natpara), serum calcium, serum phosphate, urinary calcium and urinary phosphate.

In Part I of the Study, ten patients with hypoparathyroidism completed two three-day in-patient visits. Throughout each of these three-day visits, patients remained on their current standard medications. On the first day of each visit (baseline) patients received no additional treatments. On day two, patients were randomized to receive one of three treatments: Oral PTH (1-34) twice a day (BID), Oral PTH (1-34) four times a day (QID), or injectable PTH (1-84) (Natpara*) once a day (QD). On day three, patients did not receive any additional treatments. In the second three-day visit, patients were again randomized on day two to receive one of the treatment regimens they had not received previously. Throughout the three-day visits, patients were continuously monitored clinically, and PTH, calcium, phosphate, and the hormonal metabolite of vitamin D (1,25- dihydroxyvitamin D) levels were measured. PTH has several well-known physiological effects. It increases serum calcium, decreases serum phosphate, increases reabsorption of calcium in the kidney, where it also increases 1,25-dihydroxyvitamin D synthesis.

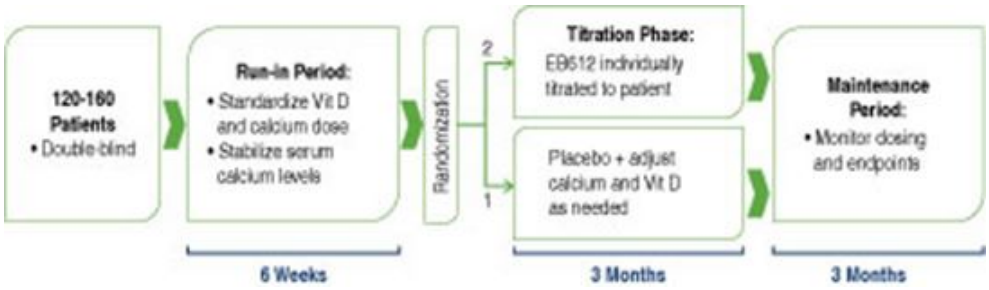
Preliminary results from the PK/PD study of Oral PTH (1-34) four times a day (QID) treatment include: (i) the serum calcium increased an average of approximately 0.3 mg/dL over baseline, and this increase was maintained over a 24-hour period; (ii) serum phosphate decreased an average of 0.5 mg/dL below baseline and this decrease was maintained over a 24-hour period; (iii) average levels of serum active vitamin D increased by approximately 90% on the day of treatment as compared to baseline; and (iv) average levels of 24-hour urinary calcium decreased by approximately 30% on the day of treatment as compared to baseline. An initial analysis of the Part 1 data suggests that the QID regimen provided a greater effect on all of the parameters measured as compared to the BID regimen. The concentration of PTH (1-34) in blood after administration of Oral PTH (1-34) in the current study was sufficient to produce the observed pharmacodynamic effects and did not induce hypercalcemia. No serious adverse events were reported in the study.

The second and final part of this PK/PD study will evaluate a three times per day (TID) treatment regimen with a high and low dose of Oral PTH (1-34), as well as Natpara. The results from the completed Phase 2 PK/PD trial will provide input for the design of our anticipated pivotal clinical trials. Details of the complete data set of this PK/PD study will be presented at scientific meetings and in publications in 2019.

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 have conducted Part I of our Phase 2 PK/PD study, and are currently conducting Part II of our Phase 2 PK/PD study comparing various dose regimens with Natpara. The second and final part of this PK/PD study will evaluate a three times per day treatment regimen with a high and low dose of Oral PTH (1-34). In our future Phase 2b/3 trial we will further evaluate the dosage, effectiveness and safety profile of EB612 in an expanded patient population at multiple trial sites. The trial would be placebo controlled with a “rescue” provision for patients who have substantial persistent symptoms, hyperphosphatemia, hypocalcemia or hypercalciuria. Key efficacy endpoints would be obtaining a serum calcium and phosphate within a “target” range, reducing hypercalciuria and from a safety perspective, the incidence of clinically important hypercalcemia and decreased renal function.

Proposed design for EB612 Phase 2b/3 pivotal trial



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 of human PTH (1-34) 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. In June 2016, we received approval from the EMA granting orphan status to our oral PTH in Europe.

Development and License Agreements

Parallel to the development of our product candidates, we have recently entered into a research collaboration and license agreement with Amgen, combining our proprietary drug delivery platform with drugs selected by Amgen to create new products. Pursuant to the agreement, in January 2019, we received a non-refundable and non-creditable initial technology access fee of $725,000 from Amgen. We will be eligible to receive from Amgen aggregate payments of up to $270 million upon achievement of various clinical and commercial milestones or Amgen's exercise of options to select an additional program to include in the collaboration, as well as tiered royalty payments ranging from the low to mid single digits based on the level of Amgen's net sales of the applicable products. The agreement is exclusive only to the specific drug candidates that are developed and discovered under the collaboration program, leaving us the rights to commercialize and develop products with other drugs using our proprietary technology while also allowing Amgen to retain all rights to its certain large molecules and any subsequent improvements. The first prospective product under the agreement with Amgen is currently in early stages. Amgen also has options, limited in time, to select up to two additional programs to include in the collaboration. Under the agreement, we will engage in preclinical development at Amgen's expense.

Our total revenues from the agreement with Amgen, recognized as of December 31, 2018, were $500,000.

Additional Research and Development

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 our 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 that have been approved to either stimulate bone healing, treat delayed union fractures or treat patients with non-union following a fracture. A number of studies suggest that PTH could be beneficial in the treatment of such fractures, to potentially speed union and/or reduce the risk of non-union. While surgery is generally required to treat patients with established fracture non-union, PTH might improve likelihood of a favorable surgical outcome. PTH could thus be a potentially new treatment option for the induction of bone healing after a fracture. Non-union fractures occur when the normal process of bone healing fails or is greatly delayed. Note the fracture malunion refers to a fracture that heals, but with an important abnormal structure or alignment of the bone fragments. 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 the rigorous requirements for new drug approval, the FDA has not required the same level of evidence for the efficacy of devices used to treat a medical condition. 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.

Our Potential Solution for Non-union or Delayed-Union of 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 a potential treatment when bone healing is delayed.

We intend to investigate the efficacy of EB613 for delayed-union or 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 treatment of non-union fractures and bone healing may entail three to six months of treatment, we believe the acceptance of oral PTH will be higher than other potential pharmacological alternatives that require injections. We believe we will be able to use the PK 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 or delayed-union of bone fractures.

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 December 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, China and India. Specifically, in the United States, Australia, Japan, China, Hong Kong, Israel and Russia divisional or continuation patent application have been filed to specifically cover PTH (1-34). Such patents have already been granted in the United States, Australia, Israel, Russia and Japan. 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, or 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. PCT is an international patent law treaty that provides a unified procedure for filing a single initial patent application to seek patent protection for an invention simultaneously in any one of the designated member states. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. The mentioned 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 such 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 "Item 3.D.–Risk Factors—Risks Related to Our Intellectual Property."

Commercialization Strategy

Our current main focus is developing an oral PTH (1-34) for the treatment of osteoporosis and orphan indications, and specifically, EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism. EB613 and EB612 are two drug candidates based on oral PTH (1-34), with significantly distinct treatment approaches. In the future we plan to also conduct clinical trials of EB613 for the treatment of non-union fractures. In addition, we have recently entered into a research collaboration and license agreement with Amgen. Under the agreement, the parties will collaborate for the development and discovery of clinical candidates in the field of inflammatory disease and other serious illnesses. Further, under the terms of the agreement, we will use our proprietary drug delivery platform to develop oral formulations for up to three large molecule biological drug candidates currently being developed by Amgen. We are also investigating applying our oral drug delivery platform to other FDA-approved proteins or large molecule therapeutics, including human growth hormone.

We have not yet established sales, marketing or product distribution operations because our product candidates are in clinical development. 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. In respect of the collaboration with Amgen, Amgen is responsible for the research, clinical development, manufacturing and commercialization of any of the resulting programs. 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.

Competition

The medical and pharmaceutical industries in which we operate are highly competitive and subject to rapid and significant technological change and changes in practice. 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 “Item 3.D.–Risk Factors—Risks Related to Commercialization of Our Product Candidates.”

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.

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.

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 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, 2018, the total royalty amount payable to the IIA, including accrued interest, was approximately $0.5 million. As of December 31, 2018, we had not paid any royalties to the IIA, as we did not have any sales from our products.

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” (in its meaning under the Research Law) in or 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 transfer of such technology to a non-Israeli entity up to 600% of the grant amounts and the interest. The IIA approved the Company’s Research Collaboration and License Agreement with Amgen Inc. as of December 2018, subject to payments to the IIA in the rate of 5.38% out of any payment received from Amgen for the license and up to a total amount of six times the amount of the IIA funding and the interest. In addition, as disclosed under “Item 4.B.–Business overview - 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 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 three times the amount of the grants and the interest. In addition, any change of control and any change of ownership of our Ordinary Shares 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 other payments to the IIA, 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 sub-licensable 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, 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.

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 manufacturing, storage and distribution of materials and oral drug formulations for early stage clinical studies. Our facility has ISO:9001:2015 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 Class D for tablet production and a dedicated chemical synthesis room designed as an ISO 8.

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. QA/QC analytical laboratory performs part of the release and stability tests for PTH tablets manufactured by the UK-based contract manufacturing facility. Entera Bio R&D laboratory supports the manufacturing activities and develop/optimize analytical methods used by the contract manufacturer in order to meet regulatory requirements for clinical trials. 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 such 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. The clinical drug supply for the Phase 2 PK/PD study was successfully manufactured and released by this subcontractor according to all required regulatory standards. Future clinical studies with our oral PTH (1-34) tablets, as well as the potential supply to market once approved, can be provided by this international subcontractor.

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, inter alia, 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 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 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 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 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 volunteers 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, 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 $2,558,478.

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 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 later this year. 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.

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;
- 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;
- 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 Article 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 Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric 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 Pediatric 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 Pediatric 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 "Item 4.B—Government Regulation and Product Approval—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 "Item 4.B—Government Regulation and Product Approval—Regulation and Marketing Authorization in the European Union—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 payers play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payers 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;

- 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 payer, 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.

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 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, in a number of jurisdictions, governing, inter alia, (i) the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; and (ii) chemical, air, water and ground contamination, air emissions and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials and sewage. Our operations at our Jerusalem research and development facility use chemicals and produce waste materials and sewage. Our activities require permits from various governmental authorities including, local municipal authorities, the Ministry of Environmental Protection and the Ministry of Health. The Ministry of Environmental Protection and the Ministry of Health, local authorities and the municipal water and sewage company conduct periodic inspections in order to review and ensure our compliance with the various regulations.

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.

In addition, laws and regulations relating to environmental, health and safety matters are often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities which were previously permitted. For instance, Israeli regulations were promulgated in 2011 relating to the discharge of industrial sewage into the sewer system. These regulations establish new and potentially significant fees for discharging forbidden or irregular sewage into the sewage system.

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 payers, 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 payer will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the drug product once coverage is approved. Third-party payers 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 payer’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 payers are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost effectiveness of medical products and in addition to their safety and efficacy. If these third-party payers 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 payers 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 ACA 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 2027, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, 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.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal and replace certain aspects of the ACA, and we expect such challenges to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been enacted. The Tax Cuts and Jobs Act of 2017, or 2017 Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans. In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation, regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a federal judge in Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the 2017 Tax Act. While the judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact our business.

Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products. There have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. The Trump administration's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients.

Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product, and on January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors, which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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.

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. 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. For more information on the risks related to Emisphere's claim, see "Item 3.D.–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."

4.C. Organizational Structure

We were formed as a company in the State of Israel on September 30, 2009.

Our corporate structure consists of Entera Bio Ltd. and Entera Bio, Inc., our wholly-owned U.S. subsidiary.

4.D. Property, Plants and Equipment

Our facilities in Israel, which house our headquarters and our research and developments facilities, are located in Jerusalem, Israel. Under a Lease Agreement with Unihead Biopark Ltd. as of December 31, 2018, we are leasing approximately 282 square meters of 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. In January 2019 we signed an addendum to the lease agreement, according to the addendum we lease additional 340 square meters. The lease agreement, including the addendum will expire on June 30, 2023, and the one-time option previously granted to the Company to terminate the lease on June 30, 2020 was replaced with a one-time option to terminate the whole lease space on December 31, 2021, subject to a notice period of six months. This facility also houses our clinical development, clinical operations, regulatory and management functions.

We believe that our current office and laboratory space in Israel is sufficient to meet our anticipated needs for the foreseeable future and is suitable for the conduct of our business. We believe that suitable additional space would be available if required in the future on commercially reasonable terms.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

5.A. 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 annual report. 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 annual report. You should read the following discussion in conjunction with "Special Note Regarding Forward-Looking Statements" and "Risk Factors" included elsewhere in this annual report. 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 needs. 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 candidates are EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism. For our EB613 product candidate in osteoporosis, a Pre-IND meeting with the FDA was held in November 2018. Following FDA guidance on our proposed preclinical and clinical development plans, we intend to further develop EB613 and conduct the required nonclinical studies and clinical trials in order to attain regulatory approval for which we intend to pursue approval of EB613 utilizing the alternative Section 505(b)(2) pathway permitted under the Federal Food, Drug and Cosmetic Act. We have begun planning for the dose ranging Phase 2 multi-center study for our lead product candidate EB613 in approximately 160 postmenopausal women with osteoporosis or patients with low BMD. 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 have recently completed the treatment phase of a clinical trial to evaluate the PK/PD profile of various EB612 dose regimens. No serious adverse events were reported, and analysis of the data will be presented once all data analyses are completed. After the completion and evaluation of our PK/PD clinical trial and subject to available funds, we expect to initiate a multicenter Phase 2b/3 clinical trial of EB612 for the treatment of hypoparathyroidism, which will further evaluate the dosage, effectiveness and safety profile of EB612 in an expanded population of patients with hypoparathyroidism. The FDA and the EMA have granted EB612 orphan drug designation for the treatment of hypoparathyroidism. 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. We have recently entered into a research collaboration and license agreement with Amgen. Under the agreement, the parties will collaborate for the development and discovery of clinical candidates in the field of inflammatory disease and other serious illnesses. We and Amgen will use our proprietary drug delivery platform to help Amgen develop oral formulations for up to three large molecule biological drug candidates within Amgen's pipeline.

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, and through our initial public offering. We have no products that have received regulatory approval and have never generated revenue from sales of our products which we are continuing to develop. From our inception, we have raised an aggregate of $42.5 million to fund our operations, including $11.2 million from our initial public offering, $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. On December 10, 2018, we entered into a research collaboration and license agreement with Amgen. Pursuant to the agreement, we received in January 2019, a non-refundable and non-creditable initial technology access fee of $725,000.

Since inception, we have incurred significant losses. For the years ended December 31, 2016, 2017 and 2018, our operating losses were $5.4 million, $11.3 million and $10.9 million, respectively. We expect to continue to incur significant expenses and losses for the next several years. As of December 31, 2018, we had an accumulated deficit of $52.1 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 the collaboration with Amgen or any future collaborations into which we may enter.

As a result of our recurring losses from operations, negative cash flows and lack of liquidity, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of, and for the year ended, December 31, 2018, expressing the existence of substantial doubt about our ability to continue as a going concern.

As of March 15, 2019, we had cash and cash equivalents of $9.6 million. In order to fund further operations, we will need to raise additional capital. 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 consolidated financial statements for the year ended December 31, 2018, included elsewhere in this annual report, note that there is substantial doubt about our ability to continue as a going concern absent sources of additional liquidity. The audited consolidated 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 “Item 3.D.–Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital.”

As of March 15, 2019, we had 20 employees, one consultant who provides consulting services to us on a full-time basis and four consultants who provide services to us on a part-time basis. In addition, we have entered into service agreements with one of our directors. Our operations are located in a single facility in Jerusalem, Israel.

Patent Transfer, Licensing Agreements 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 “Item 4.B.— Business Overview—Patent Transfer, Licensing Agreements and Grant Funding —Oramed Patent Transfer Agreement.”

Amgen Research Collaboration and License Agreement

On December 10, 2018, we entered into a research collaboration and license agreement, or the Amgen Agreement, with Amgen in inflammatory disease and other serious illnesses. Pursuant to the Amgen Agreement, we and Amgen will use our proprietary drug delivery platform to develop oral formulations for one preclinical large molecule program that Amgen has selected and will select. Amgen also has options to select up to two additional programs to include in the collaboration. Amgen is responsible for the clinical development, regulatory approval, manufacturing and worldwide commercialization of the programs.

We granted Amgen an exclusive, worldwide, sublicenseable license under certain of our intellectual property relating to our drug delivery technology to develop, manufacture and commercialize the applicable products. We will retain all intellectual property rights to our drug delivery technology, Amgen will retain all rights to its large molecules and any subsequent improvements, and ownership of certain intellectual property developed through the performance of the collaboration is to be determined by U.S. patent law. Each party is responsible for the filing and prosecution of patents relating to its owned developments and, with respect to any jointly-owned developments, we are responsible for the filing and prosecution of patents solely claiming improvements to our drug delivery technology and Amgen is responsible for the filing and prosecution of any other jointly-owned developments. Amgen has the primary right to enforce any such patents against third-party infringement with respect to a product that has the same mechanism of action as one of the collaboration programs, subject to involvement by us in certain circumstances.

Pursuant to the terms of the Amgen Agreement, Amgen is required to make aggregate payments of up to $270 million upon achievement of various clinical and commercial milestones or its exercise of options to select additional two programs to include in the collaboration, as well as tiered royalty payments of up to mid-single digits based on the level of Amgen's net sales of the applicable products.

Amgen is required to pay for the initial program $450,000 for the second year of preclinical services to be provided by us and must reimburse us for further expenses as shall be agreed between the parties. In January 2019, as required by the Amgen Agreement, Amgen paid us a non-refundable and non-creditable initial technology access fee of $725,000.

Amgen's obligation to pay royalties with respect to a product in a particular country commences upon the first commercial sale of such product in such country and expires on a country-by-country and product-by-product basis on the later of (a) the date on which the sale of the product is no longer covered by a valid claim of a patent licensed to Amgen under the Amgen Agreement, and (b) the tenth anniversary of the first commercial sale of such product in such country.

During certain periods, we may not alone, or with a third party, research, develop, manufacture or commercialize certain products primarily interacting with the targets of the applicable collaboration programs. The collaboration is governed by a joint research committee, or JRC, made up of equal representatives of us and Amgen. The JRC may establish additional subcommittees to oversee particular projects or activities. Subject to certain limitations, if the JRC is unable to make a decision by consensus, the disagreement is to be resolved through escalation to specified senior executive officers of the parties, although Amgen has the final decision-making ability with respect to certain specified issues.

The term of the Amgen Agreement commenced on December 10, 2018, and unless earlier terminated, shall continue in full force and effect, on a product-by-product basis, until expiration of the last-to-expire royalty term with respect to such product. At any point in the research, development or commercialization process, subject to certain conditions, Amgen can terminate the Amgen Agreement in its entirety or with respect to a specific development program. Both parties can terminate the agreement for a material breach by the other party that goes uncured, subject to a 90-day notice period.

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 "Item 4.B.–Business overview —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. Following the signing of the Amgen Agreement, we are required to pay 5.38% from each payment by Amgen and up to 600% of the grant received. In February 2019, we paid to the IIA $27,000 due to the Amgen Agreement.

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 “Item 4.B.–Business Overview—The Israeli Innovation Authority Grant.”

Financial Overview

Revenue

To date, we have not generated any revenue from sales of our products and 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.

On December 10, 2018, we entered into the Amgen Agreement in inflammatory disease and other serious illnesses. As part of the agreement, in January 2019, we received non-refundable and non-creditable initial access payment of $725,000 from Amgen.

Revenues from the Amgen Agreement which was signed in December 2018 are recognized according to IFRS 15 – “Revenues from Contracts with Customers.” We have adopted IFRS 15 – “Revenue from Contracts with Customers” for the first time, since we had no revenues in previous years.

In determining the appropriate amount of revenue to be recognized as we fulfill its obligations under each of its agreements, we perform the following steps:

1. Identification of the contract, or contracts, with a customer.

2. Identification of the performance obligations in the contract.

3. Determination of the transaction price.

4. Allocation of the transaction price to the performance obligations in the contract.

5. Recognition of revenue.

We identified two performance obligations in the agreement: License to use our proprietary drug delivery platform and preclinical R&D services. The preclinical R&D services include discovery, research and design preclinical activities relating to the programs selected by Amgen.

We determined the license to our intellectual property to be a right to use that has significant standalone functionality separately from the R&D services, since we are not required to continue to support, develop or maintain the intellectual property transferred and will not undertake any activities to change the standalone functionality of the intellectual property. Therefore, the license to the intellectual property is a distinct performance obligation, and as such, revenue is recognized at the point in time that control of the license is transferred to Amgen on December 10, 2018.

Each of these promises met the definition of distinct performance obligation. We evaluated the selling price of the preclinical services at $225,000, and the right to use the intellectual property at $500,000.

Revenues attributed to the preclinical services of $225,000 will be recognized upon commencement of the pre-clinical Research and Development services, over time, according the input model method on a cost-to-cost basis.

Under IFRS 15, the consideration that we would be entitled to upon the achievement of contractual milestones, which are contingent upon the occurrence of future events of development and commercial progress, are a form of variable consideration. When assessing the portion, if any, of such milestones-related consideration to be included in the transaction price, we first assess the most likely outcome for each milestone, and exclude the consideration related to milestones of which the occurrence is not considered the most likely outcome. We then evaluate if any of the variable consideration determined in the first step is constrained by including in the transaction price variable consideration, to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. We used significant judgment when we determine the first step of variable consideration. We did not recognize any revenues from milestones payments.

Sales- or usage-based royalties to be received in exchange for licenses of intellectual property are recognized at the later of when the performance obligation to which some or all of the sales- or usage-based royalty has been allocated is satisfied (in whole or in part). An entity should recognize revenue for a sales-based or usage-based royalty promised in exchange for a license of intellectual property only when (or as) the later of the following events occurs:

- The subsequent sale or usage occurs; and
- The performance obligation to which some or all of the sales based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

As royalties are payable based on future commercial sales, as defined in the agreement, which did not occur as of the financial statements date, we did not recognize any revenues from royalties.

As of December 31, 2018, we recognized $500,000 of revenues and recorded contract liability of $225,000 against account receivables in the amount of $725,000.

As a result of our recurring losses from operations, negative cash flows and lack of liquidity, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of, and for the year ended, December 31, 2018, expressing the existence of a substantial doubt about our ability to continue as a going concern.

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, 2017 and 2018, 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, 2017 and 2018, our research and development expenses were $2.6 million, $2.8 million and $8.5 million, respectively. Research and development expenses for the years ended December 31, 2016, 2017 and 2018 were primarily for the development of EB612. Research and development expenses are expected to increase as we advance the clinical development of EB613, EB612 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 EB613, EB612 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, insurance, consulting and auditing and accounting services and certain expenses with respect to our initial public offering and previous financing rounds.

Our general and administrative expenses have increased following the completion of our initial public 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, directors remuneration and increased insurance premiums. If we lose our status as a foreign private issuer we will be subject to additional reporting SEC requirements that will result in similar increased costs, see “Risk Factors—Risks Related to Our Ordinary Shares, and Warrants.”

Financial Income

Financial income was comprised mainly of gains resulting from the re-measurement of our convertible loan, Series A preferred shares, warrants and options to purchase Series A preferred shares and shares, Series B preferred shares issued from October to December 2017, Series B-1 preferred shares issued as a result of the conversion of the Convertible Loans and warrants to Series B preferred shares. We have recorded adjustments to the estimated fair value of the convertible loans, preferred shares, warrants to issue preferred shares and shares until each were converted into our Ordinary Shares or Warrants and options to our Ordinary Shares as part of our initial public offering, after which we have no longer recorded and will not record any related periodic fair value adjustments with regard to these components. Our tradable Warrants issued in the initial public offering were classified as a financial liability since their exercise price and number of shares issuable upon exercise of each Warrant are subject to certain adjustments as described in the Warrant form, therefore we recorded losses from the changes in fair value of the tradable Warrants from the initial public offering date, July 2, 2018 until December 31, 2018. We will continue to record fair value adjustments on the tradable Warrants until they will exercise to our Ordinary Shares, their expiry date or repurchase by us under “Fundamental Transactions” as described in the warrant.

Upon the consummation of our initial public offering, July 2, 2018, we adjusted our convertible loan liability, preferred shares and our warrants to issue preferred shares to their fair value, evaluated based on the quoted closing price of our Ordinary Shares on Nasdaq. We recorded additional financial expenses from the revaluation of our convertible loan liability, preferred shares and warrants. Under the terms of the applicable agreements and pursuant to the certain IPO transactions, the convertible loans and preferred shares were automatically converted into our Ordinary Shares, and the warrants to purchase preferred shares were automatically converted into warrants to purchase Ordinary Shares. The fair value of the tradable Warrants as of the initial public offering date, July 2, 2018 and as of December 31, 2018 was based on quoted price per Warrant on Nasdaq as of the respective date.

Other financial expenses are comprised mainly of exchange rate differences of certain currencies against our Functional Currency. During the year ended December 31, 2018, we recorded income from interest in the amount of $34,000.

Taxes on Income

Entera Bio Ltd. has not generated taxable income since our inception, and as of December 31, 2018 had carry-forward tax losses of $24 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.

As of December 31, 2018, Entera Bio Inc. has not carried forward tax losses.

We have not created deferred tax assets on our tax loss carryforwards because their utilization is not expected in the foreseeable future. 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.

Critical Accounting Policies and Estimates

We describe our significant accounting policies more fully in Note 2 to our audited consolidated financial statements included elsewhere in this annual report. 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.

Revenue Recognition

With respect to the Amgen Agreement, we used our judgement to identify our promises in the agreement and whether the promises are distinct performance obligation. In addition, we use our judgement to determine the allocation of the transaction price between its identified distinct performance obligations. We also used our significant judgment in order to determine the R&D services period. For a description of our revenue recognition policy see “Note 2—Summary of Significant Accounting Policies—P. Revenue Recognition” of our audited consolidated financial statements for the year ended December 31, 2018, included elsewhere in this annual report.

Share-Based Compensation

In 2013 and in 2018, we have adopted share-based compensation plans for employees, directors and service providers. Our share-based compensation plan adopted in 2013 governs issuance of equity incentive awards prior to our initial public offering, and the share-based compensation plan adopted in 2018 governs issuance of equity incentive awards from and after the closing of our initial public offering. As part of the plans, 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 service 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 prior to the initial public offering 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, 2017 and 2018, 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, prior to our initial public offering, 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 in October 2017, the fair value of our Ordinary Shares was based on the market approach and used a price per share of $908.78 (prior to split) per Series B preferred share from the Company’s preferred share issuance as a basis for fair market value.

Following the initial public offering, the fair value of our Ordinary Shares and Warrants is determined based on the closing price of our Ordinary Shares and Warrants on Nasdaq.

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,		
	2018	2017	2016
		(in thousands)	
Research and development	$ 1,333	$ 323	$ 130
General and administrative (1)	(100)	4,562	1,360
Total	$ 1,233	$ 4,885	$ 1,490

(1) The resignation of Mr. Beshar, the previous Chairman of our board of directors took effect on June 27, 2018. According to Mr. Beshar's options terms, options which have yet to fully vest are forfeited, therefore 453,050 options forfeited and were recognized in the financial statements as a reverse of expense under the General and administrative line item in the amount of $1.3 million.

Fair Value of Financial Liabilities Through Profit or Loss

Prior to the initial public offering, the Series A preferred shares and warrants to purchase Series A preferred shares, Series B preferred shares, Series B-1 preferred shares, warrants to purchase Series B preferred shares and liability to issue preferred shares and warrants were 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 used our judgment to select a variety of methods and made assumptions that are mainly based on market conditions existing at the end of each reporting period prior to the IPO. 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.

The fair value of our tradable Warrants issued in the initial public offering, immediately prior to the initial public offering closing date and as of December 31, 2018 was based on quoted price on Nasdaq (Level 1 valuation) as of the respective date. 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 (prior to split) 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,		
	July 2, 2018	2017	2016
Price per share*	865	$ 908.78	
Value of equity*		$78 million	$71 million
Volatility	62%	55%	77%
Probability of entering Phase 2b/3 trial for EB612	N/A	70%	70%
Probability for IPO/shares registration	100%	85%	50%

* The price per share as of July 2, 2018 was based on quoted price on Nasdaq prior to split. 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 Ordinary 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, 2018 and 2017

	Year Ended December 31,		Increase (Decrease)	
	2018	2017	$	%
	(In thousands, except for percentage information)			
Revenues	$ 500	$ -	$ 500	N/A
Expenses:				
Research and development expenses, net	$ 8,518	$ 2,768	$ 5,750	207.7%
General and administrative expenses	2,843	8,575	(5732)	(66.8)%
Operating loss	10,861	11,343	(482)	(4.25)%
Financial income, net	(557)	(146)	(411)	-
Net loss (income)	$ 10,304	$ 11,197	$ (893)	(7.98)%

Revenue

Revenues for the year ended December 31, 2018 were $0.5 million. Our revenues during 2018 were attributed to the right to use our intellectual property granted to Amgen pursuant to the Amgen Agreement, which was evaluated at $0.5 million. For the accounting treatment see above "—Financial Overview—Critical Accounting Policies and Estimate—Revenue Recognition." We did not have any revenues prior to the signing of the Amgen Agreement, and therefore we did not recognize any revenues in 2017.

Research and Development Expenses, Net

Research and development expenses for the year ended December 31, 2018 were $8.5 million, compared to $2.8 million for the year ended December 31, 2017, an increase of $5.7 million, or 207.7%. The increase in research and development expenses was primarily due to increases of $1.7 million in salaries and related employee expenses, (of which $1.0 million resulted from an increase in share-based compensation expenses), $2.4 million for materials, clinical manufacturing and production capabilities for advanced clinical studies and certain pre-clinical activities, and an increase in subcontractor and CRO expenses of $1.5 million comprised of $1.3 million expenses for the Phase 2 PK/PD Study in Hypoparathyroidism offset by $0.2 million in other subcontractors and CROs expenses and an increase of approximately $0.4 million mainly for regulatory consulting. In addition, there was an increase of $0.1 million in other research and development expenses.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2018 were $2.8 million, compared to $8.6 million for the year ended December 31, 2017, a decrease of $5.8 million, or 66.8%. The decrease in general and administrative expenses was primarily due to a decrease of $4.7 million in share-based compensation expenses, of which a decrease of $1.3 million due to a reversal of compensation recorded on previous period as a result of termination of services by Mr. Luke Beshar, our previous Chairman of the board of directors, a decrease of $1.5 million of consulting services, legal and accounting for our previous financing efforts of which $1.1 million is related to Preferred B round capital raise. This decrease is offset by an increase of $0.4 million for directors' and officers' insurance.

Financial Income Expenses, Net

Financial income, net for the year ended December 31, 2018 was $0.6 million, compared to $0.1 million for the year ended December 31, 2017. Financial income, net for the year ended December 31, 2018 resulted mainly from financial income of $0.5 million through the change in the fair value of convertible loans, preferred shares and warrants to purchase preferred shares that were recorded as a financial liability at fair value through profit or loss of $0.4 million (up until July 2, 2018 when they were converted to Ordinary Shares and warrants and were classified as equity), and a change of $0.1 million in fair value of the Warrants issued at the Company's initial public offering and are recorded as a financial liability through profit and loss. For the assumptions used in the valuation of the convertible loans and preferred shares components see above "—Financial Overview—Critical Accounting Policies and Estimate—Fair Value of Financial Liabilities Through Profit or Loss."

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 in 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 above "—Financial Overview—Critical Accounting Policies and Estimate—Fair Value of Financial Liabilities Through Profit or Loss."

5.B. Liquidity and Capital Resources

Since inception, we have incurred significant losses. As a result of our recurring losses from operations, negative cash flows and lack of liquidity, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of, and for the year ended, December 31, 2018, expressing the existence of substantial doubt about our ability to continue as a going concern. For the years ended December 31, 2016, 2017 and 2018, our operating losses were $5.4 million, $11.3 million and $10.9 million, respectively. In addition, during the years ended December 31, 2016, 2017, and 2018 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, 2018, we had an accumulated deficit of $52.1 million. Since our inception and through December 31, 2018, we have raised a total of $42.5 million, including $11.2 million from our initial public offering, $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 15, 2019, we had cash and cash equivalents of $9.6 million. Our primary uses of cash have been to fund research and development, general and administrative and working capital requirements, and we expect these will continue to be our primary uses of cash. On December 10, 2018, we signed the Amgen Agreement, pursuant to which we received in January 2019 a non-refundable and non-creditable initial technology access fee of $725,000.

Funding Requirements

We estimate that our existing cash and cash equivalents will not enable us to fund our research and development expenses, general and administrative expenses and working capital requirements for the next 12 months, during which we intend to conduct various development work designed to support advanced clinical trials such as 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, EB613, EB612 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.

Management is in the process of evaluating various financing alternatives in the public or private equity markets, or through license of the company's technology to additional external parties through partnerships or research collaborations, as the Company will need to finance future research and development activities and general and administrative expenses through fund raising.

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 consolidated financial statements for the year ended December 31, 2018, included elsewhere in this annual report, 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 consolidated 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 expressed substantial doubt about our ability to continue our operations without an additional infusion of capital from external sources. The audited consolidated 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 would lose all or a part of their investment.

Cash Flows

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

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,	
	2018	**2017**
	(in thousands)	
Cash used in operating activities	$ (9,796)	$ (4,526)
Cash provided by (used in) investing activities	(4,068)	1,002
Cash provided by financing activities	9,624	11,107
Net increase (decrease) in cash and cash equivalents	$ (4,240)	$ 7,583

Net Cash Used in Operating Activities

Net Cash used in operating activities for the year ended December 31, 2018 was $9.8 million consisting primarily of our operating loss of $10.9 million arising mainly from research and development expenses and general and administrative expenses, partially offset by $1.2 million of share-based compensation, $0.3 thousand due to issuance costs related to our initial public offering but further increased by $0.5 million in working capital.

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.

The increase in cash used in operating activities from 2017 to 2018 was mainly due to an increase of $0.7 million in expenses for salaries and related employee expenses in addition to an increase of $2.0 million for materials, clinical manufacturing and production's capabilities, and an increase in subcontractors and CROs of $0.8 million of Phase 2 PK/PD Study in Hypoparathyroidism, in addition to other payments for working capital including for professional services and other expenses.

Net Cash Provided by (Used in) Investing Activities

Net Cash used in investing activities for the year ended December 31, 2018 consisted primarily of our investment in short-term bank deposits.

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 Provided by Financing Activities

Net Cash provided by financing activities for the year ended December 31, 2018 resulted from net proceeds of $9.6 million from issuance of Ordinary Shares and Warrants in our initial public offering which was completed on July 2, 2018.

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.

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.

5.C. [Reserved]

5.D. Trend Information.

We are currently in the development stage and we expect to remain in that stage for the upcoming year, and therefore trends relating to production, sales, inventory, backlog and selling prices are not applicable. See “Item 5.–Operating and Financial Review and Prospects” for a summary of recent trends.

5.E. Off-Balance Sheet Arrangements

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

5.F Contractual Obligations

The following tables summarize our contractual obligations and commitments as of December 31, 2018 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(*)	$ 123	$ 87	$ 36	$ -	$ -
Accounts payable, accrued expenses and other current liabilities	$ 1,563	$ 1,563	$ -	$ -	$ -
Total	$ 1,686	$ 1,650	$ 36	$ -	$ -

(*) In January 2019, the Company entered into a new lease agreement for the building it uses in consideration of approximately additional $94 thousand per year. The new lease will begin in February 2019. The whole lease agreement will expire on June 30, 2023 with a one-time option for the Company to early terminate the agreement on December 31, 2021 subject to a notice period of six months. Upon entering into the new lease agreement, the Contractual obligation for less than one year will be $173 thousand, and for 1-3 years, the Contractual obligation will be $317 thousand.

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, 2018, our severance pay liability, net was $65,000. 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 or revenues from the Amgen Agreement. 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 "Item 4.B.—Business Overview—Patent Transfer, Licensing Agreement and Grant Funding."

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

6.A. Directors and Senior Management

The following table sets forth information relating to our executive officers and directors as of the date of this report. Unless otherwise stated, the address for our directors and executive officers is c/o Entera Bio Ltd., Kiryat Hadassah, Minrav Building - Fifth Floor, Jerusalem, Israel.

Name	Age	Position
Executive Officers		
Dr. Phillip Schwartz	57	Chief Executive Officer and Director
Mira Rosenzweig[1]	47	Chief Financial Officer
Dr. Hillel Galitzer	40	Chief Operating Officer
Dr. Arthur Santora	68	Chief Medical Officer
Non-Employee Directors		
Gerald Lieberman[3]	72	Director, Chairman of the Board of Directors
Dr. Roger J. Garceau	65	Director, Chief Development Advisor
Zeev Bronfeld	67	Director
Yonatan Malca	52	Director
Faith L. Charles[2][3] [4] [5]	57	Director, Chairman of the Compensation Committee
Miranda J. Toledano[2][3] [4] [5]	42	Director, Chairman of the Audit Committee
Gerald M. Ostrov[3] [4] [5]	69	Director

(1) On March 7, 2019, we announced that Ms. Rosenzweig will be leaving the Company in mid-April 2019 on amicable terms to pursue other professional opportunities closer to home.
(2) External Director under Israeli law.
(3) Independent director in accordance with SEC regulations and Nasdaq rules requirements applicable to us.
(4) Member of the Compensation Committee.
(5) Member of the Audit Committee.

Our executive officers

Dr. Phillip Schwartz has served as our Chief Executive Officer and as a Director since our inception in 2010. Dr. Schwartz has more than 20 years of biotech and pharmaceutical industry experience. He previously served as the manager of clinical affairs at Endo Pharmaceuticals plc 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 plc and Serono. He has also worked as an external consultant for a number of venture capital firms. 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 tier one peer-reviewed journals and has presented papers at numerous international conferences. He has also worked in the neurobiology laboratory of Nobel Laureate Professor Torsten Wiesel of the Rockefeller University. Dr. Schwartz holds a B.A. in psychology and architecture from Columbia University, an M.Sc. in immunology while studying under Professor Irun Cohen at the Weizmann Institute, and a 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. On March 7, 2019, we announced that Ms. Rosenzweig will be leaving the Company in mid-April 2019 on amicable terms to pursue other professional opportunities closer to home. Ms. Rosenzweig has over 15 years of experience in financial management. Ms. Rosenzweig previously 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. (TASE: ELRN), 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. Dr. Galitzer has more than ten years of experience in medical research and molecular biology. 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 (TASE: HDST) 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. Arthur Santora has served as our Chief Medical Officer since September 2018. Dr. Santora has more than 30 years of experience in the biopharmaceutical industry. He spent the majority of his career in the clinical research team at Merck & Co., Inc., from June 1989 to March 2017, where he was the lead clinical research physician responsible for much of the clinical development of Fosamax® (alendronate sodium), one of the world's most prescribed osteoporosis treatments. He was closely involved in the clinical development of Merck's once-weekly Fosamax Plus D (alendronate sodium/ vitamin D3 combination tablets), the first drug/vitamin combination tablet in the US. His position at Merck immediately prior to his termination of services in 2017 was Scientific Associate Vice President of Clinical Research, where he was directly responsible for the technical and scientific support for all clinical research of Fosamax/Fosamax plus D and contributed to the development of many other osteoporosis and endocrine marketed and investigational drugs. Prior to joining Merck, he served as a Medical Officer at the US FDA and subsequently was a faculty member at Wayne State University Medical School in Detroit. Dr. Santora is a Clinical Associate Professor at the clinical faculty of Rutgers Robert Wood Johnson Medical School in New Brunswick, New Jersey. He has graduate training in Internal Medicine at Emory, and its Endocrinology and Metabolism subspecialty at the NIH in Bethesda. Dr. Santora received his M.D. and Ph.D. in biochemistry from Emory University in Atlanta.

Our Directors

Gerald Lieberman has served as chairman of our board of directors since August 2018, and as a member of our board of directors since 2014. Mr. Lieberman currently serves on the board of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), a publicly traded company, serves on the board of Sesame Enable Ltd., a company which develops software enabling products for the disabled including the first touch-free smart phone and serves as a special advisor at Reverence Capital Partners, a private investment firm focused on the middle-market financial services industry. From 2011 to 2014, he served on the board of directors of Forest Laboratories Inc., which was acquired by Actavis plc in 2014. Between 2003 and 2009, Mr. Lieberman was president and chief operating officer of AllianceBernstein L.P. (NYSE: AB). 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, serving on both companies most senior management committees. 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, and served as a trustee of the University of Connecticut Foundation, Inc., where he was chairman of the finance committee and a member of the investment and executive committees.

Dr. Roger J. Garceau has served as a member of our board of directors since March 2016, and as our Chief Development Advisor since December 2016. Dr. Garceau has more than 30 years of broad pharmaceutical industry experience. He has been a director of Enterome SA since December 2016, and a director of ArTara Therapeutics since January 2019. 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, Inc., then traded on Nasdaq was acquired by Shire plc. (NASDAQ: SHPG). Previously, Dr. Garceau served in several managerial positions with Sanofi-Aventis (NYSE: SNY) from 2002 until 2008, and Pharmacia Corporation from 1986 until 2002. 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.

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 has vast experience in the management and value building of biotechnology companies. Mr. Bronfeld currently serves on the board of directors of D.N.A Biomedical Solutions Ltd., Electreon Wireless Ltd. and The Trendlines Group Ltd. as well as on the board of director of a number of privately-held companies, including, Contipi Medical Ltd. and as the chairman of the board of TransBiodiesel Ltd. Furthermore, since 2003, Mr. Bronfeld serves as the chief executive officer of M.B.R.T Development and Investments Ltd. Until January 2017, he served as a director of Macrocure Ltd. and until December 2016 he served as a director of D. Medical Industries Ltd. and Nasvax Ltd. 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. Between 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. Mr. Bronfeld holds a B.A. in Economics from the Hebrew University of Jerusalem.

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. (TASE: ARKO), Nextgen-Biomed LTD. (TASE: NXGN) and of Tamda Ltd. (TASE: TMDA), all 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 holds a B.A. in Economics and Statistics from Bar-Ilan University and an M.A. in Economics and Finance from Bar Ilan University, Israel.

Faith L. Charles has served as a member of our board of directors since September 2018. Ms. Charles is a partner in the Corporate Transactions and Securities Practice, and the chair of the Life Sciences Group at Thompson Hine, LLP., since 2010. In March 2019, Ms. Charles, joined the board of Amydis Inc., a private pharmaceutical company developing compounds and tests for the early detection of Alzheimer’s and other Amyloid associate diseases. Since September 2018, Ms. Charles serves as a member of the board of Sandstone Diagnostics, Inc., a private technology and healthcare company focused on using centrifugal testing to improve healthcare. Since 2016, Ms. Charles serves as a member of the board of AgilVax Inc., a private biotechnology company focused on cancer immunotherapies and targeted infectious vaccines, and as a member of the board of Gilda's Club New York City, an organization that provides medical, emotional and support services to cancer patients and their families. Ms. Charles also serves as steering committee member and Co- Founder, and has previously served as chair, of Metro NY Women in Bio, an organization of professionals committed to promoting careers, leadership and entrepreneurship for women in the life sciences industry, since 2013. From 2000 until 2010, Ms. Charles served as partner at Mintz, Levin, Cohn, Ferris, Glovsky & Popeo, P.C. Prior to that, starting in 1986, Ms. Charles served as partner and associate at other law firms, where she focused on capital markets, licensing and other strategic collaborations and mergers and acquisitions for emerging and public companies. Ms. Charles holds a J.D. degree from The George Washington University Law School and a B.A. in Psychology from Barnard College, Columbia University. Ms. Charles is also a graduate of Women in Bio's Boardroom Ready Program, an Executive Education Program taught by The George Washington University School of Business.

Miranda J. Toledano has served as a member of our board of directors since September 2018. Ms. Toledano serves as Chief Operating Officer / Chief Financial Officer of TRIGR Therapeutics, a clinical stage immuno-oncology company focused on bispecific antibodies. Previously, from September 2016 until August 2017, Ms. Toledano served on the executive management team of Sorrento Therapeutics (Nasdaq: SRNE) as EVP Corporate Development. From 2012 to 2016, Ms. Toledano served as Head of Healthcare Investment Banking at MLV & Co. (acquired by B. Riley FBR & Co.), where she completed equity capital market transactions totaling over $4 billion in aggregate value. Prior to joining MLV, from 2004 until 2010, Ms. Toledano served in the investment group of Royalty Pharma, a leading investment firm with over $15 billion in biotherapeutic royalty assets. From 1998 to 2003, Ms. Toledano led the Life Sciences Corporate Finance group at Ernst & Young (Israel). Ms. Toledano holds a BA in Economics from Tufts University and an MBA in Finance and Entrepreneurship from the NYU Stern School of Business.

Gerald M. Ostrov has served as a member of our board of directors since January 2019. Mr. Ostrov consults and invests in new technologies in the medical device and consumer products fields. Mr. Ostrov currently serves on the board of directors of several privately held companies, including Mother’s Choice, a natural products company working with industry giants, Addon Optics, an innovative technology company, and Nuvo, a developer of next generation baby and mother health monitoring for both hospital and home use. From 2008 to 2010, he served as Chairman and CEO of Bausch & Lomb. There Mr. Ostrov led the stabilization, streamlining and pipeline building of Bausch & Lomb following its going-private transaction. From 1998 until 2006, Mr. Ostrov very successfully served as Company Group Chairman for Johnson & Johnson's Worldwide Vision Care businesses. From 1991 to 1998, Mr. Ostrov worked for Johnson & Johnson and quickly rose to serve as Company Group Chairman of the Consumer and Personal Care businesses in North America. From 1982 to 1991 he served as President of CIBA Consumer Pharmaceuticals Company. From 1976 to 1982 he worked for the Health Care Division of Johnson & Johnson. From 1973 to 1976, Mr. Ostrov worked at Procter & Gamble. Mr. Ostrov holds a B.S. from Cornell and an M.B.A. from Harvard.

Arrangements Concerning Election of Directors; Family Relationships

We are not a party to, and are not aware of, any voting agreements among our shareholders. In addition, there are no family relationships among our executive officers and directors.

6.B. Compensation

Compensation of Executive Officers and Directors

The following table summarizes the compensation awarded to, earned by, or paid to each of our five most highly compensated directors and executive officers during the twelve months ended on December 31, 2018 (in U.S. dollars), excluding amounts paid to reimburse costs incurred in providing us services during such period:

		Annual 2018 Compensation				
Name	**Position**	**Base Salary and Related Benefits(1)**	**Bonus**	**Retirement, Service Fees and Other Similar Benefits**	**Share Based Compensation(2)**	**Total**
Dr. Phillip Schwartz	Chief Executive Officer and Director	$ 319,610	-	42,953	754,699	1,117,262
Dr. Hillel Galitzer	Chief Operating Officer	$ 214,650	-	21,023	278,320	513,993
Mira Rosenzweig	Chief Financial Officer	$ 194,680	-	26,750	177,113	398,543
Dr. Eric Lang	Previous Chief Medical Officer	$ 267,258	-	18,411	104,941	390,610
Dr. Roger J. Garceau	Chief Development Advisor	$ -	-	108,923	269,419	378,342

(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 with respect to all options granted to such officers, calculated using the actual exchange rate on the grant date.

The aggregate compensation paid and equity-based compensation and other payments expensed by us to all of our directors and executive officers with respect to the year ended December 31, 2018 was $2.5 million. This amount does not include business travel, professional and business association dues and expenses reimbursed to office holders, and other benefits commonly reimbursed or paid by companies in our industry.

As of December 31, 2018, options to purchase a total of 1,756,820 Ordinary Shares granted to our current directors and executive officers were outstanding under our Share Incentive Plan, or the 2013 Plan. The weighted average exercise price of options as of December 31, 2018, was $2.8 per share. For more information regarding our 2013 and 2018 Plans, see “Item 6.E.—Directors, Senior Management and Employees—Share Ownership—Equity Incentive Plans.”

The total amounts set aside or accrued by the company or its subsidiary to provide pension, retirement or similar benefits for our executive officers and directors in 2018 amounted to approximately 109,100.

6.C. Board practices

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.

Our board of directors currently consists of eight directors, including our two external directors, Ms. Faith L. Charles and Ms. Miranda J. Toledano, whose appointment fulfills the requirements of the Companies Law. See "Item 6.C.—External Directors." In addition, these two directors qualify as independent directors under the corporate governance standards of the Nasdaq rules and the audit committee independence requirements of Rule 10A-3 of the Exchange Act. Mr. Gerald Lieberman and Mr. Gerald M. Ostrov also satisfy the independence requirements of the Nasdaq rules and the Exchange Act.

According to our 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, is divided into three classes, with staggered three-year terms and one director class coming up for election each year. The Class I directors were re-elected at our 2018 annual meeting of shareholders to serve until our annual meeting of shareholders in 2021. The Class II and Class III directors will serve until our annual meetings of shareholders in 2019 and 2020, respectively. The members of the classes as of the date hereof is 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.

In January 2019, Mr. Gerald M. Ostrov was also appointed by our board to serve as our director. Mr. Ostrov will serve until our annual meeting of shareholders in 2019.

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.

In accordance with the exemption available to foreign private issuers, we do not follow the requirements of the Nasdaq rules with regard to the process of nominating directors, and instead, follow Israeli law and practice, in accordance with which our board of directors (or a committee thereof) is authorized to recommend to our shareholders director nominees for election.

Under the Companies Law and our Articles, nominees for directors may also be proposed by any shareholder holding at least one percent (1%) of our outstanding voting power. However, any such shareholder may propose a nominee only if a written notice of such shareholder's intent to propose a nominee has been given to our Secretary (or, if we have no such Secretary, our Chief Executive Officer). Any such notice must include certain information, including, inter alia, a description of all arrangements between the nominating shareholder and the proposed director nominee and any other person pursuant to which the nomination is to be made by the nominating shareholder, the consent of the proposed director nominee to serve as our director if elected and a declaration signed by the nominee declaring that there is no limitation under the Companies Law preventing his or her election, and that all of the information that is required under the Companies Law to be provided to us in connection with such election has been provided.

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 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).

Under the Companies Law, our board of directors must also determine the minimum number of directors who are required to have accounting and financial expertise. In determining the number of directors required to have such expertise, our board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that the minimum number of directors of our company who are required to have accounting and financial expertise is one. Our board of directors has determined that Mr. Gerald Lieberman meet such qualifications. In addition, our board of directors has determined that Mr. Lieberman, who has been nominated to serve on our audit committee, is financially literate as determined in accordance with the Nasdaq rules and that Mr. Lieberman is qualified to serve as an audit committee financial expert, ("Audit Committee Financial Expert"), as defined by SEC rules.

Our board has further determined that Ms. Miranda J. Toledano qualifies to serve as an Audit Committee Financial Expert and has financial and accounting expertise, or Financial and Accounting Expertise, as defined in the regulations promulgated under the Companies Law.

Chairman of the Board

In accordance with our Articles, our board of directors is required to appoint one or more of its members to serve as chairman of the board of directors. Our board of directors has appointed Mr. Gerald Lieberman to serve as chairman of our board of directors.

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, 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. As of December 31, 2018, Centillion holds approximately 17.5% of our issued and outstanding Ordinary Shares.

Alternate Directors

Our Articles provide that, as permitted under Israeli law, any director may appoint another person, who is qualified to be appointed as a director and 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 terminate under circumstances in which, according to our Articles, the term of any director shall terminate or 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.

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 Nasdaq, 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).

An external director must also have either Financial and Accounting Expertise or professional qualifications, as defined in regulations promulgated under the Companies Law, while 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, other than exculpation, insurance, an undertaking to indemnify or indemnification.

Under the Companies Law, external directors must be elected at a shareholder meeting by a simple majority of the votes cast on the matter, provided that (i) 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), or (ii) the total number of shares held by shareholders who do not have a personal interest (as described herein, in sub-section (i)) who voted against the election did not exceed 2% of our aggregate voting rights in the Company. External directors serve for up to three terms of three years each. Even if an external director is not nominated by our board of directors for re-election for a second or third term, the external director may be nominated for re-election by either (i) one or more shareholders holding at least 1% of our voting rights, or (ii) the external director itself. If nominated by our board of directors, the re-election should be approved by the same process for initial election as described hereinabove. If nominated by one or more shareholders holding at least 1% or by the external director itself, the re-election can be approved by a simple majority, provided that (i) votes cast by controlling shareholders and shareholders who 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 abstentions are not taken into account, and (ii) the votes cast by such non-controlling and disinterested shareholders for approval of 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. Ms. Faith L. Charles and Ms. Miranda J. Toledano were elected to serve as our external directors in our 2018 annual meeting of shareholders.

Board Committees

Our board of directors has established the following committees:

Audit Committee

Composition and Quorum

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 chairperson 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 Nasdaq, 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 Nasdaq rules and SEC regulations applicable to foreign private issuers, we are required to maintain an audit committee consisting of independent directors, and one of whom has accounting or related financial management expertise and qualifies as an Audit Committee Financial Expert as such term is defined in Item 407(d)(5) of Regulation S-K of the Securities and Exchange Act of 1934.

In order for a director to be designated as "independent" under general Nasdaq rules and SEC regulations, he or she must not have a material relationship with the company that would impair his or her independence, such as, inter alia, a commercial, consulting, legal, accounting or familial relationships. However, ownership of a significant amount of shares or affiliation with a major shareholder should not, in and of itself, preclude the board from determining that a director is independent, nor is the board precluded from appointing its chairman as a member of the audit committee or as chairman of the committee.

In order for a director to be designated as "financially literate" under Nasdaq rules and SEC regulations, he or she is required to have sufficient understanding of the language of accounting and corporate finance to act as an effective overseer of the integrity of a company's financial reporting process and its financial statements, including the selection and oversight of the performance of the external and internal auditors.

In order for a director to qualify as an Audit Committee Financial Expert under SEC regulations he or she must have education and experience as chief financial officer, chief accounting officer, controller, public accountant or auditor, or experience in one or more positions that involve the performance of similar functions or in actively supervising such positions. If no audit committee member qualifies, the company must state why its audit committee lacks a financial expert.

Our audit committee consists of Miranda J. Toledano (Chairman), Faith L. Charles and Gerald M. Ostrov. Each of the members of our audit committee is eligible to be classified as an independent director in accordance with SEC regulations and satisfies the independent director requirements under Nasdaq rules applicable to us. All designated members of our audit committee meet the requirements for financial literacy Nasdaq rules and SEC regulations. Our board has determined that Ms. Miranda J. Toledano is an Audit Committee Financial Expert, as such term is defined under applicable SEC rules. Ms. Faith L. Charles and Ms. Miranda J. Toledano, members of our audit committee, serve as our external directors.

Roles, Responsibilities and Procedures

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

Our board of directors has adopted an audit committee charter that sets forth the responsibilities of the audit committee consistent with the rules and regulations of the SEC and the Nasdaq, as well as the requirements for such committee under the Israeli Companies Law, including: (a) oversight of our independent auditor and appointment, pre-approval of the engagement, compensation, retention or termination of engagement of our independent auditor (subject to shareholder ratification), and examination of the scope of work and fees of the independent auditor and submission of recommendations to our shareholders; (b) review of the independence and quality control procedures of the independent auditor and the experience and qualifications of the independent auditor's senior personnel that are providing audit services to the Company; (c) meeting with the Company's management and independent auditor to discuss certain issues regarding the annual audit, separately meeting the independent auditor to discuss certain other audit issues regarding the annual audit, reviewing our annual audited financial statements and quarterly financial statements with management and the independent auditor, including a review of our disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations," and with respect to the annual audit, determining whether to recommend to the board of directors that the audited financial statements be included in the Company's Annual Report for the fiscal year subject to the audit; (d) discuss with management and the independent auditor the Company's earnings press releases, as well as financial information and earnings outlook provided to analysts and rating agencies; (e) reviewing any impairment in the management of the Company's business, and suggesting an appropriate course of action to the board of directors; (f) to the extent required under the applicable law, (i) conduct an appropriate review and oversight of all "related party transactions" for potential conflict of interest situations on an ongoing basis, as required under the applicable law, and approve such transactions, where required; (ii) decide if an action of an officer is "material"; and (iii) decide if a transaction of the Company with an officer or controlling shareholder (or in which they have a personal interest) is an extraordinary transaction, or Extraordinary Transaction, and the way in which a non-redundant transaction, or Non-redundant Transaction, shall be approved, including such type of Non-redundant Transaction which shall require the approval of the Committee; (g) discuss with the independent auditor and any other organ of the Company as the committee deems appropriate at its sole discretion, any correspondence from or with regulators or governmental agencies, any employee complaints or any published reports that raise material issues regarding the Company's financial statements, financial reporting process, accounting policies or internal audit function; (h) establish procedures for the receipt, retention and treatment of complaints received by the Company regarding impairment in the business management, accounting, internal accounting controls or auditing matters and establish procedures for the confidential and anonymous submission by employees regarding questionable accounting or auditing matters; (i) providing the Company with the report with respect to the audited financial statements for inclusion in each of the Company's annual proxy statements; (j) reporting regularly to, and review with the board of directors any issues that arise with respect to the quality or integrity of the Company's financial statements, the Company's compliance with legal or regulatory requirements, the performance and independence of the Company's independent auditor, the performance of the Company's internal audit function, the internal auditor's work plan or any other matter the committee determines necessary or advisable to report to the board of directors, including any new or proposed accounting policies to be adopted by the Company or any new standards promulgated by the SEC or other regulatory body; (k) at least annually, performing an evaluation of the performance of the committee and its members, and, annually reviewing and re-assessing the committee's charter and submitting any recommended changes to the board of directors for its consideration; (l) without otherwise limiting or impacting the responsibilities of any other committee of the board of directors pursuant to applicable law, proposing the appointment, termination and replacement of the internal auditor to the Board as required under the Companies Law; (m) examining the internal audit function and performance and if he/she has reasonably sufficient resources and tools in order to perform his or her role, taking into account the Company's special needs and size; (n) setting clear hiring policies for employees or former employees of the Company's independent auditor; (o) discussing the Company's information security, business continuity programs and controls and systems to monitor and manage business risk; and (p) any other responsibilities which may be assigned from time to time by the Company's board of directors.

The responsibilities of an audit committee under the Companies Law include (a) identifying and addressing deficiencies in the business management practices of the company, including, inter alia, in consultation with our internal auditor or the independent auditor, and making recommendations to the board of directors as to how to correct such practices; (b) determining whether certain related party transactions are extraordinary or material under the Israeli Companies Law, including transactions in which an office holder has a personal interest, and whether to approve such transactions; (c) establishing the approval process for certain transactions with a controlling shareholder or in which the controlling shareholder has a personal interest; (d) examining and approving the work plan of the internal auditor, subject to any modifications in its discretion; (e) examining our internal audit controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to fulfill his responsibilities; (f) examining the scope of our independent auditor's work and compensation and submitting its recommendation with respect thereto to our board of directors or shareholders, depending on which of them is considering the appointment of our auditor; and (g) establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees.

Our audit committee is also responsible for assisting our board of directors in monitoring our financial statements and our compliance with legal and regulatory requirements.

A "personal interest" includes an interest of any person in an action or transaction of a company, excluding any interest arising solely from holding the Company's shares, but including the personal interest of such person's spouse, siblings, parents, grandparents, descendants, spouse's descendants, siblings or parents or the spouse of any of such persons, and the personal interest of any entity in which such person or one of the aforementioned relatives of such person serves as a director or chief executive officer, owns 5% or more of such entity's outstanding shares or voting rights or has the right to appoint one or more directors or the chief executive officer. Further, in the case of a person voting by proxy at a shareholder meeting, "personal interest" includes the personal interest of either the proxy holder or the shareholder granting the proxy, whether or not the proxy holder has discretion how to vote.

Under the Israeli Companies Law, an Extraordinary Transaction is defined as any of the following:

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

Our audit committee may not approve any actions requiring its approval, unless, at the time of the approval, a majority of the committee's members are present, which majority consists of independent directors.

Compensation Committee

Composition and quorum

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.

Our compensation committee consists of Faith L. Charles (Chairman), Miranda J. Toledano and Gerald M. Ostrov. Our compensation committee satisfies the requirements of the Companies Law, but not Nasdaq rules applicable to compensation committees, which the Company has chosen to opt out of as a foreign private issuer. Each member of our compensation committee is independent under Nasdaq rules. Ms. Faith L. Charles and Ms. Miranda J. Toledano, members of our compensation committee, serve as our external directors. See "Item 16.G.—Corporate Governance Practices" below.

Roles, responsibilities and procedures

Our board of directors has established a compensation committee and adopted a charter setting forth its purpose, which includes: (a) assisting the board of directors in discharging its responsibilities relating to (i) the compensation of the Company's directors, chief executive officer and other executive officers, and (ii) the overall Company's compensation programs; (b) recommending the approval of a compensation policy to the board, in accordance with the requirements of the Companies Law, and any other incentive-based compensation plans and equity-based plans (collectively, the "Compensation Plans and Policies"); (c) oversight of the development and implementation of the Compensation Plans and Policies that are appropriate for the Company in light of all relevant circumstances, and recommend to the board of directors any amendments or modifications to the Compensation Plans and Policies that the committee deems appropriate, including the extension of Compensation Plans and Policies as required by the Companies Law; (d) determining whether to approve transactions concerning the terms of engagement and employment of the Company's chief executive officer, other executive officers and directors that require the Committee approval under the Companies Law or the Compensation Plans and Policies; (e) taking any further actions as the committee is required or allowed to under the Companies Law or the Compensation Plans and Policies; (f) reviewing and approving, or if required by law, approving and recommending the board of directors to approve grants and awards under the Company's equity incentive plans; and (g) reviewing the adequacy of the committee's charter on an annual basis, and recommending the board of directors any amendments or modifications to the charter that the committee deems appropriate.

Compensation Policy

Under the Israeli Companies Law, a compensation policy must be adopted by the board of directors after considering the recommendations of the compensation committee and needs to be further brought before the company's shareholders for approval, referred to herein as the Special Majority Approval for Compensation. A Special Majority Approval for Compensation requires shareholder approval by a majority vote of the shares present and voting at a meeting of shareholders called for such purpose, provided that either: (a) such majority includes at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such compensation arrangement; or (b) the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in the compensation arrangement and who vote against the arrangement does not exceed 2% of the company's aggregate voting rights.

The compensation policy must serve as the basis for decisions concerning the terms of employment or engagement of office holders, including exculpation, insurance, indemnification and any monetary payment and obligation of payment in respect of employment or engagement. The compensation policy must relate to certain factors, including advancement of the company's objectives, the company's business plan and its long-term strategy, and creation of appropriate incentives for office holders. It must also consider, inter alia, the company's risk management, size and the nature of its operations.

The compensation policy must furthermore consider additional factors, as follows: (a) the knowledge, skills, expertise and accomplishments of the relevant office holder; (b) the office holder's roles and responsibilities and prior compensation agreements with him or her; (c) the ratio between the terms offered and the average compensation of the other employees of the company, including those employed through manpower companies; (d) the impact of disparities in salary upon work relationships in the company; (e) the possibility of reducing variable compensation at the discretion of the board of directors; (f) as to variable compensation, the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and (g) as to severance compensation, the period of service of the office holder, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contribution towards the company's achievement of its goals and the maximization of its profits, and the circumstances of termination of service.

The compensation policy must also include the following principles: (a) the link between variable compensation and long-term performance and measurable criteria; (b) the ratio between variable and fixed compensation, and the ceiling for the value of variable compensation; (c) the conditions under which an office holder would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements; (d) the minimum holding or vesting period for variable, equity-based compensation; and (e) maximum limits for severance.

Under the Israeli Companies Law, every three years we are required to re-obtain the approval of our compensation committee, board of directors and shareholders for either the continuation of our existing compensation policy or adoption of a new compensation policy, provided however that the compensation policy adopted within nine months from the closing of our initial public offering is valid for five years, specifically July 2, 2023. Our compensation policy was adopted by our shareholders on September 27, 2018 (following our initial public offering dated July 2, 2018), after having been recommended by our compensation committee and approved by our board of directors, and will therefore need to be either re-approved, amended, or replaced by a new policy only in 2023, and every three years thereafter.

Our compensation committee may conduct or authorize investigations into, or studies of, matters within its scope of responsibilities, and may retain or obtain the advice of a compensation consultant, legal counsel or other advisor in its sole discretion. The compensation committee is directly responsible for the appointment, compensation and oversight of the work of any compensation consultant, legal counsel or other advisor that it retains, at the expense of the Company. The compensation committee may select, or receive advice from, a compensation consultant, legal counsel or other advisor to the compensation committee, other than in-house legal counsel, only after conducting an assessment of, and determining, the advisor's independence, including whether the advisor's work has raised any questions of independence or conflicts of interest, taking into consideration the Exchange Act, the factors set forth in Nasdaq rules and any other factors that the committee deems relevant.

In 2017, in determining the compensation of our chief executive officer and other executive officers, including bonus amounts, and in 2018 in determining our compensation policy, the compensation committee retained the services of a compensation consultant, Brightman Almagor Zohar & co., or Deloitte, to conduct a comparative survey of the compensation of such office holders. The surveys examined the publicly-reported cash and equity compensation of chief executive officers and other executive officers, of 8 comparable Israeli pharmaceutical and biotechnology companies.

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, inter alia, 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 any person on its behalf. In January 2019, Ms. Irena Ben-Yakar from Deloitte was appointed as the Company's internal auditor.

Exculpation, Insurance and Indemnification of Directors and Officers

Under the Companies Law, a company may not exculpate an office holder (including director) from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our Articles include such a provision. Notwithstanding, a company may not exculpate in advance a director from liability arising out of a breach of duty of care caused by dividend or distribution to shareholders.

Under the Companies Law, a company may indemnify an office holder in respect of the following liabilities and expenses incurred for acts performed by him or her as an office holder, either pursuant to an undertaking made in advance or following the indemnified event, if its articles of association includes a provision allowing such indemnification:

- financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail such foreseen events and amount or criteria;

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding, and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (2) in connection with a forfeit; and

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Companies Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder, if and to the extent provided in the company's articles of association:

- a breach of the duty of loyalty to the company, provided that the office holder acted in good faith and had reasonable grounds to believe that the act would not harm the company;
- a breach of the duty of care to the company or to a third party; and
- a financial liability imposed on the office holder in favor of a third party.

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

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable grounds to believe that the act would not harm the company;
- a breach of the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, monetary sanction, forfeit or penalty levied against, or imposed upon, the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders in a public company must be approved by the compensation committee and the board of directors, and with respect to certain office holders or under certain circumstances, also by the shareholders.

Our Articles permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by the Companies Law.

We have obtained, subject to shareholder approval, directors and officers liability insurance for the benefit of our office holders of $15 million per annum. We intend to maintain such coverage and pay all premiums thereunder to the fullest extent permitted by the Companies Law. In addition, we have entered into agreements with each of our directors and executive officers exculpating them from liability to us for damages caused to us as a result of a breach of duty of care and undertaking to indemnify them, in each case, to the fullest extent permitted by our Articles and Israeli Law.

6.D. Employees

As of December 31, 2018, we had 19 full time employees, and one full-time consultant who are all based in Israel and four additional part-time consultants, including our CMO, who are all based in the U.S. Five of our employees and consultants have either PhDs or MDs. The distribution of our full-time employees according to main areas of activity is set forth in the following table:

	Employees
Area of Activity:	
Research and development	15
General and administrative	4
Total	19

Israeli labor laws govern the length of the workday and workweek, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination, payments to the National Insurance Institute, and other conditions of employment and include equal opportunity and anti-discrimination laws. While we are not, and none of our employees is, party to any collective bargaining agreements, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees in Israel by order of the Israeli Ministry of the Economy. These provisions primarily concern pension fund benefits for all employees, insurance for work-related accidents, recuperation pay and travel expenses. We generally provide our employees with benefits and working conditions beyond the required minimums. We have never experienced any employment-related work stoppages, and believe our relationships with our employees are good.

In addition, we have entered into service agreements with three of our directors. See “Item 7.B.—Related Party Transaction—Service Agreements.”

6.E. Share Ownership

The following table provides information with respect to our securities held by our directors and executive officers as of March 15, 2019:

Name	Type of Security	Number of Securities[1]	Options/warrants Exercise Price ($)	Options/warrants Exercise Date	Percent of Shares Outstanding[2]
Dr. Phillip Schwartz	Shares	780	-	-	
	Options	428,480	NIS 0.0000769	05/02/2019	
	Options	150,150	NIS 0.0000769	01/20/2020	
	Options	357,500	$ 6.31	11/23/2023	
					5.7%
Dr. Roger J. Garceau	Shares	4,940	-	-	
	Warrants	1,950	$ 6.99	06/14/2020	
	Options	147,290	$ 3.69	03/29/2022	
	Options	209,040	$ 6.31	12/31/2026	
					2.7%
Mira Rosenzweig	-	-	$ -	-	
	Options	36,010	$ 2.43	05/29/2020	
	Options	91,000	$ 6.31	11/15/2023	
					*
Dr. Hillel Galitzer	Options	19,500	NIS 0.0000769	09/01/2019	
	Options	16,510	$ 1.85	09/01/2019	
	Options	143,000	$ 6.31	11/15/2023	
					*
Dr. Eric Lang[3]	-	-	$ -	-	-

* Less than 1%
(1) As of March 15, 2019.
(2) The percent of shares outstanding held by each beneficial ownership of our Ordinary Shares is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership, generally, includes any shares over which a person exercises sole or shared voting or investment power, or the right to receive the economic benefit of ownership. For purposes of the table and the related footnotes, unless described otherwise within the footnotes, we deem Ordinary Shares issuable pursuant to options or warrants that are currently exercisable or exercisable within 60 days as of March 15, 2019 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.
(3) Dr. Lang’s employment was terminated in September 2018 and the options expired in December 2018. The options had not been exercised before the date of expiration.

On January 17, 2019, the Company granted additional options to its non-executive directors and its Chief Medical Officer. See Note 16 to our audited financial statements included elsewhere in our annual report.

Equity Incentive Plans

Share Incentive Plan

On March 17, 2013, our board of directors approved our 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 December 31, 2018, 2,438,410 Ordinary Shares were issuable upon the exercise of outstanding awards under the 2013 Plan, at a weighted-average exercise price of $4.36 per share. Of the foregoing outstanding awards, options to purchase 1,837,160 Ordinary Shares, in the aggregate, had vested under the 2013 Plan as of that date, with a weighted-average exercise price of $1.67 per share.

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, or 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 our initial public offering, the remaining pool of reserved Ordinary Shares under the 2013 Plan were cancelled, and the only reserved Ordinary Shares available for grants to our employees, directors, consultants and service providers following the completion of our initial public offering are those under the 2018 Plan (as defined below).

2018 Equity Incentive Plan

On July 2, 2018, in connection with the consummation of our initial public offering, our board of directors approved our 2018 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 governs issuances of equity incentive awards from and after the closing of our initial public offering. The maximum number of Ordinary Shares initially available for issuance under equity incentive awards granted pursuant to the 2018 Plan could not exceed 12% of the total outstanding Ordinary Shares as of the time of adoption. 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 our board of directors) have and will become available for issuance under the 2018 Plan. As of December 31, 2018, a total of 1,371,398 Ordinary Shares representing 12% of the total outstanding shares as of the initial public offering date remained available for issuance under the 2018 Plan. In January 2019, the Company granted (i) 124,000 options to purchase 124,000 Ordinary Shares under the 2018 Plan, and (ii) subject to shareholder approval, additional 226,828 options to purchase 226,828 Ordinary Shares 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 is 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.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

7.A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our Ordinary Shares (i) each person or entity known by us to own beneficially 5% or more of our outstanding Ordinary Shares (as of the date of such shareholder's Schedule 13G filing for Entera Bio Ltd. with the SEC); (ii) each of our directors and executive officers individually; and (iii) all of our executive officers and directors as a group.

According to our transfer agent, as of March 15, 2019, there were 56 record holders of our Ordinary Shares, among whom 40 are U.S. holders who beneficially own in the aggregate 4,734,620 of our Ordinary Shares, representing approximately 41.32%. None of our shareholders has different voting rights from other shareholders.

The beneficial ownership of our Ordinary Shares is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership, generally, includes any shares over which a person exercises sole or shared voting or investment power, or the right to receive the economic benefit of ownership. For purposes of the table and the related footnotes, unless described otherwise within the footnotes, we deem Ordinary Shares issuable pursuant to options or warrants that are currently exercisable or exercisable within 60 days as of March 15, 2019 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, except with respect to the percentage ownership of all executive officers and directors as a group. The percentage of Ordinary Shares beneficially owned is based on 11,459,780 Ordinary Shares outstanding as of March 15, 2019. The beneficial ownership data provided below is based solely on information available to our Company and, in the case of major shareholders, has not been verified further. Except where otherwise indicated, we believe, based on information furnished to us by such owners, that the beneficial owners of the Ordinary Shares listed below have sole investment and voting power with respect to such shares.

Unless otherwise noted below, each shareholder's address is c/o Entera Bio Ltd., Kiryat Hadassah, Minrav Building - Fifth Floor, Jerusalem 9112002, Israel.

Name	Number and Percentage of Ordinary Shares	
	Number	Percent
5% or Greater Shareholders (other than directors and executive officers)		
D.N.A Biomedical Solutions Ltd.(1)	3,978,780	34.7%
Centillion Fund(2)	2,192,060	17.5%
Capital Point Ltd.(3)	1,151,806	9.9%
Menachem Ehud Raphael(4)	661,180	5.7%
Pontifax Management 4 GP (2015) Ltd. (5)	853,450	7.3%
Executive Officers and Directors:		
Zeev Bronfeld(6)	3,978,780	34.7%
Yonatan Malca(7)	3,978,780	34.7%
Dr. Phillip Schwartz(8)	691,080	5.7%
Gerald Lieberman(9)	200,980	1.7%
Dr. Roger J. Garceau(10)	322,530	2.7%
Mira Rosenzweig(11)	*	*
Dr. Hillel Galitzer(12)	*	*
Dr. Arthur Santora	-	-
Faith L. Charles	-	-
Miranda J. Toledano	-	-
Gerald M. Ostrov	-	-
All Directors and Executive Officers as a Group (7 persons)(13)	5,353,270	41.8%

* Less than 1%

(1) Based solely on the Schedule 13G filed by D.N.A Biomedical with the SEC on February 14, 2019 regarding its holdings as of December 31, 2018. D.N.A Biomedical's address is at 43 Hatarsi St., Tel Aviv, Israel. Zeev Bronfeld is the controlling shareholder of D.N.A Biomedical Solutions Ltd. By reason of such control, Zeev Bronfeld may be deemed to be beneficial owner of, and to share the power to vote and dispose of, the shares beneficially owned by D.N.A Biomedical Solutions Ltd. Mr. Bronfeld disclaims beneficial ownership of the shares held by D.N.A Biomedical Solutions Ltd. 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 Ltd, while the remaining 568,360 Ordinary Shares, or approximately 14.3%, have been pledged to Menachem Raphael.

(2) Consists of (i) 1,131,130 Ordinary Shares and (ii) warrants to purchase 1,060,930 Ordinary Shares, exercisable within 60 days as of March 15, 2019.

(3) Based solely on the Schedule 13G filed by Capital Point Ltd with the SEC on February 14, 2019 regarding its holdings as of December 31, 2018. Capital Point Ltd further reported that the option to purchase 722,150 Ordinary Shares of the issuer granted by D.N.A, or D.N.A Option, contains a limitation that prohibits the holder from exercising any portion of the D.N.A Option to the extent that after giving effect to the exercise and subsequent transfer of the ordinary shares of the issuer from D.N.A to the reporting person, the reporting person (together with its investment vehicles, affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates) would beneficially own in excess of 9.99% of the ordinary shares of the issuer outstanding immediately after giving effect to such transfer, or the Beneficial Ownership Limitation. Consequently, as of December 31, 2018, Capital Point Ltd was not able to exercise options to purchase 548,815 Ordinary Shares of the Company granted by D.N.A due to the Beneficial Ownership Limitation. Therefore, the amount of holdings reported by Capital Point Ltd on its 13G gives effect to the Beneficial Ownership Limitation. Capital Point's address is at Azrieli 1, Tel Aviv, Israel.

(4) Based solely on the Schedule 13G filed by Menachem Ehud Raphael with the SEC on February 13, 2019 regarding its holdings as of December 31, 2018. Menachem Ehud Raphael further reported that its holdings consist of (i) 384,540 Shares, and (ii) 276,640 Ordinary Shares underlying options to acquire Ordinary Shares, exercisable within 60 days as of December 31, 2018. Menachem Raphael's address is at 12 Ha'seora, Tel Aviv, Israel.

(5) Based solely on the Schedule 13G filed by Pontifax Management 4 GP (2015) Ltd. with the SEC on February 14, 2019 regarding its holdings as of December 31, 2018. Consists of (a) 300,690 ordinary shares owned by Pontifax (Israel) 4, Limited Partnership and warrants to purchase 120,250 ordinary shares, exercisable within 60 days of December 31, 2018, (b) 146,380 ordinary shares owned by Pontifax (Cayman) IV, L.P. and warrants to purchase 58,630 ordinary shares, exercisable within 60 days of December 31, 2018, and (c) 162,500 ordinary shares owned by Pontifax (China) IV, L.P. and warrants to purchase 65,000 ordinary shares, exercisable within 60 days of December 31, 2018. Pontifax 4 GP, Limited Partnership is the general partner of Pontifax (Israel) 4, Limited Partnership, Pontifax (Cayman) IV, L.P. and Pontifax (China) IV, L.P. Pontifax Management 4 GP (2015) Ltd. is the general partner of Pontifax 4 GP, Limited Partnership. Ran Nussbaum and Tomer Kariv are directors of Pontifax IV G.P. (2015) Ltd.

(6) Based solely on the Schedule 13G filed by Mr. Zeev Bronfeld with the SEC on February 14, 2019 regarding its holdings as of December 31, 2018. Mr. Bronfeld is the controlling shareholder of D.N.A Biomedical Solutions Ltd. By reason of such control, Mr. Bronfeld may be deemed to be beneficial owner of, and to share the power to vote and dispose of, the shares beneficially owned by D.N.A Biomedical Solutions Ltd. Mr. Bronfeld disclaims beneficial ownership of the shares held by D.N.A Biomedical Solutions Ltd.

(7) Mr. Yonatan Malca is the CEO and a director of D.N.A Biomedical.

(8) Consists of (i) 780 Ordinary Shares and (ii) 690,300 Ordinary Shares underlying options to acquire Ordinary Shares, exercisable within 60 days of March 15, 2019.

(9) Consists of (i) 34,580 Ordinary Shares, (ii) 158,340 Ordinary Shares underlying options to acquire Ordinary Shares, exercisable within 60 days of March 15, 2019, and (iii) warrants to purchase 8,060 Ordinary Shares.

(10) Consists of (i) 4,940 Ordinary Shares (ii) 315,640 Ordinary Shares underlying options to acquire Ordinary Shares, exercisable within 60 days of March 15, 2019, and (iii) warrants to purchase 1,950 Ordinary Shares.

(11) Consists of 70,200 Ordinary Shares underlying options to acquire Ordinary Shares, exercisable within 60 days of March 15, 2019.

(12) Consists of 89,700 Ordinary Shares underlying options to acquire Ordinary Shares, exercisable within 60 days of March 15, 2019.

(13) Consists of (i) 4,019,080 Ordinary Shares, (ii) options to acquire 1,324,180 Ordinary Shares, exercisable within 60 days of December 31, 2018, and (iii) warrants to purchase 10,010 Ordinary Shares.

7.B. Related Party Transactions

For information regarding compensation of our directors and officers, see "Item 6.B.–Compensation."

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

Convertible Debt Financing

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 a Convertible Promissory Note and Loan Agreement the Company has entered into on August 5, 2015, was 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 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 Company issued to each lender warrants, or the 2016 warrants, under the 2016 Convertible Loan, to purchase an additional 40% of the amount of our securities issued to such lender as a result of the automatic conversion following a 2016 Triggering Event. The 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.

Our directors, Roger Garceau, Gerald Lieberman and then our then presiding director Luke Beshar, each participated, in amounts of $25,000, $50,000 and $50,000, respectively, in our 2016 Convertible Loan. In addition, Corundum Open Innovation Fund, L.P., or Corundum, of which David Ben Ami, then a member of our board of directors, is the managing partner, invested an amount of $1.0 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.

Following the closing of the initial public offering, all our preferred shares, warrants and options to purchase preferred shares were automatically converted into Ordinary Shares, warrants and options to purchase Ordinary Shares and adjusted by split of the Ordinary Shares of 1 for 130.

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 (before the Ordinary Shares split), 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 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 our initial public offering, the Series B and B-1 preferred shares were automatically converted into our Ordinary Shares, and the warrants to purchase Series B preferred shares were automatically converted into warrants to purchase Ordinary Shares.

In addition, as a result of the Series B Private Placement, the 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 then 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 was approved by the Company's shareholders and paid.

Service Agreements

In April 2017, the Company entered into a Service Agreement with our then active chairman, Mr. Luke Beshar, effective as of December 2016, pursuant to which Mr. Beshar was 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 was 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 (prior to split) Ordinary Shares, with an exercise price of $820 per share (prior to the Ordinary Shares split). 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). On June 27, 2018, Mr. Beshar resigned from our board of directors, and therefore his service agreement terminated. According to Mr. Beshar's options terms, options which have yet to fully vest are forfeited, and therefore 3,485 options (before share split) granted to Mr. Beshar were forfeited following his resignation.

In April 2017, effective as of December 2016, the Company entered into a Service Agreement with our director Dr. Roger J. Garceau, pursuant to which Dr. 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 Dr. 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 Dr. Garceau upon the exercise of his options will be 1,608 (prior to split) Ordinary Shares, with an exercise price of $820 per share (prior to split). 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 Dr. Garceau for Good Reason and termination without Cause (as such terms are defined in the Service Agreement). On January 17, 2019, our board of directors approved an amendment to Dr. Garceau Service Agreement. According to the amendment, the monthly payment provided to Dr. Garceau was reduced to $4,000 effective as of November 1, 2018.

Pursuant to an arrangement between us and Mr. Chaim Davis, a former member of our board of directors, Mr. Davis provided 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. Effective as of January 1, 2019, Mr. Davis' monthly payment, for his services reduced to $4,000.

In September 2018, we have entered into arrangements with Kinexum Services LLC, or Kinexum, for the provision of Chief Medical Officer services, to be rendered by Dr. Arthur Santora. Such arrangements include a Statement of Work for the term ending September 3, 2019, or the SOW, with an unlimited option to extend by mutual written consent. Pursuant to the SOW, Kinexum is entitled to a monthly retainer fee in the amount of $17,812.5 for providing a minimum of fifty hours of work of Chief Medical Officer services (at a discounted rate). If Dr. Santora exceeds the monthly fifty-hour cap but does not exceed eighty hours, Kinexum shall be entitled to an hourly fee of $356.25, for any hour exceeding the fifty-hour cap. In addition, Kinexum is entitled to $475 per hour, for any hour exceeding eighty hours per month. In no event shall the amount of hours per each calendar month shall exceed 120 hours (maximum monthly fees are $47,500). Additionally, pursuant to the SOW, Kinexum is entitled to receive expenses and other costs such as travel, lodging, production/shipping, etc.

In addition, the Company and Dr. Santora entered into a direct arrangement for Dr. Santora's services on behalf of Kinexum on September 20, 2018, under which the Company undertook, inter alia, to appoint Dr. Santora as an executive officer of the Company, and to grant Dr. Santora equity compensation to be determined by the company.

Kinexum also provides general regulatory services to the Company, in the ordinary course of business, in addition to the services provided by Dr. Santora as Chief Medical Officer.

Registration Rights

We, certain of our shareholders and certain lenders with which we entered into loan agreements in 2012, 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 have the right, following the closing of our initial public 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 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 our initial public 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 the pricing of our initial public offering, 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 our initial public 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 a 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).

Director Designation Rights

Pursuant to the terms of the Investors' Rights Agreement among us, Centillion and other parties thereto, following the consummation of our initial public 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. As of December 31, 2018, Centillion hold approximately 9.87% 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 have issued to it, Centillion will hold approximately 17.5% of our issued and outstanding Ordinary Shares.

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.

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.

7.C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

8.A. Consolidated Statements and Other Financial Information

See "Item 18.–Financial Statements."

Legal proceedings

From time to time, we may become party to litigation or other legal proceedings that we consider to be a part of the ordinary course of our business. We are not currently involved in any legal proceedings. However, we may become involved in material legal proceedings in the future. 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 "Item 3.D.—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."

Dividends

We have never declared or paid cash dividends to our shareholders and we do not intend to pay cash dividends in the foreseeable future. We intend to reinvest any earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, our strategic goals and plans to expand our business, applicable law and other factors that our board of directors may deem relevant.

The Companies Law imposes further restrictions on our ability to declare and pay dividends. According to the Companies Law, a company may distribute dividends out of its profits if there is no reasonable concern that the distribution may prevent the company from meeting its existing and expected obligations when they become due. The Companies Law defines 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 shareholders' approval.

Payment of dividends may be subject to Israeli withholding taxes. See “Item 10.E.—Taxation” for additional information.

8.B. Significant changes

Except as disclosed elsewhere in this annual report, there have been no other significant changes since December 31, 2018.

ITEM 9. THE OFFER AND LISTING

9.A.4 Offer and Listing Details

Not applicable.

9.B. Plan of Distribution

Not applicable.

9.C. Market for Ordinary Shares and Warrants

Our Ordinary Shares and Warrants have been listed on Nasdaq since June 28, 2018, under the symbol “ENTX” and “ENTXW,” respectively.

9.D. Selling Shareholders

Not applicable.

9.E. Dilution

Not applicable.

9.F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

10.A. Share Capital

The following description of our share capital and provisions of our Articles are summaries and are qualified by reference to our Articles and the applicable warrant agreements filed with this annual report on form 20-F.

General

We are an Israeli company incorporated with limited liability, and our affairs are governed by the provisions of our Articles, as amended and restated from time to time, and by the provisions of applicable Israeli law, including the Companies Law.

Ordinary Shares

Our authorized share capital consists of 140,010,000 Ordinary Shares, par value NIS 0.0000769 per share. All of our Ordinary Shares have been validly issued, fully paid and are non-assessable. The Ordinary Shares are listed on Nasdaq under the symbol “ENTX.”

Preferred Shares

Under the terms of our Articles, we are not authorized to issue preferred shares. No preferred shares are outstanding.

Outstanding Warrants – Tradable and Others

The Tradeable Warrants

The Warrants are listed on Nasdaq under the symbol "ENTXW," and trade separately from our Ordinary Shares.

Exercisability, Exercise Price and Term

Each Warrant represents the right to purchase 0.5 of an Ordinary Share. 1,610,000 Warrants are outstanding and represent the rights to purchase an aggregate of up to 805,000 Ordinary Shares.

The Warrants are exercisable at any time up to the five-year anniversary of the original issuance date, the date of our initial public offering, July 2, 2018, and is referred 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 Ordinary 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 of less than $8.00 per share (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 annual report.

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), or Distribution, 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 under the 2018 Plan), 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 Ordinary 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 our 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 holders of our Ordinary Shares in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of our Ordinary Shares 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) a transaction 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, in connection with such Fundamental Transaction consists of Ordinary Shares, common shares or American depository shares that are listed or quoted on any of the NYSE American, the Nasdaq, 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 $24.00 per share, which is 300% of the initial public offering price per unit (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 30th 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.

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 are 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.

Other Warrants

The following section is a summary of our warrants issued prior to our initial public offering. Following the initial public offering, such pre-IPO warrants provide the applicable holder, subject to the terms and conditions of the applicable warrant, rights to acquire Ordinary Shares.

Series A Warrants

As of December 31, 2018, we had 332,020 warrants, or Series A Warrants, outstanding to purchase 332,020 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 previously preferred A shareholders, preferred A shareholders have the right to purchase 332,020 of our ordinary shares, at an exercise price of $3.69 up to July 20, 2019, or Preferred A Option, and to receive additional Series A Warrants to purchase 83,201 of our Ordinary Shares.

In addition, Centillion has a preemptive right to purchase 44,460 of our Ordinary Shares, at an exercise price of $3.69 up to July 20, 2019, and to receive additional Series A Warrants to purchase 11,180 of our Ordinary Shares. Further, upon exercise of the Preferred A Option by pre-IPO preferred A shareholders except Centillion, Centillion has the right to purchase additional 11,050 of our ordinary shares, at an exercise price of $3.69 up to July 20, 2019 and to receive additional Series A Warrants to purchase 2,730 of our Ordinary Shares.

The following summary is of certain material terms and provisions of our Series A warrants which after the completion of our initial public offering became warrants to purchase Ordinary Shares. The summary 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 this annual report.

Exercisability. The Series A Warrants are exercisable immediately from issuance, and at any time up to the date that is two years after our initial public offering, specifically, July 2, 2020. The Series A 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 our Ordinary Shares, and upon any conversion, exchange, reclassification or change, any security into which our Ordinary Shares may be converted, exchanged, reclassified or otherwise changed.

Exercise Price. $3.69 per share.

Transferability. Absent an effective registration statement filed with the SEC covering the disposition or sale of the Series A Warrants or the shares issued or issuable upon exercise of the Series A Warrants, and registration or qualification under applicable state securities laws, the holder cannot transfer any or all of the Series A 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 Series A Warrants or by virtue of such holder's ownership of our Ordinary Shares, the holder of a Series A Warrants does not have the rights or privileges of a holder of Ordinary Shares, including any voting rights, until the holder exercises the Series A Warrants.

Additional Warrants

As of December 31, 2018, we had 467,220 additional warrants, or Additional Warrants outstanding to purchase 467,220 of our Ordinary Shares at an exercise price of $5.24 per share.

The following summary is of certain material terms and provisions of our Additional Warrants. The summary 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 this annual report.

Exercisability. The Additional Warrants are exercisable on or before October 4, 2019.

Applicable Shares. Ordinary shares.

Exercise Price. $5.24 per share.

Transferability. Absent an effective registration statement filed with the SEC covering the disposition or sale of the Additional Warrants or the shares issued or issuable upon exercise of the Additional Warrants, and registration or qualification under applicable state securities laws, the holder cannot transfer any or all of the Additional 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 Additional Warrants or by virtue of such holder's ownership of our Ordinary Shares, the holder of an Additional Warrant does not have the rights or privileges of a holder of Ordinary Shares, including any voting rights, until the holder exercises the Additional Warrant.

2016 Warrants

As of December 31, 2018, we had 687,960 2016 Warrants outstanding to purchase 687,960 of our Ordinary Shares at an exercise price of $6.99 per Ordinary Share.

The following summary is of certain material terms and provisions of our 2016 Warrants. The summary is not complete and is subject to, and qualified in its entirety by the provisions of, the form of the 2016 Warrant, which is filed as an exhibit to this annual report.

Exercisability. The 2016 Warrants are exercisable until June 2020.

Applicable Securities. Ordinary shares.

Exercise Price. $6.99 per share.

Transferability. Absent an effective registration statement filed with the SEC covering the disposition or sale of the 2016 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 2016 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 2016 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

As of December 31, 2018, we had 68,380 outstanding warrants, or Series B Warrants, to purchase 68,380 Ordinary Shares, at an exercise price of $6.99 per Ordinary Share.

The following is a summary of certain material terms and provisions of the Series B Warrants, which following the completion of our initial public offering became warrants to purchase Ordinary Shares.

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 Warrants, specifically, 59,800 Series B Warrants exercisable until October 25, 2022, and 8,580 Series B Warrants exercisable until November 25, 2022 or (ii) the occurrence of a liquidation, bankruptcy, reorganization, dissolution or winding up of the Company, whether voluntary or involuntary.

Applicable Securities. Ordinary Shares.

Exercise Price. $6.99 per share.

Transferability. The Series B Warrants cannot be transferred to a third party, other than an affiliate of the holder of such Series B Warrants (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 Warrants, addressed to the Company stating that the proposed transfer of the Series B Warrants 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 Warrants does not have the rights or privileges of a holder of Ordinary Shares, including any voting rights, until the holder exercises the Series B Warrants.

Underwriter Warrants

As of December 31, 2018, we had 70,000 outstanding warrants, or Underwriter Warrants, granted to our initial public offering underwriters, to purchase 70,000 Ordinary Shares, at an exercise price of $8.8 per Ordinary Share.

The following is a summary of certain material terms and provisions of the Underwriter Warrants. The summary is not complete and is subject to, and qualified in its entirety by the provisions of, the form of the Underwriter Warrant, which is filed as an exhibit to this annual report.

Exercisability. The underwriter warrants will be exercisable on or before the expiration of five years from the date of the Underwriter Warrants, specifically, July 2, 2023. The Underwriter Warrants 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 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 July 2, 2018, 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 July 2, 2018.

Exercise Price. $8.8 per share. The exercise price of the Underwriter Warrants (and the ordinary shares underlying such warrants) is subject to adjustment provided under the Underwriter Warrants, for dilutive events such as a stock dividend or stock split and for recapitalizations, mergers and other fundamental transactions.

Transferability. The Underwriter Warrants cannot be transferred to a third party, other than an affiliate of the holder of such Underwriter Warrants (as defined and subject to the terms and conditions of the Underwriter 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 Underwriter Warrants addressed to the Company stating that the proposed transfer of the Underwriter Warrants 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 Underwriters Warrants or by virtue of such holder's ownership of our Ordinary Shares, the holder of an Underwriters Warrant does not have the rights or privileges of a holder of our Ordinary Shares, including any voting rights, until the holder exercises the Underwriters Warrant.

10.B. Memorandum and Articles of Association

We incorporate by reference into this Annual Report on Form 20-F the description of our Articles of Association effective upon the closing of our initial public offering contained in our F-1 Registration Statement (File No. 333-221472) under "Description of Share Capital" originally filed with the SEC on June 27, 2018. Such description sets forth a summary of certain provisions of our articles of association, and certain descriptions of applicable Israeli law, each as currently in effect.

10.C. Material Contracts

Other than the Amgen Agreement, described above in Patent Transfer and Licensing Agreements and Grant Funding—Amgen Research Collaboration and License Agreement, we are currently in the development stage and therefore we have not entered into any agreements, other than in the ordinary course of our business, that we deem material in the reporting period.

10.D. Exchange Controls

There are currently no Israeli currency control restrictions on the import or export of capital or the remittances of dividends on our Ordinary Shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of countries that are, or have been, in a state of war with Israel.

10.E. Taxation

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our Ordinary Shares 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. 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. 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 or in the "area," as such term is defined under Section 3a of the Ordinance. 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 649,560 for 2019).

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

The Ordinance generally imposes a capital gains tax on the sale of any capital assets by Israeli residents, 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-Israeli residents, unless a specific exemption is available or unless a tax treaty between Israel and the shareholder's country of residence provides otherwise, and subject to the receipt in advance of a valid certificate from the Israeli Tax Authority. The Ordinance 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 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 capital gain will generally be taxed at a rate of 30%, until the determination of provisions and conditions for the deduction under section 101a(a)9 and 101a(b) of the Ordinance.

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, alone or with another, 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).

An additional tax of 3% will be imposed on individuals whose annual taxable income exceeds a certain threshold (NIS 649,560 for 2019).

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 shareholders dealing in securities in Israel are taxed at their marginal tax rates applicable to business income: 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 649,560 for 2019).

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 our Ordinary Shares and Warrants, provided, among other things, that such holders did not acquire their Ordinary Shares or Warrants prior to the company's initial public offering and the gains were not derived from a permanent establishment of such holders in Israel.

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, 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 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 Ordinary 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 July 31 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. Capital gain is also reportable on the annual income tax return.

Taxation of Dividend Distributions

Israeli Residents

Israeli resident individuals are generally subject to Israeli income tax on the receipt of dividends paid on our Ordinary Shares (other than bonus shares). The tax rate applicable to such dividends is 25%, or 30% for a shareholder that is considered a Significant Shareholder at any time during the 12-month period preceding such distribution. Dividends paid from income attributed to “preferred enterprises” are generally subject to tax at the rate of 20%. Dividends distributed by a “preferred technology enterprise” or a “special preferred technology enterprise,” paid out of Preferred Technology Income, are generally subject to tax at the rate of 20%.

Israeli resident companies are generally exempt from tax on the receipt of dividends paid on our Ordinary Shares.

If the dividend is attributable partly to income derived from a “preferred enterprise” or to Preferred Technology Income of a “preferred technology enterprise” or a “special preferred technology enterprise” and partly to other sources of income, the tax rate will be a blended rate reflecting the relative portions of the two types of income. We cannot assure you that we will designate the profits that 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 649,560 for 2019).

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 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 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 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

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. 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.

Material U.S. Federal Income Tax Considerations for U.S. Holders

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 or 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 own the Ordinary Shares or Warrants. This discussion applies only to a U.S. Holder that holds our Ordinary Shares or Warrants as capital assets for U.S. federal income tax purposes. This discussion does not address tax consequences of a fundamental transaction (as defined under the terms of the Warrants) to U.S. Holders of Warrants. 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 or Warrants 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 annual report 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 or Warrants, as the case may be, 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 or Warrants in their particular circumstances.

Taxation of Distributions on Ordinary Shares

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 taxable 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

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. 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 believe we were not a PFIC for 2018, but there can be no assurance that we will not be a PFIC for the 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, 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 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 hold, and expect to continue to hold, a significant amount of cash, and (iii) a company's annual PFIC status can be determined only after the end of each taxable year, we cannot express a view as to whether we will be a PFIC for the current or any future taxable year. In addition, it is not clear how to apply the income test to a company such as our company, whose overall losses from research activities significantly exceed the amount of its income (including passive income).

For purposes of the PFIC rules, 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 (or 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.

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.

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, where our Ordinary Shares are 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 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 their ownership in our Ordinary Shares or 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 specified entities may be required to report information relating to the Ordinary Shares or 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.

10.F. Dividends and Paying Agents

Not applicable.

10.G. Statement by Experts

Not applicable.

10.H. Documents on Display

We are subject to certain of the information reporting requirements of the Exchange Act. As a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act prescribing the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act, with respect to their purchase and sale of our shares. In addition, we are not required to file reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we are required to file with the SEC, within four months after the end of each fiscal year, an annual report on Form 20-F containing financial statements audited by an independent accounting firm. We publish unaudited interim financial information after the end of each quarter. We furnish this quarterly financial information to the SEC under cover of a Form 6-K.

The SEC maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The address of this website is http://www.sec.gov. The company's website is www.enterbio.com.

10.I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

In the ordinary course of our operations, we are exposed to certain market risks. 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. Although a substantial portion of our expenses (mainly salaries and related costs) are denominated in Israeli shekels, accounting for 28%, 24% and 48% of our expenses in the years ended December 31, 2018, 2017 and 2016, respectively, our revenues were generated under agreement denominated in U.S. dollars and our proceeds from our public offerings, share issuance and convertible loan agreements, which are the main source of our financing, are denominated in U.S. dollars. 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. See "Item 3.D.—Risk Factors—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."

A devaluation of the shekel in relation to the U.S. dollar has the effect of reducing the U.S. dollar amount of our expenses or payables that are payable in shekels, unless those expenses or payables are linked to the U.S. dollar. Conversely, any appreciation of the shekel in relation to the U.S. dollar has the effect of increasing the U.S. dollar value of our unlinked shekel expenses, which would have a negative impact on our profit margins. In 2018, the value of the NIS devaluated in relation to the U.S. dollar by 8.1%. In 2017, the value of the NIS appreciated in relation to the U.S. dollar by approximately 9.8%.

Because exchange rates between the U.S. dollar and the shekel (as well as between the U.S. dollar and other currencies) fluctuate continuously, such fluctuations have an impact on our results and period-to-period comparisons of our results. The effects of foreign currency re-measurements are reported in our statements of operations.

We will continue to monitor exposure to currency fluctuations. 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.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

12.A-D.2.

Not applicable.

12D.3-4.

Not Applicable.

PART TWO

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

On July 2, 2018, we completed an initial public offering in the United States on the Nasdaq of our Ordinary Shares, par value NIS 0.0000769 per share, pursuant to Registration Statement on Form F-1, as amended (File No. 333-221472), which became effective on June 27, 2018. Maxim Group LLC acted as sole book-running manager for the offering. We registered 1,400,000 Ordinary Shares and 1,400,000 Warrants to purchase 700,000 Ordinary Shares in the offering and granted the underwriters a 30-day over-allotment option to purchase up to additional 210,000 Ordinary Shares and/or 210,000 additional Warrants from us. The option to purchase an additional 210,000 Warrants was exercised on July 26, 2018.

Pursuant to the initial public offering, we sold a total of 1,400,000 Ordinary Shares and 1,400,000 Warrants at a price of $8.00 per unit. The over-allotment Warrants pursuant to the over-allotment option were exercised and $0.01 per Warrant. The aggregate offering price of the shares sold (including the over-allotment option) was approximately $11.2 million. The total expenses of the offering in cash, excluding underwriting discounts and commissions, were approximately $0.7 million. The net proceeds we received from the offering (including the over-allotment option) were approximately $9.6 million.

Between the effective date of the Registration Statement on Form F-1, filed under the Securities Act with the SEC on June 27, 2018, and December 31, 2018, we used approximately $4.6 of the cash reserves and net proceeds to fund research and development expenses, general corporate expenses and for working capital. The intended use of these proceeds has not changed substantially from the information mentioned in the prospectus relating to the Registration Statement on Form F-1 filed under the Securities Act with the SEC on June 27, 2018.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act and regulations promulgated thereunder) as of December 31, 2018, or the Evaluation Date. Based on such evaluation, those officers have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be included in periodic filings under the Exchange Act and that such information is accumulated and communicated to management, including our principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosure.

(b) Management's Annual Report on Internal Control over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

(c) Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Further, as long as we are deemed to be an emerging growth company, we will not be required to include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting, due to an exemption for emerging growth companies provided in the JOBS Act.

(d) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this annual report that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16A. Audit Committee Financial Expert

Our board has determined that Ms. Miranda J. Toledano qualifies to serve as an Audit Committee Financial Expert, as defined under the SEC rules, and has Financial and Accounting Expertise, as defined in the regulations promulgated under the Companies Law. Ms. Miranda J. Toledano, also qualifies as an external director under the Companies Law and as an independent director under the corporate governance standards of the Nasdaq listing requirements and the audit committee independence requirements of Rule 10A-3 of the Exchange Act. For more information see "Item 6.C.—Board Practices—Board of Directors."

ITEM 16B. CODE OF ETHICS

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics applicable to all of our directors, executive officers and employees, including our Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer, or other persons performing similar functions, which is a code of ethics as defined in Item 16B of Form 20-F promulgated by the SEC. The full text of the Code of Business Conduct and Ethics can be found on our website at www.enterabio.com. Information contained on, or that can be accessed through, our website does not constitute a part of this report and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code of ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC. Under Item 16B of Form 20-F, if a waiver or amendment of the Code of Business Conduct and Ethics applies to our principal executive officer, principal financial officer, principal accounting officer or controller and relates to standards promoting any of the values described in Item16B(b) of Form 20-F, we are required to disclose such waiver or amendment on our website in accordance with the requirements of Instruction 4 to such Item 16B.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Kesselman & Kesselman (a member firm of PricewaterhouseCoopers International Limited, or PwC), has served as our principal independent registered public accounting firm for each of the two years ended December 31, 2018 and 2017.

The following table provides information regarding fees paid by us to PwC for all services, for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
Audit fees [1]	$ 397,721	$ 98,324
Tax fees[2]	5,000	15,000
Other services	-	26,192
Total fees	$ 402,721	$ 139,516

(1) Includes professional services rendered in connection with the audit of our annual financial statements and the review of our interim financial statements and services related to the company's initial public offering and other registration statements.

(2) Tax consulting services.

Pre-Approval of Auditors' Compensation

Our audit committee is responsible for pre-approving audit and non-audit services provided to us by our independent registered public accounting firm. All of the non-audit services provided to us by the independent auditors following the formation of our audit committee, were pre-approved by the audit committee.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

None.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

None.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

None.

ITEM 16G. CORPORATE GOVERNANCE

Corporate Governance Practices

We are incorporated in Israel and therefore are subject to various corporate governance practices under 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 Nasdaq and other applicable provisions of U.S. securities laws. As a foreign private issuer whose securities are listed on Nasdaq, we have the option to follow certain Israeli corporate governance practices rather than those of Nasdaq, 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. Under the Nasdaq rules, a foreign private issuer, such as us, may generally follow its home country rules of corporate governance in lieu of the comparable requirements of the Nasdaq rules, except for certain matters including (among others) the composition and responsibilities of the audit committee and the independence of its members within the meaning of the rules and regulations of the SEC.

We rely on the Foreign Private Issuer Exemption with respect to the following Nasdaq requirements:

- Shareholder Approval. Although the Nasdaq rules 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 rules 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. Nasdaq rules require that an issuer have a quorum requirement for shareholder 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, 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. Nasdaq rules 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 are governed by the Companies Law, rather than the Nasdaq rules. In addition, under the Companies Law, there are no specific independence evaluation requirements for outside consultants.

- Independent Approval of Board Nominations. The Nasdaq rules 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 Nasdaq rules, 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 "Item 6.C.—Board Practices—External Directors."

- Executive Sessions. Nasdaq rules 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 Nasdaq.

Except as stated above, we intend to substantially comply with the rules applicable to U.S. companies listed on the Nasdaq. 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 rules 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 Nasdaq, may provide less protection than is accorded to investors under the Nasdaq rules applicable to domestic issuers.

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.

Disclosure of Personal Interests and Approval of Related Party Transactions

The Companies Law requires that an office holder promptly disclose to the board of directors any personal interest that he or she may be aware of and all related material information or documents concerning any existing or proposed transaction with the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. Pursuant to Israeli law, the disclosure requirements regarding personal interests that apply to directors and executive officers also apply to a controlling shareholder of a public company. In the context of a transaction involving a shareholder of the company, a controlling shareholder also includes a shareholder who holds 25% or more of the voting rights in the company if no other shareholder holds more than 50% of the voting rights in the company. For this purpose, the holdings of all shareholders who have a personal interest in the same transaction will be aggregated. For a description regarding who is considered to have a personal interest, see "Item 6.C.—Board Practices—Board Committees."

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 the compensation policy adopted within nine months from the closing of the Company's initial public 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 have adopted a compensation policy on September 27, 2019.

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.

Shareholder Duties

Pursuant to the Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the company and other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at a general meeting and at shareholder class meetings with respect to the following matters:

- an amendment to the company's articles of association;
- an increase of the company's authorized share capital;
- a merger; or
- the approval of related party transactions and acts of office holders that require shareholder approval.

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

In addition, certain shareholders have a duty of fairness toward the company. These shareholders include a controlling shareholder, a shareholder who knows that he or she has the power to determine the outcome of a shareholder vote and a shareholder who has the power to appoint or to prevent the appointment of an office holder of the company or other power towards the company. The Companies Law does not define the substance of the duty of fairness, except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness.

Anti-Takeover Measures under Israeli Law

The Companies Law allow us to create and issue shares having rights different from those attached to our Ordinary Shares, including shares providing certain preferred rights with respect to voting, distributions or other matters and shares having preemptive rights. Currently there are no preferred shares authorized under our Articles. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their Ordinary Shares. The authorization and designation of a class of preferred shares will require an amendment to our Articles, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares at a general meeting. The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Companies Law.

Acquisitions under Israeli Law

Full tender offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of the tender offer, petition an Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If (i) the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (ii) the shareholders who did not accept the tender offer hold 2% or more of the issued and outstanding share capital of the company (or of the applicable class), the acquirer may not acquire shares from shareholders who accepted the tender offer that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class.

Special tender offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company. This requirement does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the 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 holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company, subject to certain exceptions.

A special tender offer must be extended to all shareholders of a company but the offeror is not required to offer to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) the offeror acquired shares representing at least 5% of the voting power in the company and (ii) the number of shares tendered by shareholders who accept the offer exceeds the number of shares held by shareholders who object to the offer (excluding the controlling shareholders of the purchaser and 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). If a special tender offer is accepted, the purchaser or any person or entity controlling it at the time of the offer or under common control with the purchaser or such controlling person or entity at the time of the offer may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, by a majority vote of each party's shareholders. In the case of the target company, approval of the merger further requires a majority vote of each class of its shares.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of shares represented at the meeting of shareholders that are held by parties other than the shares held by the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same Special Majority approval that governs all Extraordinary Transactions with controlling shareholders, as described in “Item 6.C.–Board Practices—Board Committees.”

If the transaction would have been approved by the shareholders of a merging company if it weren't for the need for separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the petition of holders of at least 25% of the voting rights of a company. For such petition to be granted, the court must find that the merger is fair and reasonable, taking into account the respective values assigned to each of the parties to the merger and the consideration offered to the shareholders of the target company.

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

In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger is filed with the Israeli Registrar of Companies and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

PART THREE

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

The following audited consolidated financial statements, and the related notes thereto, and the Report of Independent Public Accounting Firm are filed as a part of this annual report.

ITEM 19. EXHIBITS

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
1.1	Sixth Amended and Restated Articles of the Registrant (incorporated herein by reference to Exhibit 3.2 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 20, 2017)
2.1	Amended and Restated Investor's Rights Agreement, dated as of October 4, 2017, between the Registrant and the other parties thereto (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.2	Specimen Form of Ordinary Share Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.3	Form of Warrant issued by the Registrant pursuant to our initial public offering (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on May 17, 2018)
4.4	Form of Underwriter Warrant issued by the Registrant to Maxim Group LLC (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on May 17, 2018)
4.5	Form of Warrant issued by the Registrant to Centillion Fund on each of January 29, 2014 and January 21, 2015 (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.6	Form of additional Warrant issued by the Registrant to Centillion Fund on January 21, 2015 (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.7	Form of Warrant issued by the Registrant to the lenders on June 24, 2016 (incorporated herein by reference to Exhibit 4.4 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.8	Form of Warrant issued by the Registrant to GP Nurmenkari Inc. (incorporated herein by reference to Exhibit 4.5 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.9	Patent Transfer Agreement, dated as of February 22, 2011, between the Registrant and Oramed Ltd. (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.10	Convertible Financing Agreement, dated as of November 8, 2012, among the Registrant, D.N.A Biomedical Solutions, Ltd. and the lenders thereto (incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.11	Convertible Financing Agreement, dated as of December 31, 2012, among the Registrant, D.N.A Biomedical Solutions, Ltd. and the lenders thereto (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.12	The Entera Bio Ltd. Share Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.13	Series A Preferred Share Purchase Agreement, dated as of January 29, 2014, between the Registrant and Centillion Fund (incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.14	First Amendment to Series A Preferred Share Purchase Agreement, dated as of June 18, 2014, between the Registrant and Centillion Fund (incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.15	Second Amendment to Series A Preferred Share Purchase Agreement, dated as of January 21, 2015, between the Registrant and Centillion Fund (incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.16	Third Amendment to Series A Preferred Share Purchase Agreement, dated as of November 2015, between the Registrant and Centillion Fund (incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 20, 2017)

4.17	Fourth Amendment to Series A Preferred Share Purchase Agreement, dated as of July 20, 2017, between the Registrant and Centillion Fund (incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 20, 2017)
4.18	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 (incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.19	Series B Preferred Share Purchase Agreement (incorporated herein by reference to Exhibit 10.10 to the Amendment No.2 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on January 5, 2018)
4.20	Form of indemnification agreement between the Registrant and its directors and executive officers (incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 20, 2017)
4.21	Form of Convertible Financing Agreement, dated as of June 14, 2016, among the Registrant and the lenders thereto (incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 20, 2017)
4.22	Service Agreement, dated April 6, 2017, between Roger Garceau and the Company (incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.23	Service Agreement, dated April 6, 2017, between Luke Beshar and the Company (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.24	2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 99 to the Company's Registration Statement on Form S-8 (File No. 333-227488) filed with the SEC on September 24, 2018)
4.25*	Form of Stock Option Award Agreement under the 2018 Equity Incentive Plan
4.26	Amendment No. 1 to the Series B Preferred Share Purchase Agreement, dated December 18, 2017, between the Registrant and the other parties thereto (incorporated herein by reference to Exhibit 10.17 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on January 5, 2018)
4.27	Form of Warrant Agency Agreement (incorporated herein by reference to Exhibit 10.18 to the Company's Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on June 15, 2018)
4.28 *†	Research Collaboration and License Agreement, dated as of December 10, 2018, between Amgen Inc. and Entera Bio Ltd.
8.1*	List of subsidiaries
12.1*	Certification pursuant to section 302 of the Sarbanes-Oxley Act of 2002
12.2*	Certification pursuant to section 302 of the Sarbanes-Oxley Act of 2002
13.1**	Certification pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002
13.2**	Certification pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002
15.1*	Consent of Kesselman & Kesselman, Certified Public Accountants, a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm.
101	The following materials from our Annual Report on Form 20-F for the year ended December 31, 2018 formatted in XBRL (Extensible Business Reporting Language) are furnished herewith: (i) the Report of Independent Registered Public Accounting Firm, (ii) the consolidated statements of financial position, (iii) the consolidated statements of comprehensive loss, (iv) the consolidated statements of changes in shareholders' equity (capital deficiency), (v) the consolidated statements of cash flows, and (vi) the notes to consolidated financial statements, tagged as blocks of text and in detail.

* Filed herewith.

** Furnished herewith.

† Confidential treatment granted as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

SIGNATURES

Entera Bio Ltd. hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

ENTERA BIO LTD.

By: /s/ Phillip Schwartz
Dr. Phillip Schwartz
Title: Chief Executive Officer
Date: March 28, 2019

ENTERA BIO LTD.
2018 CONSOLIDATED
FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the board of directors and shareholders of

ENTERA BIO LTD.

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Entera Bio Ltd and its subsidiary (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of comprehensive loss, changes in shareholders' equity (capital deficiency) and cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the " consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1a.3 to the consolidated 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.3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated 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 25, 2019

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.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31 2018	December 31 2017
		U.S. dollars in thousands	
A s s e t s			
CURRENT ASSETS:			
Cash and cash equivalents	5	7,506	11,746
Short-term bank deposits		4,015	-
Accounts receivable	12	725	-
Other current assets	13a	220	671
TOTAL CURRENT ASSETS		12,466	12,417
NON-CURRENT ASSETS:			
Property and equipment		224	207
Intangible assets	6	651	654
TOTAL NON-CURRENT ASSETS		875	861
TOTAL ASSETS		13,341	13,278
Liabilities and shareholders' equity (net of capital deficiency)			
CURRENT LIABILITIES:			
Accounts payable:			
Trade		473	596
Other	13b	1,090	1,424
Contract liabilities		225	
TOTAL CURRENT LIABILITIES		1,788	2,020
NON-CURRENT LIABILITIES:			
Convertible loan	7	-	3,893
Preferred shares	8	-	33,455
Warrants to purchase ordinary shares and preferred shares	7,8	1,372	5,398
Severance pay obligations, net		65	70
TOTAL NON-CURRENT LIABILITIES		1,437	42,816
TOTAL LIABILITIES		3,225	44,836
COMMITMENTS AND CONTINGENCIES	9		
SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY):	10		
Ordinary Shares, NIS 0.0000769 par value:			
Authorized - as of December 31, 2018 and December 31, 2017, 140,010,000 and 130,000,000 shares, respectively; issued and outstanding: as of December 31, 2018, and December 31, 2017-11,459,780 and 4,490,720 shares, respectively		*	*
Accumulated other comprehensive income		41	41
Other reserves		13,019	7,361
Additional paid in capital		49,173	2,853
Accumulated deficit		(52,117)	(41,813)
TOTAL SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)		10,116	(31,558)
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		13,341	13,278

* Represents an amount less than one thousand US dollars.

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

ENTERA BIO LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Note	Year ended December 31		
		2018	2017	2016
		U.S. dollars in thousands		
REVENUE	12	500	-	-
RESEARCH AND DEVELOPMENT EXPENSES, NET		8,518	2,768	2,648
GENERAL AND ADMINISTRATIVE EXPENSES		2,843	8,575	2,719
OPERATING LOSS		10,861	11,343	5,367
FINANCIAL INCOME:	7,8			
Income from change in fair value of financial liabilities at fair value through profit or loss		(523)	(251)	(4,311)
Other financial expenses (income), net		(34)	105	143
FINANCIAL INCOME, net		(557)	(146)	(4,168)
NET COMPREHENSIVE LOSS		10,304	11,197	1,199
		U.S. dollars (except for share numbers)		
LOSS PER ORDINARY SHARE* -	14			
Basic		1.30	2.49	0.27
Diluted		1.31	2.49	0.78
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES* -				
Basic		7,955,447	4,490,720	4,473,170
Diluted		7,983,402	4,490,720	6,756,360

***Retroactively adjusted due to ordinary shares split, see note 10.

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

ENTERA BIO LTD.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (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	4,471,480	*	41	1,354	2,335	(29,417)	(25,687)
CHANGES DURING THE YEAR							
ENDED DECEMBER 31, 2016:							
Issuance of shares	19,240	*	-	-	150	-	150
Loss for the year	-	-	-	-	-	(1,199)	(1,199)
Share based compensation	-	-	-	1,490	-	-	1,490
BALANCE AT DECEMBER 31, 2016	4,490,720	*	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 expired	-	-	-	(35)	35	-	-
BALANCE AT DECEMBER 31, 2017	4,490,720	*	41	7,361	2,853	(41,813)	(31,558)
CHANGES DURING THE YEAR							
ENDED DECEMBER 31, 2018:							
Loss for the year	-	-	-	-	-	(10,304)	(10,304)
Share-based compensation	-	-	-	1,233	-	-	1,233
Issuance of shares and warrants, net	1,410,000	*	-	427	8,011	-	8,438
Conversion of Preferred shares into Ordinary shares	4,905,420	*	-	-	32,621	-	32,621
Conversion of convertible loan into Ordinary shares	622,180	*	-	-	4,138	-	4,138
Classification of Warrants to purchase preferred shares and shares into Warrants to purchase ordinary shares	-	-	-	5,548	-	-	5,548
Reclassification due to share-based compensation expired	-	-	-	(1,195)	1,195	-	-
Exercise of options to ordinary shares	31,460	*	-	(304)	304	-	-
Reclassification of capital contribution from controlling shareholder (note 7a)	-	-	-	(51)	51	-	-
BALANCE AT DECEMBER 31, 2018	11,459,780	*	41	13,019	49,173	(52,117)	10,116

* Represents an amount of less than one thousand.

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

ENTERA BIO LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31		
	2018	2017	2016
	U.S. dollars in thousands		
CASH FLOWS USED INOPERATING ACTIVITIES:			
Loss for the year	(10,304)	(11,197)	(1,199)
Adjustments required to reflect net cash used in operating activities (see appendix A)	508	6,671	(1,943)
Net cash used in operating activities	(9,796)	(4,526)	(3,142)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES:			
Decrease (increase) in restricted deposits	-	1,053	(1,075)
Purchase of short-term bank deposits	(4,000)	-	-
Purchase of property and equipment	(68)	(51)	(41)
Net cash provided by (used in) investing activities	(4,068)	1,002	(1,116)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:			
Issuance of ordinary shares and tradable warrants, net of issuance costs	9,624	-	-
Proceeds from convertible loan and warrants, net	-	-	7,216
Proceeds from issuance of preferred shares and warrants, net	-	12,087	-
Payment for maturity of Convertible loans	-	(980)	-
Net cash generated from financing activities	9,624	11,107	7,216
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(4,240)	7,583	2,958
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR	11,746	4,163	1,205
CASH AND CASH EQUIVALENTS AT END OF THE YEAR	7,506	11,746	4,163

ENTERA BIO LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31		
	2018	2017	2016
	U.S. dollars in thousands		
APPENDIX A:			
Adjustments required to reflect net cash used in operating activities:			
Depreciation and amortization	54	43	35
Income from change in fair value of financial liabilities at fair value through profit or loss	(523)	(251)	(4,311)
Issuance costs	270	1,091	363
Financial expenses	21	48	105
Net changes in severance pay obligation	(5)	19	22
Share-based compensation	1,233	4,885	1,490
	1,050	5,835	(2,296)
Changes in working capital:			
Decrease (increase) in other current assets	451	(454)	500
(Increase) decrease in accounts receivable	(725)	-	-
Increase (decrease) in accounts payable:			
Trade	(123)	543	(298)
Other	(334)	820	151
Increase in contract liabilities	225		
	(506)	909	353
Cash used for operating activities -			
Interest paid	(36)	(73)	-
	508	6,671	(1,943)
APPENDIX B:			
Supplementary information on financing activities not involving cash flows:			
Conversion of preferred shares into ordinary shares	32,621		
Conversion of convertible loan into ordinary shares	4,138		

SUPPLEMENTARY INFORMATION ON FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:
As to extinguishment and conversion of convertible loans to preferred shares 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 consolidated financial statements

NOTE 1 - GENERAL INFORMATION:

a. General:

1. Entera Bio Ltd. (the "Company") was incorporated on September 30, 2009 and commenced operation on June 1, 2010. The Company is 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 needs. Currently the Company is focused on the development of oral capsules for the treatment of osteoporosis and hypoparathyroidism . Our lead oral PTH product candidates are EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism.

   On January 8, 2018, the Company incorporated Entera Bio Inc., a fully owned subsidiary based in Delaware USA.

2. Initial Public Offering (IPO)–

   The Company filed final prospectus with the Securities and Exchange Commission ("SEC") which became effective on June 27, 2018. On July 2, 2018 the Company Completed the IPO in the Nasdaq Capital Market (the “Nasdaq”), for further information see note 10.

3. Since the Company is engaged in research and development activities, it has not derived significant income from its activities and has incurred accumulated losses in the amount of $52,117 thousand through December 31, 2018 and cash outflows from operating activities. The Company's management is of the opinion that its available funds as of December 31, 2018 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, debt financings, government grants or through license of the company's technology to additional external parties through partnerships or research collaborations as the Company will need to finance future research and development activities, general and administrative expenses and working capital 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.

4. On December 10, 2018, the Company entered into a research collaboration and license agreement (the “Amgen Agreement”) with Amgen Inc. (“Amgen”) in inflammatory disease and other serious illnesses. Pursuant to the Amgen Agreement, the Company and Amgen will use the Company’s proprietary drug delivery platform to develop oral formulations for one preclinical large molecule program that Amgen has selected. Amgen also has options to select up to two additional programs to include in the collaboration. Amgen is responsible for the clinical development, regulatory approval, manufacturing and worldwide commercialization of the programs.

   The Company granted Amgen an exclusive, worldwide, sublicenseable license under certain of its intellectual property relating to its drug delivery technology to develop, manufacture and commercialize the applicable products. The Company will retain all intellectual property rights to its drug delivery technology, and Amgen will retain all rights to its large molecules and any subsequent improvements, and ownership of certain intellectual property developed through the performance of the collaboration is to be determined by U.S. patent law.

   Pursuant to the terms of the Amgen Agreement, Amgen is required to make aggregate payments of up to $ 270 million upon achievement of various clinical and commercial milestones or its exercise of options to select additional two programs to include in the collaboration, as well as tiered royalty payments ranging from the low to mid-single digits based on the level of Amgen’s net sales of the applicable products. Amgen is required to pay for the initial program $450,000 for the second year of preclinical services to be provided by the Company, and must reimburse the Company for further expenses as shall be agreed between the parties. In January 2019, as required by the Amgen Agreement, Amgen paid the Company a non-refundable and non-creditable initial technology access fee of $725,000.

NOTE 1 - GENERAL INFORMATION (continued):

Amgen's obligation to pay royalties with respect to a product in a particular country commences upon the first commercial sale of such product in such country and expires on a country-by-country and product-by-product basis on the later of (a) the date on which the sale of the product is no longer covered by a valid claim of a patent licensed to Amgen under the Amgen Agreement, and (b) the tenth anniversary of the first commercial sale of such product in such country.

The term of the Amgen Agreement commenced on December 10, 2018, and unless earlier terminated, shall continue in full force and effect, on a product-by-product basis, until expiration of the last-to-expire royalty term with respect to such product.

b. Approval of financial statements

These financial statements were approved by the Company's Board of Directors on March 25, 2019.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a. Basis of preparation of the financial statements:

The consolidated statements of financial position of as of December 31, 2018 and 2017, and the related consolidated statements of comprehensive loss, changes in shareholders' equity (capital deficiency) and consolidated statement of cash flows for each of the three years in the period ended December 31, 2018 have been prepared in accordance with International Financial Reporting Standards, ("IFRS"), as issued by the International Accounting Standards Board ("IASB").

The significant accounting policies described below have been applied consistently in relation to all the periods presented, unless otherwise stated.

The financial statements have been prepared under the historical cost convention, subject to adjustments in respect of revaluation of financial liabilities at fair value through profit or loss. The Company's financial liabilities at fair value through profit or loss include convertible loans, preferred shares, warrants to preferred shares and shares and liability to issue preferred shares and warrants.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the financial statements are disclosed in note 3. Actual results could differ from those estimates and assumptions.

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

b. Functional and presentation currency:

1) Functional and presentation currency

Items included in the financial statements of the Company are measured using the currency of the primary economic environment in which the entity operates ("the functional currency"). The U.S. dollar is the currency of the primary economic environment in which the operations of the Company is conducted. The financial statements are presented in U.S. dollars.

2) Transactions and balances

Foreign currency transactions are translated into the functional currency using exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the statements of comprehensive loss within financial income or expenses.

Translation differences on non-monetary financial assets and liabilities at fair value through profit or loss are recognized in profit or loss as part of the fair value gain or loss within financial income or expenses.

c. Basis of consolidation:

The consolidated financial statements include the accounts of the Company and its subsidiary, Entera Bio Inc. Intercompany transactions and balances have been eliminated upon consolidation**.**

d . 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.

e. Short-term bank deposits

Bank deposits with maturities of more than three months but less than one year are included in short-term bank deposits. Such short-term bank deposits are stated at cost which approximates market values. The short-term bank deposit as of December 31, 2018 is in U.S. dollar and bear an annual interest rate of 2.38%.

f. Restricted deposits:

Restricted deposits relate to accounts where withdrawals are restricted under contractual agreements.

g. Property and equipment:

1) Property and equipment are stated at historical cost less accumulated depreciation and impairment. Historical cost includes expenditures that are directly attributable to the acquisition of the items. Repairs and maintenance are charged to the statement of comprehensive loss during the period in which they are incurred.

2) Assets are depreciated using the straight-line method to allocate their cost over their estimated useful lives.

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

h. Intangible assets:

1) Research and development expenses

Research expenses are charged to profit or loss as incurred. An intangible asset arising from development of the Company's products is recognized if all of the following conditions are met:

- It is technically feasible to complete the intangible asset so that it will be available for use;
- Management intends to complete the intangible asset and use it or sell it;
- There is an ability to use or sell the intangible asset;
- It can be demonstrated how the intangible asset will generate probable future economic benefits;
- Adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available; and costs associated with the intangible asset during development can be measured reliably.

Other development costs that do not meet the above criteria are recognized as expenses as incurred. Development costs previously recognized as an expense are not recognized as an asset in a subsequent period.

During the years ended December 31, 2018 and 2017, 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. As of December 10, 2018, The IPR&D has a finite useful life through patent expiration in August 2029, and is subsequently carried at cost less accumulated amortization. IPR&D is amortized using the straight line method.

i. 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, 2018 and 2017, no impairment has been recognized.

j. 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.

k. financial instruments

Commencing January 1, 2018, accounts receivables that are considered as loans and receivables under IAS 39, are now classified at amortized cost. This category is also subject to an impairment test under the expected credit losses model in accordance with IFRS 9.

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

l. Financial Liabilities:

1) Financial liabilities at fair value through profit or loss

This category included 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.

As for the preferred shares and convertible loans, changes in fair value that are the result of a change in the Company's credit risk are required to be recognized in Other Comprehensive Income rather than in profit or loss, following the adoption of IFRS 9. The amounts that should be recognized in Other Comprehensive Income (upon the adoption of IFRS 9 on January 1, 2018 as well as during 2018 until the conversion of these instruments to ordinary shares) is not material.

2) Other financial liabilities

Other financial liabilities, including the 2015 Convertible Loan (see note 7a(2)), are initially measured at fair value. In subsequent periods, the other financial liabilities are measured at amortized cost. Any difference between the consideration (net of transaction costs) and the redemption value is accreted to profit or loss over the term of the liability, using the effective interest method.

Interest expense is calculated using the effective interest rate method as described in Accounting standards regarding 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.

m. 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.

n. Deferred income tax

Deferred income taxes are recognized using the liability method on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements. Deferred income tax assets are recognized only to the extent that it is probable that future taxable income will be available against which the temporary differences can be utilized. Deferred income tax is determined using tax rates and laws that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

In the absence of expectation of taxable income in the future, no deferred tax assets are recorded in the financial statements.

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

o. Share-based payments

In 2013 and 2018, the Company has adopted share-based compensation plans for employees, directors and service providers. As part of the plans, 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.

p. Revenue recognition:

Revenues from the Amgen Agreement which was signed in December 2018 are recognized according to IFRS 15, "Revenues from Contracts with Customers". The Company has adopted for the first time standard, IFRS 15 – “Revenue from Contracts with Customers” since the Company had no revenues in previous years.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, the Company performs the following steps:

1. Identification of the contract, or contracts, with a customer.
2. Identification of the performance obligations in the contract.
3. Determination of the transaction price.
4. Allocation of the transaction price to the performance obligations in the contract.
5. Recognition of revenue.

On December 10, 2018, the Company entered into the Amgen Agreement in inflammatory disease and other serious illnesses. As part of the agreement, the Company received non-refundable and non-creditable initial access payment of $725 thousand from Amgen in January 2019. The Company identified two promises in the agreement: License to use the Company's proprietary drug delivery platform and preclinical R&D services. The preclinical R&D services include discovery, research and design preclinical activities relating to the programs selected by Amgen.

The Company determined the license to the intellectual property to be a right to use that has significant standalone functionality separately from the R&D services since the Company is not required to continue to support, develop or maintain the intellectual property transferred and will not undertake any activities to change the standalone functionality of the intellectual property. Therefore, the license to the intellectual property is a distinct performance obligation and as such revenue is recognized at the point in time that control of the license is transferred to Amgen on December 10, 2018.

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

p. Revenue recognition (continued):

Each of these promises met the definition of distinct performance obligation. The Company evaluated the selling price of the preclinical services at $225 thousand and the right to use the intellectual property at $500 thousand.

Revenues attributed to the preclinical services of $225 thousand will be recognized upon commencement of the pre-clinical Research and Development services, over time according the input model method on a cost-to-cost basis.

Under IFRS 15, the consideration that the Company would be entitled to upon the achievement of contractual milestones, which are contingent upon the occurrence of future events of development and commercial progress, are a form of variable consideration. When assessing the portion, if any, of such milestones-related consideration to be included in the transaction price, the Company first assesses the most likely outcome for each milestone and excludes the consideration related to milestones of which the occurrence is not considered the most likely outcome. The Company then evaluates if any of the variable consideration determined in the first step is constrained by including in the transaction price variable consideration to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company used significant judgment when it determined the first step of variable consideration. The Company did not recognize any revenues from milestones payments.

Sales- or usage-based royalties to be received in exchange for licenses of intellectual property are recognized at the later of when the performance obligation to which some or all of the sales- or usage-based royalty has been allocated is satisfied (in whole or in part). An entity should recognize revenue for a sales-based or usage-based royalty promised in exchange for a license of intellectual property only when (or as) the later of the following events occurs:

a. The subsequent sale or usage occurs; and
b. The performance obligation to which some or all of the sales based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

As royalties are payable based on future commercial sales, as defined in the agreement, which did not occur as of the financial statements date, the Company did not recognize any revenues from royalties.

As of December 31, 2018, the Company recognized $500 thousand of revenues and recorded contract liability of $225 thousand against account receivables in the amount of $725 thousand.

q. Government grants

Government grants, which are received from Israel Innovation Authority (the "IIA") by way of participation in research and development that is conducted by the Company, fall within the scope of "forgivable loans", as set forth in International Accounting Standard Number 20 "The Accounting Treatment of Government Grants and Disclosure in respect of Government Assistance" ("IAS 20"). Since at the time of the receipt of the grants there is no reasonable assurance that the grants that have been received will be repaid, at the time of their receipt they are offset against the related research and development expenses in the statement of comprehensive loss. To the extent that it will be considered "more likely than not" that the grants will be repaid in the future, the Company would record a financial liability. To date, the Company has recorded government grants as a financial liability in the amount of $27 thousand.

Other government grants which are not subject to royalties are offset against related research and development expenses in the statements of comprehensive loss.

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

r. 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 loans 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 consisted prior to the IPO of shares issuable upon conversion of convertible loan and preferred shares, warrants and options and as of December 31, 2018 consist of 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.

s. Newly issued and recently 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, 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 did not have a material impact on the financial statements.

t. New standards, amendments to standards or interpretations

IFRS 16, "Leases"

IFRS 16 was issued in January 2016. It will result in almost all leases being recognized on the balance sheet by lessees, as the distinction between operating and finance leases is removed. Under the new standard, an asset (the right to use the leased item) and a financial liability to pay rentals are recognized.
The only exceptions are short-term and low-value leases.

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

The Company has reviewed all of the Company's and its subsidiary's leasing arrangements over the last year in light of the new lease accounting rules in IFRS 16. The standard willaffect primarily the accounting for the Company's operating leases. As at the reporting date, the Company has non-cancellable operating lease commitments of $210 thousand, see note 9a and 9b.

The Company expects to recognize right-of-use assets and lease liabilities of approximately $172 thousand on January 1, 2019.

The Company will apply the standard from its mandatory adoption date of January 1, 2019. The Company intends to apply the simplified transition approach and will not restate comparative amounts for the year prior to first adoption.

The Company expects that net loss will increase by an immaterial amount for 2019 as a result of adopting the new rules. Operating cash flows for 2019 will increase, and financing cash flows will decrease by approximately $70 thousand as repayment of the principal portion of the lease liabilities will be classified as cash flows from financing activities.

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 10c.

Fair value of financial liabilities at fair value through profit or loss

Prior to the IPO, 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 or measurement date. 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.

Revenue recognition

With respect to the Amgen Agreement the Company used its judgement to identify the Company's the promises in the agreement and whether the promises are distinct performance obligation. In addition, the Company uses its judgement to determine the allocation of the transaction price between its identified distinct performance obligations. The Company also used its significant judgment in order to determine the R&D services period.

NOTE 4 - FINANCIAL INSTRUMENTS:

a. Financial risk management:

1) Financial risk factors

The Company's activities expose it to a variety of financial risks. The Company's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Company's financial performance.

Risk management is performed by the Chief Financial Officer of the Company, who identifies and evaluates financial risks in close cooperation with the Company's Chief Executive Officer.

The Company does not use financial instruments for hedging activity.

2) Credit risk

Credit and interest risk arises from cash and cash equivalents and deposits with banks. A portion of the liquid instruments of the Company is invested in short-term deposits in leading Israeli banks. The Company estimates that since the liquid instruments are mainly invested for the short-term and with a highly-rated institution, the credit and interest risk associated with these balances is immaterial.

3) Liquidity risk

Prudent liquidity risk management implies maintaining sufficient cash.

The Company is in a research stage and has not yet generated revenues. It is therefore exposed to liquidity risk, taking into consideration the forecasts of cash flows required to finance its investments and other activities.

4) Market risk—Foreign exchange risk

The Company might be exposed to foreign exchange risk as a result of making payments to employees or service providers and investment of some liquidity in currencies other than the Company's functional currency. The Company manages the foreign exchange risk by aligning the currencies for holding liquidity with the currencies of expected expenses, based on the expected cash flows of the Company.

b. Capital risk management

The Company's objectives when managing capital are to safeguard the Company's ability to continue as a going concern in order to provide returns for shareholders and to maintain an optimal capital structure to reduce the cost of capital. It should be noted that the Company is in the research and development stage and has not yet generated significant 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.

NOTE 4 - FINANCIAL INSTRUMENTS (continued)**:**

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, 2018, and 2017, the fair value of cash and cash equivalents, deposits, accounts receivable, other receivables and accounts payable approximates their carrying value.

NOTE 4 - FINANCIAL INSTRUMENTS (continued):

d. Classification of financial instruments by groups:

	Financial instruments
	U.S. dollars in thousands
As of December 31, 2018:	
Cash and cash equivalents	7,506
Short-term bank deposits	4,015
Receivables (excluding prepaid expenses)	836
	12,357
As of December 31, 2017:	
Cash and cash equivalents	11,746
Receivables (excluding prepaid expenses)	182
	11,928

	Financial liabilities at fair value through profit or loss	Financial liabilities at amortized cost	Total
	U.S. dollars in thousands		
As of December 31, 2018:			
Trade and other payable	-	1,563	1,563
Warrants to purchase ordinary shares (Level 1) (1)	1,372		1,372
	1,372	1,563	2,935
As of December 31, 2017:			
Trade and other payable	-	2,020	2,020
Convertible loan (Level 3)	3,893	-	3,893
Preferred shares (Level 3)	33,455	-	33,455
Warrants to purchase preferred shares and shares (Level 3)	5,398	-	5,398
	42,746	2,020	44,766

(1) Tradable warrants presented above are valuated based on the market price (a Level 1 valuation) as of December 31, 2018.

NOTE 5 - CASH AND CASH EQUIVALENTS

	December 31,	
	2018	2017
	U.S. dollars in thousands	
Cash in bank	5,499	11,741
Short-term bank deposits (1)	2,007	5
	7,506	11,746

(1) The short-term bank deposit as of December 31, 2018 is in U.S. dollar and bear an annual interest rate of 2.17%.

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). Due to the Amgen Agreement, the Company’s IPR&D Is subject to amortization. Amortization is calculated on the straight-line method for the remaining expected life of the IPR&D Patent (which is expected to expire on August 11, 2029)

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, 2018 the Company applied the market approach and calculated its enterprise value based on the quoted price per share of $3.05.

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 $6.99 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 three 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 (the “2012 Convertible Loan”). Each of the loans bears interest at a rate of 0.6% per year, which is to be repaid every five years, the loan is due and payable after a term of twenty years. Each of the investors has the right during the term to convert its respective loan amount into ordinary shares at a conversion price of $240.26 per ordinary share (before the IPO shares split) (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. Following the Closing of the IPO, see Note 10b, the Company’s outstanding 2012 Convertible loans in the amount of $4,138 were automatically converted into 622,180 Ordinary Shares of the Company.
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.

NOTE 7 - CONVERTIBLE LOANS (continued)**:**

3. 2016 Convertible Loan

In June 2016, the Company closed a private placement (the "2016 Convertible Loan") with certain lenders in an aggregate amount of approximately $7.44 million in exchange for the following instruments:

a) Loan for a term of 18 months. The loan bears interest at a rate of 5% per year. The loan will be automatically converted upon occurrence of the following events as described in the agreement: IPO of at least $20 million, private placement in an aggregate amount of no less than $10 million or change of control (the "Triggering Event"). Furthermore, in case of private placement in an aggregate amount of $4-$10 million the lenders shall have the right to convert the loan to shares. The loan will convert into the same class of shares issued in such a transaction at the lower of a 25% discount to the applicable price per share in the Triggering Event or value of equity on a fully diluted basis of $65 million.

The Company has designated the 2016 Convertible Loan on initial recognition as a financial liability at fair value through profit or loss.

b) Warrants to purchase additional shares (“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 which occurred in October 2017, the 2016 convertible loan together with the accrued interest was converted into 1,719,770 series B-1 preferred shares at a price per share of $5.24. Also, the 2016 Warrants became warrant to purchase Series B preferred shares at an exercise price of $6.99.

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 conversion of the 2012 Convertible loans into ordinary shares was performed according to their fair value as of the IPO closing date, July 2, 2018. The following parameters were used:

	July 2 2018	December 31 2017
Price per share*	$ 865	$ 908.78
Volatility	62%	55%
Probability of entering Phase 2b/3	NA	70%
Probability for IPO	100%	85%

* The price per share as of July 2, 2018 was based on quoted price on Nasdaq before the shares split. As of December 31, 2017, the valuation of the Company's financial liabilities was based on the market approach by using the price per share, prior to IPO split, of $908.78 per preferred B share as a basis for the fair market value (see Note 8b).

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
Changes in fair value up to IPO	245
Conversion into Ordinary shares on IPO (see Note 10b)	(4,138)
Balance as of December 31, 2018	-

	Warrants to purchase preferred shares and shares (Level 3)
	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 additional proceeds of $1,000 thousand) and the Company was required to issue to Centillion a warrant to purchase an additional 522 preferred shares at the per share purchase price. Centillion also had the right to acquire the preferred shares and warrant to be issued upon either of the milestones prior to the applicable milestone date.

On June 18, 2014, the Company and Centillion entered into the first amendment to the Centillion preferred share purchase agreement, pursuant to which the date for the first milestone was extended from June 29, 2014 to November 1, 2014, and the date for the second milestone was extended from December 29, 2014 to May 1, 2015.

On January 21, 2015, the Company and Centillion entered into the second amendment to the Centillion preferred share purchase agreement, or the "second amendment". Pursuant to the second amendment, Centillion exercised its right to acquire the preferred shares and warrant to be issued upon the first milestone although as of such date the Company had not filed a registration statement for its initial public offering and paid the Company $2,000 thousand. In consideration therefor, the Company also issued to Centillion an additional warrant, or the "additional Centillion warrant". The additional Centillion warrant is exercisable upon (and for a period of one year following) the first to occur of a significant financing round, an M&A event (as defined in the warrant agreement) or the Company's initial public offering, to purchase up to $2,000 thousand of the type of shares issued in such a transaction at a 25% discount to the applicable price per share. In addition, pursuant to the second amendment the date for the second milestone was extended from May 1, 2015 to October 1, 2015. According to the second amendment as the second milestone was not achieved by October 1, 2015, Centillion has extended it until October 1, 2017.

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

In the course of 2014, and on January 11, 2015 the Company consummated the closing of the Series A Preferred Share Purchase Agreements with certain shareholders (the Additional preferred A shareholders), and such agreements together the Additional preferred share purchase agreements. Pursuant to the terms of the additional share purchase agreements the Additional preferred A shareholders purchased from the Company 939 preferred shares for an aggregate purchase price of $450 thousand, and the Company issued to each of the additional preferred A shareholders a warrant to purchase up to 234 of its applicable shares 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 the Additional preferred A shareholders an additional warrant, or together with the additional Centillion warrant the "additional warrants", to purchase up to $450 thousand, 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.

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 the Additional preferred A shareholders became warrants to purchase Series B-1 preferred shares at an exercise price of $681.585.

Following the Closing of the IPO, see Note 10b, the Company’s 10,222 preferred A shares were automatically converted into 1,328,860 Ordinary Shares of the Company (after share split). In addition, the 2,554 warrants to purchase preferred A shares were converted into 332,020 warrants to purchase ordinary shares of the Company (after share split) and certain additional options and warrants to issue preferred A shares were automatically converted into options and warrants to purchase ordinary shares of the Company (after share split). In addition, the 3,594 additional warrants and options to purchase Preferred B-1 shares automatically converted into 467,220 warrants to ordinary shares of the Company (after share split).

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

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 (before share split). See also note 10c(2)(e).

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 had the right to convert such preferred shares into the Company's ordinary shares at the then-applicable conversion price. In addition, the preferred shares will be automatically converted into ordinary shares at the then-applicable conversion price upon the consummation of a Qualified IPO.

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

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

d. For accounting of purposes, the preferred shares were 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 was 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 were exercisable into a financial liability. These warrants were measured at fair value through profit or loss at each balance sheet date up to July 2, 2018 and on July 2, 2018.

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.

Following the Closing of the IPO, all the Company’s preferred shares, warrants and options to purchase preferred shares were automatically converted into Ordinary Shares and warrants and options to purchase ordinary shares. Therefore, the company classified the financial liabilities to equity according to their value as of the IPO closing date.

e. Tradable warrants

As described in Note 10(b), On July 2, 2018 the Company issued 1,400,000 tradable warrants to purchase 700,000 ordinary shares of the Company. The tradable warrants are exercisable immediately at an initial exercise price of $8.4 per ordinary share for a period of five years, unless earlier repurchased by the Company under "Fundamental Transactions” as described in the warrant or early expired as described below and in the warrant.

The exercise of the warrants is in cash, unless the warrant holder is utilizing the “cashless” exercise provision of the warrants, prior to the termination date under certain circumstances as described in the warrant. On the termination date, any warrants not previously exercised, repurchased by the Company or subject to early expiration will terminate and expire worthless.

The exercise price and number of shares issuable upon exercise of each warrant are subject to standard adjustments. The exercise price is subject to reduction if, within two years of the date of original issuance of the warrants, the Company sells or grants any warrant or option (except in certain circumstances as described in the warrant) at an effective price per share less than $8.0 per share (as adjusted in proportion with any adjustments made from time to time), which reduction will be based on a weighted average, as described in the warrant.

The Company 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 $24.00 per share, which is 300% of the IPO price per unit (subject to adjustments) for a 10 consecutive trading day period. For accounting purposes, the tradable warrants issued to the public were classified as a financial liability since their exercise price and number of shares issuable upon exercise of each warrant are subject to certain adjustments as described in the warrant form and also due to option to cashless exercise. The fair value of the tradable warrants as of the IPO closing date and as of December 31, 2018 was based on quoted price on Nasdaq (Level 1 valuation) as of the respective date.

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

f. The table below presents the movements in the three components during 2018, 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
Conversion of Preferred shares to Ordinary shares on IPO	(32,621)	-	-	(32,621)
Conversion of Warrants to purchase preferred shares to Warrants to purchase ordinary shares on IPO	-	(5,548)	-	(5,548)
Changes in fair value	(834)	150	-	(684)
Balance as of December 31, 2018	-	-	-	-

g. As of the closing of the IPO, July 2, 2018 and as of December 31, 2017, the Company prepared valuations of the fair value of the instruments described above using a combination of the Probability-Weighted Expected Return Method and Back Solve option pricing method model. The following parameters were used:

	July 2	December 31
	2018	2017
Price per share*	$ 865	$ 908.78
Volatility	62%	55%
Probability of entering Phase 2b/3	NA	70%
Probability for IPO	100%	85%

* The price per share as of July 2, 2018 was based on quoted price on Nasdaq before shares split. As of December 31, 2017, the valuation of the Company's financial liabilities was based on the market approach by using the price per share, prior to IPO split) of $908.78 per preferred B share as a basis for the fair market value.

Immediately prior to the IPO, the fair value measurement of the preferred shares and the convertible loan was based upon the fair value of the Company's share (the IPO price) only, which represents a level 1 measurement, while the Fair value of the warrants to ordinary shares represent a level 3 measurement.

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. In January 2019 the Company signed an addendum to the lease agreement, according to the addendum the Company leased additional space for approximately $94 thousands per year. The whole lease agreement will expire on June 30, 2023 and the one-time option previously granted to the Company to terminate the lease on June 30, 2020 replaced by one-time option to terminate to whole lease space on December 31, 2021 subject to a notice period of 6 months.

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, 2018, the total royalty amount that would be payable by the Company, before the additional Libor interest, is approximately $460 thousand.

Following the signing of the Amgen Agreement (see note 1a(4)), the Israeli Innovation Authority (the "IIA") determined that the Company should pay 5.38% of each payment that will be received by the Company from Amgen on the license of IP up to 6 times the grant received. On February 10, 2019 the Company paid $27 thousands to the Government of Israel.

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 statement. 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. Following the closing of the IPO and the 1-for-130 split of the Company's ordinary shares, the share capital composed of ordinary shares of NIS 0.0000769 par value, as follows:

	Number of ordinary shares	
	December 31	
	2018	2017
Authorized	140,010,000	130,000,000
Issued	11,459,780	4,490,720

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. Initial Public Offering (IPO)

On July 02, 2018 the Company completed the IPO and offered 1,400,000 ordinary shares and 1,400,000 warrants (the “tradable warrants”) to purchase up to 700,000 ordinary shares for a gross consideration of $11.2 million before issuance costs ($9.6 million net of issuance costs in cash which include $0.9 million underwriters’ fees and an additional approximately $0.7 million of other issuance costs). The ordinary shares and the tradable warrants sold in units (each a “unit”), with each unit consisting of one ordinary share and one tradable warrant to purchase 0.5 of an ordinary share. The public offering price was $8.0 per unit.

The ordinary shares and warrants were immediately separable and issued separately and started to trade on June 28, 2018 , following the effectiveness of the registration statement filed with the SEC on June 27, 2018.

NOTE 10 - SHARE CAPITAL (continued):

The closing of the IPO was on July 2, 2018 following which the Company was entitled to receive the proceeds from the IPO. Certain actions were completed in connection with the closing of the IPO, including:

A. A 1-for- 130 split of the Company's ordinary shares. Following the split, the Company retrospectively reflected the change in the share capital of the Company for all periods presented. Unless otherwise indicated, all of the ordinary share numbers, losses per ordinary share, share prices, options and warrants in these financial statements have been adjusted, on a retroactive basis, to reflect this 1-for-130 split.

B. The Company’s outstanding 2012 Convertible loans were automatically converted into 622,180 Ordinary Shares of the Company.

C. The Company's series A preferred shares, series B preferred shares and series B-1 preferred shares were automatically converted into 1,328,860, 1,856,790 and 1,719,770, Ordinary Shares of the Company, respectively.

D. The Company's warrants to series A preferred shares, Warrants to Series B preferred shares and Warrants to Series B-1 preferred shares were automatically converted into 343,200, 756,340 and 467,220 warrants, respectively, to purchase Ordinary Shares of the Company.

E. Existing options to purchase Series A preferred shares and warrants to purchase Series A preferred shares, granted to certain holders of our Series A preferred shares that are exercisable upon the closing of the IPO, were automatically converted into options to purchase 387,530 ordinary shares and into warrants to purchase 85,931 ordinary shares.

The Company granted the underwriters an over-allotment option. This option, which is exercisable for up to 30 days after the date of the Effective registration statement, permits the underwriters to purchase a maximum of 210,000 additional ordinary shares and/or 210,000 additional warrants to purchase up to 105,000 ordinary shares to cover over-allotments, if any.

On July 26, 2018, the Company's underwriters exercised their overallotment option to purchase 210,000 warrants to purchase 105,000 Ordinary Shares of the Company for a total consideration of $2,100. The fair value of the warrants on the issuance date was $172 thousand. The Company recorded the fair value as issuance costs.

The Company also issued to the underwriters 10,000 ordinary shares following the closing of the IPO, as well as 70,000 underwriter warrants at an exercise price of $8.8 to purchase 70,000 ordinary shares. The underwriter warrants may be exercised on a cashless basis under certain circumstances as described in the warrant. The underwriter warrants will be exercisable 180 days following June 29, 2018 until the fifth anniversary of such effective date. The underwriter warrants are not redeemable by the company and have some registration rights as described in the warrant. 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 shares and warrants issued to the underwriters recorded as an issuance cost based on fair value of $66.5 thousand and $255 thousand, respectively.

The Company allocated the total consideration from the issuance of the units between the ordinary shares and the tradable warrants as following: the tradable warrants recorded at fair value based on quoted price on Nasdaq as of July 2,2018 and the residual allocated to the ordinary shares.

Issuance costs were allocated to the ordinary shares and the tradable warrants according to their fair values. Issuance costs which were allocated to the ordinary shares were deducted from shareholders' equity, and issuance costs that were allocated to the tradable warrants were expensed immediately.

NOTE 10 - SHARE CAPITAL (continued)**:**

c. Share based compensation:

1) Share based compensation plan

Prior to the closing of the IPO as detailed in Note 10b the Company's board of directors and shareholders of the Company approved a new Share Incentive Plan (the “2018 Plan”), subject to the closing of the IPO (see note 10b) and has reserved 1,371,398 Ordinary Shares 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 for issuance under the 2018 Plan. Each Option is exercisable to one ordinary share NIS 0.0000769 par value.

Any option granted under the New Plan that is not exercised within 10 years from the date upon which it becomes exercisable will expire.
As of December 31, 2018, no options granted under the 2018 Incentive Plan.

On March 17, 2013, the Company's board of directors approved a Share Incentive Plan (the “2013 Plan”). Under the 2013 Plan, the Company shall reserve sufficient number of Ordinary Shares, NIS 0.000769 par value, of the Company for allocation of stock options, restricted share units, restricted share awards and performance-based awards (the "Option"), to employees and non-employees. Each Option is exercisable to acquire one ordinary share.

Any option granted under the 2013 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 or NSO. The Company will be allowed to claim as an expense for tax purposes in the year in which the related parties or non-employees exercised the options into shares.

NOTE 10 - SHARE CAPITAL (continued)**:**

2) Options grants:

a) In March 2016, the Company granted options to purchase 147,290 ordinary shares to a certain director with an exercise price of $3.68. 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 3,120 ordinary shares to a certain consultant, with an exercise price of par value (0.0000769 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 64,220 ordinary shares to certain employees with an exercise price of $3.68. 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 1,560 ordinary shares to a certain consultant, with an exercise price of par value (0.0000769 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 of the Company, to be granted to Mr. Beshar and Dr. Garceau of 906,100 and 209,040, respectively. The exercise price of the options is $ 6.308 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.

The resignation of Mr. Beshar, the Chairman of the board took effect on June 27, 2018. According to the Mr. Beshar's options terms, options which have yet to fully vest are forfeited, therefore 453,050 options forfeited and were recognized in the financial statements as a reverse of expense under the General and Administrative line item in the amount of $1,326 thousand.

NOTE 10 - SHARE CAPITAL (continued):

f) On April 6, 2017, the Company granted options to purchase 147,290 ordinary shares to a certain director, with an exercise price of $7.538. 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 591,500 ordinary shares to the CEO, COO and the CFO of the Company, with an exercise price of $6.308. 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 13,000 ordinary shares to a certain consultant, with an exercise price $6.308. 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 76,180 ordinary shares to certain employees, with an exercise price of $6.308. 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.

j) On January 10, 2018, the Company appointed Dr. Eric Lang as the Company's Chief Medical Officer, effective January 15, 2018. In connection with Dr. Lang's appointment as the Company's Chief Medical Officer, the Company's Board of Directors granted Dr. Lang options to purchase 110,500 ordinary shares at an exercise price of $6.308 per share. The options vest over 4 years from the date of grant; 1/4 vest on 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 $420 thousand. In September 2018, Dr. Eric Lang's employment was terminated and the options were forfeited in December 2018.

k) In January 2018, the Company granted options to purchase 32,500 ordinary shares to a certain consultant, with an exercise price of $2.107. The options vested immediately. The fair value of the options at the date of grant was $138 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:

	2018	2017	2016
Ordinary share price	$ 6.31	$ 5.95	7.83
Exercise price	$ 5.35	$ 5.95	3.68
Dividend yield	-	-	-
Expected volatility	68%	73.77%	76%
Risk-free interest rate	2.23%	1.67%	1.05%
Expected life – in years	4.07	7.94	4.11

NOTE 10 - SHARE CAPITAL (continued)**:**

The fair value of each option with an exercise price of NIS 0.0000769 is based on the fair value of ordinary share at the date of grant. The ordinary share price is derived from the value of equity and was based on the valuation performed (as detailed in note 6). The expected volatility is based on comparable companies. The risk-free interest rate is determined based on rates of return on maturity of unlinked treasury bonds with a time to maturity that equals the average life of the options.

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

	Year ended December 31,					
	2018		2017		2016	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of year	3,044,990	$ 4.59	1,136,590	$ 1.43	921,960	$ 0.92
Forfeited	(718,120)	5.73	(36,270)	2.27	-	-
Exercised (*)	(31,460)	-	-	-	-	-
Granted	143,000	$ 5.35	1,944,670	$ 6.39	214,630	3.63
Outstanding at end of year	2,438,410	$ 4.36	3,044,990	$ 4.59	1,136,590	1.43
Exercisable at end of year	1,837,160	$ 1.67	1,430,780	$ 2.92	835,380	0.721

(*) The total intrinsic value of options exercised during the year ended December 31, 2018, was approximately $181 thousand.

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

December 31, 2018			December 31, 2017		
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
602,810	*	0.55	634,270	*	1.67
27,560	$ 1.85	0.67	33,020	$ 1.85	1.7
36,010	$ 2.43	1.41	36,010	$ 2.43	2.42
65,000	$ 2.11	1.05	32,500	$ 2.11	2.05
11,050	$ 1.85	2.21	11,050	$ 1.85	3.21
205,920	$ 3.69	3.36	355,030	$ 3.69	4.2
1,342,770	$ 6.31	6.39	1,795,820	$ 6.31	7.77
147,290	$ 7.54	4.26	147,290	$ 7.54	5.26

* Par value

6) The remaining unrecognized compensation expense as of December 31, 2018 is $1,123 thousand. This amount will be expensed in full by December 2021.

NOTE 11 - TAXES ON INCOME:

a. Entera Bio Ltd.

The Company is taxed according to Israeli tax laws:

1) 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.

2) Tax rates

The income of the Company is subject to the Israel corporate tax rates.

In January 2016, the Law for the Amendment of the Income Tax Ordinance (No. 216) was published, enacting a reduction of corporate tax rate beginning in 2016 and thereafter, from 26.5% to 25%.

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 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.

b. Entera Bio Inc.

Entera Bio Inc. is taxed according to U.S. tax laws. The Company's income is taxed in the United States at the rate of 21%.

c. Losses for tax purposes carried forward to future years

Entera Bio Ltd.

The balance of carryforward losses as of December 31, 2018 and 2017 are approximately $24 million and $15.3 million, respectively.

Under Israeli tax law, tax loss carry forwards have no expiration date.

Deferred tax assets on losses for tax purposes carried forward to subsequent years are recognized if utilization of the related tax benefit against a future taxable income is expected. The Company has not created deferred tax assets on its carry forward losses and other temporary assets since their utilization is not expected in the foreseeable future.

NOTE 11 - TAXES ON INCOME (continued)**:**

d. Reconciliation of the theoretical tax expense to actual tax expense

The main reconciling item between the statutory tax rate of the Company and the effective rate is unrecognized tax benefits from carry forward tax losses due to the uncertainty of the realization of such tax benefits (see above).

e. Tax assessments

In accordance with the Income Tax Ordinance, as of December 31, 2018, all of the Company's tax assessments through tax year 2013 are considered final.

NOTE 12 – REVENUE FROM CONTRACTS WITH CUSTOMERS

Regarding the Amgen Agreement as detailed in Note 1(d), the Company recorded revenues as follows:

	Year ended December 31,
	2018
	U.S. dollars
Revenues from license	500
Revenues from preclinical research and development	-
Total revenues	500

In addition, the company recorded a contract liability of $225 thousand under the current liabilities line item.

NOTE 13 - SUPPLEMENTARY FINANCIAL INFORMATION:

		December 31,	
		2018	2017
		U.S. dollars in thousands	
a.	**Other current assets:**		
	Prepaid expenses	109	489
	Restricted deposits	21	23
	Other	90	159
		220	671

		December 31,	
		2018	2017
		U.S. dollars in thousands	
b.	**Accounts payable - other:**		
	Employees and employees related	120	215
	Provision for vacation	215	214
	Accrued expenses and other	755	995
		1,090	1,424

NOTE 14 –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

The 2012 Convertible Loan, preferred shares, warrants to issue preferred shares A, warrants to issue preferred shares B up to the closing of the IPO and warrants to issue ordinary shares and all the options, have been excluded from the calculation of the diluted loss per share for the year ended December 31, 2018 since their effect was anti-dilutive. The total number of shares related to the outstanding options, 2012 Convertible Loan, preferred shares, warrants to issue preferred shares A, warrants to issue preferred shares B and warrants to issue ordinary shares excluded from the calculation of diluted loss per share was 10,596,130 for the year ended December 31, 2018.

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 7,687,030 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.

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 1,057,680 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.

	Year ended December 31,		
	2018	2017	2016
	U.S. dollars (except for share numbers)		
Loss attributable to equity holders of the Company	10,304,000	11,197,000	1,199,000
Income from change in fair value of financial liabilities at fair value	135,000	-	4,125,000
Loss used for the computation of diluted loss per share	10,439,000	11,197,000	5,324,000
Weighted average number of Ordinary Shares used in the computation of basic loss per share	7,955,447	4,490,720	4,473,170
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 and shares	27,955	-	2,283,190
Weighted average number of Ordinary Shares used in the computation of diluted loss per share	7,983,402	4,490,720	6,756,360
Basic loss per Ordinary Share	1.30	2.49	0.27
Diluted loss per Ordinary Share	1.31	2.49	0.78

NOTE 15 - 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, Chief Medical 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 receive a monthly fee in the amount of $21,500 and $6,500, respectively.

   On June 27, 2018 Mr. Beshar, the Chairman of the board resigned from the Board of Director and therefore his service agreement terminated. On January 17, 2019 the board of director approved the amendment to Dr. Garceau agreement according to it the monthly payment reduced to $4,000 effective as of November 1, 2018.

3) During 2018 and 2017, the Company granted stock options to certain key management personnel and directors, see note 10c.

4) In 2017, certain related parties were 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).

5) On September 27, 2018 the shareholders of the Company approved for all external directors and non-executive directors a compensation in the amount equal to the maximum fixed statutory amounts set forth in the Companies Regulations (Rules Regarding the Compensation and Expenses of an External Director), 5760-2000, for companies with equity similar to the Company.

NOTE 15 - RELATED PARTIES - TRANSACTIONS AND BALANCES (continued)**:**

6) Key management compensation:

	Year ended December 31,		
	2018	**2017**	**2016**
	U.S. dollars in thousands		
Labor cost and related expenses	1,180	1,048	830
Share-based compensation	868	4,694	1,351
Directors fee and services	429	577	73
Others	30	109	25
	2,507	6,428	2,279

b. Balances with related parties:

	December 31,	
	2018	**2017**
	U.S. dollars in thousands	
Key management:		
Payables and accrued expenses	9	93
Severance pay obligations	65	70
Provision for vacation	186	186
Directors fee and services	74	76

NOTE 16 - SUBSEQUENT EVENTS

1. On January 17, 2019, the Company granted options to purchase 124,000 ordinary shares to certain employees, with an exercise price of $3.97. 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 instalment following the first anniversary of the grant date. The fair value of the options at the date of grant was $341 thousand.

2. On January 17, 2019, the Company granted options to purchase 25,000 ordinary shares to the CMO, with an exercise price of $3.97. From the total options, 25% will vest on March 1, 2019 and the remaining 75% options shall vest in 12 installments (equal or rounded), upon the lapse of each three-month period following the first anniversary of the grant date. The options granted to the CMO are subject to the approval by the shareholders of the Company that yet to occurred as of the signing of the financial statement. The fair value of the options at the date of grant was $68 thousand.

3. On January 17, 2019, the Company granted options to purchase 201,828 ordinary shares to non-executive directors of the Company, with an exercise price of $3.97. The options will vest in 3 years in twelve quarterly instalments starting in the first quarter following their appointment of each director as a board member. The options granted to the non-executive directors are subject to the approval by the shareholders of the Company that yet to occurred as of the signing of the financial statement. The fair value of the options at the date of grant was $542 thousand.

Exhibit 4.25

ENTERA BIO LTD.
2018 EQUITY INCENTIVE PLAN

STOCK OPTION AWARD AGREEMENT - ISRAELI EMPLOYEES – TRUSTEE
CAPITAL GAIN ROUTE

_____, 20__

Subject to the terms and conditions set forth in this grant letter (the "**Grant Letter**") and the award agreement set forth in Exhibit A (the Grant Letter and Exhibit A, collectively this "**Agreement**"), Entera Bio Ltd., a company organized under the laws of the State of Israel (the "**Company**"), has granted you as of the Grant Date set forth below an option to purchase Shares (the "**Award**"). The Award is granted under and is subject to the Entera Bio Ltd. 2018 Equity Incentive Plan (together with the Israeli Sub Plan, the "**Plan**"). Unless defined in this Agreement, capitalized terms shall have the meanings assigned to them in the Plan. The provisions of the Plan shall control in the event of a conflict among the provisions of the Plan, this Agreement and any descriptive materials provided to you.

AWARD TERMS

PARTICIPANT:
GRANT DATE:
SHARES SUBJECT TO AWARD:
PER SHARE EXERCISE PRICE:
VESTING TERMS:
TAX ROUTE: Trustee Capital Gains Route

Please review this Agreement and let us know if you have any questions about this Agreement, the Award or the Plan. You are advised to consult with your own tax advisors in respect of any tax consequences arising in connection with this Award.

If you have questions please contact [●] via email at [●]. If not, please provide your signature, address and the date for this Agreement where indicated below.

By signing below, you declare as follows: (i) you shall comply with all terms and conditions set forth in Section 102 with regard to the applicable tax track and the rules and regulations promulgated thereunder, as amended from time to time; (ii) you are familiar with, and understand the provisions of Section 102 in general, and the tax arrangement under the applicable tax track in particular, and its tax consequences; (iii) you agree that the Option and any Shares that may be issued in connection with the Option (or otherwise in relation to the Option), will be held by the Trustee for at least the duration of the Holding Period; (iv) you understand that any release of such option or shares from trust, or any sale of the share prior to the termination of the Holding Period, will result in taxation at marginal tax rate, in addition to deductions of appropriate social security, health tax contributions or other compulsory payments; and (v) you agree to the provisions of the form Trust Deed signed between the Trustee, the Company.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first written above.

ENTERA BIO LTD.

By: _____

Name:

Title:

PARTICIPANT

_____

Name

_____

_____

Address

Date: _____

ENTERA BIO LTD. 2018 EQUITY INCENTIVE PLAN
STOCK OPTION AWARD AGREEMENT – TRUSTEE CAPITAL GAINS ROUTE

The following award agreement (this "**Award Agreement**") sets forth the agreement of the parties to the Grant Letter to which this Award Agreement is appended with respect to the grant of stock options described in the Grant Letter. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Plan and the Grant Letter.

1. Grant of Option. The Company hereby grants to the Participant an option to purchase all or any part of the number of Shares set forth in the Grant Letter ("**Option Shares**") at the per-share exercise price set forth in the Grant Letter (the "**Exercise Price**"), pursuant to the provisions of the Plan, the terms of which are incorporated herein by reference, and further subject to the terms and conditions set forth herein (the "**Option**").

2. Terms and Conditions. It is understood and agreed that the Award evidenced hereby is subject to the following terms and conditions:

(a) Vesting of Award. Subject to the provisions of this Section 2 and Sections 3 and 4, the Option shall vest and become exercisable in accordance with the vesting schedule set forth in the Grant Letter. In the event of a Termination of Service of the Participant prior to the date on which the Award otherwise becomes vested, the unvested portion of the Award shall immediately be forfeited by the Participant and become the property of the Company.

(b) Term of Option. The term of the Option shall expire at close of the principal stock market or exchange on which the Shares are quoted or traded on the tenth (10^{th}) anniversary of the Grant Date, unless terminated earlier in accordance herewith. In no event may any portion of the Option be exercised after it has expired.

(c) Manner of Exercise. The Participant may, subject to the limitations in this Agreement and the Plan, exercise all or any portion of the Option that has vested. In order to exercise the Option, the Participant shall (i) deliver to the Company a written notice specifying the number of Option Shares to be purchased and (ii) remit the aggregate Exercise Price to the Company in full, payable (A) in cash or by check, bank draft or money order payable to the order of the Company or (B) any other method acceptable to the Administrator.

(d) No Right to Future Awards. 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.

3. Exercise in Event of Death, Disability or Other Termination of Service.

(a) Death or Disability. If the Participant incurs a Termination of Service due to such Participant's death or Disability, all or any part of the Option which was exercisable by the Participant immediately prior to his or her death or Disability may be exercised by the Participant or the Participant's designated Beneficiary, estate or the person to whom such Option is transferred by will or the applicable law of descent and distribution, at any time before the earlier of (i) the twelve (12) month anniversary of the date of the Termination of Service and (ii) the time such Option would otherwise expire. To the extent the Option was not exercisable on the date of the Participant's Termination of Service as a consequence of his or her death or Disability, such portion of the Option shall terminate.

(b) For Cause. If the Participant incurs a Termination of Service by the Company for Cause, any Options held by the Participant shall be immediately cancelled and may not thereafter be exercised, even if exercisable on the date of such Termination of Service.

(c) Exercise Following Termination of Service. If the Participant incurs a Termination of Service for any reason other than the Participant's death or Disability or for Cause, the Option held by the Participant at the time of such Termination of Service, to the extent vested at such time, may be exercised at any time before the earlier of (i) the three (3) month anniversary of the date of the Termination of Service and (ii) the time such Option would otherwise expire; *provided* that if the Participant dies within such three-month period, the Options (to the extent vested) may be exercised by the Participant's designated Beneficiary, estate or the person to whom such Option is transferred by will or the applicable law of descent and distribution, at any time before the earlier of (i) the twelve (12) month anniversary of the date of the Termination of Service and (ii) the time such Option would otherwise expire. Except as set forth in this Section 3(c), to the extent the Option was not exercisable on the date of the Participant's Termination of Service, such portion of the Option shall terminate.

4. Treatment on Change in Control. In the event of a Change in Control, the Option will be treated in accordance with Section 11(b) of the Plan.

5. Trust. The Option is intended to be subject to tax under the trustee capital gains route pursuant to section 102(b)(2) of the Israeli Income Tax Ordinance [New Version] 1961 ("Section 102"), subject to compliance with the terms and conditions of Section 102 and the Income Tax Rules (Tax Benefits in Share Issuance to Employees) 5763-2003 (the "Rules"). The Options and the Shares issued upon exercise or otherwise and/or any additional rights, including without limitation any right to receive any dividends or any Shares received as a result of an adjustment made under the Plan, that may be granted in connection with the Option (the "Additional Rights") shall be issued to or controlled by the Trustee for the benefit of the Participant under the provisions of Section 102 and the Rules pursuant to the capital gains route for at least the period stated in Section 102. In the event the Option or underlying Shares do not meet the requirements of Section 102, such Option and the underlying Shares shall not qualify for the favorable tax treatment under the Capital Gains Route of Section 102. The Company makes no representations or guarantees that the Option will qualify for favorable tax treatment and will not be liable or responsible if favorable tax treatment is not available under Section 102. Any fees associated with any vesting, sale, transfer or any act in relation to the Option shall be borne by the Participant and the Trustee and/or the Company and/or any Affiliate shall be entitled to withhold or deduct such fees from payments otherwise due to from the Company or an Affiliate or the Trustee. In accordance with the requirements of Section 102 and the Capital Gains Route, the Participant shall not sell nor transfer the Shares or Additional Rights from the Trustee until the end of the required Holding Period. Notwithstanding the above, if any such sale or transfer occurs before the end of the required Holding Period, the sanctions under Section 102 shall apply to and shall be borne by the Participant.

6. Tax Liability; Withholding Requirements. The Participant shall be solely responsible for any applicable taxes (including, without limitation, income and excise taxes) and penalties, and any interest that accrues thereon, that the Participant incurs in connection with the receipt, vesting or exercise of any Option granted hereunder. The Company and/or the Trustee shall withhold taxes according to the requirements under Applicable Law, including withholding taxes at source. Furthermore, the Participant agrees to indemnify the Company 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 Participant. The Company and/or the Trustee may make such provisions and take such steps as they may deem necessary or appropriate for the withholding of all taxes required by law to be withheld with respect to Options under the Plan and the exercise, vesting and/or sale or other disposition thereof, including, but not limited to, (i) deducting the amount so required to be withheld from any other amount (or Shares issuable) then or thereafter to be provided to the Participant, including by deducting any such amount from the Participant's salary or other amounts payable to the Participant, to the maximum extent permitted under law and/or (ii) requiring the Participant to pay to the Company the amount so required to be withheld as a condition of the issuance, delivery, distribution or release of any Shares. The Company and/or the Trustee shall not be required to release any Shares to the Participant until all required withholding taxes have been paid by the Participant. In addition, the Participant will be required to pay any amount due in excess of the tax withheld and transferred to the ITA, pursuant to applicable tax laws, regulations and rules.

7. References. References herein to rights and obligations of the Participant shall apply, where appropriate, to the Participant's legal representative or estate without regard to whether specific reference to such legal representative or estate is contained in a particular provision of this Agreement.

8. Not Salary, Pensionable Earnings or Base Pay. The Participant acknowledges that the Award shall not be included in or deemed to be a part of (a) salary, normal salary or other ordinary compensation, (b) any definition of pensionable or other earnings (however defined) for the purpose of calculating any benefits payable to or on behalf of the Participant under any pension, retirement, termination or dismissal indemnity, severance benefit, retirement indemnity or other benefit arrangement of the Company or any Subsidiary or (c) any calculation of base pay or regular pay for any purpose.

9. Forfeiture Upon Breach of Certain Other Agreements. Subject to Section 10, the Participant's breach of any non-competition, non-solicitation, confidentiality, non-disparagement, assignment of inventions or other intellectual property agreement that the Participant may be a party to with the Company or any Affiliate (the "**Restrictive Covenant Agreement**") is incorporated herein by reference, in addition to whatever other equitable relief or monetary damages that the Company or any Affiliate may be entitled to, shall result in automatic rescission, forfeiture, cancellation or return of any Shares (whether or not vested) held by the Participant. To the extent that the Participant has not executed the Restrictive Covenant Agreement, this Agreement and the Award thereunder shall not be effective unless and until the Participant executes the Restrictive Covenant Agreement, and this Agreement and the Award thereunder shall be revoked if the Participant does not execute the Restrictive Covenant Agreement within thirty (30) days following the Grant Date.

10. Whistleblower Protection; Defend Trade Secrets Act.

(a) Nothing in this Agreement or otherwise limits the Participant's ability to communicate directly with and provide information, including documents, not otherwise protected from disclosure by any Applicable Law or privilege to the Securities and Exchange Commission (the "**SEC**"), any other federal, state or local governmental agency or commission ("**Government Agency**") or self-regulatory organization regarding possible legal violations, without disclosure to the Company. The Company may not retaliate against the Participant for any of these activities, and nothing in this Agreement requires the Participant to waive any monetary award or other payment that the Participant might become entitled to from the SEC or any other Government Agency or self-regulatory organization.

(b) Pursuant to the Defend Trade Secrets Act of 2016, the parties hereto acknowledge and agree that the Participant shall not have criminal or civil liability under any Federal or State trade secret law for the disclosure of a trade secret that (i) is made (A) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney and (B) solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition and without limiting the preceding sentence, if the Participant files a lawsuit for retaliation by the Company for reporting a suspected violation of law as contemplated by the preceding sentence, the Participant may disclose the relevant trade secret to his attorney and may use such trade secret in the ensuing court proceeding, if the Participant (X) files any document containing such trade secret under seal and (Y) does not disclose such trade secret, except pursuant to court order.

11. Recoupment/Clawback. This Award (including any amounts or benefits arising from this Award) shall be subject to recoupment or "clawback" as may be required by Applicable Law, stock exchange rules or by any applicable Company policy or arrangement the Company has in place from time to time.

12. Miscellaneous.

(a) Notices. Any notice required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been given when delivered personally or by courier, or sent by certified or registered mail, postage prepaid, return receipt requested, duly addressed to the party concerned at the address indicated below or to such changed address as such party may subsequently by similar process give notice of:

If to the Company:

Entera Bio Ltd.
Kiryat Hadassah
Minrav Building – Fifth Floor
Jerusalem 9112002
Israel
Attention: [●]
Email: [●]

If to the Participant:

At the Participant's most recent address shown on the signature page of the Grant Letter, or at any other address which the Participant may specify in a notice delivered to the Company in the manner set forth herein.

(b) Entire Agreement. This Agreement, the Plan and any other agreements, schedules, exhibits and other documents referred to herein or therein constitute the entire agreement and understanding between the parties in respect of the subject matter hereof and supersede all prior and contemporaneous arrangements, agreements and understandings, both oral and written, whether in term sheets, presentations or otherwise, between the parties with respect to the subject matter hereof.

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

(d) Amendment; Waiver. No amendment or modification of any provision of this Agreement that has a material adverse effect on the Participant shall be effective unless signed in writing by or on behalf of the Company and the Participant; *provided* that the Company may amend or modify this Agreement without the Participant's consent in accordance with the provisions of the Plan or as otherwise set forth in this Agreement. No waiver of any breach or condition of this Agreement shall be deemed to be a waiver of any other or subsequent breach or condition, whether of like or different nature. Any amendment or modification of or to any provision of this Agreement, or any waiver of any provision of this Agreement, shall be effective only in the specific instance and for the specific purpose for which made or given.

(e) Successors and Assigns; No Third-Party Beneficiaries. This Agreement shall inure to the benefit of and be binding upon the Company and the Participant and their respective heirs, successors, legal representatives and permitted assigns. Nothing in this Agreement, express or implied, is intended to confer on any Person other than the Company and the Participant, and their respective heirs, successors, legal representatives and permitted assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement.

(f) Dispute Resolution. All controversies and claims arising out of or relating to this Agreement, or the breach hereof, shall be settled by the Company's mandatory dispute resolution procedures, if any, as may be in effect from time to time with respect to matters arising out of or relating to the Participant's employment or service with the Company.

(g) Participant Undertaking; Acceptance. The Participant agrees to take whatever additional action and execute whatever additional documents the Company may deem necessary or advisable to carry out or give effect to any of the obligations or restrictions imposed on either the Participant or the Option pursuant to this Agreement. The Participant acknowledges receipt of a copy of the Plan and this Agreement and understands that material definitions and provisions concerning the Option and the Participant's rights and obligations with respect thereto are set forth in the Plan. The Participant has read carefully, and understands, the provisions of this Agreement and the Plan.

(h) Counterparts. This Agreement may be executed in two counterparts, each of which shall constitute one and the same instrument.

(i) Israeli Securities Law. The Company may obtain an exemption from prospectus requirements in Israel pursuant to Section 15D of the Israeli Securities Law. If such exemption is obtained the documents filed with the SEC regarding the Plan and the Plan itself will be available at the Company's offices.

(j) Governing Law. The Award shall be governed by the laws of the State of Israel. The Company, its Affiliates and each Participant (by acceptance of the 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.

ENTERA BIO LTD.
2018 EQUITY INCENTIVE PLAN

STOCK OPTION AWARD AGREEMENT

_____, 20__

Subject to the terms and conditions set forth in this grant letter (the "**Grant Letter**") and the award agreement set forth in Exhibit A (the Grant Letter and Exhibit A, collectively this "**Agreement**"), Entera Bio Ltd., a company organized under the laws of the State of Israel (the "**Company**"), has granted you as of the Grant Date set forth below an option to purchase Shares (the "**Award**"). The Award is granted under and is subject to the Entera Bio Ltd. 2018 Equity Incentive Plan (the "**Plan**"). Unless defined in this Agreement, capitalized terms shall have the meanings assigned to them in the Plan. The provisions of the Plan shall control in the event of a conflict among the provisions of the Plan, this Agreement and any descriptive materials provided to you.

AWARD TERMS

PARTICIPANT:
GRANT DATE:
SHARES SUBJECT TO AWARD:
PER SHARE EXERCISE PRICE:
VESTING TERMS:

Please review this Agreement and let us know if you have any questions about this Agreement, the Award or the Plan. You are advised to consult with your own tax advisors in respect of any tax consequences arising in connection with this Award.

If you have questions please contact [●] via email at [●]. If not, please provide your signature, address and the date for this Agreement where indicated below.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first written above.

ENTERA BIO LTD.

By: _____

Name:

Title:

PARTICIPANT

_____

Name

_____

_____

Address

Date: _____

ENTERA BIO LTD. 2018 EQUITY INCENTIVE PLAN
STOCK OPTION AWARD AGREEMENT

The following award agreement (this "**Award Agreement**") sets forth the agreement of the parties to the Grant Letter to which this Award Agreement is appended with respect to the grant of stock options described in the Grant Letter. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Plan and the Grant Letter.

1. Grant of Option. The Company hereby grants to the Participant an option to purchase all or any part of the number of Shares set forth in the Grant Letter ("**Option Shares**") at the per-share exercise price set forth in the Grant Letter (the "**Exercise Price**"), pursuant to the provisions of the Plan, the terms of which are incorporated herein by reference, and further subject to the terms and conditions set forth herein (the "**Option**").

2. Terms and Conditions. It is understood and agreed that the Award evidenced hereby is subject to the following terms and conditions:

(a) Vesting of Award. Subject to the provisions of this Section 2 and Sections 3 and 4, the Option shall vest and become exercisable in accordance with the vesting schedule set forth in the Grant Letter. In the event of a Termination of Service of the Participant prior to the date on which the Award otherwise becomes vested, the unvested portion of the Award shall immediately be forfeited by the Participant and become the property of the Company.

(b) Term of Option. The term of the Option shall expire at close of the principal stock market or exchange on which the Shares are quoted or traded on the tenth (10^{th}) anniversary of the Grant Date, unless terminated earlier in accordance herewith. In no event may any portion of the Option be exercised after it has expired.

(c) Manner of Exercise. The Participant may, subject to the limitations in this Agreement and the Plan, exercise all or any portion of the Option that has vested. In order to exercise the Option, the Participant shall (i) deliver to the Company a written notice specifying the number of Option Shares to be purchased and (ii) remit the aggregate Exercise Price to the Company in full, payable (A) in cash or by check, bank draft or money order payable to the order of the Company or (B) any other method acceptable to the Administrator.

(d) No Right to Future Awards. 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.

3. Exercise in Event of Death, Disability or Other Termination of Service.

(a) Death or Disability. If the Participant incurs a Termination of Service due to such Participant's death or Disability, all or any part of the Option which was exercisable by the Participant immediately prior to his or her death or Disability may be exercised by the Participant or the Participant's designated Beneficiary, estate or the person to whom such Option is transferred by will or the applicable law of descent and distribution, at any time before the earlier of (i) the twelve (12) month anniversary of the date of the Termination of Service and (ii) the time such Option would otherwise expire. To the extent the Option was not exercisable on the date of the Participant's Termination of Service as a consequence of his or her death or Disability, such portion of the Option shall terminate.

(b) For Cause. If the Participant incurs a Termination of Service by the Company for Cause, any Options held by the Participant shall be immediately cancelled and may not thereafter be exercised, even if exercisable on the date of such Termination of Service.

(c) Exercise Following Termination of Service. If the Participant incurs a Termination of Service for any reason other than the Participant's death or Disability or for Cause, the Option held by the Participant at the time of such Termination of Service, to the extent vested at such time, may be exercised at any time before the earlier of (i) the three (3) month anniversary of the date of the Termination of Service and (ii) the time such Option would otherwise expire; *provided* that if the Participant dies within such three-month period, the Options (to the extent vested) may be exercised by the Participant's designated Beneficiary, estate or the person to whom such Option is transferred by will or the applicable law of descent and distribution, at any time before the earlier of (i) the twelve (12) month anniversary of the date of the Termination of Service and (ii) the time such Option would otherwise expire. Except as set forth in this Section 3(c), to the extent the Option was not exercisable on the date of the Participant's Termination of Service, such portion of the Option shall terminate.

4. Treatment on Change in Control. In the event of a Change in Control, the Option will be treated in accordance with Section 11(b) of the Plan.

5. Tax Liability; Withholding Requirements. The Participant shall be solely responsible for any applicable taxes (including, without limitation, income and excise taxes) and penalties, and any interest that accrues thereon, that the Participant incurs in connection with the receipt, vesting or exercise of any Option granted hereunder.

6. References. References herein to rights and obligations of the Participant shall apply, where appropriate, to the Participant's legal representative or estate without regard to whether specific reference to such legal representative or estate is contained in a particular provision of this Agreement.

7. Not Salary, Pensionable Earnings or Base Pay. The Participant acknowledges that the Award shall not be included in or deemed to be a part of (a) salary, normal salary or other ordinary compensation, (b) any definition of pensionable or other earnings (however defined) for the purpose of calculating any benefits payable to or on behalf of the Participant under any pension, retirement, termination or dismissal indemnity, severance benefit, retirement indemnity or other benefit arrangement of the Company or any Subsidiary or (c) any calculation of base pay or regular pay for any purpose.

8. Forfeiture Upon Breach of Certain Other Agreements. Subject to Section 9, the Participant's breach of any non-competition, non-solicitation, confidentiality, non-disparagement, assignment of inventions or other intellectual property agreement that the Participant may be a party to with the Company or any Affiliate (the "**Restrictive Covenant Agreement**") is incorporated herein by reference, in addition to whatever other equitable relief or monetary damages that the Company or any Affiliate may be entitled to, shall result in automatic rescission, forfeiture, cancellation or return of any Shares (whether or not vested) held by the Participant. To the extent that the Participant has not executed the Restrictive Covenant Agreement, this Agreement and the Award thereunder shall not be effective unless and until the Participant executes the Restrictive Covenant Agreement, and this Agreement and the Award thereunder shall be revoked if the Participant does not execute the Restrictive Covenant Agreement within thirty (30) days following the Grant Date.

9. Whistleblower Protection; Defend Trade Secrets Act.

(a) Nothing in this Agreement or otherwise limits the Participant's ability to communicate directly with and provide information, including documents, not otherwise protected from disclosure by any applicable law or privilege to the Securities and Exchange Commission (the "**SEC**"), any other federal, state or local governmental agency or commission ("**Government Agency**") or self-regulatory organization regarding possible legal violations, without disclosure to the Company. The Company may not retaliate against the Participant for any of these activities, and nothing in this Agreement requires the Participant to waive any monetary award or other payment that the Participant might become entitled to from the SEC or any other Government Agency or self-regulatory organization.

(b) Further, nothing in this Agreement precludes the Participant from filing a charge of discrimination with the Equal Employment Opportunity Commission or a like charge or complaint with a state or local fair employment practice agency. However, once this Agreement becomes effective, the Participant may not receive a monetary award or any other form of personal relief from the Company in connection with any such charge or complaint that the Participant filed or is filed on the Participant's behalf.

(c) Pursuant to the Defend Trade Secrets Act of 2016, the parties hereto acknowledge and agree that the Participant shall not have criminal or civil liability under any Federal or State trade secret law for the disclosure of a trade secret that (i) is made (A) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney and (B) solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition and without limiting the preceding sentence, if the Participant files a lawsuit for retaliation by the Company for reporting a suspected violation of law as contemplated by the preceding sentence, the Participant may disclose the relevant trade secret to his attorney and may use such trade secret in the ensuing court proceeding, if the Participant (X) files any document containing such trade secret under seal and (Y) does not disclose such trade secret, except pursuant to court order.

10. Recoupment/Clawback. This Award (including any amounts or benefits arising from this Award) shall be subject to recoupment or "clawback" as may be required by applicable law, stock exchange rules or by any applicable Company policy or arrangement the Company has in place from time to time.

11. Miscellaneous.

(a) Notices. Any notice required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been given when delivered personally or by courier, or sent by certified or registered mail, postage prepaid, return receipt requested, duly addressed to the party concerned at the address indicated below or to such changed address as such party may subsequently by similar process give notice of:

If to the Company:

Entera Bio Ltd.
Kiryat Hadassah
Minrav Building – Fifth Floor
Jerusalem 9112002
Israel
Attention: [●]
Email: [●]

If to the Participant:

At the Participant's most recent address shown on the signature page of the Grant Letter, or at any other address which the Participant may specify in a notice delivered to the Company in the manner set forth herein.

(b) Entire Agreement. This Agreement, the Plan and any other agreements, schedules, exhibits and other documents referred to herein or therein constitute the entire agreement and understanding between the parties in respect of the subject matter hereof and supersede all prior and contemporaneous arrangements, agreements and understandings, both oral and written, whether in term sheets, presentations or otherwise, between the parties with respect to the subject matter hereof.

(c) Severability. If any provision of this Agreement is or becomes or is deemed to be invalid, illegal or unenforceable in any jurisdiction, or would disqualify the Plan or this Agreement under any law deemed applicable by the Board, 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 Board, materially altering the intent of this Agreement, such provision shall be stricken as to such jurisdiction, and the remainder of this Agreement shall remain in full force and effect.

(d) Amendment; Waiver. No amendment or modification of any provision of this Agreement that has a material adverse effect on the Participant shall be effective unless signed in writing by or on behalf of the Company and the Participant; *provided* that the Company may amend or modify this Agreement without the Participant's consent in accordance with the provisions of the Plan or as otherwise set forth in this Agreement. No waiver of any breach or condition of this Agreement shall be deemed to be a waiver of any other or subsequent breach or condition, whether of like or different nature. Any amendment or modification of or to any provision of this Agreement, or any waiver of any provision of this Agreement, shall be effective only in the specific instance and for the specific purpose for which made or given.

(e) Successors and Assigns; No Third-Party Beneficiaries. This Agreement shall inure to the benefit of and be binding upon the Company and the Participant and their respective heirs, successors, legal representatives and permitted assigns. Nothing in this Agreement, express or implied, is intended to confer on any Person other than the Company and the Participant, and their respective heirs, successors, legal representatives and permitted assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement.

(f) Waiver of Jury Trial. TO THE EXTENT ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY IS NOT GOVERNED BY THE ARBITRATION AGREEMENT, EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY WITH RESPECT TO SUCH LEGAL PROCEEDING.

(g) Dispute Resolution. All controversies and claims arising out of or relating to this Agreement, or the breach hereof, shall be settled by the Company's mandatory dispute resolution procedures, if any, as may be in effect from time to time with respect to matters arising out of or relating to the Participant's employment or service with the Company.

(h) Participant Undertaking; Acceptance. The Participant agrees to take whatever additional action and execute whatever additional documents the Company may deem necessary or advisable to carry out or give effect to any of the obligations or restrictions imposed on either the Participant or the Option pursuant to this Agreement. The Participant acknowledges receipt of a copy of the Plan and this Agreement and understands that material definitions and provisions concerning the Option and the Participant's rights and obligations with respect thereto are set forth in the Plan. The Participant has read carefully, and understands, the provisions of this Agreement and the Plan.

(i) Counterparts. This Agreement may be executed in two counterparts, each of which shall constitute one and the same instrument.

Exhibit 4.28

CONFIDENTIAL TREATMENT REQUESTED – SUBMITTED WITH CONFIDENTIAL TREATMENT REQUEST OF ENTERA BIO LTD.

[*] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.

RESEARCH COLLABORATION

AND

LICENSE AGREEMENT

by and between

AMGEN INC.

and

ENTERABIO LTD.

Dated as of December 10, 2018

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RESEARCH COLLABORATION AND LICENSE AGREEMENT

This Research Collaboration and License Agreement ("**Agreement**") is entered into as of December 10, 2018 (the "**Effective Date**") by and between Amgen Inc., a Delaware corporation having an address at One Amgen Center Drive, Thousand Oaks, California 91320, USA ("**Amgen**") and EnteraBio Ltd., an Israeli company having an address at Minrav Building, 5th Floor, PO Box 12117, Jerusalem 91220, Israel ("**EnteraBio**"). Amgen and EnteraBio are each hereafter referred to individually as a "**Party**" and together as the "**Parties**".

WHEREAS, Amgen has research, development, manufacturing and commercialization expertise for the development and commercialization of pharmaceutical and biologics products;

WHEREAS, EnteraBio has technology and expertise relating to oral drug delivery of large molecule products;

WHEREAS, Amgen and EnteraBio desire to collaborate in the performance of a preclinical research and development program for purposes of the discovery of clinical candidates from the Collaboration Programs (as defined below); and

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1. DEFINITIONS

All references to particular Exhibits, Articles or Sections mean the Exhibits to, and Articles and Sections of, this Agreement, unless otherwise specified. For the purposes of this Agreement and the Exhibits and Appendices hereto, the following words and phrases have the following meanings:

Section 1.1 "**Abandoned Patent Right**" has the meaning set forth in Section 8.2.3.

Section 1.2 "**Affiliate**" means, with respect to any Person, any other Person that controls, is controlled by or is under common control with such Person, for as long as such control exists. For purposes of this Section, "control" means the direct or indirect ownership of more than fifty percent (50%) (or, if local law restricts foreign ownership, of the maximum ownership percentage that may, under such local law, be owned by foreign interests) of the voting or economic interest of a Person, or the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of a Person. For clarity, once a Person ceases to be an Affiliate of a Party, then, without any further action, such Person shall cease to have any rights, including license and sublicense rights, under this Agreement by reason of being an Affiliate of such Party.

Section 1.3 "**Agreement**" has the meaning set forth in the Preamble.

Section 1.4 "**Amgen**" has the meaning set forth in the Preamble.

Section 1.5 "**Amgen Acquiree**" has the meaning set forth in Section 14.9.

Section 1.6 "**Amgen Acquisition**" has the meaning set forth in Section 14.9.

Section 1.7 "**Amgen Indemnified Parties**" has the meaning set forth in Section 10.1.1.

Section 1.8 "**Amgen IP**" means [*].

Section 1.9 "**Amgen Licensed Know-How**" means [*].

Section 1.10 "**Amgen Patents**" means [*].

Section 1.11 "**Anti-Bribery and Anti-Corruption Laws**" has the meaning set forth in Section 9.4(c)(i)(b).

Section 1.12 "**Anti-Corruption Policies**" has the meaning set forth in Section 9.4(c)(i)(a).

Section 1.13 "**Background IP**" means Patent Rights and Know-How (a) Controlled by a Party prior to the Effective Date or (b) Controlled by such Party during the Term, but not generated in the performance of the activities contemplated under this Agreement.

Section 1.14 "**Blocking Patents**" means as to a Product, in the case of Amgen, any Patent Rights Controlled by a Third Party that claim, in a particular country, the composition of matter or method of use of such Product, and which such Patent Rights would be infringed by the manufacture, use, offer for sale, sale, import, or export of such Product in such country.

Section 1.15 "**Change of Control**" means (a) the closing of the sale, transfer, exclusive license or other disposition of all or substantially all of EnteraBio's assets or intellectual property, (b) the consummation of the merger or consolidation of EnteraBio with or into another entity (except a merger or consolidation in which the holders of capital stock of EnteraBio immediately prior to such merger or consolidation continue to hold more than 50% of the voting power of the capital stock of EnteraBio or the surviving or acquiring entity), (c) the closing of the transfer (whether by merger, consolidation or otherwise), in one transaction or a series of related transactions, to a person or group of affiliated persons (other than an underwriter of EnteraBio's securities), of EnteraBio's securities if, after such closing, such person or group of affiliated persons would hold 50% or more of the outstanding voting stock of EnteraBio (or the surviving or acquiring entity) or (d) a liquidation, dissolution or winding up of EnteraBio.

Section 1.16 "**Collaboration IP**" means [*].

Section 1.17 "**Collaboration Know-How**" means [*].

Section 1.18 "**Collaboration Patents**" means [*].

Section 1.19 "**Collaboration Program(s)**" [*].

Section 1.20 "**Combination Product**" has the meaning set forth in Section 1.67.

Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Section 1.21 "**Commercially Reasonable Efforts**" means, with respect to a Party, [*].

Section 1.22 "**Confidential Disclosure Agreement**" means that certain Confidential Disclosure Agreement entered into between the Parties as of May 5, 2017, as amended.

Section 1.23 "**Confidential Information**" has the meaning set forth in Section 12.1.1.

Section 1.24 "**Control**" or "**Controlled**" means, with respect to any Know-How, Patent Right, or other intellectual property right, the possession (whether by ownership or license) by a Party or its Affiliate of the ability to grant to the other Party a license or access as provided herein to such Know-How, Patent Right, or other intellectual property right, without violating the terms of any agreement or other arrangement with any Third Party, or being obligated to pay any royalties or other consideration therefor, in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license or access; [*].

Section 1.25 "**Cover**" means, with respect to an issued and unexpired claim of a Patent Right and a product, such claim would (absent a license thereunder or ownership thereof) be Infringed by the Exploitation of such product, and with respect to a Patent Right which is a pending application of a patent, the application shall be treated as if issued in the form then currently being prosecuted. Cognates of the word "**Cover**" have correlative meanings.

Section 1.26 "**Defending Party**" has the meaning set forth in Section 8.4.

Section 1.27 "**Derivatives**" has the meaning set forth in Section 8.1.3.

Section 1.28 "**Disclosing Party**" has the meaning set forth in Section 12.1.1.

Section 1.29 "**EMA**" means the European Medicines Agency or any successor entity thereto.

Section 1.30 "**Enforcing Party**" has the meaning set forth in Section 8.5.3.

Section 1.31 "**EnteraBio**" has the meaning set forth in the Preamble.

Section 1.32 "**EnteraBio Acquiree**" has the meaning set forth in Section 14.10.

Section 1.33 "**EnteraBio Acquisition**" has the meaning set forth in Section 14.10.

Section 1.34 "**EnteraBio IP**" means [*].

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Section 1.35 "**EnteraBio Indemnified Parties**" has the meaning set forth in Section 10.1.2.

Section 1.36 "**EnteraBio Licensed Know-How**" means [*].

Section 1.37 "**EnteraBio Patents**" means [*].

Section 1.38 "**EnteraBio Platform**" means the technology platform as agreed upon in writing by the Parties.

Section 1.39 "**E.U.**" means those countries, nations, states or other territories under the jurisdiction of the EMA, as such jurisdiction may change from time to time.

Section 1.40 "**Executive Officers**" means (a) with respect to EnteraBio, the Chief Executive Officer, and (b) with respect to Amgen, a Vice President, or in the case of both parties, any other person that such officer designates, who has the authority to make decisions on behalf of such respective company, from time to time.

Section 1.41 "**Exploit**" means to discover, research, develop, make, have made, use, offer for sale, sell, have sold, import, export, or otherwise exploit, or transfer possession of or title in. Cognates of the word "**Exploit**" shall have correlative meanings.

Section 1.42 "**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

Section 1.43 "**First Commercial Sale**" means, [*].

Section 1.44 "**First Year**" has the meaning set forth in Section 7.1.2(a).

Section 1.45 "**First Year FTE Payment**" has the meaning set forth in Section 7.1.2(a).

Section 1.46 "**GAAP**" means the then current generally accepted accounting principles in the United States as established by the Financial Accounting Standards Board or any successor entity or other entity generally recognized as having the right to establish such principles in the United States, in each case consistently applied.

Section 1.47 "**Generic Version**" means, with respect to a Product, any pharmaceutical product that (a) is sold by a Third Party that is not a licensee or sublicensee of Amgen or its Affiliates, or any of their licensees or sublicensees; (b) contains the same active pharmaceutical ingredient as such Product; and (c) is approved in reliance, in whole or in part, on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of such Product as determined by the applicable Regulatory Authority, including any product authorized for sale (i) in the U.S. pursuant to Section 505(b)(2) or Section 505(j) of the FD&C Act (21 U.S.C. 355(b)(2) and 21 U.S.C. 355(j), respectively), (ii) in the E.U. pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision), or (iii) in any other country or jurisdiction pursuant to any equivalent of such provisions.

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Section 1.48 "**GLP Toxicology Study**" means a toxicology study that meet the requirements set forth in 21 CFR Part 58 pertaining to good laboratory practice for use or intended for use in an IND and are required to be included in the filing of an IND, but excluding any toxicology study performed in the course of evaluating compounds prior to selection of a development candidate by the JRC.

Section 1.49 "**GMP**" or "**Good Manufacturing Practices**" means the then-current Good Manufacturing Practices required by the FDA, as set forth in the U.S. Food, Drug and Cosmetic Act and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable laws or regulations applicable to the manufacture and testing of pharmaceutical materials promulgated by other Regulatory Authorities, as they may be updated from time to time.

Section 1.50 "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

Section 1.51 "**Improvement**" means an advancement, modification, development or improvement.

Section 1.52 "**IND**" means, with respect to the United States, an investigational new drug application as defined in applicable regulations promulgated by the FDA and filed with the FDA for human clinical testing of a drug or, with respect to any jurisdiction other than the United States, an equivalent filing thereof.

Section 1.53 "**Indemnitee**" has the meaning set forth in Section 10.1.3.

Section 1.54 "**Indemnitor**" has the meaning set forth in Section 10.1.3.

Section 1.55 "**Initial Program**" means the initial Collaboration Program as agreed upon in writing by the Parties.

Section 1.56 "**Initiation**" means, [*]. Cognates of the word "**Initiation**" have correlative meanings.

Section 1.57 "**Issuing Party**" has the meaning set forth in Section 12.2.2.

Section 1.58 "**Joint Research Committee**" or "**JRC**" has the meaning set forth in Section 2.1.1.

Section 1.59 "**Know-How**" means proprietary techniques, technology, trade secrets, inventions (whether patentable or not), methods, know-how, data and results (including pharmacological, toxicological and clinical data and results), analytical and quality control data and results, regulatory documents, and other information, compositions of matter, cells, cell lines, assays, animal models, reagents and other physical, biological, or chemical material.

Section 1.60 "**Law**" means, individually and collectively, any and all laws, ordinances, rules, directives, administrative circulars and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.

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Section 1.61 "**Licensed Field**" means [*].

Section 1.62 "**Losses**" has the meaning set forth in Section 10.1.1.

Section 1.63 "**Marketing Approval**" means all approvals, licenses, registrations or authorizations of the Regulatory Authority in a country, necessary for the manufacture, use, storage, import, marketing and sale (including with respect to pricing and reimbursement) of a Product in such country.

Section 1.64 "**Material Anti-Corruption Law Violation**" means a violation of any Anti-Bribery and Anti-Corruption Laws relating to the subject matter of this Agreement which would, if it were publicly known, in the reasonable view of a Party, have a material adverse effect on it or its reputation because of its relationship with the other Party.

Section 1.65 "**Milestone Events**" has the meaning set forth in Section 7.2.1.

Section 1.66 "**Milestone Payments**" has the meaning set forth in Section 7.2.1.

Section 1.67 "**Net Sales**" means, with respect to a certain time period and Product, [*]

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Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

[*].

Section 1.68 "**Non-Publishing Party**" has the meaning set forth in Section 12.3.

Section 1.69 "**Party**" and "**Parties**" has the meaning set forth in the Preamble.

Section 1.70 "**Patent Rights**" means (a) all patents, priority patent filings and patent applications, and (b) any renewal, divisional, continuation (in whole or in part), or request for continued examination of any of such patents, and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reviews, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

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Section 1.71 "**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

Section 1.72 "**Phase 1 Clinical Trial**" means any first in human clinical trial of a Product conducted mainly to evaluate the safety of chemical or biologic agents or other types of inventions (e.g., a new radiation therapy technique) that would satisfy the requirements of 21 CFR § 312.21(a) or its non-U.S. equivalents.

Section 1.73 "**Phase 2 Clinical Trial**" means any human clinical trial of a Product conducted mainly to test the effectiveness of chemical or biologic agents or other types of interventions for purposes of identifying the appropriate dose for a Phase 3 Clinical Trial for a particular indication or indications that would satisfy the requirements of 21 CFR § 312.21(b) or its non-United States equivalents. A "**Phase 2/3 Clinical Trial**" shall be deemed to be a Phase 2 Clinical Trial with respect to the portion of that clinical trial that is regarded as its Phase 2 component, in accordance with the applicable protocol.

Section 1.74 "**Phase 3 Clinical Trial**" means any human clinical trial of a Product designed to: (a) establish that such Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed; and (c) support regulatory approval of such Product, that would satisfy the requirements of 21 CFR § 312.21(c) or its non-U.S. equivalents. A "**Phase 2/3 Clinical Trial**" shall be deemed to be a Phase 3 Clinical Trial with respect to the portion of that clinical trial that is regarded as its Phase 3 component, in accordance with the applicable protocol.

Section 1.75 "**Preclinical Research & Development**" means, with respect to a particular Collaboration Program, any discovery, research, design, preclinical and process development activities relating to such Collaboration Program, as set forth in the applicable Work Plan.

Section 1.76 "**Preclinical R&D Term**" means, [*].

Section 1.77 "**Product**" means a pharmaceutical or biologic product [*].

Section 1.78 **"Public Official or Entity"** means (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party or any official of a political party.

Section 1.79 "**Publishing Party**" has the meaning set forth in Section 12.3.

Section 1.80 "**Receiving Party**" has the meaning set forth in Section 12.1.1.

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Section 1.81 **Regulatory Authority**" means any Governmental Authority or other authority responsible for granting Marketing Approvals for Products, including the FDA, EMA and any corresponding national or regional regulatory authorities.

Section 1.82 "**Regulatory Filing**" means any filing with any Governmental Authority with respect to the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of a Product.

Section 1.83 "**Release**" has the meaning set forth in Section 12.2.2.

Section 1.84 "**Reviewing Party**" has the meaning set forth in Section 12.2.2.

Section 1.85 "**Royalty Term**" has the meaning set forth in Section 7.5.2.

Section 1.86 "**Sale Transaction**" has the meaning set forth in Section 14.8.

Section 1.87 "**Second Year**" has the meaning set forth in Section 7.1.2(b).

Section 1.88 "**Second Year FTE Payment**" has the meaning set forth in Section 7.1.2(b).

Section 1.89 "**Second Year Prepayment Amount**" has the meaning set forth in Section 7.1.2(f).

Section 1.90 "**Selling Party**" has the meaning set forth in Section 1.90.

Section 1.91 "**Sublicensee(s)**" means shall mean any Third Party to which a Party has granted a sublicense under this Agreement.

Section 1.92 "**Termination Party**" means (a) Amgen, in the case of termination by (i) Amgen pursuant to Sections 13.3.1, 13.3.2 or (ii) EnteraBio pursuant to Section 13.2.1, and (b) EnteraBio, in the case of termination by Amgen pursuant to Section 13.3.1.

Section 1.93 "**Term**" has the meaning set forth in Section 13.1.

Section 1.94 "**Territory**" means the entire world.

Section 1.95 "**Third Party**" means a Person other than (a) Amgen or any of its Affiliates and (b) EnteraBio or any of its Affiliates.

Section 1.96 "**Third Party Acquirer**" has the meaning set forth in Section 14.9.

Section 1.97 "**Third Party Claim**" has the meaning set forth in Section 10.1.1.

Section 1.98 "**U.S.**" means the United States of America and its territories and possessions.

Section 1.99 "**Valid Claim**" means a claim in an issued and unexpired Patent Right that has not been disclaimed, revoked, held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been admitted to be invalid or unenforceable through re-examination, re-issue, disclaimer or otherwise, or lost in an interference proceeding; [*].

Section 1.100 "**VAT**" has the meaning set forth in Section 7.11.2.

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Section 1.101 "**Work Plan**" means, for each Collaboration Program, the comprehensive plan, setting forth the research strategy, activities and deliverables for the Preclinical Research & Development of Products under the applicable Collaboration Program, which shall be agreed upon in writing by the Parties.

ARTICLE 2. RESEARCH COLLABORATION

Section 2.1 Management.

2.1.1 Overview. Within thirty (30) days after the Effective Date, the Parties shall establish a joint research committee (the "**Joint Research Committee**" or the "**JRC**") which shall manage the progress and direction of Preclinical Research & Development collaboration between the Parties.

2.1.2 Joint Research Committee.

(a) **Composition**. The Joint Research Committee shall be comprised of three (3) named representatives of each Party (or such other number as the Parties may agree). The JRC will be led by two (2) co-chairs, one (1) appointed by each Party. Within thirty (30) days after the Effective Date, each Party shall designate by written notice to the other Party its initial representatives on the JRC. Each Party may replace one or more of its representatives, in its sole discretion, effective upon written notice to the other Party of such change.

(b) **Function and Powers of the JRC**. The JRC shall, consistent with the terms and conditions set forth in this Agreement:

(i) amend a Work Plan, provided that the JRC shall have no authority, without the express written consent of both Parties, to amend a Work Plan in a manner that would require a Party to incur aggregate expenses that are higher than those contemplated by the previously agreed upon Work Plan;

(ii) review progress of the Preclinical Research & Development against the goals and/or deliverables set forth in a Work Plan;

(iii) extend the Preclinical R&D Term for one or more Collaboration Programs;

(iv) identify Product development candidates, subject to the procedure in Section 3.6 for selecting Post-Effective Date Programs, provided however that Amgen shall have the right to elect, in its sole discretion, whether to Initiate a GLP Toxicology Study of a Product pursuant to Section 4.5.1; establish subcommittees, as appropriate, as described more fully in Section 2.1.2(d) below;

(v) direct and oversee any subcommittee;

(vi) approve annual Out-of-Pocket Expense budget, in accordance with Section 3.1;

(vii) resolve disputed matters that may arise at any subcommittee; and

(viii) perform any and all tasks and responsibilities that are expressly attributed to the JRC under this Agreement.

Subject to Section 14.12, the JRC shall have the foregoing authority on a Collaboration Program-by-Collaboration Program basis only during the applicable Preclinical R&D Term. The JRC shall only have such powers as are specifically assigned to it in this Agreement, and such powers shall be subject to the terms and conditions set forth in this Agreement. Without limiting the generality of the foregoing, the JRC shall have no power to amend or modify this Agreement or to amend, modify or waive compliance with the terms of this Agreement, and no decision of the JRC shall be in contravention of any terms and conditions of this Agreement.

(c) **Meetings**. The Joint Research Committee shall meet at least twice per year or more or less often as otherwise agreed by the Parties, and such meetings may be conducted by telephone, videoconference or in person as determined by the co-chairs. As appropriate, and provided that not less than two (2) business days' prior written notice has been given to the other Party, other employees of the Parties may attend Joint Research Committee meetings as observers, but a Party shall not bring a Third Party to a meeting without the other Party's prior consent, which consent shall not be unreasonably withheld. Each Party may also call for special meetings of the Joint Research Committee with reasonable prior written notice to the other Party (it being agreed that at least ten (10) business days shall constitute reasonable notice) to resolve particular matters requested by such Party and within the decision-making responsibility of the Joint Research Committee. Minutes will be kept of all JRC meetings and will reflect material decisions made at such meetings. Meeting minutes will be prepared by the Parties on a rotating basis and sent to each member of the JRC for review and approval promptly following each meeting. Minutes will be deemed approved unless a member of the JRC objects to the accuracy of such minutes within thirty (30) days of receipt. Each Party shall be responsible for all of its own expenses incurred in connection with participating in all such meetings.

(d) **Subcommittees**. The JRC may establish and disband subcommittees as deemed necessary by the JRC. Each such subcommittee shall consist of the same number of representatives designated by each Party, which number shall be mutually agreed by the Parties. Each Party shall be free to change its representatives on written notice to the other Party or to send a substitute representative to any subcommittee meeting. Each Party's representatives and any substitute for a representative shall be bound by the obligations of confidentiality set forth in Article 12. Except as expressly provided in this Agreement, no subcommittee shall have the authority to bind the Parties hereunder and each subcommittee shall report to the JRC. Each Party shall be responsible for all of its own expenses incurred in connection with participating in all such meetings.

2.1.3 Cooperation. Each Party shall provide the JRC such information as reasonably required under any Work Plan, or as reasonably requested by the other Party and reasonably available, relating to the progress of the goals or performance of activities under such Work Plan.

2.1.4 Decisions. Other than as expressly set forth herein, in order to make any decision required of it hereunder, the JRC must have present (in person, by videoconference or telephonically) at least the co-chair of each Party (or his/her designee for such meeting). Decisions of the JRC shall be by consensus, with each Party having one (1) vote. If the JRC cannot reach consensus or a dispute arises, in each case, that cannot be resolved in good faith discussions of the JRC for a period of at least sixty (60) days (whether the matter originated at the JRC or within a subcommittee), the co-chair of either Party may cause such dispute to be referred to the Executive Officers for resolution, [*].

2.1.5 **Discontinuation of JRC.** Subject to Section 14.12, the JRC shall continue to exist and execute its functions and powers set forth herein until the expiration of the last Preclinical R&D Term.

ARTICLE 3. PRECLINICAL RESEARCH & DEVELOPMENT ACTIVITIES; EXCLUSIVITY

Section 3.1 Preclinical Research & Development of Products.

3.1.1 Within thirty (30) days of the Effective Date, each Party shall commence Preclinical Research & Development activities assigned to it under the Work Plan for the Initial Collaboration Program. During the Preclinical R&D Term of any Collaboration Program, each Party shall use its Commercially Reasonable Efforts to conduct its Preclinical Research & Development activities of the Products in accordance with the applicable Work Plan. In performing its activities under each Work Plan, each Party shall (and shall cause its Affiliates and Third Party subcontractors, as applicable, to) perform such activities in compliance with all applicable scientific standards, laboratory practices and all applicable Laws, and engage and appropriately control adequately qualified personnel.

3.1.2 The Parties agree that Amgen shall prepay or reimburse EnteraBio for its costs (i.e., internal and out-of-pocket expenses, including costs of shipping Materials, as described in Section 3.5) with respect to the Preclinical Research & Development activities EnteraBio conducts (including through its Affiliates or Third Party contractors) under each Work Plan (collectively, "**Preclinical Research & Development Costs**") as set forth in this Section 3.1.2, which, for clarity, subject to the first sentence of Section 3.1.2(a), shall be in addition to the payments to EnteraBio contemplated in Sections 3.7 (Extension of Preclinical R&D Term), 7.1.1 (Technology Access Payment; Upfront Payment), 7.2 (Milestone Payments) and 7.3 (Royalties).

(a) *Internal Preclinical Research & Development Costs*. The Parties agree that, unless otherwise agreed in writing, the Amgen payments to EnteraBio contemplated in Section 7.1.1 (Technology Access Payment; Upfront Payment) and 7.1.2 (R&D Costs) shall cover EnteraBio's internal Preclinical Research and Development Costs for the first two years of each Collaboration Program. [*].

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(b) *Out-of-Pocket Preclinical Research & Development Costs*. On an annual basis, the JSC shall discuss in good faith and approve an annual budget for EnteraBio out-of-pocket Preclinical Research and Development Costs for each Collaboration Program (each, an "**Annual Out-of-Pocket Budget**"), which shall include an agreed-upon timeline for any Amgen prepayment of anticipated out-of-pocket Preclinical Research & Development Costs. Unless otherwise agreed to by the Parties in writing, following approval of the EnteraBio Out-of-Pocket Budget, Amgen shall prepay and/or reimburse, as applicable, EnteraBio's reasonably documented out-of-pocket Preclinical Research & Development Costs in accordance with the Annual Out-of-Pocket Budget. In the event that Amgen prepays an amount of out-of-pocket Preclinical Research and Development Costs and such amount of such costs were not incurred by EnteraBio during such year, then, at Amgen's option, EnteraBio shall either promptly refund to Amgen the remaining prepayment amount or apply such amount against the following year's out-of-pocket Preclinical Research and Development Costs.

(c) *No Obligation to Incur Preclinical Research & Development Costs*. Notwithstanding anything in this Agreement to the contrary, EnteraBio shall have no obligation to conduct (or engage any Affiliate or Third Party subcontractor to conduct) any Preclinical Research & Development activity if the Parties have not agreed on Amgen's reimbursement of the EnteraBio internal and out-of-pocket Preclinical Research & Development Costs incurred in connection with such activity pursuant to Section 3.1.2(a) and/or (b).

Section 3.2 Subcontracting. Each Party may engage its Affiliates, or Third Party subcontractors (including contract research organizations and contract manufacturing organizations) to perform certain of its obligations under this Agreement; [*]. Any Third Party subcontractor to be engaged by a Party to perform such Party's obligations set forth in this Agreement will meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity. The activities of any such Third Party subcontractors will be considered activities of such subcontracting Party under this Agreement. The subcontracting Party will be responsible for ensuring compliance by any such Third Party subcontractors with the terms of this Agreement, as if such Third Party(ies) are such Party hereunder. Each subcontracting Party will, and will contractually require that its Affiliates and subcontractors, if any, conduct the relevant Preclinical Research & Development activities in accordance with such subcontracting Party's commitments with respect to the applicable Work Plan.

Section 3.3 Data. EnteraBio shall, at Amgen's written request, promptly make available to Amgen all data generated by or on behalf of EnteraBio and/or its Affiliates that is related to any and all Collaboration Programs and/or Products during the applicable Preclinical R&D Term. Amgen shall, at EnteraBio's written request, promptly make available to EnteraBio all data generated by or on behalf of Amgen and/or its Affiliates that is reasonably necessary by EnteraBio to conduct its activities contemplated under the applicable Work Plan during the applicable Preclinical R&D Term and to carry out its obligations and exercise its rights under this Agreement.

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Section 3.4 Exclusivity.

3.4.1 [*].

Section 3.5 Material Transfer. To facilitate the Preclinical Research & Development, either Party may provide to the other Party certain biological materials or chemical compounds, owned by or licensed to the supplying Party for use by the other Party in furtherance of Preclinical Research & Development (such materials or compounds provided hereunder are referred to, collectively, as "**Materials**"). Except as otherwise expressly provided under this Agreement, all such Materials delivered to the other Party shall remain the sole property of the supplying Party, shall be used only in furtherance of the exercise of rights or performance of obligations under this Agreement and in accordance with this Agreement and solely under the control of the other Party, shall not be used or delivered to or for the benefit of any Third Party without the prior written consent of the supplying Party, and shall not be used in research or testing involving human subjects or in animals intended for food use, in each case unless otherwise specifically contemplated hereunder), and will be used in compliance with all applicable Law. The provision of Materials to the receiving Party hereunder does not grant such Party any rights other than those specifically granted in this Agreement. Delivery of the Materials shall be EXW Incoterms 2010 (the supplying Party's facilities). The receiving Party shall bear all responsibility for the shipped Materials thereafter, provided however, that Amgen shall bear the entire costs of transferring the Materials to EnteraBio and the insurance costs, to the extent applicable. The receiving Party shall be responsible for any and all consents, approvals, authorizations or other permits necessary for the use, handling, transfer, and/or storage of the Materials. The receiving Party shall: (a) receive the Materials; (b) promptly notify the supplying Party when the Materials have been received; and (c) forward to the supplying Party any applicable chain of custody forms, in-transport temperature record(s) and receipt verification documentation and such other documentation reasonably requested by the supplying Party. The receiving Party shall be responsible for import clearance (including preparing any necessary documentation with respect thereto) and making entry of shipment. The supplying Party shall provide the relevant shipping documentation, pro forma invoice and airway bill, together with such other documentation necessary for the use, handling, transfer, and/or storage of the Materials. The Materials supplied under this Section 3.5 are supplied "as is" and must be used with prudence and appropriate caution in any experimental work, since not all of their characteristics may be known. Except as expressly set forth herein, THE MATERIALS ARE WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY. During the Preclinical R&D Term for any Collaboration Program, for record-keeping purposes, the Parties shall compile a list (that shall include the type of material, quantity, shipping date and any other relevant details) on a quarterly basis setting forth the Materials provided to/from each Party, which document shall be signed by an authorized representative of each Party. For clarity, this Section 3.5 shall apply during the applicable Preclinical R&D Term only, after which the Parties will enter into an appropriate material transfer agreement with respect to any transfer of Materials, which agreement will be subject to this Agreement and will be interpreted consistent with the terms hereof.

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Section 3.6 **Post-Effective Date Programs.** At any time within the [*] period following the Effective Date, Amgen shall have the right to select up to two (2) additional Collaboration Programs (each, a "**Post-Effective Date Program**"). During such aforementioned [*] period, Amgen may propose by written notice to EnteraBio any Post-Effective Date Program. Upon EnteraBio's receipt of any proposed Post-Effective Date Program, the Parties shall discuss in good faith the proposed program and negotiate a reasonable Work Plan related thereto. [*]. In the event that Amgen proposes any Post-Effective Date Program(s) within the applicable [*] period and the Parties are ultimately unable to agree on any such Post-Effective Date Program or the Work Plan related thereto, Amgen shall be entitled to propose alternative Post-Effective Date Program(s) in place of the earlier proposed program(s) to which the Parties are unable to agree during such [*] period.

Section 3.7 **Extension of Preclinical R&D Term.** [*].

Section 3.8 [*].

Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

ARTICLE 4.LICENSE GRANT

Section 4.1 License Grant.

4.1.1 Preclinical License. During the Preclinical R&D Term for each Collaboration Program, EnteraBio hereby grants to Amgen a non-exclusive, worldwide, royalty-free right under EnteraBio IP solely to conduct Preclinical Research & Development as contemplated to be performed by Amgen under each Work Plan. During the Preclinical R&D Term for each Collaboration Program, Amgen hereby grants to EnteraBio a non-exclusive, worldwide, royalty-free right under Amgen IP solely to conduct Preclinical Research & Development as contemplated to be performed by EnteraBio under each Work Plan.

4.1.2 License Grant to Amgen. Subject to the terms and conditions of this Agreement, EnteraBio hereby grants to Amgen an exclusive (even as to EnteraBio and its Affiliates, except as expressly set forth herein and subject to EnteraBio and its Affiliates retaining the non-exclusive rights reasonably necessary or useful to perform EnteraBio's obligations under each Work Plan), royalty-bearing, sublicenseable (but only in accordance with Section 4.2), license under EnteraBio IP to Exploit Products in the Licensed Field in the Territory during the Term.

Section 4.2 Sublicenses. Amgen and its Affiliates shall be entitled, without the prior consent of EnteraBio, to grant one or more sublicenses under the licenses granted to Amgen under Section 4.1, in full or in part, by means of written agreement to Third Parties (with the right to sublicense through multiple tiers); *provided*, *however*, that as a condition precedent to and requirement of any such sublicense: (a) any such permitted sublicense shall be consistent with and subject to the terms and conditions of this Agreement; and (b) Amgen will continue to be responsible for full performance of Amgen's obligations under this Agreement and will be responsible for all actions of such Sublicensee as if such Sublicensee were Amgen hereunder.

Section 4.3 Transfer of Know-How. Amgen shall transfer to EnteraBio the Amgen Licensed Know-How contemplated to be so transferred as set forth in the applicable Work Plan. EnteraBio shall transfer to Amgen the EnteraBio Licensed Know-How contemplated to be so transferred as set forth in the applicable Work Plan.

Section 4.4 No Other Rights. No right or license under any Patent Rights or other intellectual property rights of a Party is granted or shall be granted by implication to the other Party, and each Party covenants not to practice or use any Patent Rights or other intellectual property rights of the other Party except pursuant to the licenses expressly granted in this Agreement or any other written agreement between the Parties. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement.

Section 4.5 Initiation of a GLP Toxicology Study.

4.5.1 [*].

4.5.2 [*]

ARTICLE 5. REGULATORY MATTERS

Section 5.1 Amgen Responsibilities. Except as expressly provided in the Work Plans, Amgen will be solely responsible for the preparation, submission and maintenance of all Regulatory Filings and obtaining all Marketing Approvals with respect to Products. EnteraBio will reasonably cooperate with Amgen, at Amgen's reasonable request and expense, with respect to any regulatory matters related to Products. Amgen will own all right, title and interest in and to any and all Regulatory Filings and Marketing Approvals and all such Regulatory Filings and Marketing Approvals will be held in the name of Amgen or its designee, and EnteraBio will execute all documents and take all actions as are reasonably requested by Amgen to vest such title in Amgen or such designee, as applicable.

Section 5.2 Regulatory Updates. Amgen shall keep EnteraBio reasonably informed of all material regulatory developments relating to Products in the Territory through the annual development reports under Section 6.3 or as otherwise reasonably requested by EnteraBio from time to time.

ARTICLE 6. DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION MATTERS

Section 6.1 General.

6.1.1 Products. Following the Effective Date and at all times during the Term, except as otherwise expressly set forth herein, Amgen shall be responsible for, and shall bear all costs associated with, the research, development, manufacture and commercialization of Products, including development, distribution, marketing and sales activities. For clarity, after completion of the applicable Work Plan, Amgen shall continue to have the right to conduct Preclinical Research & Development with respect to the applicable Products. Subject to the express written terms of this Agreement, all decisions concerning the discovery, research, development, marketing and sales of Products including the clinical and regulatory strategy, design, sale, price and promotion of Products covered under this Agreement shall be within the sole discretion of Amgen. Upon [*] EnteraBio will transfer (subject to the license grant in Section 4.1.2) to Amgen all EnteraBio Licensed Know-How, at Amgen's costs and expense, as is reasonably necessary for Amgen to manufacture, develop and seek Marketing Approval for the applicable Products, including all materials for supporting regulatory filings consistent with Amgen's obligations under Article 5. Amgen understands and acknowledges that EnteraBio Licensed Know-how constitutes highly sensitive and Confidential Information of EnteraBio and prior to any transfer to any Third Party, Amgen will notify EnteraBio to discuss the proposed transfer to ensure the reasonable safeguards are in place with regard to maintaining the confidentiality of EnteraBio Licensed Know-How.

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Section 6.2 Diligence. Each Party shall use Commercially Reasonable Efforts to carry out its obligations under each Work Plan. Following [*] Amgen shall (directly and/or through one or more Affiliates and/or Sublicensees) use Commercially Reasonable Efforts to develop and commercialize the applicable Product under such Collaboration Program in the Territory.

Section 6.3 Reports. For each Product, during the period from the end of the applicable Preclinical R&D Term until the First Commercial Sale of such Product, Amgen shall provide EnteraBio with reports [*] per Calendar Year of the status of Amgen's and its Affiliates' and Sublicensees' activities related to the Exploitation of such Product during the preceding [*] period. In addition, the Parties shall conduct [*] teleconference meetings to discuss the progress of each Collaboration Program. All reports and other Information provided by Amgen under this Section 6.3 will be Amgen's Confidential Information subject to the terms of Article 12.

ARTICLE 7. FEES, ROYALTIES, & PAYMENTS

Section 7.1 Technology Access Payment; Upfront Payment and R&D Funding.

7.1.1 Technology Access Payment; Upfront Payment. For the Initial Program, Amgen shall pay to EnteraBio a non-refundable, non-creditable payment equal to Seven Hundred and Twenty Five Thousand Dollars ($725,000) within thirty (30) days after the Effective Date (the "**Technology Access Payment**"). For each Post Effective-Date Program, Amgen shall pay to EnteraBio a non-refundable, non-creditable payment equal to [*] within thirty (30) days of the parties entering into the applicable Work Plan (the "**Upfront Payment**").

7.1.2 R&D Costs.

(a) Amgen shall pay to EnteraBio for the performance of EnteraBio's activities under the Work Plan of each Post Effective-Date Program during the one (1) year period following the date in which the Parties agree in writing on the initiation of the applicable Post Effective-Date Program (the "**First Year**"), an aggregate amount of Two Hundred and Twenty-Five Thousand Dollars ($225,000) (such payment amount contemplated in this Section 7.1.2(a), the "**First Year R&D Payment**").

(b) Amgen shall pay to EnteraBio for the performance of EnteraBio's activities under the Work Plan of each Collaboration Program, during the one (1) year period following the one (1) year anniversary of the date in which the Parties agreed in writing on the initiation of the applicable Collaboration Program, which for the Initial Program shall mean the Effective Date (the "**Second Year**"), an aggregate amount of Four Hundred and Fifty Thousand Dollars ($450,000) (such payment amount contemplated in this Section 7.1.2(b), the "**Second Year R&D Payment**").

(c) Within thirty (30) days after the initiation of the applicable Post Effective-Date Program, Amgen shall pay to EnteraBio an amount equal to Two Hundred Twenty-Five Thousand Dollars ($225,000) as a prepayment for the First Year R&D Payment.

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(d) Within thirty (30) days after the one (1) year anniversary of the Effective Date, or the initiation of the applicable Collaboration Program, as applicable, Amgen shall pay to EnteraBio an amount equal to Two Hundred Twenty-Five Thousand Dollars ($225,000) as a prepayment for the Second Year R&D Payment.

(e) Within thirty (30) days after the two (2) year anniversary of the Effective Date, or the initiation of the applicable Collaboration Program, as applicable, Amgen shall pay to EnteraBio an amount equal to Two Hundred Twenty-Five Thousand Dollars ($225,000) for the remaining balance of the Second Year R&D Payment.

(f) The Parties shall discuss in good faith additional Amgen payments to EnteraBio for R&D activities performed by EnteraBio under the Work Plan of any Collaboration Program following the Second Year.

Section 7.2 Milestone Payments.

7.2.1 Amgen shall pay to EnteraBio one-time milestone payments ("**Milestone Payments**") following the first occurrence of the corresponding milestone events ("**Milestone Events**") as set forth in the following tables:

(i) Milestone Payments for the Initial Program, subject to Section 3.8:

(a) GLP Toxicology Study Milestone Events for the Initial Program

Milestone Event	Milestone Payment
Initiation of first GLP Toxicology Study of a Product under the Initial Program	[*]

(b) Other Development Milestone Events for the Initial Program

Milestone Event	Milestone Payment
Initiation of first Phase 1 Clinical Trial of a Product under the Initial Program	[*]
Initiation of first Phase 2 Clinical Trial of a Product under the Initial Program	[*]
Initiation of first Phase 3 Clinical Trial of a Product under the Initial Program	[*]

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(c) Commercial Milestone Events for the Initial Program

Milestone Event	Milestone Payment
First Commercial Sale of a Product under the Initial Program	[*]
Worldwide Net Sales of Products under the Initial Program exceed [*] in a calendar year	[*]
Worldwide Net Sales of Products under the Initial Program exceed [*] in a calendar year	[*]
Worldwide Net Sales of Products under the Initial Program exceed [*] in a calendar year	[*]

(ii) Milestone Payments for each of the Second and Third Collaboration Program:

(a) Development Milestone Events for each of the Second and Third Collaboration Program

Milestone Event	Milestone Payment
Initiation of first GLP Toxicology Study of a Product under the applicable Post-Effective Date Program	[*]

(b) Development Milestone Events for each of the Second and Third Collaboration Program

Milestone Event	Milestone Payment
Initiation of first Phase 1 Clinical Trial of a Product under the applicable Post-Effective Date Program	[*]

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Milestone Event	Milestone Payment
Initiation of first Phase 2 Clinical Trial of a Product under the applicable Post-Effective Date Program	[*]
Initiation of first Phase 3 Clinical Trial of a Product under the applicable Post-Effective Date Program	[*]

(c) Commercial Milestone Events for each of the Second and Third Collaboration Program

Milestone Event	Milestone Payment
First Commercial Sale of a Product under the applicable Post-Effective Date Program	[*]
Worldwide Net Sales of Products under the applicable Post-Effective Date Program exceed [*] in a calendar year	[*]
Worldwide Net Sales of Products under the applicable Post-Effective Date Program exceed [*] in a calendar year	[*]
Worldwide Net Sales of Products under the applicable Post-Effective Date Program exceed [*] in a calendar year	[*]

7.2.2 The Parties agree that Amgen shall pay to EnteraBio the applicable Milestone Payment in the manner described below after the first occurrence of the applicable Milestone Event with respect to the first Product under a given Collaboration Program. For clarity, each Milestone Payment payable pursuant to Section 7.2.1(i) and (ii), as applicable, is payable only once per Collaboration Program and the maximum Milestone Payment amount payable for Products with respect to the Initial Program under Section 7.2.1(i) and [*]. The maximum Milestone Payment amount payable for Products with respect to each Post-Effective Date Program is [*]. No Milestone Payment shall be payable for subsequent or repeated achievements of such Milestone Event with one or more of the same or different Products under a Collaboration Program. Each of the Milestone Payments shall be non-refundable and non-creditable. Amgen shall report to EnteraBio its achievement of each Milestone Event for which payment to EnteraBio is due promptly after Amgen determines such achievement has occurred, and EnteraBio shall invoice Amgen for the applicable Milestone Payment. Amgen will pay each such invoice within forty-five (45) days of its receipt thereof.

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Section 7.3 Royalties.

7.3.1 Royalties. Subject to the provisions of this Section 7.3 and Section 3.8, Amgen shall pay to EnteraBio, with respect to Products, on a Product-by-Product and country-by-country basis, royalties on annual Net Sales of Products during the applicable Royalty Term, calculated as set forth in Section 7.3.3. Royalties will be payable on a calendar quarterly basis and any such payments shall be made within [*] after the end of the calendar quarter during which the applicable Net Sales of Products occurred.

7.3.2 Royalty Term. Amgen's obligation to pay royalties with respect to a Product in a particular country shall commence upon the First Commercial Sale of such Product in such country and shall expire on a country-by-country and Product-by-Product basis on the later of (a) the date on which the sale of the Product is no longer Covered by a Valid Claim of an EnteraBio Patent or Collaboration Patent, and (b) the tenth (10th) anniversary of the First Commercial Sale of such Product in such country (the "**Royalty Term**").

7.3.3 Royalty Rates. The royalty rates payable under Section 7.3.1 shall be calculated as follows:

Aggregate Annual Net Sales of Products under a Collaboration Program	Royalty Rate
(a) With respect to the Initial Program: commencing on the first year in which aggregate annual Net Sales of Products under the Initial Program is greater than or equal to [*], for aggregate annual Net Sales of Products less than [*]; and (b) With respect to each Post-Effective Date Program: for aggregate annual Net Sales of Products less than [*].	[*]
If aggregate annual Net Sales of Products under a Collaboration Program is greater than or equal to [*] and less than [*]	[*]

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If aggregate annual Net Sales of Products under a Collaboration Program greater than or equal to [*]	[*]

For the avoidance of doubt, if the sale of a Product is Covered by more than one Valid Claim, the above royalty shall be paid only once.

7.3.4 Royalty Reduction.

(a) On a country-by-country and Product-by-Product basis, in the event that (i) the Exploitation of a Product is not Covered by a Valid Claim of an EnteraBio Patent or Collaboration Patent in such country and the Royalty Term for such Product in such country has not expired, and (ii) a Third Party commences commercial sale of a Generic Version of a Product in a country, then the royalty rates set forth in Section 7.3.3 with respect to Net Sales for such Product in such country shall be reduced by [*], effective as of the later of: (x) the date such Product is no longer Covered by a Valid Claim of an EnteraBio Patent or Collaboration Patent in such country; and (y) the first day of the first calendar quarter following the calendar quarter in which Net Sales of such Product in the applicable country decrease by more than[*] from the Net Sales of such Product in such country in the calendar quarter immediately preceding the first commercial sale of such Generic Version.

7.3.5 Mutual Convenience of the Parties. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts required hereunder.

Section 7.4 Invoicing. To the extent an invoice is required to be submitted to Amgen hereunder, such invoice shall be addressed to:

Amgen Inc.
Accounts Payable
PO Box 667
Newbury Park, CA 91319-0667
Attention: [*]

Section 7.5 Method of Payment. Unless otherwise agreed by the Parties, all payments due from Amgen under this Agreement shall be paid by wire transfer or electronic funds transfer of immediately available funds to an account designated in writing by EnteraBio. After the First Commercial Sale of the first Product and until expiration of the last Royalty Term for a Product, Amgen shall prepare and deliver to EnteraBio reports of the sale of Products by the Selling Parties for each calendar quarter together with the corresponding royalty payment or other consideration to be paid to EnteraBio in accordance with Section 7.3.1, specifying on a Product-by-Product and country-by-country basis, a detailed and itemized calculation of Net Sales in a manner that is consistent with the method generally used by the Amgen Finance Department to track such information for Amgen's other commercialized products in the Territory.

Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Section 7.6 Currency Conversion. All royalties shall be payable in full in U.S. Dollars. Any sales of Products incurred in a currency other than U.S. Dollars shall be converted to the U.S. Dollar equivalent using Amgen's then-current standard exchange rate methodology as applied to its external reporting for the conversion of foreign currency sales into U.S. Dollars.

Section 7.7 Records and Audits. The Parties shall keep complete and accurate records of payments required under this Agreement for a period of [*] after the end of the calendar year in which any such payment was due. Each Party will have the right, [*] annually at its own expense, to have a nationally recognized, independent, certified public accounting firm, selected by it and subject to the other Party's prior written consent (which shall not be unreasonably withheld, conditioned or delayed), review any such records of such other Party and its Affiliates and their Sublicensees upon reasonable written notice (which shall be no less than thirty (30) days' prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under this Agreement for the period under audit. No calendar year will be subject to audit under this Section 7.7 more than once. The audited Party will receive a copy of each such report concurrently with receipt by the auditing Party, and such accounting firm shall report to the Parties whether or not such calculations are correct and the amount of any discrepancy. Each Party agrees to treat the results of any such review of the audited Party's and its Affiliates' records under this Section 7.7 as Confidential Information of the audited Party and subject to the terms of Article 12. Should such inspection lead to the discovery of a discrepancy to either EnteraBio's or Amgen's detriment, the other Party will promptly pay EnteraBio or Amgen, as applicable, any undisputed amount of the discrepancy together with interest at the rate set forth in Section 7.8. If an audit reveals an underpayment of more than the greater of [*] of the amount that should have been paid to EnteraBio during the audited period, Amgen shall bear the full expenses of the audit.

Section 7.8 Late Payments. In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the day following the due date thereof, calculated at the annual rate of [*] the prime interest rate quoted by *The Wall Street Journal*, Internet U.S. Edition at www.wsj.com on the date said payment is due, the interest being compounded on the last day of each calendar quarter; *provided, however*, that in no event shall said annual interest rate exceed the maximum rate permitted by Law. Each such payment when made shall be accompanied by all interest so accrued. With respect to any disputed payments, no interest payment shall be due until such dispute is resolved and the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.

Section 7.9 Taxes.

7.9.1 Withholding. In the event that any Law requires Amgen to withhold taxes with respect to any payment to be made by Amgen pursuant to this Agreement, Amgen will notify EnteraBio of such withholding requirement prior to making the payment to EnteraBio and provide such assistance to EnteraBio, including the provision of such standard documentation as may be required by a tax authority, as may be reasonably necessary in EnteraBio's efforts to claim an exemption from or reduction of such taxes. Amgen will, in accordance with such Law, withhold taxes from the amount due, remit such taxes to the appropriate tax authority, and furnish EnteraBio with proof of payment of such taxes within thirty (30) days following the payment. If taxes are paid to a tax authority, Amgen shall provide reasonable assistance to EnteraBio to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid. If any taxes are so withheld, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to EnteraBio. EnteraBio shall provide Amgen any tax forms (including Internal Revenue Service Form W-8BEN or W-8ECI or other applicable Internal Revenue Service Form) that may be reasonably necessary in order for Amgen to determine whether to withhold tax on any such payments or to withhold tax on such payments at a reduced rate under applicable tax Law, including any applicable bilateral income tax treaty.

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7.9.2 **VAT.** All payments due to EnteraBio from Amgen pursuant to this Agreement shall be paid exclusive of any value-added tax ("**VAT**") (which, if applicable, shall be payable by Amgen upon receipt of a valid VAT invoice). If EnteraBio determines that it is required to report any such tax, Amgen shall promptly provide EnteraBio with applicable receipts and other documentation necessary or appropriate for such report. For clarity, this Section 7.9.2 is not intended to limit Amgen's right to deduct value-added taxes in determining Net Sales.

ARTICLE 8. INTELLECTUAL PROPERTY

Section 8.1 Intellectual Property Ownership.

8.1.1 **Background IP.** Each Party will own all right, title and interest in its Background IP.

8.1.2 **Collaboration IP**. Ownership of Collaboration IP shall follow inventorship. Inventorship will be determined according to U.S. Patent Law (without reference to any conflict of law principles). Amgen, on behalf of itself and its Affiliates and Sublicensees, hereby grants and agrees to grant to EnteraBio a fully paid up, perpetual, worldwide, non-exclusive license, with a right to grant sublicenses, under Collaboration IP solely owned by Amgen, its Affiliates and Sublicenses, solely to the extent such Collaboration IP claims an Improvement to the EnteraBio Platform, to Exploit such Improvement to the EnteraBio Platform for all purposes, subject to the exclusivity granted to Amgen under this Agreement.

8.1.3 **Joint IP**. Except as expressly provided in this Agreement, it is understood that neither Party will have any obligation to obtain any approval or consent of, nor pay a share of the proceeds to or account to, the other Party to practice, enforce, license, assign or otherwise exploit inventions or intellectual property owned jointly by the Parties hereunder, and each Party hereby waives any right it may have under the laws of any jurisdiction to require such approval, consent or accounting. Each Party agrees to cooperate with the other Party, as reasonably requested, and to take such actions as may be required to give effect to this Section 8.1.3 in a particular country within the Territory. Notwithstanding the foregoing, Amgen shall retain all rights to the antibody nucleic acid sequences provided to EnteraBio under this Agreement, along with the polypeptide sequences, and nucleic acids encoded by such said nucleic acid sequences, Derivatives of said polypeptide sequences and nucleic acids encoding said Derivatives. "**Derivatives**" shall include [*].

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Section 8.2 Patent Prosecution and Maintenance.

8.2.1 EnteraBio Patent(s). Other than with respect to any Collaboration Patents, EnteraBio will be solely responsible, at its own cost, for preparing, filing, prosecuting (including, but not limited to provisional, reissue, continuing, continuation-in-part, and substitute applications and any foreign counterparts thereof), and maintaining all EnteraBio Patents and conducting any interferences and oppositions or similar proceedings relating to EnteraBio Patents. Amgen acknowledges and agrees that (a) neither EnteraBio nor any of its Affiliates will have any liability of any kind relating to the preparation, filing, prosecution and maintenance of Patent Rights as provided in this Section 8.2.1; and (b) EnteraBio and its Affiliates have the right to cease all activities relating to the preparation, filing, prosecution or maintenance of any Patent Rights as provided in this Section 8.2.1 for any reason, in which case EnteraBio will promptly inform Amgen of such planned cessation.

8.2.2 Amgen Patent(s). Other than with respect to any Collaboration Patents, Amgen will be solely responsible, at its own cost, for preparing, filing, prosecuting (including, but not limited to provisional, reissue, continuing, continuation-in-part, and substitute applications and any foreign counterparts thereof), and maintaining all Amgen Patents and conducting any interferences and oppositions or similar proceedings relating to Amgen Patents. EnteraBio acknowledges and agrees that (a) neither Amgen nor any of its Affiliates will have any liability of any kind relating to the preparation, filing, prosecution and maintenance of Patent Rights as provided in this Section 8.2.2; and (b) Amgen and its Affiliates have the right to cease all activities relating to the preparation, filing, prosecution or maintenance of any Patent Rights as provided in this Section 8.2.2 for any reason, in which case Amgen will promptly inform EnteraBio of such planned cessation.

8.2.3 Collaboration Patents. EnteraBio will be primarily responsible, at its own cost, for preparing, filing, prosecuting (including, but not limited to provisional, reissue, continuing, continuation-in-part, and substitute applications and any foreign counterparts thereof), and maintaining all Patent Rights constituting Collaboration Patents that: (i) solely claim Improvements to the EnteraBio Platform; or (ii) solely claim Collaboration Know-How generated solely by EnteraBio after the applicable Preclinical R&D Term or (iii) pursuant to Section 8.1.2 are owned solely by EnteraBio (the "**EnteraBio Prosecuted Collaboration Patents**"), and conducting any interferences and oppositions or similar proceedings relating to such Patent Rights. Other than the EnteraBio Prosecuted Collaboration Patents, Amgen will be primarily responsible, at its own cost, for preparing, filing, prosecuting (including, but not limited to provisional, reissue, continuing, continuation-in-part, and substitute applications and any foreign counterparts thereof), and maintaining all other Patent Rights constituting Collaboration Patents and conducting any interferences and oppositions or similar proceedings relating to such Patent Rights. The filing Party will provide the non-filing Party with copies of and an opportunity to review and comment upon the text of the applications relating to the applicable Collaboration Patents at least thirty (30) days before filing; *provided*, *however*, that if it is not reasonably practicable to provide such application in such thirty (30) day period, then the filing Party will provide either a draft copy of such application or a statement of intent to file such application in such thirty (30) day period. The filing Party will provide the non-filing Party with a copy of each submission made to and document received from a patent authority, court or other tribunal regarding any Collaboration Patent reasonably promptly after making such filing or receiving such document, including a copy of each application for each Collaboration Patent as filed together with notice of its filing date and application number. The filing Party will keep the non-filing Party advised of the status of all material communications, and actual and prospective filings or submissions regarding the Collaboration Patents, and will give the non-filing Party copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any patent authority or judicial body. The filing Party will consider in good faith the non-filing Party's comments on such communications, filings and submissions for the Collaboration Patents. With respect to any filings or other materials provided to the non-filing Party under this Section 8.2.3, the filing Party will have the right to redact information relating to manufacturing, CMC or devices, any product other than Products or any Know-How other than Collaboration Know-How from any such filings and materials. In the event either Party declines to file, prosecute or maintain any of the foregoing Patent Rights, elects to allow any Patent Rights to lapse in any country, or elects to abandon any Patent Rights (in each case to the extent contained in the Collaboration Patents) before all appeals within the respective patent office have been exhausted (each, an "**Abandoned Patent Right**"), then: (1) such Party shall provide the other Party with reasonable notice of such decision so as to permit the non-abandoning Party to decide whether to file, prosecute or maintain such Abandoned Patent Rights and to take any necessary action (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Abandoned Patent Right with the U.S. Patent & Trademark Office or any foreign patent office); (2) the non-abandoning Party, at the non-abandoning Party's expense, may assume control of the filing, prosecution or maintenance of such Abandoned Patent Rights; (3) the non-abandoning Party shall have the right, at its expense, to transfer the responsibility for such filing, prosecution and maintenance of such Abandoned Patent Rights to patent counsel (outside or internal) selected by the non-abandoning Party; and (4) the abandoning Party shall, at the non-abandoning Party's reasonable request and at the non-abandoning Party's expense, assist and cooperate in the filing, prosecution and maintenance of such Abandoned Patent Rights.

Section 8.3 Patent Term Extensions. The Parties will cooperate with each other in gaining Patent Right term extension where applicable to Products, and in the case of any disagreement, Amgen shall have the final say as to term extension for any Patent Right claiming the composition of matter or method of use of a Product.

Section 8.4 Defense and Settlement of Third Party Claims. If either (a) any Product Exploited by or under authority of either Party becomes the subject of a Third Party's claim or assertion of infringement of a patent, or (b) a declaratory judgment action is brought naming either Party as a defendant and alleging invalidity of any of the Patent Rights contained in Collaboration Patents, EnteraBio Patents or Amgen Patents, the Party first having notice of the claim or assertion shall promptly notify the other Party, and the Parties shall promptly confer to consider the claim or assertion and the appropriate course of action. Unless the Parties otherwise agree in writing, each Party shall have the right to defend itself against a suit that names it as a defendant (the "**Defending Party**"). Neither Party shall enter into any settlement of any claim described in this Section 8.4 that admits to the invalidity or unenforceability of any Patent Right Controlled by the other Party or jointly by the Parties (or otherwise affects the scope, validity or enforceability of such Patent Right), incurs any financial liability on the part of any other Party or requires an admission of liability, wrongdoing or fault on the part of the other Party without such other Party's written consent. In any event, the other Party shall reasonably assist the Defending Party and cooperate in any such litigation at the Defending Party's request and expense. Additionally, if the Defending Party is not the Party that Controls the Patent Right in question, then the other Party has the right to join any such action.

Section 8.5 Enforcement.

8.5.1 Notice of Infringement. The Parties shall inform each other promptly of any infringement or colorable cause of action for infringement of any Patent Right within the Collaboration Patents, EnteraBio Patents or Amgen Patents, and the Parties shall promptly confer to consider the best appropriate course of action.

8.5.2 **Enforcement.** In the event that such infringement or alleged infringement is with respect to a product that has the same primary mechanism of action as a Product, then Amgen shall have the right to enforce the following Patent Rights against any such infringement or alleged infringement thereof: with respect to (a) an Amgen Patent, such right shall be a sole right and shall not require the prior written consent of EnteraBio, (b) EnteraBio Patents or Collaboration Patents which constitute an Improvement of the EnteraBio Platform, such right shall require the prior written consent of EnteraBio, and (c) any Patent Right within the Collaboration Patents, other than the aforementioned, such right shall be a sole right and shall not require the prior written consent of EnteraBio. Amgen shall at all times keep EnteraBio informed as to the status thereof. In such case, Amgen may, at its own expense, institute suit against any infringer or alleged infringer and control and defend such suit in a manner consistent with the terms and provisions hereof and recover any damages, awards or settlements resulting therefrom, subject to Section 8.5.5. EnteraBio shall reasonably cooperate in any such litigation at Amgen's expense. [*]. In the event that Amgen does not elect to enforce any Patent Right within the EnteraBio Patents or Collaboration Patents, then EnteraBio shall be entitled to do so, [*].

8.5.3 **Progress Reporting.** The Party initiating or defending any such enforcement action (the "**Enforcing Party**") shall keep the other Party reasonably informed of the progress of any such enforcement action, and such other Party shall have the individual right to participate with counsel of its own choice at its own expense.

8.5.4 **Allocation of Recoveries.** [*]

[*]

[*]

Section 8.6 **Trademarks.** As between the Parties, Amgen shall own all right, title and interest in and to any trademarks adopted by Amgen for use with a Product, and shall be responsible for the registration, filing, maintenance and enforcement thereof.

Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

ARTICLE 9.REPRESENTATIONS, WARRANTIES AND COVENANTS

Section 9.1 Mutual Representations and Warranties. Each of Amgen and EnteraBio represents and warrants to the other Party, as of the Effective Date, that:

(a) it is duly incorporated and validly existing under, with respect to Amgen, the Law of Delaware, and with respect to EnteraBio, the Law of the State of Israel, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action; and

(c) this Agreement is legally binding upon it and enforceable in accordance with its terms and the execution, delivery and performance of this Agreement by it have been duly authorized by all necessary corporate action and do not and will not: (x) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, or violate any material applicable Law or (y) require any consent or approval of its stockholders or similar action.

Section 9.2 Additional EnteraBio Representations, Warranties and Covenants. EnteraBio represents and warrants to Amgen that, as of the Effective Date (except as specifically stated otherwise):

(a) EnteraBio has full legal or beneficial title and ownership of, or an exclusive license to, the EnteraBio Patents as is necessary to grant the licenses (or sublicenses) to Amgen to such EnteraBio Patents that EnteraBio purports to grant pursuant to this Agreement;

(b) EnteraBio has the rights necessary to grant the licenses to Amgen under EnteraBio Licensed Know-How that EnteraBio purports to grant pursuant to this Agreement;

(c) To EnteraBio's knowledge, the EnteraBio Patents licensed to EnteraBio and its Affiliates are not subject to, any liens or encumbrances, and EnteraBio has not, and will not during the Term, grant any right to any Third Party under or with respect to the EnteraBio IP that would conflict with the rights granted to Amgen hereunder or terminate any rights granted by a Third Party to EnteraBio or its Affiliates that are further granted to Amgen hereunder;

(d) Except as disclosed in EnteraBio's SEC filings, no claim or action has been brought or, to EnteraBio's knowledge, threatened by any Third Party alleging that (i) the EnteraBio Patents are invalid or unenforceable or (ii) use of the EnteraBio IP infringes or misappropriates or would infringe or misappropriate any right of any Third Party, and no EnteraBio Patent is the subject of any interference, opposition, cancellation or other protest proceeding. EnteraBio has not received any written notice from any Third Party asserting or alleging that the development, manufacture, use or sale of any Product infringes the rights of such Third Party in the Territory;

(e) There are no pending actions, claims, investigations, suits or proceedings against EnteraBio or its Affiliates, at law or in equity, or before or by any Regulatory Authority, and neither EnteraBio nor any of its Affiliates has received any written notice regarding any pending or threatened actions, claims, investigations, suits or proceedings against EnteraBio or such Affiliate, at law or in equity, or before or by any Regulatory Authority, in either case with respect to the EnteraBio IP; and

(f) To EnteraBio's knowledge, no Third Party, including any current or former employee or consultant of EnteraBio, is infringing or misappropriating or has infringed or misappropriated the EnteraBio IP.

Section 9.3 Additional Amgen Representations, Warranties and Covenants. Amgen represents and warrants to EnteraBio that, as of the Effective Date (except as specifically stated otherwise):

(a) Amgen has full legal or beneficial title and ownership of, or an exclusive license to, the Amgen Patents as is necessary to grant the licenses (or sublicenses) to EnteraBio to such Amgen Patents that Amgen purports to grant pursuant to this Agreement;

(b) The Amgen Patents owned by Amgen and its Affiliates are not subject to, and to Amgen's knowledge the Amgen Patents licensed to Amgen and its Affiliates are not subject to, any liens or encumbrances and Amgen has not granted to any Third Party any rights or licenses under such Patent Rights that would conflict with the licenses granted to EnteraBio hereunder;

(c) Amgen has no knowledge of any claim or litigation that has been brought or threatened in writing by any Third Party alleging that (i) the Amgen Patents are invalid or unenforceable or (ii) the use of the Amgen IP infringes or misappropriates or would infringe or misappropriate any right of any Third Party, and no Amgen Patent is the subject of any interference, opposition, cancellation or other protest proceeding.

Section 9.4 Mutual Covenants.

(a) **Employees, Consultants and Contractors.** Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants and contractors who perform research or development activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign inventions in a manner consistent with the provisions of this Agreement.

(b) **Debarment.** Each Party represents, warrants and covenants to the other Party that it is not debarred, excluded, disqualified, or the subject of disbarment, exclusion or disqualification proceedings under the U.S. Food, Drug and Cosmetic Act or comparable Laws in any country or jurisdiction other than the U.S. and, to its knowledge, does not, and will not during the Term knowingly, employ or use, directly or indirectly, including through Affiliates or Sublicensees, the services of any person who is debarred, excluded, disqualified, or the subject of disbarment, exclusion or disqualification proceedings in connection with activities relating to any Product. In the event that either Party becomes aware of the debarment, exclusion or disqualification or threatened debarment, exclusion or disqualification of any person providing services to such Party, directly or indirectly, including through Affiliates or Sublicensees, which directly or indirectly relate to activities contemplated by this Agreement, such Party shall promptly notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

(c) **Compliance.**

(i) Each Party agrees, on behalf of itself and its officers, directors, employees, Affiliates and agents, that, in connection with the matters that are the subject of this Agreement, and the performance of its obligations hereunder:

(a) It shall use its commercially reasonable efforts to comply with all applicable (i) U.S. Laws prohibiting the re-export, directly or indirectly, of certain controlled U.S.-origin items without a license to parties located in certain countries or appearing on certain U.S. Government lists of restricted parties; (ii) U.S. Laws prohibiting participation in non-U.S. boycotts that the United States does not support; (iii) U.S. Laws prohibiting the sale of products to parties from any country subject to U.S. economic sanctions or who are identified on related U.S. Government lists of restricted parties; and (iv) data privacy laws of the applicable jurisdiction, including the national and sub-national laws based on the European Union Data Protection Directive 95/46/EC, and all data breach notification and information securities laws and regulations specific thereto.

(b) It will comply with the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable Law relating to or concerning public or commercial bribery or corruption (collectively, "**Anti-Bribery and Anti-Corruption Laws**") and its applicable anti-corruption policies ("**Anti-Corruption Policies**"), and will not take any action that will cause the other Party or its Affiliates to be in violation of any such laws or policies.

(c) It will not, directly or indirectly, pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give or authorize the giving of anything of value to any Public Official or Entity for the purpose of influencing the acts of such Public Official or Entity to induce them to use their influence with any Governmental Authority, or obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Anti-Bribery and Anti-Corruption Laws or Anti-Corruption Policies.

(d) It will not directly or indirectly solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Bribery and Anti-Corruption Laws or the Anti-Corruption Policies.

(ii) Each Party, on behalf of itself and its officers, directors, employees, Affiliates, agents and Representatives, represents and warrants to the other Party that, in connection with the matters that are the subject of this Agreement, and the performance by each Party of its obligations hereunder:

(a) To its knowledge, as of the Effective Date, it and its Affiliates have not committed any Material Anti-Corruption Law Violation, other than, in the case of Amgen, the mis-promotion activities preceding the Corporate Integrity Agreement, entered into between Amgen and the Office of the Inspector General of the Department of Health and Human Services in December 2012.

(b) To its knowledge, none of its contracts, licenses or other assets that are the subject of this Agreement were procured in violation of the Anti-Bribery and Anti-Corruption Laws.

(iii) Each Party will keep and maintain accurate books, accounts, invoices and reasonably detailed records in connection with the performance of its obligations under, and payments made in connection with, this Agreement, including all records required to establish compliance with the provisions of this Section 9.4(c), until the later of (a) [*] after the end of the period to which such books and records pertain or (b) the expiration of the applicable statute of limitations (or any extension thereof).

(iv) If a Party becomes aware that any of its officers, directors or employees becomes during the Term a Public Official or Entity in a position to take or influence official action for or against a Party in connection with the performance of its obligations under this Agreement, that Party will promptly notify the other Party. A Party shall notify the other Party upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of its representatives that any of them is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation in connection, in either case in connection with this Agreement.

(v) If either Party requests that any other Party complete a compliance certification certifying compliance with this Section 9.4(c), which request shall occur no more than [*] per calendar year, such other Party shall promptly complete and deliver such compliance certification truthfully and accurately. If either Party requests, in connection with a Corporate Integrity Agreement or similar arrangement with a Governmental Authority, that any other Party complete a compliance certification certifying adherence to and compliance with such other Party's code of conduct and compliance program with respect to such other Party's activities under this Agreement, which request shall occur no more than [*] per calendar year, such other Party shall cooperate with the first Party to promptly complete and deliver such compliance certification truthfully and accurately, and should there be reasonable additional requests of such other Party as a result of a Corporate Integrity Agreement or similar arrangement with a Governmental Authority of the requesting Party, such other Party shall comply with such requests at the requesting Party's cost and expense.

(vi) In the event that a Party has a good faith reason to believe that the other Party may be in breach or violation of any representation, warranty or undertaking in this Section 9.4(c), such Party shall have the right to conduct an examination and audit of relevant books and records of the other Party and, during the pendency of such examination, to suspend any obligations on the part of such Party to the other Party. In the event that a Party becomes aware, whether or not through audit, that the other Party is in breach of or in violation of any representation, warranty or undertaking in this Section 9.4(c), then that Party shall have the right to take such steps as are reasonably necessary in order to avoid a violation or continuing violation of the Anti-Bribery and Anti-Corruption Laws, including by requesting such additional representations, warranties, undertakings and other provisions including a further audit as it believes in good faith are reasonably necessary.

Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Section 9.5 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS ARTICLE 9, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF PATENT CLAIMS. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY EITHER PARTY THAT EITHER PARTY WILL BE SUCCESSFUL IN OBTAINING ANY PATENT RIGHTS, OR THAT ANY PATENT RIGHTS WILL ISSUE BASED ON A PENDING APPLICATION. WITHOUT LIMITING THE RESPECTIVE RIGHTS AND OBLIGATIONS OF THE PARTIES EXPRESSLY SET FORTH HEREIN, EACH PARTY SPECIFICALLY DISCLAIMS ANY GUARANTEE THAT THE PRODUCTS WILL BE SUCCESSFUL, IN WHOLE OR IN PART.

ARTICLE 10. INDEMNIFICATION

Section 10.1 Indemnity.

10.1.1 By EnteraBio. EnteraBio agrees to defend Amgen, its Affiliates, and each of their respective directors, officers, employees and agents (the "Amgen Indemnified Parties"), at EnteraBio's cost and expense, and will indemnify and hold Amgen and the other Amgen Indemnified Parties harmless from and against any claims, losses, costs, damages, fees or expenses (including reasonable legal fees and expenses) (collectively, "**Losses**") to the extent resulting from any claims, actions, suits or proceedings brought by a Third Party (including product liability claims) (a "**Third Party Claim**") arising out of (a) the gross negligence or willful misconduct of EnteraBio, its Affiliates or their respective Sublicensees in connection with its activities under this Agreement; (b) the material breach of this Agreement or the representations, warranties and covenants made hereunder by EnteraBio, (c) the material breach by EnteraBio or its Affiliates of any agreement or arrangement with a subcontractor performing its obligations under this Agreement pursuant to Section 3.2, and (d) other matters that the Parties agree to in writing; except, in each case, to the extent such Losses result from clause (a), (b), or (c) of Section 10.1.2.

10.1.2 By Amgen. Amgen agrees to defend EnteraBio, its Affiliates and their respective directors, officers, employees and agents (the "**EnteraBio Indemnified Parties**"), at Amgen's cost and expense, and will indemnify and hold EnteraBio and the other EnteraBio Indemnified Parties harmless from and against any Losses to the extent resulting from any Third Party Claims arising out of (a) the gross negligence or willful misconduct of Amgen, its Affiliates, or their respective Sublicensees in connection with its activities under this Agreement; (b) the material breach of this Agreement or the representations, warranties and covenants made hereunder by Amgen; (c) the material breach by Amgen or its Affiliates of any agreement or arrangement with a subcontractor performing its obligations under this Agreement pursuant to Section 3.2, and or (d) the research, development, manufacture or other Exploitation of any Product by or on behalf of Amgen, its Affiliates, or their respective Sublicensees (including from product liability and intellectual property infringement claims); except, in each case, to the extent such Losses result from clause (a), (b), (c) or (d) of Section 10.1.1.

10.1.3 Procedure. The foregoing indemnity obligations shall be conditioned upon (x) the indemnified Party ("**Indemnitee**") promptly notifying the indemnifying Party ("**Indemnitor**") in writing of the assertion or the commencement of the relevant Third Party Claim (*provided, however*, that any failure or delay to notify shall not excuse any obligation of the Indemnitor, except to the extent the Indemnitor is actually prejudiced thereby), (y) the Indemnitee granting the Indemnitor sole management and control, at the Indemnitor's sole expense, of the defense of such Third Party Claim and its settlement (*provided, however*, that the Indemnitor shall not settle any such Third Party Claim without the prior written consent of the Indemnitee if such settlement does not include a complete release from liability or if such settlement would involve the Indemnitee undertaking an obligation (including the payment of money by the Indemnitee), would bind or impair the Indemnitee, or includes any admission of wrongdoing by the Indemnitee or that any intellectual property or proprietary right of Indemnitee or this Agreement is invalid, narrowed in scope or unenforceable, and (z) the Indemnitee reasonably cooperating with the Indemnitor (at the Indemnitee's expense). The Indemnitee shall have the right (at its own expense) to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification. Notwithstanding the foregoing, the Indemnitee will have the right to employ separate counsel at the Indemnitee's expense and to control its own defense of the applicable Third Party Claim only if: (i) there are or may be legal defenses available to the Indemnitee that are different from or additional to those available to the Indemnitor or (ii) in the reasonable opinion of counsel to the Indemnitee, a conflict or potential conflict exists between the Indemnitee and the Indemnitor that would make such separate representation advisable. The Indemnitee shall not settle or compromise such Third Party claim without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld, conditioned or delayed.

ARTICLE 11. LIMITATIONS OF LIABILITY

Section 11.1 LIMITATION OF DAMAGES. IN NO EVENT SHALL A PARTY BE LIABLE HEREUNDER TO THE OTHER PARTY FOR ANY PUNITIVE, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST REVENUE, LOST PROFITS, OR LOST SAVINGS) HOWEVER CAUSED AND UNDER ANY THEORY, EVEN IF IT HAS NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE LIMITATIONS SET FORTH IN THIS SECTION 11.1 SHALL NOT APPLY WITH RESPECT TO ANY BREACH OF ARTICLE 12. NOTHING IN THIS SECTION 11.1 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER ARTICLE 10 WITH RESPECT TO ANY DAMAGES REQUIRED TO BE PAID TO A THIRD PARTY IN CONNECTION WITH A THIRD PARTY CLAIM.

Section 11.2 Insurance. Each of the Parties will, at their own respective expense procure and maintain during the Term and for [*] thereafter, insurance policies adequate to cover their obligations hereunder and consistent with the normal business practices of prudent biopharmaceutical companies of similar size and scope (or reasonable self-insurance sufficient to provide materially the same level and type of protection), and will upon request provide the other Party with a certificate of insurance in that regard, along with any amendments and revisions thereto. Such insurance will not create a limit to either Party's liability hereunder.

ARTICLE 12. CONFIDENTIALITY

Section 12.1 Confidential Information.

12.1.1 Confidential Information. Each Party (the "**Receiving Party**") may receive during the course and conduct of activities under this Agreement, certain proprietary or confidential information of the other Party (the "**Disclosing Party**") as furnished to the Receiving Party by or on behalf of the Disclosing Party. The term "**Confidential Information**" means all ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available by Disclosing Party or at the request of Receiving Party, including any of the foregoing of Affiliates or Third Parties.

Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

12.1.2 Restrictions. During the Term and for [*] thereafter, Receiving Party will keep all Disclosing Party's Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information (but in no event less than a commercially reasonable degree of care). Receiving Party will not use Disclosing Party's Confidential Information except in connection with the performance of its obligations and exercise of its rights under this Agreement. For clarity, Amgen shall have the right to use any Confidential Information of EnteraBio in the Exploitation of a Product. Receiving Party has the right to disclose Disclosing Party's Confidential Information without Disclosing Party's prior written consent to Receiving Party's Affiliates and their employees, subcontractors, consultants or agents who have a need to know such Confidential Information in order to perform its obligations and exercise its rights under this Agreement and who are bound by restrictions on use and disclosure consistent with this Section 12.1.2. Receiving Party will use diligent efforts to cause those entities and persons to comply with the restrictions on use and disclosure in this Section 12.1.2. Receiving Party assumes responsibility for those entities and persons maintaining Disclosing Party's Confidential Information in confidence and using same only for the purposes described herein.

12.1.3 Exceptions. Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information will not apply to the extent that Receiving Party can demonstrate that the Disclosing Party's Confidential Information: (a) was known to Receiving Party or any of its Affiliates prior to the time of disclosure by Disclosing Party hereunder; (b) is or becomes public knowledge through no fault or omission of Receiving Party or any of its Affiliates; (c) is obtained by Receiving Party or any of its Affiliates from a Third Party not known by the Receiving Party after reasonable inquiry to be under an obligation of confidentiality to Disclosing Party; (d) has been independently discovered or developed by employees, subcontractors, consultants or agents of Receiving Party or any of its Affiliates without the reference to or use of Disclosing Party's Confidential Information, as evidenced by contemporaneous written records; or (e) was released from the restrictions set forth in this Agreement by express prior written consent of the Disclosing Party.

12.1.4 Permitted Disclosures. Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(a) in order to comply with applicable Law (including any securities law or regulation or the rules of a securities exchange or as a requirement in filing for an International Nonproprietary Name (INN) or the like) or with a legal or administrative proceeding, or in connection with prosecuting or defending litigation;

(b) in connection with prosecuting and defending litigation, Marketing Approvals and other Regulatory Filings and communications, and filing, prosecuting and enforcing Patent Rights in connection with Receiving Party's rights and obligations pursuant to this Agreement; and

(c) [*]; permitted acquirers or assignees; and investment bankers, investors and lenders;

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provided, however, that (1) with respect to each of Sections 12.1.4(a) and 12.1.4(b), where reasonably possible, Receiving Party will notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed; and (2) with respect to Section 12.1.4(c), [*].

Section 12.2 Terms of this Agreement; Publicity.

12.2.1 Restrictions. The Parties agree that the terms of this Agreement, including the identity of each Collaboration Program, will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 12.1.4. Except as required by Law or as permitted under Section 12.1.4, each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed (or as such consent may need to be obtained in accordance with Section 12.3). Notwithstanding the foregoing, a press release in the form attached hereto as Exhibit D shall be issued by EnteraBio on or as promptly as practicable after the Effective Date.

12.2.2 Review. Subject to Section 12.1.4, in the event either Party (the "**Issuing Party**") desires to issue a press release (other than as set forth on Exhibit D) or other public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof, the Issuing Party will provide the other Party (the "**Reviewing Party**") with a copy of the proposed press release or public statement (the "**Release**"). The Issuing Party will specify with each such Release, taking into account the urgency of the matter being disclosed, a reasonable period of time within which the Receiving Party may provide any comments on such Release (but in no event less than ten (10) business days). If the Reviewing Party provides any comments, the Parties will consult on such Release and work in good faith to prepare a mutually acceptable Release. Either Party may subsequently publicly disclose any information previously contained in any Release, provided that (a) the other Party provided its written consent hereto as stated in Section 12.2.1, and (b) circumstances have not changed such that such previous disclosure is rendered inaccurate or misleading. For the avoidance of doubt (and notwithstanding anything contained in this Agreement to the contrary), Amgen, in its sole discretion, may make disclosures relating to the development or commercialization of a Product, including the results of research and any clinical trial conducted by Amgen or any health or safety matter related to a Product.

Section 12.3 Publication. Amgen will have the sole right to publish and make scientific presentations with respect to Products, and to issue press releases (except with respect to the terms of this Agreement, which is governed by Section 12.2) or make other public disclosures regarding any such Products, and EnteraBio will not do so without Amgen's prior written consent, except as required by Law; *provided, however,* that any publication or presentation to be made by Amgen that names EnteraBio will require the prior written consent of EnteraBio. The Party that is entitled hereunder to make a publication or presentation (the "**Publishing Party**") will deliver to the other Party (the "**Non-Publishing Party**") a copy of any proposed written publication or outline of presentation to be made by the Publishing Party in advance of submission for publication or presentation at least thirty (30) days in advance of submission (or, where a copy of such publication or presentation is not available at such time, a draft or outline of such publication or a description of such presentation), and the Non-Publishing Party will have the right to: (a) require a delay in submission of not more than sixty (60) days to enable patent applications protecting any product; and (b) prohibit disclosure of any of its Confidential Information in any such proposed publication or presentation. If there is any dispute between the Parties with regard to a proposed publication, presentation or other communication regarding this Agreement, such dispute shall be referred to the JRC for resolution. Each Party agrees that it will not unreasonably withhold, condition or delay its consent to requests for (i) extensions of the above timelines in the event that material late-breaking clinical data becomes available or (ii) shortening of the above timelines if the requesting Party has a good faith belief that circumstances warrant such acceleration. The Parties acknowledge and agree that all publications and presentations pursuant to this Section 12.3 shall comply with the International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. Consistent with those guidelines, authorship will be based upon substantial contribution to the design, analysis, interpretation of data, drafting and/or critically revising any publication(s) derived from this Agreement, and authors must engage in the drafting of the publication or revise it critically for important intellectual content. Each party agrees to maintain evidence of its compliance with the ICMJE guidelines for authorship, and that it will provide such evidence to the other Party upon request.

Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Section 12.4 Relationship to the Confidentiality Agreement. This Agreement supersedes the Confidential Disclosure Agreement; *provided*, *however*, that all "Confidential Information" disclosed or received by the Parties thereunder will be deemed "Confidential Information" hereunder and will be subject to the terms and conditions of this Agreement.

Section 12.5 Attorney-Client Privilege. Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges recognized under the applicable Law of any jurisdiction as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the Receiving Party, regardless of whether the Disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties may become joint defendants in proceedings to which the information covered by such protections and privileges relates and may determine that they share a common legal interest in disclosure between them that is subject to such privileges and protections, and in such event, may enter into a joint defense agreement setting forth, among other things, the foregoing principles but are not obligated to do so.

ARTICLE 13. TERM & TERMINATION

Section 13.1 Term. The term of this Agreement shall commence on the Effective Date, and unless terminated earlier as provided in this Article 13 or Section 4.5.2, shall continue in full force and effect, on a Product-by-Product basis, until expiration of the last-to-expire Royalty Term with respect to such Product (the "**Term**"). On a country-by-country and Product-by-Product basis, the licenses granted under this Agreement to Exploit all Products to a terminated Collaboration Program shall be fully paid-up, irrevocable and non-exclusive upon the expiration of the Royalty Term in each country applicable to each such Product.

Section 13.2 Termination by EnteraBio.

13.2.1 Amgen Breach. EnteraBio will have the right to terminate this Agreement in the event of any material breach by Amgen of any terms and conditions of this Agreement; *provided*, *however*, that such termination will not be effective if such breach has been cured within ninety (90) days after written notice thereof is given by EnteraBio to Amgen specifying the nature of the alleged breach. Notwithstanding the foregoing in this Section 13.2.1, in the event of a good faith dispute as to whether performance has been made by either Party pursuant to this Agreement, the foregoing cure period with respect thereto will be tolled pending final resolution of such dispute in accordance with the terms of this Agreement; *provided*, *however*, if such dispute relates to payment, such tolling of the cure period will only apply with respect to payment of the disputed amounts, and not with respect to any undisputed amount.

Section 13.3 Termination by Amgen.

13.3.1 EnteraBio Breach. Amgen will have the right to terminate this Agreement in the event of any material breach by EnteraBio of any terms and conditions of this Agreement; *provided*, *however*, that such termination will not be effective if such breach has been cured within ninety (90) days after written notice thereof is given by Amgen to EnteraBio specifying the nature of the alleged breach. . Notwithstanding the foregoing in this Section 13.3.1, in the event of a good faith dispute as to whether performance has been made by either Party pursuant to this Agreement, including any good faith dispute as to any payment due under this Agreement, the foregoing cure period with respect thereto will be tolled pending final resolution of such dispute in accordance with the terms of this Agreement; *provided*, *however*, if such dispute relates to payment, such tolling of the cure period will only apply with respect to payment of the disputed amounts, and not with respect to any undisputed amount.

13.3.2 Discretionary Termination. [*]

Section 13.4 Effects of Termination. Upon termination by a Party, as applicable, under Section 4.5.2, Section 13.2 or Section 13.3 (provided that, to the extent this Agreement is terminated solely with respect to a particular Collaboration Program or Product, then the remainder of this Section 13.4 shall only apply to the terminated Collaboration Program or Product):

13.4.1 Ongoing Clinical Studies. The Termination Party will responsibly wind-down, in accordance with accepted biopharmaceutical industry norms and ethical practices, any on-going clinical studies for which it has responsibility hereunder in which patient dosing has commenced, and Amgen will be responsible for any costs and expenses reasonably associated with or actually incurred with such wind-down.

13.4.2 Termination of Licenses and Sublicense. All relevant licenses and sublicenses granted under Article 4, as of the effective date of such termination, shall terminate automatically unless otherwise agreed by the Parties in writing.

Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

13.4.3 Destruction of Confidential Information. Each Party shall destroy, at the other Party's request, Confidential Information that it has received from such other Party and is in its possession as of the effective date of expiration or termination (with the exception of one copy of such Confidential Information, which may be retained by the legal department of the Party that received such Confidential Information to confirm compliance with the non-use and non-disclosure provisions of this Agreement); provided that each Party may retain and continue to use all such Confidential Information of the other Party to the extent necessary to exercise any surviving rights, licenses or obligations under this Agreement. Notwithstanding the foregoing, a Party shall not be required to destroy any computer files created during automatic system back up that are subsequently stored securely by it and not readily accessible to its employees, consultants, or others who received Confidential Information under this Agreement.

13.4.4 Prior Payments. Each Party shall pay all undisputed amounts then due and owing to the other Party as of the termination date. In addition, Amgen shall pay EnteraBio all non-cancelable expenses and costs EnteraBio is obliged to pay and which are to be reimbursed according to Section 3.1.

Section 13.5 Survival. In addition to the expiration or termination consequences set forth in Section 13.4 and the provisions that are expressly stated to survive termination, the following provisions will survive termination or expiration of this Agreement: Articles 1, 10, 11 and 14, Section 7.2 (with respect to a Milestone Events reached prior to such expiration or termination), Section 7.3 (with respect to sales made before such expiration or termination), Sections 7.4 through 7.9 inclusive (with respect to periods with sales of Products made before such expiration or termination), Section 8.1, Sections 8.4 and 8.5 (with respect to any action initiated prior to such expiration or termination), Sections 9.5, 12.1, 12.2, 12.3 (with respect to any paper or presentation proposed, or any paper or presentation including data or results of clinical studies conducted, prior to such expiration or termination), 12.4, 12.5 (solely the first sentence) 13.4 and 13.5. Termination or expiration of this Agreement are neither Party's exclusive remedy and will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. All other rights and obligations will terminate upon termination or expiration of this Agreement.

ARTICLE 14. MISCELLANEOUS

Section 14.1 Entire Agreement; Amendment. This Agreement and all Exhibits attached hereto constitute the entire agreement between the Parties as to the subject matter hereof. All prior and contemporaneous negotiations, representations, warranties, agreements, statements, promises and understandings with respect to the subject matter of this Agreement, including the Confidential Disclosure Agreement, are hereby superseded and merged into, extinguished by and completely expressed by this Agreement. Neither of the Parties shall be bound by or charged with any written or oral agreements, representations, warranties, statements, promises or understandings not specifically set forth in this Agreement. No amendment, supplement or other modification to any provision of this Agreement shall be binding unless in writing and signed by Amgen and EnteraBio.

Section 14.2 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code to the extent permitted thereunder. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

Section 14.3 Independent Contractors. The relationship between Amgen and EnteraBio created by this Agreement is solely that of independent contractors. This Agreement does not create any agency, distributorship, employee-employer, partnership, joint venture or similar business relationship between the Parties. No such Party is a legal representative of the other Party, and no such Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. Each such Party shall use its own discretion and shall have complete and authoritative control over its employees and the details of performing its obligations under this Agreement.

Section 14.4 Governing Law; Disputes. This Agreement and its effect are subject to and shall be construed and enforced in accordance with the law of the State of New York, without regard to its conflicts of laws, except as to any issue which depends upon the validity, scope or enforceability of any Amgen Patent, EnteraBio Patent or Collaboration Patent, which issue shall be determined in accordance with the laws of the country in which such patent was issued. If a dispute regarding this Agreement or the activities contemplated hereby arises between the Parties, the Parties shall attempt to solve the issue through good faith discussions for a period of at least sixty (60) days, and the Parties will use reasonable efforts to reach an amicable resolution of the issue during such period. During such sixty (60)-day period, the Parties may agree to submit such dispute for non-binding mediation. If, notwithstanding the efforts of the Parties in accordance with the previous sentence, after such sixty (60)-day period, a dispute cannot be amicably resolved, then such dispute shall be finally settled under the Rules of Arbitration of the International Institute for Conflict Prevention and Resolution by [*] arbitrators, of whom each Party shall designate [*], with the [*] arbitrator to be designated by the [*] Party-appointed arbitrators. Such arbitration shall be conducted in New York, NY, U.S.A. The arbitration shall be governed by the Federal Arbitration Act, 9 U.S.C.§1 et seq., and judgment upon the award rendered by the arbitrator(s) may be entered by any court having jurisdiction thereof. The arbitrator shall not have the power to grant any award or remedy other than such awards or remedies that are available under the applicable Law. Notwithstanding the foregoing, each Party understands and agrees that a Party shall be entitled to seek injunctive and/or equitable relief and enforcement of any arbitration award from the applicable courts in any appropriate jurisdiction.

Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Section 14.5 Notice. Any notice required or permitted to be given by this Agreement shall be in writing, in English. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective if (a) delivered by hand or by overnight courier with tracking capabilities, (b) mailed postage prepaid by first class, registered, or certified mail, or (c) delivered by facsimile followed by delivery via either of the methods set forth in clauses (a) and (b) of this Section 14.5, in each case, addressed as set forth below unless changed by notice so given:

If to EnteraBio:

EnteraBio Ltd.
Minrav Building, 5th Floor, PO Box 12117
Jerusalem 91220
Israel
Attn: Philip Schwartz, CEO

with a copy (which shall not constitute notice) to:

Herzog, Fox & Neeman
Asia House, 4 Weizmann St.
Tel Aviv 6423904
Israel
Attn: Yair Geva, Adv. and Tomer Farkash, Adv.

If to Amgen:

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320
USA
Attn: [*]

with a copy (which shall not constitute notice) to:

One Amgen Center Drive
Thousand Oaks, CA 91320
USA
Attn: [*]

Any such notice shall be deemed given on the date received, except any notice received after 5:00 p.m. (in the time zone of the receiving Party) on a business day or received on a non-business day shall be deemed to have been received on the next business day. A Party may add, delete, or change the Person or address to which notices should be sent at any time upon written notice delivered to the Party's notices in accordance with this Section 14.5.

Section 14.6 Compliance With Law; Severability. Nothing in this Agreement shall be construed to require the commission of any act contrary to Law. If any one or more provisions of this Agreement is held to be invalid, illegal or unenforceable, the affected provisions of this Agreement shall be curtailed and limited only to the extent necessary to bring it within the applicable legal requirements and the validity, legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.

Section 14.7 Non-Use of Names. EnteraBio shall not use the name, trademark, logo, or physical likeness of Amgen or any of its respective officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without Amgen's prior written consent. EnteraBio shall require its Affiliates to comply with the foregoing. Amgen shall not use the name, trademark, logo, or physical likeness of EnteraBio or any of its officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without EnteraBio's prior written consent. Amgen shall require its Affiliates and Sublicensees to comply with the foregoing.

Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Section 14.8 Successors and Assigns. Neither this Agreement nor any of the rights or obligations created herein may be assigned by either Party, in whole or in part, without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed except that either Party shall be free to assign this Agreement (a) to an Affiliate of such Party (for so long as such Affiliate remains an Affiliate) provided that such Party shall remain liable and responsible to the other Party for the performance and observance of all such duties and obligations by such Affiliate, or (b) in connection with any sale of all or substantially all of the assets of the Party that relate to this Agreement to a Third Party, whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets or otherwise (a "**Sale Transaction**"), provided that the party to which this Agreement is assigned expressly agrees in writing to assume and be bound by all obligations of the assigning Party under this Agreement. A copy of such written agreement by such assignee shall be provided to the non-assigning Party within ten (10) calendar days of execution of such written agreement. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the Parties hereto. Any attempted assignment of this Agreement in contravention of this Section 14.8 shall be null and void.

Section 14.9 Sale Transaction or Amgen Acquisition. In the event of (x) a Sale Transaction involving Amgen, or (y) the acquisition by Amgen of all or substantially all of the business of a Third Party (together with any entities that were Affiliates of such Third Party immediately prior to such acquisition, an "**Amgen Acquiree**"), whether by merger, sale of stock, sale of assets or otherwise (an "**Amgen Acquisition**"), intellectual property rights of the acquiring party in a Sale Transaction, if other than one of the Parties to this Agreement (together with any entities that were affiliates of such Third Party immediately prior to such Sale Transaction, a "**Third Party Acquirer**"), or the Amgen Acquiree, as applicable, shall not be included in the Patent Rights or Know-How licensed hereunder by Amgen to EnteraBio or otherwise subject to this Agreement.

Section 14.10 Sale Transaction or EnteraBio Acquisition. In the event of (x) a Sale Transaction involving EnteraBio, or (y) the acquisition by EnteraBio of all or substantially all of the business of a Third Party (together with any entities that were Affiliates of such Third Party immediately prior to such acquisition, a **"EnteraBio Acquiree**"), whether by merger, sale of stock, sale of assets or otherwise (a "**EnteraBio Acquisition**"), intellectual property rights of the Third Party Acquirer in a Sale Transaction, or the EnteraBio Acquiree, as applicable, shall not be included in the Patent Rights or Know-How licensed hereunder by EnteraBio to Amgen, or otherwise subject to this Agreement, except that to the extent the EnteraBio Acquiree or Third Party Acquirer owns any Blocking Patents relative to any Product, EnteraBio shall and hereby does grant to Amgen a non-exclusive license, [*] until the expiration of the last to expire of such Blocking Patents, on a country-by-country basis or termination of this Agreement relative to such Product, whichever comes first, provided that at the time of such Sale Transaction or EnteraBio Acquisition, such non-exclusive license rights are available for such grant and have not been exclusively licensed to any Third Party.

Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Section 14.11 Waivers. A Party's consent to or waiver, express or implied, of any other Party's breach of its obligations hereunder shall not be deemed to be or construed as a consent to or waiver of any other breach of the same or any other obligations of such breaching Party. A Party's failure to complain of any act, or failure to act, by the other Party, to declare the other Party in default, to insist upon the strict performance of any obligation or condition of this Agreement or to exercise any right or remedy consequent upon a breach thereof, no matter how long such failure continues, shall not constitute a waiver by such Party of its rights hereunder, of any such breach, or of any other obligation or condition. A Party's consent in any one instance shall not limit or waive the necessity to obtain such Party's consent in any future instance and in any event no consent or waiver shall be effective for any purpose hereunder unless such consent or waiver is in writing and signed by the Party granting such consent or waiver.

Section 14.12 Rights upon Change of Control of EnteraBio. [*]

Section 14.13 No Third Party Beneficiaries. Nothing in this Agreement shall be construed as giving any Person, other than the Parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof, except for the provisions of Article 10 (with respect to which the persons to which Article 10 applies shall be Third Party beneficiaries for Article 10 only in accordance with the terms and conditions of Article 10).

Section 14.14 Headings; Exhibits. Article and Section headings used herein are for convenient reference only, and are not a part of this Agreement. All Exhibits are incorporated herein by this reference.

Section 14.15 Interpretation. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, and the use of any gender shall be applicable to all genders. The term "including" as used herein means including, without limiting the generality of any description preceding such term. The word "will" shall be construed to have the same meaning and effect as the word "shall". The words "herein", "hereof" and "hereunder" and words of similar import will be construed to refer to this Agreement in its entirety and not to any particular provision hereof. The word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. All references to "$" or "dollars" in this Agreement means "U.S. dollars". All references to a "business day" or "business days" in this Agreement means any day other than a day which is a Saturday, a Sunday or any day banks are authorized or required to be closed in the State of California. The language in all parts of this Agreement shall be deemed to be the language mutually chosen by the Parties. The Parties and their counsel have cooperated in the drafting and preparation of this Agreement, and this Agreement therefore shall not be construed against any Party by virtue of its role as the drafter thereof.

Section 14.16 Counterparts Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

[signature page follows]

Certain confidential information has been omitted from this document, as indicated by the notation "[*]". The omitted information has been filed on a confidential basis with the Securities and Exchange Commission pursuant to a request for confidential treatment.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

AMGEN INC.

By: /s/ Raymond Deshaies
Name: Raymond Deshaies
Title: SVP Global Research

ENTERABIO LTD.

By: /s/ Phillip Schwartz
Name: Phillip Schwartz
Title: CEO

[Signature Page to Research Collaboration and License Agreement]

Exhibit A

Press Release

See attached.

Entera Bio Ltd.

Phillip Schwartz,
Chief Executive Officer
Tel: +972-2- 532-7151
phillip@enterabio.com

INTERNATIONAL INVESTOR RELATIONS

Bob Yedid
LifeSci Advisors, LLC
646-597-6989
bob@lifesciadvisors.com

Entera Bio and Amgen Enter Strategic Research Collaboration in Inflammatory Disease and Other Serious Illnesses

- - -

Amgen will have the option to advance up to three large molecule programs using Entera's oral delivery technology

- - -

Entera will be eligible to receive up to $270 million in clinical and commercial milestone payments

Jerusalem, Israel – December 11 2018 – Entera Bio Ltd. (Nasdaq: ENTX) announced today that it has entered into a research collaboration and license agreement with Amgen in inflammatory disease and other serious illnesses. Entera will use its proprietary drug delivery platform to develop oral formulations for one preclinical large molecule program that Amgen has selected. Amgen also has an option to select up to two additional programs to include in the collaboration.

"We are excited to leverage our proprietary oral drug delivery platform in collaboration with Amgen, a leader in the development of large molecule and biologic treatments in inflammatory disease and numerous other disorders," stated Dr. Phillip Schwartz, chief executive officer of Entera. "This collaboration is an important validation of our platform technology. Importantly, the first program included in this agreement is very different from the Oral PTH (1-34) in Entera's pipeline, highlighting the broad applicability of our technology."

Under the terms of the agreement, Entera will receive a modest initial technology access fee from Amgen and will be responsible for preclinical development at Amgen's expense. Entera will be eligible to receive up to $270 million in aggregate payments, as well as tiered royalties up to mid-single digits, upon achievement of various clinical and commercial milestones if Amgen decides to move all of these programs forward. Amgen is responsible for clinical development, manufacturing and commercialization of any of the resulting programs.

Entera will retain all intellectual property rights to its drug delivery technology, which under this collaboration will be licensed to Amgen exclusively for Amgen's nominated drug targets. Amgen will retain all rights to its large molecules and any subsequent improvements.

About Entera Bio Ltd.

Entera Bio is 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 needs. The Company is initially applying its technology to develop an oral formulation of a human parathyroid hormone analog, Oral PTH (1-34), for treatment of hypoparathyroidism and osteoporosis.

++++++

Entera's proprietary platform technology, consists of two components: a small molecule that enhances the absorption of a large molecule therapeutic agents and a second component that “protects” the large molecule from digestion in the gastrointestinal tract. This synergistic system is intended to increase oral bioavailability and decrease the variability associated with the oral administration of large molecule biologics and synthetic protein therapeutic agents.

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Currently, biological entities and other large molecules can only be delivered via injections and or other non-oral pathways. However, oral drug delivery is the easiest method for self-administering medications, offers patients greater dosing flexibility, and has the highest patient acceptance and compliance rates as compared to all other routes of drug administration.

Forward Looking Statements

This press release contains "forward-looking statements." Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, often signify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information that the Company has when those statements are made or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. For a discussion of these and other risks that could cause such differences and that may affect the realization of forward-looking statements, please refer to the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" in the Company's Registration Statement on Form F-1 and other filings with the Securities and Exchange Commission (SEC). Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

Contact:
Bob Yedid
LifeSci Advisors, LLC 646-597-6989
bob@lifesciadvisors.com

Exhibit 8.1

Entera Bio Ltd.

The following is a list of subsidiaries of Entera Bio Ltd. as of December 31, 2018:

STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION	SUBSIDIARY
Delaware	Entera Bio Inc.

Exhibit 12.1

Form of 302 Certification

CERTIFICATIONS*

I, Dr. Phillip Schwartz, certify that:

1. I have reviewed this annual report on Form 20-F of Entera Bio Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Reserved]

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 28, 2019

/s/ Dr. Phillip Schwartz
Name: Dr. Phillip Schwartz
Title: Chief Executive Officer

Exhibit 12.2

Form of 302 Certification

CERTIFICATIONS*

I, Mira Rosenzweig, certify that:

1. I have reviewed this annual report on Form 20-F of Entera Bio Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Reserved]

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 28, 2019

/s/ Mira Rosenzweig
Name: Mira Rosenzweig
Title: Chief Financial Officer

Exhibit 13.1

CERTIFICATION BY THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The certification set forth below is being submitted in connection with the Annual Report on Form 20-F of Entera Bio Ltd. (the "Company") for the fiscal year ended December 31, 2018 (the "Report"), I, Dr. Phillip Schwartz, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2019

By: /s/ Dr. Phillip Schwartz
Name: Dr. Phillip Schwartz
Title: Chief Executive Officer

Exhibit 13.2

CERTIFICATION BY THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The certification set forth below is being submitted in connection with the Annual Report on Form 20-F of Entera Bio Ltd. (the "Company") for the fiscal year ended December 31, 2018 (the "Report"), I, Mira Rosenzweig, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 28, 2019

By: /s/ Mira Rosenzweig
Name: Mira Rosenzweig
Title: Chief Financial Officer

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-227488) of Entera Bio Ltd. of our report dated March 25, 2019, relating to the financial statements, which appears in this Form 20-F.

/s/ Kesselman & Kesselman
Kesselman & Kesselman
Certified Public Accountants (lsr.)
A member firm of PricewaterhouseCoopers International Limited

Tel-Aviv, Israel
March 28, 2019

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