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DELTA REPORT

10-K

ENTX - ENTERA BIO LTD.

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	4488
CHANGES	258
DELETIONS	1847
ADDITIONS	2383

REFINITIV

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022 December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _ to _ .

Commission file number 001-38556

Entera Bio Ltd.

(Exact Name of Registrant as Specified in Its Charter)

Israel	**00-0000000**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

Kiryat Hadassah
Minrav Building - Fifth Floor
Jerusalem, Israel 9112002
(Address of Principal Executive Offices) (Zip Code)
972-2-532-7151
(Registrant's Telephone Number, Including Area Code)
Securities registered pursuant to Section 12(b) of the Act:

972-2-532-7151
(Registrant's Telephone Number, Including Area Code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Ordinary shares, par value NIS 0.0000769 per share	**ENTX**	**Nasdaq Capital Market**
Warrants to purchase ordinary shares	ENTXW	**Nasdaq Capital Market**

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

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

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

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 and posted 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, smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒ ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting fi rm firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

The aggregate market value of the outstanding voting stock held by non-affiliates of the registrant was approximately $32.9 million $20.7 million as of June 30, 2022 June 30, 2023.

As of March 27, 2023 March 1, 2024, the registrant had 28,809,922 35,481,341 ordinary shares, par value NIS 0.0000769 per share (“Ordinary Shares”) outstanding.

Documents Incorporated by Reference

None.

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Various statements in this report are "forward-looking statements" within the meaning of the PSLRA and other U.S. Federal securities laws. 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 trial results. Forward-looking statements include all statements that are not historical facts. 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 involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements are subject to risks and uncertainties and are based on information currently available to our management. Words such as, but not limited to, "anticipate," "believe," "contemplates," "continue," "could," "design," "estimate," "expect," "intend," "likely," "may," "ongoing," "plan," "potential," "predict," "project," "will," "would," "seek," "should," "target," or the negative of these terms and similar expressions or words, identify forward-looking statements. The events and circumstances reflected in our forward-looking statements may not occur and actual results could differ materially from those projected in our forward-looking statements. These factors include those described in "Item 1A-Risk Factors" of this Annual Report on Form 10-K. Report. Meaningful factors which could cause actual results to differ include, but are not limited to: to, the following:

- Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates;
- The regulatory approval processes of the U.S. Food and Drug Administration ("FDA") and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed;
- Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all;
- Positive results from preclinical studies and early-stage clinical trials may not be predictive of future results. Initial positive results in any of our clinical trials may not be indicative of results obtained when the trial is completed or in later stage trials;
- The scope, progress and costs of developing our product candidates such as EB613 for Osteoporosis and EB612 or other oral peptides for Hypoparathyroidism may alter over time based on various factors such as regulatory requirements, collaboration agreements, the competitive environment and new data from pre-clinical and clinical studies;
- The accuracy of our estimates regarding expenses, capital requirements, the sufficiency of our cash resources and the need for additional financing;

- Our ability to continue as a going concern absent access to sources of liquidity;
- Our ability to raise additional funds or consummate strategic partnerships to offset additional required capital to pursue our business objectives, which may not be available on acceptable terms or at all. A failure to obtain this additional capital when needed, or failure to consummate strategic partnerships, could delay, limit or reduce our product development, and other operations;
- Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success;
- The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and third-party payors establish adequate coverage and reimbursement levels and pricing policies;

Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates;

- The regulatory approval processes of the U.S. Food and Drug Administration ("FDA") and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed;

- Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all;
- Positive results from preclinical studies and early-stage clinical trials may not be predictive of future results. Initial positive results in any of our clinical trials may not be indicative of results obtained when the trial is completed or in later stage trials;

- The scope, progress and costs of developing our product candidates such as EB613 for Osteoporosis and EB612 for Hypoparathyroidism may alter over time based on various factors such as regulatory requirements, the competitive environment and new data from pre-clinical and clinical studies;
- The accuracy of our estimates regarding expenses, capital requirements, the sufficiency of our cash resources and the need for additional financing;
- our ability to continue as a going concern absent access to sources of liquidity;

- Our ability to raise additional funds or consummate strategic partnerships to offset additional required capital to pursue our business objectives, which may not be available on acceptable terms or at all. A failure to obtain this additional capital when needed, or failure to consummate strategic partnerships, could delay, limit or reduce our product development, and other operations;

- Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue;
- If we are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be adversely affected;
- Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain;
- Our reliance on third parties to conduct our clinical trials and on third-party suppliers to supply or produce our product candidates;
- Our interpretation of FDA feedback and guidance and how such guidance may impact our clinical development plan;
- Our ability to use and expand our drug delivery technology ("N-Tab™")to additional product candidates;
- 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 competitive position with respect to other products on the market or in development for the treatment of osteoporosis, hypoparathyroidism, short bowel syndrome, obesity, metabolic conditions and other disease categories we pursue;
- Our ability to establish and maintain development and commercialization collaborations;
- Our ability to manufacture and supply enough material to support our clinical trials and any potential future commercial requirements;
- The size of any market we may target and the adoption of our product candidates, if approved, by physicians and patients;
- Our ability to obtain, maintain and protect our intellectual property and operate our business without infringing, misappropriating, or otherwise violating any intellectual property rights of others;
- Our ability to retain key personnel and recruit additional qualified personnel;
- Our ability to comply with laws and regulations that currently apply or become applicable to our business in Israel, the United States and internationally;
- Our ability to manage growth; and
- The duration and intensity of the ongoing Israel-Hamas War and its impact on our operations and workforce, including our research and development and clinical trials.

Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success;
- The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and third-party payors establish adequate coverage and reimbursement levels and pricing policies;
- Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue;

- If we are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be adversely affected;
- We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors;
- Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain;
- Our reliance on third parties to conduct our clinical trials and on third-party suppliers to supply or produce our product candidates;
- our interpretation of FDA feedback and guidance and how such guidance may impact our clinical development plan;
- our ability to use and expand our drug delivery technology to additional product candidates;
- 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 competitive position with respect to other products on the market or in development for the treatment of osteoporosis and hypoparathyroidism and other disease categories we pursue;
- our ability to establish and maintain development and commercialization collaborations;
- our ability to manufacture and supply enough material to support our clinical trials and any potential future commercial requirements;
- the size of any market we may target and the adoption of our product candidates, if approved, by physicians and patients;
- our ability to obtain, maintain and protect our intellectual property and operate our business without infringing misappropriating or otherwise violating any intellectual property rights of others;
- our ability to retain key personnel and recruit additional qualified personnel;

- the possibility that competing products or technologies may make any product candidates we may develop and commercialize or our oral delivery technology obsolete;
- our ability to comply with laws and regulations that currently apply or become applicable to our business in Israel, the United States and internationally; and
- our ability to manage growth.

All forward-looking statements contained in this Annual Report are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. Except as required by applicable law, we are under no duty, and expressly disclaim any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in any annual, quarterly or current reports that we may file with the Securities and Exchange Commission ("SEC").

We encourage you to read the discussion and analysis of our financial condition and our consolidated financial statements contained in this Annual Report. We also encourage you to read Item 1A of this Annual Report, entitled "Risk Factors," and Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operation-Liquidity and Capital Resources" of this Annual Report for additional discussion of the risks and uncertainties associated with our business. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

PART I

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the "Company," "Entera," "we," "our," and "us" refer to Entera Bio Ltd., an Israeli company, including its consolidated subsidiary.

ITEM 1 1. BUSINESS. BUSINESS

Overview

Entera is a clinical stage biopharmaceutical company and focused on developing first-in-class oral tablet formats of peptides or protein replacement therapies. We focus on underserved, chronic medical conditions for which oral administration of a leader in protein therapy has the development of orally delivered macromolecule therapeutics, including peptides and therapeutic proteins. potential to significantly shift a treatment paradigm.
Currently, most protein therapies are administered via frequent intravenous, subcutaneous or intramuscular injections. In chronic diseases where patients require persistent management, these cumbersome, often painful and high-priced injections can create a major treatment gap. Furthermore, from
From a technical standpoint, oral delivery of therapeutic proteins has historically been is challenging due to the enzymatic degradation within the gastrointestinal tract and poor absorption into the blood stream due to the protein's polarity and variable drug exposures. Entera's proprietary molecular weight. We leverage our N-Tab™ oral delivery technology, which is designed to deliver orally administered proteins simultaneously stabilize the peptide in the gastrointestinal tract and promote its absorption into the bloodstream.

Pipeline

The following chart summarizes the current stage of development for each of our oral peptide candidates.

Oral PTH(1-34) Programs

Our most advanced product candidate, EB613, oral PTH (1-34), is being developed as the first oral, osteoanabolic (bone building) once-daily tablet treatment for post-menopausal women with sufficient bioavailability low bone mineral density ("BMD") and high-risk osteoporosis with no prior fracture. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (pharmacodynamic/bone turnover biomarker) and secondary endpoints (BMD). Following the completion of a Type C and a Type D meeting with the U.S. Food and Drug Administration's (FDA), we announced the FDA's concurrence that a 2-year, placebo-controlled phase 3 (registrational) study with Total Hip BMD as primary endpoint could support a new drug application ("NDA") for EB613. In November 2023, we reported that the American Society for Bone and Mineral Research (ASBMR) announced that the SABRE (Strategy to meet treatment goals, using white mini tablets (around 6mm Advance BMD as a Regulatory Endpoint) project team had submitted its full qualification plan to the FDA for the use of BMD as a surrogate endpoint for fractures in diameter) future trials of new anti-osteoporosis drugs. We believe EB613 stands as the first program to potentially avail itself of the desired protein. ASBMR-SABRE BMD endpoint.

We strategically focus on underserved, chronic medical conditions whereThe EB612 program is being developed as the first oral administration of a mini PTH(1-34) tablet peptide replacement tablet therapy for hypoparathyroidism. With respect to our EB612 program, we are currently testing new generations of our N-Tab™ Technology with the naked PTH(1-34) peptide to assess the effectiveness of once or twice a day dosing regimens, as well as collaborating with a third party on another peptide replacement therapy has the potential to significantly shift a treatment paradigm. in this field.

We currently have two product candidates in the clinical stage of development: EB613 and EB612. Both candidates are first-in-class daily mini tablets of human parathyroid hormone (hPTH (1-34), teriparatide). To date, Entera's proprietary PTH tablets have been safely administered to a total of 72 102 healthy subjects in Phase 1 studies and 153 patients across in Phase 2 studies in osteoporosis and hypoparathyroidism, two diseases that remain underserved with the current standard of care and which disproportionately affect women. In addition to these product candidates, we have various internal early stage research programs in other approved peptides such as GLP-2 and hGH, as well as outside early stage collaborations to potentially diversify our revenue stream.

Pipeline

The following chart summarizes the current stage of development of each of our current product candidates and their potential indications.

Our Product Candidates

The following table summarizes our clinical stage product candidates. We retain global rights to both EB613 and EB612.

Program	Indication	Stage	Status
EB613 **Oral PTH Tablets**	**Osteoporosis**	**Phase 3**	Phase 2 Trial Completed (Q2 2021) End-of-Phase 2 Meeting with FDA (December 2021) Type C Meeting with FDA (October 2022) Type D Meeting with FDA (March 2023E) Phase 3 Registrational Study Initiation (H2'2023E)
EB612 **Oral PTH Tablets**	**Hypoparathyroidism**	**Phase 1**	Phase 2A Old Formulation (2015) Phase 2b Old Formulation PK/PD vs. Natpara (2019) Phase 1 PK Study of New Formulation Initiation H1'2023E

Our lead product candidates, EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism are first-in-class mini tablet formulations of synthetic human PTH (1-34) (teriparatide), designed to have differing pharmacokinetic, or PK, profiles. We believe these product candidates, if approved, have hold the potential to become standards of care for patients with osteoporosis and hypoparathyroidism.

Additionally, givenOur ability to deliver our expertise oral PTH(1-34) peptide in a simple mini tablet format with reproduceable, dose dependent pharmacokinetics and rapid biological responses across gender, age, and health status was highlighted as part of two poster sessions at the ASBMR 2023 Annual Meeting. We believe our work to date has built the foundation for our oral PTH we may investigate (1-34) tablets to potentially treat diverse patient populations, including younger men and women athletes at risk of stress fractures. We are exploring the efficacy use of alternative oral PTH our PTH(1-34) tablets for the treatment of delayed-union or non-union stress fractures independently or in collaboration athletes and expect to collaborate with a strategic partner. Currently, no pharmacological treatments an investigator sponsored study in this area. More details on this study are approved to 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 expected in the treatment second half of such fractures by potentially accelerating union and/or reduce the risk of non-union. 2024.

Oral GLP-2 and Oral GLP-1/Glucagon Programs in Collaboration with OPKO Biologics

In May 2023, the results from our oral GLP-2 program were published in the International Journal of Peptide Research and Therapeutics, "Oral Delivery Technology Enabling Gastro-Mucosal Absorption of Glucagon-Like-Peptide-2 Analog (Teduglutide) - A Novel Approach for Injection-Free Treatment of Short Bowel Syndrome." We believe GLP-2 represents a strong candidate for our N-Tab™ Technology and warrants further development as an injection-free alternative to patients suffering from short bowel syndrome and other gastrointestinal disorders where GLP-2 plays a role.

In September 2023, we entered into a research collaboration agreement with OPKO Biologics, Inc., a subsidiary of OPKO Health, Inc. (“OPKO”). Under the terms of this agreement, OPKO has agreed to supply its proprietary long-acting GLP-2 peptide and certain Oxyntomodulin analogs for the development of oral tablet formulations using our proprietary N-Tab™ technology.

Oxyntomodulin (OXM) is a naturally occurring peptide hormone found in the colon, with glucagon-like-peptide 1 (GLP-1) and glucagon dual agonist activity which suppresses appetite and induces weight loss. OPKO has developed several proprietary, modified OXM analogs as potential candidates for treating obesity, including an injectable pegylated peptide which demonstrated significant reductions in weight loss and decreased plasma triglyceride levels in over 430 patients in phase 2/2B studies.

We expect in vivo PK/PD data from both the oral GLP-2 tablet program and the oral OXM tablet program in 2024. We and OPKO have each agreed to be responsible for specific phases of development of the two oral peptides to the point of demonstrated *in vivo* feasibility.

Our Strategy

Our goal is to develop first-in-class orally delivered therapies for underserved, chronic medical conditions where for which a mini tablet peptide or peptide replacement therapy has the potential to significantly shift a treatment paradigm. We are developing our product candidates to potentially become the first oral, daily mini tablet peptide or peptide replacement therapies designed for patients to live injection-free as they actively manage their chronic diseases. We aspire to continue to validate our platform across a variety of additional high value therapeutic proteins. Our strategy to achieve these goals includes:

- **Advancing EB613, Potentially the First Daily Anabolic PTH Mini PTH(1-34) Tablet into Phase 3 for the Treatment of Post-Menopausal Women with Low Bone Mass and Osteoporosis: Osteoporosis**: Our six-month placebo-controlled Phase 2 double-blind, dose-ranging trial of EB613 in 118 161 patients with low bone mass and osteoporosis met both primary and secondary endpoints and was selected for oral presentation at the American Society of Bone Mineral Research (ASBMR) annual conference in 2021. Based on the outcome of our October 2022 Type C meeting with the FDA, we believe that EB613 may be the first osteoporosis program to be permitted by FDA to pursue a placebo controlled, bone mineral density (“BMD”) BMD endpoint registrational Phase 3 study to support a potential new drug application (“NDA”) pursuant to the FDA’s pathway under section 505(b)2 of the U.S. Federal Food, Drug, and Cosmetic Act. NDA. We view this outcome as testament to the treatment gap and unmet need for a viable alternative to treat the millions of osteoporosis patients who, despite current guidelines and availability of highly efficacious anabolic agents, are unwilling to take daily or monthly injections. We are planning preparing to enable initiate a Phase 3 registrational study initiation for EB613 pursuant to the FDA’s qualification of a quantitative BMD endpoint which is expected to occur in the second half of 2023. 2024.

- **Advancing the New Formulation of EB612 Through Clinical Development as the First Daily PTH Mini PTH(1-34) Peptide Replacement Tablet Therapy for the Treatment of Hypoparathyroidism:** In 2015, we successfully completed a Phase 2a four-month trial in 19 patients with hypoparathyroidism which demonstrated clinical benefit, including a statistically significant reduction in calcium supplementation, maintenance of calcium levels above the lower target level for Hypoparathyroidism patients (>7.5 mg/dL) throughout the study and statistically significant rapid decline of in median serum phosphate levels two hours following the first dose, which was maintained for the duration of the study. We expect to carry out a PK Phase 1 study for the new formulation of EB612 in the first half of 2023. The FDA and the European Medicines Agency, or EMA, have granted EB612 orphan drug designation for the treatment of hypoparathyroidism. With respect to our EB612 program, we are currently testing new generations of our N-Tab™ Technology with the naked PTH(1-34) peptide to assess the effectiveness of once or twice a day dosing regimens as well as collaborating with a third party on another peptide in this field.

- **Establishing Select Global and Regional Development and Commercial Partnerships: Partnerships**: Our technology N-Tab™ Technology platform and intellectual property are designed to generate a pipeline of product candidates across various therapeutic indications. We intend to explore opportunities to diversify and shorten the preclinical and clinical development of these candidates in a capital-efficient manner, including selectively pursuing research and clinical development partnerships with biopharmaceutical companies with specific domain expertise as well as with biopharmaceutical companies with proven commercial footprints to de-risk our late-stage programs.

- **Identifying and Developing Additional Products Internally based on FDA-Approved Injectable Protein Therapeutics: Potentially High Value Oral Peptides in Collaboration with Strategic Partners such as our GLP-2 and Oxyntomodulin Programs:** We intend to leverage our technology N-Tab™ Technology platform by applying it to the development of additional, currently approved injectable peptides and therapeutic proteins with known mechanisms of action and established safety profiles. We believe this will allow us to advance our product candidates more efficiently and predictably through the research and clinical development cycle. For example, in collaboration with OPKO, we are focusing on the development of the first oral OXM, a dual targeted GLP1/glucagon peptide, in tablet form for the treatment of obesity and the first oral GLP-2 peptide tablet as an injection-free alternative for patients suffering from rare malabsorption conditions, such as short bowel syndrome. Both these peptides have well characterized pre-clinical PK/PD and toxicology.

PTH

Parathyroid hormone (PTH) is an 84-amino acid hormone that regulates calcium and phosphate homeostasis and bone metabolism in the body. In healthy individuals, PTH is generally produced at very low basal levels, at a blood concentration of 15 - 25 pg/mL. On top of the basal PTH levels, there are physiological pulses two to three times per day that result in transient increases in PTH levels reaching up to 65 pg/mL. The changes in PTH secretion are in response to ionized calcium concentrations in the blood resulting from the entry of calcium from nutrients in the intestine and resorption of calcium from bone.

PTH in Osteoporosis

The effects of PTH on bone depends on the duration of exposure. The physiological pulses help encourage bone turnover through activation of both osteoblasts and osteoclasts, the two main types of cells responsible for bone remodeling. In the absence of adequate parathyroid function producing these pulses, it is difficult for the body to regulate homeostatic processes, and osteoporosis may ensue. The synthetic analog of PTH, human parathyroid hormone (1-34) peptide, Forteoâ® (teriparatide), has been approved in the

United States and the EU (Forsteo®) and has been a mainstay anabolic (bone forming) therapy for the treatment of osteoporosis patients since 2002 and 2003, respectively. Forteo® requires a daily subcutaneous injection.

EB613: First Daily Osteoanabolic Mini Tablets for the Treatment of Osteoporosis

EB613 is the first once daily mini tablet formulation of hPTH (1-34), (teriparatide) and has the same amino acid sequence as Forteoâ® (teriparatide daily subcutaneous injection), a leading anabolic agent which achieved peak annual sales of $1.7 billion prior to patent expiration.

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, which leads to greater fragility of bones and an increase in fracture risk. Osteoporosis is most frequently associated with menopause in women, aging in both women and men and glucocorticoid steroid use (greater than three months). The bone remodeling cycle can be separated into two distinct processes: (i) bone resorption, where cells called osteoclasts function in the resorption of mineralized tissue; and (ii) bone formation, where cells called osteoblasts are responsible for bone matrix synthesis and subsequent mineralization of the bone. In healthy individuals, bone resorption is matched by new bone formation. Osteoporosis develops as the 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.

Prevalence

The Bone Health & Osteoporosis Foundation (formerly named the National Osteoporosis Foundation) estimates that 10.2 million approximately 10 million Americans have osteoporosis and that an additional 40 million 44 million have low bone mass. More than two million osteoporosis-related fractures occur annually in the United States, and more than 70% of these occur in women. In U.S. women 55 years of age and older, the hospitalization burden, including hospital costs of osteoporotic fractures, is greater than that of myocardial infarction, stroke, or breast cancer. Furthermore, it estimated 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 to 6 million. The IOF estimates that, in Europe alone, the annual cost of osteoporotic fractures could surpass €76 billion by 2050.

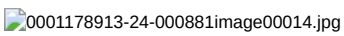
Current Osteoporosis Treatment Paradigm

The goal of pharmacological treatment of osteoporosis is to maintain or increase bone mass and strength and to prevent fractures throughout a patient's life. Ensuring that nutrients important to bone health is vital to the prevention and treatment of osteoporosis, and calcium and vitamin D3 supplements are often required to achieve that goal. However, many patients with osteoporosis require prescription drug therapy to reduce their risks of fractures. It is critical to identify patients who have significant bone loss. Pharmacologic therapy is strongly recommended for patients with a BMD T-score of -2.5 or lower in the spine, femoral neck, total hip, or 1/3 radius.

OsteoporosisCurrent osteoporosis drugs may be divided into two categories: antiresorptive and anabolic. Drugs that inhibit bone resorption (or bone degradation) include oral and injectable options such as estrogen (for postmenopausal women), oral and intravenous bisphosphonates, selective estrogen receptor modulators (SERMs), the RANK-ligand inhibitor (denosumab) and (salmon) calcitonin. According to the American Association of Clinical Endocrinology (AACE) 2020 Guidelines, injectable anabolic agents, such as teriparatide, abaloparatide or romosozumab, can be considered as an initial therapy for patients who are at very high fracture risk (which include women who have had multiple vertebral fractures or hip fractures and high-risk patients who have very low T-scores), and who have had an inadequate response to antiresorptive therapies. For patients undergoing treatment, stable or increasing BMD at the spine and hip indicates a satisfactory response. The three currently approved osteoanabolic drugs that stimulate bone formation all require daily or monthly subcutaneous injections: teriparatide (hPTH[1-34]); abaloparatide (a PTH-related protein analog); and romosozumab (an antibody that inhibits sclerostin and also inhibits bone resorption). It is estimated that less than 10% of currently treated osteoporosis patients agree to injectable osteoanabolic treatment despite guideline recommendations, their efficacy versus the anti-resorptives and the approval of lower cost generics.
There are currently no FDA-approved oral anabolic treatments for osteoporosis. EB613 is positioned to potentially be the first, once daily osteoanabolic mini tablet treatment for women with high-risk post-menopausal osteoporosis and no prior fractures.

One substantial limitation of currently approved anabolic therapies is that osteoporotic patients often report that the injections are inconvenient and occasionally painful. Many are unwilling to use injections even when their physicians recommend it. In a recent review of bone anabolic drugs, the need for subcutaneous administration was cited as a major reason for why anabolic medications are not a first-line treatment choice for osteoporosis. Thus, we believe that there is a substantial need for a more generally acceptable oral anabolic alternative with bioavailability adequate to produce therapeutic effects 

Classification and Guidelines



According to the AACE 2020 Guidelines, injectable anabolic agents, such as teriparatide, abaloparatide or romosozumab, can be considered as initial therapy for patients who are at very high fracture risk (which include women who have had multiple vertebral fractures or hip fractures and high risk patients who have very low T-scores), and who have had an inadequate response to antiresorptive therapies. For patients undergoing treatment, stable or increasing BMD at the spine and hip indicates a satisfactory response. If BMD decreases significantly, patients should be evaluated for noncompliance, among other factors.

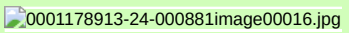
In July 2022, we engaged a third-party firm to conduct primary market research with endocrinologist and general practice clinicians who treat osteoporosis patients and to analyze prescription and sales data for osteoporosis treatments. According to IQVIA, reported sales and qualitative surveys, it is estimated that less than 10% of osteoporosis patients use current anabolic drugs (including the injectable PTH receptor activators currently available).

Phase 1 Safety, PK and PD Data for Entera Oral PTH(1-34) Tablet Programs

Our Oral PTH Tablet Programs

Our Oral PTH (1-34) formulations, including EB613 and EB612, have been administered collectively to a total of 72 102 healthy subjects in two three Phase 1 studies. In an ongoing phase 1 study evaluating the first Phase 1a study of 42 current EB613 formulation, Forteo and new formulations for EB613 and EB612, 30 healthy subjects escalating single have been administered various doses (PTH (1-34) 1.5 mg – 2.5 mg) tablets and regimens (QD or BID) of oral PTH tablets containing up to 1.8 mg of hPTH(1-34) were well tolerated. There were no serious in the first two cohorts completed in 2023. No drug-related severe adverse events (SAEs) reported. In the subsequent Phase 1b study were reported, and four subjects reported four mild adverse events (AEs) of 30 healthy subjects, single doses of five formulations of oral PTH tablets containing up to 3 mg of hPTH(1-34), administered collectively a total of 280 times (up to 14 times per person) were well tolerated, with no SAEs reported. Adverse events considered by the investigator as possibly or probably drug-related were all transient and mild and included mild hypercalcemia (calcium of 2.56, 2.62 mmol/L, both levels went back to normal within one hour) (N=2), mild tachycardia (N=3), headache (N=2), nausea (N=1), anemia palpitation (N=1), and mild knee cramp headache (N=1) 2). These AEs are consistent with those reported with injectable PTH analogs.

In the Phase 1 studies, in healthy subjects, the PK profile of EB613 daily tablets was characterized by a rapid increase in plasma hPTH(1-34) levels, with peak concentrations of the drug observed within 30 minutes after dose, with and a rapid decline thereafter. The blood half-life of hPTH(1-34) in humans is less than five minutes (see Forteo® USPI). Due to this very short elimination time and a short absorption phase, hPTH(1-34) hPTH(1-34) levels decrease below limit of quantitation within two hours after the 0.5 mg x3 dose (1.5 mg hPTH[1-34]) thus drug administration. As a result, no drug accumulation is expected with once daily tablet dosing. Total systemic exposure (AUC) following the administration of three 0.5 mg EB613 daily tablets (as were tested in Phase 2) was similar to that of a 0.02 mg subcutaneous injection of Forteo®.



EB613 Phase 2 Study in Post-Menopausal Women with Low Bone Mass and Osteoporosis

The Phase 2 clinical trial of EB613 was a dose-ranging, placebo-controlled, double-blind study in 161 postmenopausal women with osteoporosis or low BMD conducted at four leading medical centers in Israel. The trial evaluated 0.5 mg to 2.5 mg daily tablets on BMD, pharmacodynamic bone markers, including P1NP and Osteocalcin - bone Osteocalcin-bone formation markers, CTX - a bone resorption marker, and various safety endpoints. The initial treatment regimen included a top dose of 1.5 mg.

A planned limited interim analysis of the first 80 patients indicated that a dose higher than 1.5 mg could produce greater effects on bone formation. A 2.5 mg dose was added, and enrollment of new patients in the 0.5 and 1.0 mg groups was ended. After orthostasis, an adverse event (AE), typical across PTH receptor activating agents, was observed in patients initiating the constant 2.5 mg dose, the protocol was subsequently amended to introduce a titration regimen whereby patients received 1.5 mg for one month, 2.0 mg for the next month and 2.5 mg during the remaining four months. There were no reported drug-related SAEs. All adverse events were mild or moderate in intensity.*Safety*

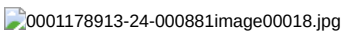
Safety

The most common drug-related adverse events associated with the discontinuation of the Phase 2 clinical study's medication AEs reported were headache, nausea, dizziness and presyncope. There were no treatment emergent hypercalcemia adverse events, and serial serum chemistry evaluations found no increase in group mean calcium or changes in calcium exceeding predefined limits in patients treated with EB613 2.5 mg daily tablets. Only one subject in the EB613 2.5 mg titrated group did not tolerate 2.5 mg but continued in the study and was asymptomatic with a reduced 1.5 mg dose.

There were no reported drug-related SAEs. All adverse events were mild or moderate in intensity.

Bone Biomarkers (PD Effect)

The primary bone biomarker endpoint of the Phase 2 clinical study—change in P1NP at Month 3—was met. Statistically significant increases were observed in P1NP (key anabolic marker) at Month 1 ($p<0.001$), Month 2 ($p<0.005$) and Month 3 ($p<0.05$) for the 2.5 mg EB613 dose group. Similar to the increase in P1NP, a significant increase in Osteocalcin was also observed in the 2.5 mg group after 3 months ($P <0.01$). A statistically significant decrease also occurred in Serum CTX (marker of resorption) from baseline to Month 6 ($p<0.01$).

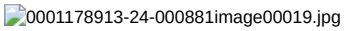


The decrease in bone resorption (CTX) resulting from EB613 daily tablets was unanticipated based on historical results from subcutaneously daily injectable PTH, Forteo®; however, we believe that this was and indicates a potentially positive development, reflecting potential dual mechanism of action for the EB613 PTH (1-34) tablets which seems to induce bone formation and decrease bone resorption, with a lower rate of bone turnover. The finding of no increase in P1NP after three months and decreased bone resorption that persists through six months may indicate that the "anabolic window" remains open after six months of treatment with EB613. Clinical trials have shown that early changes in biomarkers of bone formation and resorption are associated with long-term BMD changes in women taking antiresorptive or anabolic drugs. Furthermore, significant dose response was observed for 0.5, 1.0, 1.5 and 2.5 mg of EB613 on P1NP, Osteocalcin.

Bone Mineral Density

Dose-related changes in BMD were also observed at the total hip (TH), femoral neck (FN) and lumbar spine (LS) locations with a linear regression showing a statistically significant dose response at all sites; TH (p=0.008), FN (p=0.001), and LS (p<0.0001).

The placebo-adjusted increases in TH BMD (1.84%) and FN BMD (2.76%) for the pooled (titrated and non-titrated) 2.5 mg EB613 daily tablets were both statistically significant (P<0.02 and P<0.002, respectively). The increases in proximal femoral BMD (TH and FN) after six months of EB613 daily tablet treatment were unanticipated given that the reported subcutaneous Forteo® injection increases are typically small and not significant (TH 0.1% and FN 0.3% p=NS (Leder, 2015) at six months. The placebo-adjusted increase in LS BMD was 3.78% in the EB613 2.5 mg non-titrated dose group. This increase compares to the 3.9% placebo-adjusted increase versus placebo seen in a previously reported study (Leder, 2015). Increases in TH (2.07%) and FN (2.92%) BMD in the 2.5 mg EB613 daily tablet titrated group were greater than those previously reported with Forteo® at six months (0.1% and 0.3%) (Leder, 2015).
The increases in proximal femoral BMD (TH and FN) and cortical bone after six months of EB613 daily tablet treatment were unanticipated given that the reported subcutaneous Forteo® injection increases are typically small and not significant at six months.



The results of the Phase 2 study supported the selection of the 2.5 mg dose with a titration regimen to be used in the proposed pivotal Phase 3 study of EB613.

FDA End of Phase 2 Meeting Meetings (EOP2) and Phase 3 Plans

After successful completion of the Phase 2 dose ranging study of EB613, we held an end-of-Phase 2 meeting at the end of 2021 with the FDA to discuss various aspects of our nonclinical and clinical development plan. The meeting focused on the potential use of BMD, rather than fracture incidence, as the primary endpoint, and a 12-month non-inferiority head-to-head study versus Forteo® phase 3 study design to support an NDA under the 505(b)2 (2) regulatory pathway.

Early in the first quarter of 2022, Entera received EOP2 minutes from the FDA, suggesting that a non-inferiority head-to-head study versus Forteo® Phase 3 design may not be favorable to the success of the study and potential approvability of EB613 oral PTH tablets. The agency also commented on a possible exploration of a placebo controlled phase 3 study and a potential Total Hip (TH) BMD endpoint given recently published 24-month Surrogate Threshold Effects (STEs) that are considered associated with fracture risk reduction .
We subsequently requested an additional EOP2 to meeting with the FDA to seek agreement on the specifications and control of the drug substance, drug product and excipients to support the Phase 3 study and eventual product registration. The meeting request was granted, and we received a written response from the FDA towards the end of the first quarter of 2022, confirming that the specifications for the drug substance, excipients and drug product appear reasonable and that final determination on the adequacy of the proposed excipients and drug product specification will be made during the NDA review. The FDA also provided guidance regarding the proposed process scale-up, process qualification approach and stability plan for EB613.

Early in the first quarter of 2022, Entera received additional EOP2 minutes from the FDA, suggesting that a non-inferiority head-to-head study versus Forteo® Phase 3 design may not be favorable to the success of the study and potential approvability of EB613 oral PTH tablets given EB613's different PK profile, PD (biomarker) profile and BMD outcomes from the phase 2. The FDA also commented on a possible exploration of a placebo controlled phase 3 study and a potential Total Hip (TH) BMD endpoint given recently published 24-month Surrogate Threshold Effects (STEs) that are considered associated with fracture risk reduction.
About ASBMR-FNIH SABRE
Initiated in 2013, the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium Bone Quality Project assembled data from more than 150,000 participants across more than 50 clinical trials of anti-osteoporosis drugs. The project team re-evaluated these existing data to understand which measurements could predict the ability of the treatment to reduce fractures. The study findings identified an increase in BMD, as measured by a low-dose X-ray imaging technique, as a strong predictor of the extent to which treatments reduce fracture risk. A change in BMD could therefore be used in future clinical trials to determine the effectiveness of osteoporosis drugs. Through a partnership with ASBMR, the FNIH extended and continues to support the original study, renamed SABRE, to seek FDA approval for the surrogate biomarker as a replacement to fracture outcomes.

FDA Type C Meeting

In July 2022, we announced that the FDA had granted our request for a Type C meeting based on the revised phase 3 registrational study plan for EB613. In October 2022, we announced the successful conclusion of our Type C meeting with the FDA and the FDA's agreement that a single Phase 3 placebo-controlled study with a BMD endpoint could support a NDA submission of EB613 oral PTH tablets under the 505(b)(2) regulatory pathway.
tablets. The FDA also agreed (i) that TH BMD could serve as the primary endpoint for the registrational study of EB613 in post-menopausal women patients diagnosed with osteoporosis, (ii) with the proposed 2:1 randomization (EB613 vs. placebo) design and (iii) that 400 patients exposed to EB613 would be sufficient to support both the safety and efficacy assessments for the NDA. Furthermore, the FDA agreed with our proposed enrollment of post-menopausal women diagnosed with osteoporosis based on a BMD T-score of ≤-2.5 to -3.0 and no major fracture history. This patient population is consistent with that studied during our Phase 2 six-month dose ranging study of EB613, which met all primary and key secondary endpoints of biochemistry and BMD. Finally, we agreed to submit relative PK data, comparing EB613 versus the subcutaneous injection of teriparatide, Forteo® to support a NDA under the 505(b)2 regulatory pathway.

FDA Type D Meeting

In February 2023, we announced that a Type D meeting protocol review had been accepted by the FDA to provide responses by March 30th, 2023. The pivotal, Phase 3 study protocol is entitled “A 24-Month Phase 3, Randomized, Double-Blind, Global Multicenter Study Comparing the Effects of Oral hPTH(1-34) (EBP05[EB613]) Daily Tablets vs. Placebo on Bone Mineral Density (BMD) in Postmenopausal Women with Osteoporosis.” The objective of the Type D meeting review is was to confirm that the protocol fully meets met the FDA's expectations, including the analysis of the primary endpoint and the population PK evaluations, ahead of potential initiation of the Phase 3 study in the second half of 2023. study.

In April 2023, we reported that the FDA would not be opposed to Entera initiating the Phase 3 study under the proposed FNIH BQP pathway and that the Company’s proposed PK sampling scheme seemed reasonable. On the same day, we announced that we plan to continue our dialogue with the FDA and await the final qualification of the ASBMR-FNIH SABRE BQP criteria and their guidance on the statistical evaluation of our BMD endpoint before initiating a Phase 3 study for EB613.
In November 2023, we announced that the SABRE project team has submitted to the FDA its full qualification plan to use the treatment-related change in BMD as a surrogate endpoint for fractures in future trials of new anti-osteoporosis drugs.
BMD is the first surrogate endpoint undergoing qualification by the FDA under the 21st Century Cures Act which was signed into law on December 13, 2016, to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently. An update on the qualification of this endpoint is expected in 2024.

EB612: First Daily PTH Replacement Therapy Tablets for the Treatment of Hypoparathyroidism

Hypoparathyroidism is a rare condition in which the body either fails to produce sufficient amounts of PTH or the PTH produced lacks normal biologic activity. Individuals with a deficiency of parathyroid hormone may exhibit hypocalcemia and hyperphosphatemia. Hypocalcemia can cause weakness, muscle cramps, excessive nervousness, headaches and uncontrollable twitching and tetany. Hyperphosphatemia can result in soft tissue calcium deposition, which may lead to severe issues, including damage to the circulatory and central nervous systems. The most common cause of hypoparathyroidism is damage to, or removal of, the parathyroid glands due to surgery for another condition.

PTH in Hypoparathyroidism

In contrast to osteoporosis, longer persistence of PTH in plasma is a desirable property for the treatment of hypoparathyroidism. Here, hormone replacement therapy is warranted.

Prevalence

It is estimated that hypoparathyroidism affects approximately 200,000 people across the United States, the European Union and Japan, with approximately 43% of cases characterized as mild, 39% characterized as moderate, and 18% characterized as severe.

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 can result in many serious side effects. 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-dihydroxy vitamin D, the active hormone derived from vitamin D. Drugs like calcitriol and alfacalcitol must often 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 many years of treatment, kidney stones may develop, and kidney failure may ultimately occur due to either kidney stones or deposition of calcium phosphate in kidney tissue (called nephrocalcinosis). Despite the use of calcium and vitamin D supplements and other medications, many patients with hypoparathyroidism continue to experience physical and cognitive symptoms.

An injectable form of full length human PTH (1-84) marketed under the name Natpara®, was approved for the treatment of hypoparathyroidism in 2015. However, it was recalled in 2019 due to a plastic particulate and will be permanently phased out globally by the end of 2024. There are two injectable PTH candidates for hypoparathyroidism undergoing late-stage clinical development: TransCon™ PTH, developed by Ascendis Pharma (PDUFA date of April 30, 2023, for adults with hypoparathyroidism; European MAA decision expected in the fourth quarter of 2023) and Eneboparatide, a parathyroid hormone receptor 1 (PTHR1) agonist, developed by Amolyt Pharma (Phase 3 initiation expected in the first half of 2023). Pharma. Both TransCon™ PTH and Eneboparatide eneboparatide require a daily subcutaneous injection.

EB612

Our product candidate for hypoparathyroidism, EB612, is the first oral formulation of PTH (1-34, teriparatide) hormone replacement treatment developed in a mini tablet form. The FDA and the EMA have granted EB612 orphan drug designation for the treatment of hypoparathyroidism. We believe that EB612 may have inherent advantages compared to injectable forms including convenience of administration without any special preparation of the medication, as well as convenience of storage (room temperature or refrigeration for because this is a protein replacement therapy requiring long term storage). use, and we believe that patients have a preference for oral medication, and our tablets may enable more flexibility for titration and more individualized treatment.

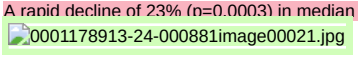
Phase 2a Clinical Trial

In 2015, we successfully completed a multicenter Phase 2a clinical trial of EB612 in hypoparathyroidism patients. This study demonstrated the safety and tolerability of EB612 administered four times daily for 16 weeks to patients with hypoparathyroidism. In this study, patients were titrated up to a maximum of 12 EB612 0.75 mg tablets a day (total daily dose of 9 mg) according to each subject’s albumin-adjusted serum calcium (ACa), and supplement treatment regimen. Of the 19 enrolled patients, 17 completed the trial. No drug-

related serious adverse events were reported and most of the adverse events were not considered study drug-related. The study achieved its primary and secondary endpoints, including a reduction in calcium supplements, reductions in serum phosphate and 24-hour urine calcium excretion, maintenance of ACa within the reference range, and an improvement in quality of life. Specific results of this trial included:

A significant reduction of 42% (p=0.001) from baseline in median calcium supplement use;

- Maintenance of median ACa levels above the lower target level for HypoPT patients (>7.5 mg/dL) throughout the study;
- A rapid decline of 23% (p=0.0003) in median serum phosphate levels 2 hours following the first dose that was maintained within the normal range for the duration of the study;



A notable median decrease of 21% (p=0.07) in 24-hour urine calcium excretion between the first and last treatment days; and

- An increase in quality of life score of 5% (p=0.03) from baseline by the end of the treatment period.

Phase 2 PK/PD Clinical Trial

We initiated a two-part Phase 2 PK/PD trial in 2014. This trial was designed to provide a bridge from one of our completed Phase 2a trials, which was conducted prior to the marketing approval of Natpara, and our planned future clinical trials, and to also allow us to better understand the relative strength and dose of our product as compared to the then marketed product, Natpara. The relevant endpoints for the PK/PD trial included an examination of levels of PTH (1-34), PTH (1-84) (Natpara), serum calcium, serum phosphate, urinary calcium and urinary phosphate.

In November 2018, we announced the completion of part I of this Phase 2 PK/PD trial which showed (i) an increase in the serum calcium by an average of approximately 0.3 mg/dL over baseline, with such increase maintained over a 24-hour period; (ii) a decrease in serum phosphate by an average of 0.5 mg/dL below baseline with such decrease maintained over a 24-hour period; (iii) an increase in average levels of serum active vitamin D of approximately 90% on the day of treatment as compared to baseline; and (iv) a decrease in average levels of 24-hour urinary calcium of approximately 30% on the day of treatment as compared to baseline. The concentration of PTH (1-34) in blood after administration of Oral PTH (1-34) in the trial was sufficient to produce the observed pharmacodynamic effects and did not induce hypercalcemia. No serious adverse events were reported.

The second part of the PK/PD trial evaluated a variety of dosing treatment regimens with a high and low dose of EB612 as well as Natpara with patients also receiving calcium supplements and either alfacalcidol or calcitriol. There were no treatment-emergent adverse events of hypercalcemia, as well as no treatment-emergent serious adverse events reported in the trial. In September 2019, we presented the results of Part 2 at the American Society for Bone and Mineral Research (ASBMR) Annual Meeting.

Planned Additional Clinical Development and Regulatory Pathway

We have since developed an improved formulation of EB612 based on new intellectual property of our N-Tab™ Technology, which we have designed to optimize its PK profile and the potential for reduced daily dosing. We expect to carry out initiated a PK study in May 2023, which is testing various potential drug candidates based on our new platform, including several which could be developed for the new formulation treatment of EB612 in the first half of 2023. We anticipate that the outcome of the PK study will help determine the design of hypoparathyroidism. Additionally, we are also collaborating with a Phase 2/3 trial of EB612 in patients third party to combine our N-Tab™ Technology with hypoparathyroidism. If successful, the phase 2/3 clinical trial of EB612 in hypoparathyroidism may potentially support a submission another peptide for regulatory approval of EB612.

Our Technology

We are focused on the development and commercialization of product candidates that leverage our proprietary platform technology for the oral delivery of large molecule therapeutics, including peptides and therapeutic proteins. Historically, peptides, proteins and other large molecule therapeutics have typically been delivered via frequent and often painful injections 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.

Our proprietary technology is designed to address both 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. 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 select protease inhibitors and other excipients that act by specifically inhibiting several gastrointestinal enzymes designed to assist in the degradation and digestion of proteins without interfering with normal gastrointestinal activity. hypoparathyroidism.

Development and License Agreements

Intellectual Property

In addition to the development of our product candidates, we have an early stage research collaboration and license agreement with Amgen, Inc. (“Amgen”) centered on combining our proprietary drug delivery platform with drugs selected by Amgen to create new products. In January 2019, we received a non-refundable and non-creditable initial technology access fee of $725,000 from Amgen, of which $500,000 was attributed to the right to use our intellectual property, and $225,000 was attributed to the pre-clinical R&D services that we are obligated to perform under the agreement. We are eligible to receive from Amgen aggregate payments of up to $270 million upon achievement of various clinical and commercial milestones or at Amgen’s exercise of options to select up to two additional programs to include in the collaboration, as well as tiered royalty payments. Through December 31, 2022, we had received an aggregate of $968,000 from Amgen for research and development services.

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 preventing others from infringing on our proprietary rights. We seek to protect our proprietary position by, among other methods, seeking patent protection in the United States and in certain other jurisdictions for our product candidates and other technology that we consider important to the development of our business, where such

protection is available. We believe that our success will depend in part on our ability to obtain patent protection for our intellectual property. We also intend to rely on trade secret protection, know-how and the exploitation of in-licensing opportunities to develop our proprietary position.

Patent Rights

As of March 27, 2023 March 1, 2024, 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, Hong Kong, Israel, Canada, New Zealand and Russia and have been granted by the European Patent Office (EPO) and validated accordingly in Belgium, France, Germany, Great Britain, Ireland, Italy, Liechtenstein, Luxembourg, Netherlands, Spain, Sweden, and Switzerland. Related patent applications are pending before the European Patent Office (EPO) and in the United States, Hong Kong, Brazil China and India. Patents specifically covering PTH have already been granted in the United States, Hong Kong, Israel, Australia, Russia and Japan, and have been granted by the EPO and validated in Belgium, France, Germany, Great Britain, Ireland, Italy, Liechtenstein, Luxembourg, Netherlands, Spain, Sweden, and Switzerland. In addition, patent applications which specifically cover PTH are currently pending in Hong Kong, Brazil China and India. The current issued patent in China is limited to insulin. This issued patent and any patent 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.

Three patent families filed in various jurisdictions, which we believe, if issued as patents containing substantially the same claims as those in the applications, would cover certain oral administration technologies. 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. Patent applications covering certain formulations with a controlled absorption profile were filed with the EPO and in the United States, Canada, Hong Kong, Israel and Mexico (the application filed in Israel has matured into a patent and a divisional application has been filed therein). Other patent applications covering certain formulations for co-administration and/or co-formulation with an antacid and/or protease inhibitor were filed with the EPO and in the United States, Canada and Hong Kong (the application in the United States has matured into a patent, and a divisional application has been filed therein). Any patents that issue from these patent applications are expected to expire in February 2036, assuming all annuity and maintenance payments are paid thereon. Patent applications covering certain formulations and regimens were filed with the EPO and in the United States, Australia, Brazil, Canada, China, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Singapore, South Africa and South Korea (the application applications filed in New Zealand has and India have matured into a patent) patent; the application filed in Israel has recently been allowed). Any patents that issue from this patent application are expected to expire in August 2037, assuming all annuity and maintenance payments are paid thereon.

Three patent families were 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 (filed with the EPO and in the United States, Canada, China, Hong Kong, Israel and Japan; the applications in Japan, Canada, China and Israel have matured into patents, and a divisional applications has have been filed therein) in Japan, Israel and China), hypoparathyroidism (filed with the EPO and in the United States, Brazil, Canada, Hong Kong, Israel and Japan; the applications in Japan, Brazil and Israel have matured into patents and divisional applications have been filed therein) and bone fractures and related conditions (filed with the EPO and in the United States, Canada and Hong Kong). Any patents that issue from these patent applications are expected to expire in February 2036, assuming all annuity and maintenance payments are paid thereon, and while not considering patent term extension when applicable.

Seven international PCT patent applications have been were filed in February 2023, which we believe, if issued as patents containing substantially the same claims as those in the applications, would cover new discoveries for the oral delivery of large molecules. Any patents that issue from these patent applications are expected to expire in February 2043, assuming all annuity and maintenance payments are paid thereon and while not considering patent term extension when applicable.

Two U.S. provisional patent applications have been filed in August 2023, which, if issued as patents containing substantially the same claims as those in the applications, we believe would cover additional new discoveries for the oral delivery of large molecules. Any patents that issue from these patent applications are expected to expire in August 2043, assuming all annuity and maintenance payments are paid thereon and while not considering patent term extension when applicable.

Two U.S. provisional patent applications have been filed in November 2023, which, if issued as patents containing substantially the same claims as those in the applications, we believe would cover features uncovered during the clinical studies conducted with EB613. Any patents that issue from these patent applications are expected to expire in November 2043, assuming all annuity and maintenance payments are paid thereon and while not considering patent term extension when applicable.

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 United States 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, 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 NDA for the product, plus the time between the submission date of the NDA 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 EU 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 (the "Board"), 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 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 1A.-Risk Factors-Risks Related to Our Intellectual Property."

Commercialization Strategy

We hold global rights to all of our internally developed product candidates (including EB613 and EB612), which provide us the optionality to grow our internal pipeline independently or license selected rights to our product candidates in different geographies or throughout the world. We aim to maximize the value of our product candidates by either independently commercializing our products in one or more major geographies by building an internal sales and marketing organization, or by seeking collaborations with third parties with commercialization infrastructure, in either case subject to applicable regulatory approval.

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 osteoporosis, hypoparathyroidism 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 osteoporosis, hypoparathyroidism 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 in relation to our oral drug delivery platform, N-Tab™, 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 1A.-Risk Factors-Risks Related to Commercialization of Our Product Candidates."

The Israeli Innovation Authority (IIA) 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 under Encouragement of Industrial Research, Development and Technological Innovation in Industry Law 5744-1984 and the Israeli research law, IIA regulations, which we refer to collectively as the Research Law. "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 EB613, EB612 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 up to six times the amount of the grant received plus interest. The rate of royalties may be accelerated, and the royalty liability may increase (up to three times the amount of the grant amount and the interest) if manufacturing of the products developed with the grant money is transferred outside of the State of Israel. As of December 31, 2022 December 31, 2023, the total royalty amount that would be payable by the Company to the IIA, before interest and payments as described above, is approximately $460 thousand. Through December 31, 2022 As of December 31, 2023, we had paid royalties to the IIA in the amount of $83 thousand $83,000 related to a collaboration agreement and other material transfer agreements ("MTAs").As of December 31, 2023, we owed $13,000 to the IIA. IIA, which was paid in February 2024.

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 "Manufacturing", we have signed a contract with a U.K.-based contract manufacturing organization to produce and supply tablets 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 Solutions Ltd. ("D.N.A Biomedical") and Oramed Ltd. ("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 at the time of the transaction in February 2011. 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 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 for and oral drug formulations to be used in clinical trials. The facility includes a dedicated Class D clean room for tablet production and a dedicated chemical synthesis room designed to meet ISO 8 specifications.

Our manufacturing activities include the chemical synthesis of one of our non-active but functional drug components in our facility. In addition, we have a contract with a contract manufacturing organization, to produce and supply tablets for trials performed worldwide, including formulation and production of the final drug, packaging, storage and distribution. The manufacturer's facility is an FDA/EMA inspected-GMP site and we expect future clinical studies with our oral PTH (1-34) tablets, as well as the potential commercial supply, if approved, will be provided by the same subcontractor. This contract is not exclusive and we may enter into additional contracts. Our QA/QC analytical laboratory performs part of the release and stability testing for PTH tablets manufactured by the contract manufacturing facility. In addition, our research and development team supports the manufacturing activities and develops/optimizes analytical methods used by the contract manufacturer in order to meet regulatory requirements for our clinical trials. 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.

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

Review and Approval of Drugs in the United States

In the United States, our product candidates are regulated by the FDA as drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, or the PHSA, and regulations implemented by the FDA. 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, customer notifications, product recalls, product seizures, refusal to grant export or import approval total or partial suspension of production or distribution, consent decrees, 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 new drug or 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 initial new drug, or IND, application for human clinical testing, which must become effective before human clinical trials may begin;

preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the FDA's Good Laboratory Practice regulations;

- approval by an independent review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product candidate for each proposed indication for use and conducted in accordance with Good Clinical Practice, or GCP, requirements;
- submission of data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- preparation and submission to the FDA of a New Drug Application, or an NDA, or Biologics License Application, or BLA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practice, or cGMP, standards and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the non-clinical and clinical trial sites to assure compliance with GCP requirements and the integrity of clinical data in support of the NDA or BLA;
- payment of user fees and securing FDA approval of the NDA or 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.

submission to the FDA of an initial new drug, or IND, application for human clinical testing, which must become effective before human clinical trials may begin;

- approval by an independent review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product candidate for each proposed indication for use and conducted in accordance with Good Clinical Practice, or GCP, requirements;
- submission of data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- preparation and submission to the FDA of a New Drug Application, or an NDA, or Biologics License Application, or BLA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practice, or cGMP, standards and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the non-clinical and clinical trial sites to assure compliance with GCP requirements and the integrity of clinical data in support of the NDA or BLA;
- payment of user fees and securing FDA approval of the NDA or 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 animal studies to evaluate the potential for efficacy and toxicity. 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 Investigational New Drug ("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 a proposed 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 GCP 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 NDA so long as the clinical trial is conducted in consistent with 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, where appropriate, the protection of privacy of the human subjects. An IRB must operate in compliance with the FDA regulations. The FDA, IRB, the clinical trial sponsor, or the principal investigator 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 and 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. For some products for severe or life-threatening diseases, especially if the product may be too toxic to administer to healthy humans, the initial clinical trials may be conducted in individuals having a specific disease for which use the tested product is indicated.

- *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 an NDA or 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 NDA or BLA approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional data from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs 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 an NDA or 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 able 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 regulatory bodies. 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 New Drug Application and Biologics 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 an NDA or a BLA requesting approval to market the product. The NDA or 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.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA or BLA must be accompanied by a user fee, which the FDA adjusts on an annual basis. Fee waivers or reductions are available in certain instances, such as a waiver of the application fee for an initial application filed by a small business. Moreover, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product has a non-orphan indication for use.

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 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 an NDA or 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.

The Drug Price Competition and Patent Term Restoration Act, or the Hatch-Waxman Act added Section 505(b)(2) to the FDCA, allowing a company to submit an NDA application that relies on clinical trial data not conducted by or for the application, such as previously published scientific literature and prior FDA findings of safety and efficacy of another company's drug. An NDA application under Section 505(b)(2) is typically used when the applicant product modifies or improves a predicate drug leading to a new drug product. Because an application under Section 505(b)(2) can rely on prior clinical trial data and published scientific literature, FDA approval is generally quicker than a normal NDA application. However, an application under Section 505(b)(2) can also be delayed if the predicate drug is still under patent or exclusivity protections.

Fast Track, Breakthrough Therapy and Priority Review Designations**Post-Approval Regulation**

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, or in the event of an emergency. 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.
Fourth, the Secretary of Health and Human Services may authorize unapproved drugs and biologics to be marketed in the event an actual or potential emergency has been designated by the U.S. government. After an emergency has been designated, the FDA may issue an Emergency Use Authorization, or EUA, for the use of a specific product based on criteria established by the FDCA. An EUA is product specific and is subject to specific conditions and restrictions. Once the emergency underlying the EUA ends, then the EUA terminates.

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 indicated that intermediate clinical 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.
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

Once 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 spend 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.

After 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;

restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;

- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, 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.

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- 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. Drugs and 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 NDA 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 an NDA to market the same drugs or 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. 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 NDA for the product, plus the time between the submission date of the NDA 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 that govern, 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 European Medicines Agency, or EMA is the scientific agency of the European Union, or the EU, that coordinates the evaluation and monitoring of new and approved medicinal products such as drugs and biologics. 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 process regarding approval of medicinal products in the EU 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 regulatory agencies in EU member states, or 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 national authorities of a Marketing Authorisation 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 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 national authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical Studies

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- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
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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 EU including cGCP, are implemented in the currently current 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 EU has been implemented through national legislation of the EU member states. Under this system, approval must be obtained from the competent national authority 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.

On January 31, 2022, the Clinical Trials Regulation (EU) No. 536/2014 replaced the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the EU, the Clinical Trials Regulation (EU) No. 536/2014 was passed as a regulation which is directly applicable in all EU member states. 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 EU. The main characteristics of the regulation include:

- A streamlined application procedure via a single entry point, known as the Clinical Trials Information System;
- 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 and different national authorities;

- A harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts;
- 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

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- 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 EU proceeds under one of four procedures: a centralized procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

Centralized 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, based on the opinion of the EMA, is automatically valid in all EU member states. Sponsors may elect to file an MAA through the centralized procedures for other classes of products.

The centralized procedure is mandatory for certain types of products such as, medicines derived from biotechnology processes such as genetic engineering, advanced-therapy medicines such as gene-therapy or tissue engineered medicine, orphan medicines, and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, diabetes, neurodegenerative disorders, autoimmune and other immune dysfunctions, and viral diseases. The centralized authorization procedure is optional for other medicinal products if they contain a new active substance, 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 public interest of the EU.

Administrative Procedure

Under the centralized 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 coordination 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 active 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 EU 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 Authorisations 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.

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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 a national authority. 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 nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization will be valid for an unlimited period, unless the European Commission or the national 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

The European Commission can grant 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 EU, or (2) a life threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that sales of the drug in the EU 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 EU 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 "Government Regulation and Product Approval-Regulation Outside the United States-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 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

EU legislation also provides for a system of regulatory data and market exclusivity. 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 EU from referencing the innovator's data to assess a generic or biosimilar (abbreviated) application. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar 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 "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' five-year supplementary protection certificates, or SPCs. 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 EU, 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 APIs active pharmaceutical ingredients ("APIs") 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 EU. 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 EU 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 compliance with the EMA's cGMP requirements and comparable requirements of other national authorities, 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 EU. 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 national 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 from the medical director of the institution (i.e., the Director of Hospital - DOH) Hospital) in which the clinical trials are scheduled to be conducted. All clinical trials must first be approved by the Institutional Review Board (IRB) / Independent Ethics Committee (IEC) which may request additional prior approval from the Israeli Ministry of Health (IMOH), 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.

The IRB/IEC Institutional Review Board / Independent Ethics Committee and IMOH prioritizes the safety, rights and the wellbeing of the participants are addressed, as well as among other things, evaluating 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. The institution may also conduct audits to insure that all international GCP and IMOH guidelines are being adhered to in order to maintain the proper conduct and accuracy of the information gathered in the course of the clinical testing.

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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, the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (i) the referral of a person, (ii) the furnishing or arranging for the furnishing of items or services reimbursable under the Medicare, Medicaid or other governmental programs, or (iii) the purchase, lease or order or arranging or recommending purchasing, leasing or ordering of any item or service reimbursable under the Medicare, Medicaid or other governmental programs. 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, items or services resulting from a violation of the federal Anti-Kickback Statute may constitute 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 Anti-Kickback Statute prohibits, among other things, the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (i) the referral of a person, (ii) the furnishing or arranging for the furnishing of items or services reimbursable under the Medicare, Medicaid or other governmental programs, or (iii) the purchase, lease or order or arranging or recommending purchasing, leasing or ordering of any item or service reimbursable under the Medicare, Medicaid or other governmental programs. 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, items or services resulting from a violation of the federal Anti-Kickback Statute may constitute a false or fraudulent claim for purposes of the False Claims Act;

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;
- 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 that is stored or transmitted electronically;
- the Physician Payments Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require 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.

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 Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;
- 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 that is stored or transmitted electronically;
- 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 may 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 payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. Concerns about drug pricing have been expressed by both members of the United States Congress and the 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 in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products if approved 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 EU 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. EU member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect that it 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 Affordable Care Act 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 Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2027, unless additional Congressional action is taken; however, pursuant to the CARES Act, and subsequent legislation, these reductions are were suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. 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 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.

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 FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. 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. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

Additionally, CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer 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 if it is equal to or greater than $35 for a monthly supply or usual course of treatment. Prescription drugs and biological products advertisements that are in violation of these requirements will be included on a public list.

Any adopted health reform measure could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future.

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.

Employees

As of December 31, 2022 December 31, 2023, we had 20 a total of 19 employees, and consultants of whom 17 are full-time employees all based in Israel including (including our Chief Executive Officer and Chief Operating Officer, as well as 15 other full-time employees, two part time employees, Officer), and one part-time consultant based in Israel who serves as our Chief Financial Officer. In addition, we employ a number of specialized outside advisors and expert consultants based in the United States, the United Kingdom and Europe, including our Chief Medical Officer. Officer, key clinical advisors and our regulatory team. 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 Development	15
General and administrative Administrative	2
Total	17

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.

Facilities

For more information regarding our facilities, see "Item 2—Properties" contained in this Annual Report on Form 10-K. Report.

Legal Proceedings

For more information regarding legal proceedings, see 'Item "Item 3—Legal Proceedings" contained in this Annual Report on Form 10-K. Report.

Additional Information

Our website is at www.enterabio.com. www.enterabio.com. We make available, free of charge, on our investor relations "Investor Relations" section under the heading "SEC Filings", our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports filed with or furnished to the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act, of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our website address is included in this report only as an inactive textual reference. Information contained on, or available through, our website is not incorporated by reference in, or made a part of, this report.

ITEM 1A.RISK FACTORS

You should carefully consider the risks described below, as well as other information contained in this Annual Report, including the consolidated financial statements and the notes thereto and "Item 7-Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events discussed below could significantly and adversely affect our business, prospects, results of operations, financial condition, and cash flows.

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 publicly traded warrants to purchase our Ordinary Shares listed on the Nasdaq under the symbol ENTXW (the "IPO Warrants"). Shares. 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.

Risk Factor Summary

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows and prospects. These risks are discussed more fully later in this Item 1A, and include, but are not limited to, the following:

- We have incurred significant losses since our inception and anticipate that we will continue to incur substantial losses for the next several years;
    - We have incurred significant losses since our inception and anticipate that we will continue to incur substantial losses for the next several years;
- Management has performed an analysis of our ability to continue as a going concern and our independent registered public accounting firm has raised substantial doubt as to our ability to continue as a going concern;
    - Management has performed an analysis of our ability to continue as a going concern and our independent registered public accounting firm has raised substantial doubt as to our ability to continue as a going concern;
- All of our product candidates, including EB613 and EB612, are in preclinical or clinical development and we have not yet successfully completed the development of any product candidates;
    - All of our product candidates, including EB613 and EB612, are in preclinical or clinical development and we have not yet successfully completed the development of any product candidates;
- If serious adverse, undesirable or unacceptable side effects are identified during the development of our product candidates, marketing approval may be delayed or we may need to abandon our development of such product candidates, and if such side effects are identified following regulatory approval, any approved product label may be limited or we may be subject to other significant negative consequences;
    - If serious adverse, undesirable or unacceptable side effects are identified during the development of our product candidates, marketing approval may be delayed or we may need to abandon our development of such product candidates, and if such side effects are identified following regulatory approval, any approved product label may be limited or we may be subject to other significant negative consequences;
- The commencement and completion of clinical trials can be delayed or prevented for a number of reasons;
    - The commencement and completion of clinical trials can be delayed or prevented for a number of reasons;
- 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;

- 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;

- 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 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;

- Healthcare legislative changes may harm our business and future prospects;
  - Healthcare legislative changes may harm our business and future prospects;

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

- We are highly dependent upon our ability to raise additional capital or enter into agreements with collaborators to develop, commercialize and market our products;
  - We are highly dependent upon our ability to raise additional capital or enter into agreements with collaborators to develop, commercialize and market our products;

- We may fail to establish, maintain, defend and enforce intellectual property rights with respect to our technology;
  - We may fail to establish, maintain, defend and enforce intellectual property rights with respect to our technology;

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

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

- Security, political and economic instability in the Middle East may harm our business.
  - Security, political and economic instability in the Middle East may harm our business, including the duration and intensity of the ongoing Israel-Hamas War and its impact on our operations and workforce.

Risks Related to Our Financial Position

We have incurred significant losses since our inception and anticipate that we will continue to incur substantial losses for the next several years.

We have incurred net losses in each year since our inception, including net losses of $8.9 Million in 2023 and $13.1 million in 2022 and $12.2 million in 2021. 2022. As of December 31, 2022 December 31, 2023 we had an accumulated deficit of $95.5 million $104.4 million. We expect to continue to incur substantial losses for the next several years, and we expect these losses to increase as we continue our development of and potentially seek regulatory approval for, EB613 and EB612 and potentially develop future product candidates, including an additional oral PTH formulation for non-union fractures. our GLP-2 and OXM candidates with OPKO. We anticipate that our net losses and accumulated deficit for the next several years will be significant as we conduct our planned operations. Given our current plans, we anticipate that our existing cash and cash equivalents will be sufficient to fund our operations into through the third second quarter of 2024. 2025. This assumes capital required to fund our ongoing operations, including R&D and the completion of the Phase 1 PK study related to the new formulation of EB612. generation platform and the GLP-2/OXM collaborative research we are conducting with OPKO. This does not include the capital required to fund our proposed Phase 3 pivotal study for EB613 in osteoporosis and comparative PK study of EB613 and Forteo®. osteoporosis. Delays in securing additional capital or entering into strategic collaborations to capitalize the EB613 Phase 3 program will result in delays in this program. Accordingly, these factors, among others, raise substantial doubt about our ability to continue as a going concern. Our expectations are based on management's current assumptions, clinical development plans and regulatory submission timelines, which may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to accurately predict the timing or amount of the development and clinical expenses or when, or if we will be able to achieve, or maintain, profitability. In addition, our expenses could increase if we are required by the FDA or comparable foreign regulatory authorities to perform preclinical or clinical studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development and potential commercialization of EB613 or any other product candidates. The amount of our future net losses will depend, in part, on the amount and timing of our expenses, our ability to generate revenue and our ability to raise additional capital. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and working 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 27, 2023 March 1, 2024, we had cash and cash equivalents of approximately $11.0 million $9.8 million. Given our current plans, we anticipate that our existing cash and cash equivalents will be sufficient to fund our operations into through the third second quarter of 2024. 2025. This assumes capital required to fund our ongoing operations, including R&D, and the completion of the Phase 1 PK study related to the new formulation EB612. generation platform and the GLP-2/OXM collaborative research we are conducting with OPKO. This does not include the capital required to fund our proposed Phase 3 pivotal study for EB613 in osteoporosis and comparative PK study of EB613 and Forteo®. osteoporosis. Our expectations are based on management's current assumptions, clinical development plans and regulatory submission timelines, which may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Our ability to continue as a going concern will depend on our ability to obtain additional financing. The Company constantly evaluates options with respect to various financing alternatives including public or private equity offerings, debt financings and strategic collaborations to finance future clinical trials, including the Phase 3 pivotal study for EB613 in osteoporosis, and comparative PK study of EB613 and Forteo®, research and development activities and general and administrative expenses. 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 delay, 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, would be jeopardized and we may not be able to continue operations.

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 current and any potential future 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 product candidate. As such, we are currently primarily focused on the development of five differentiated, first-in-class oral peptide programs, expected to enter the into various stages of clinical development by 2025, including two programs under the collaboration agreement with OPKO. Our most advanced programs are 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 with respect to certain product development programs may also be sub-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.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, reduce or cease our product development activities and operations.

We are currently advancing our lead most advanced product candidate, EB613, through clinical development. Developing therapeutics, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional capital in order to complete research and development, clinical trials, file with the regulatory agencies, including the FDA and EMA, secure commercial manufacturing supply for and commercialize our product candidates. If the FDA or comparable foreign regulatory authorities require that we perform additional preclinical studies or clinical trials at any point, our expenses would further increase beyond what we currently expect, and the anticipated timing of any future clinical development activities and potential regulatory approvals may be delayed depending upon our allocation of resources and available funding. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, or on acceptable terms, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of manufacturing, sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

We expect that we would need to raise additional funds to support the execution of our long-term growth strategy, including for a potential Phase 3 trial of EB613, and a comparative PK trial of EB613 with Forteo®, additional non-clinical and clinical studies for EB612, and further development of our N-Tab™ technology platform and pre-clinical product candidates. 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 amount of financing we will require to complete research and development and to commercialize our product candidates. The amount and timing of our funding requirements will depend on many factors, including but not limited to:

- the scope, progress, timing, cost and results of research, preclinical development, and clinical trials;

- the scope, progress, timing, cost and results of research, preclinical development, and clinical trials;

- the costs, timing and outcome of seeking and obtaining approvals from the FDA, EMA or other regulatory agencies in relation to registrational strategies and potential NDA or BLA approvals for our product candidates;
  - the costs, timing and outcome of seeking and obtaining approvals from the FDA, EMA or other regulatory agencies in relation to registrational strategies and potential NDA or BLA approvals for our product candidates;

- the costs associated with manufacturing our product candidates and potentially establishing sales, marketing, and distribution capabilities in the absence of commercial partnerships;
  - the costs associated with manufacturing our product candidates and potentially establishing sales, marketing, and distribution capabilities in the absence of commercial partnerships;

- 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 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;
  - the extent to which we acquire or in-license other products or technologies;

- 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;
  - 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;
  - 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;

our need and ability to hire additional management, scientific, and medical personnel;

- 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; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems to support our current operations as a public company.

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 residual impact of COVID-19 on our clinical trials, regulatory timelines, business operations and financial stability.

Many of these factors are outside of our control. Based upon our currently expected level of operating expenditures, we believe that we will be able to fund our operations into through the third second quarter of 2024. 2025. This assumes capital required to fund our ongoing operations, including R&D, and the completion of the Phase 1 PK study related to the new formulation EB612. generation platform and the GLP-2/OXM collaborative research we are conducting with OPKO. This does not include the capital required to fund our proposed Phase 3 pivotal study for EB613 in osteoporosis and comparative PK study of EB613 and Forteo®. osteoporosis. Delays in securing additional capital or entering into strategic collaborations to capitalize the EB613 Phase 3 program will result in delays in this program. Our expectations are based on management's current assumptions, clinical development plans and regulatory submission timelines, which may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. This period could be shortened if there are any unanticipated increases in spending on development programs or other unanticipated increases in spending related to circumstances outside of our control, including, without limitation, costs associated with litigation or other legal proceedings, hiring of additional consultants and personnel or procurement of additional raw materials. Our existing cash and cash equivalents will not be sufficient to obtain regulatory approval for any of our product candidates. Accordingly, we continue to require substantial additional capital. In order to fund our future capital needs, we may seek additional funding through equity or debt financings, development partnering arrangements, lines of credit or other sources. 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, including strategic partnerships, 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 delay the initiation of core activities, curtail or cease operations.

Our fundraising efforts in the future to secure additional financing will divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, reduce or discontinue the development or commercialization of one or more of our product candidates or curtail our operations, which will have an adverse effect on our business, operating results and prospects.

We have a limited operating history and no history of late stage clinical studies and commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability and making an investment in our Ordinary Shares unsuitable for many investors.

We began operations in 2010. Our operations to date have been limited to financing and staffing our company, developing our drug delivery technology, N-Tab™, and early clinical development of 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.

Raising additional capital may cause dilution to our shareholders, and these financings, or disputes with shareholders in connection therewith, may restrict our operations or require us to relinquish substantial rights or result in unanticipated legal or other costs.

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 and strategic collaborations. We do not have any committed external sources of funds and 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 the rights of 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 could cause our operating results to fluctuate on a quarterly basis.

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.

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. a non-accelerated filer.

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.

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, 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, a non-accelerated filer, we may have been able to 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 IPO, 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 a non-accelerated filer or the timing of such costs.

Our Ordinary Shares and IPO Warrants are listed on Nasdaq. As a public company listed on Nasdaq, we incur significant legal, accounting and other expenses. 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. Furthermore, because we are a publicly traded company in the United States and subject to U.S. rules and regulations, it is 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 may also make it more difficult for us to attract and retain qualified members of our board of directors, the Board, particularly to serve on our audit committee, Audit Committee, and qualified executive officers.

Risks Related to Our Business and the Development of Our Product Candidates

All of our product candidates are in preclinical or clinical development and we have not yet successfully completed the development of any product candidates.

We are a clinical-stage company focused on the development of orally delivered peptide and protein therapeutics to treat unmet medical needs. We commenced operations in 2010 and have a limited operating history. Since inception, we have devoted substantially all of our resources to the development of our technology N-Tab™ Technology platform, the clinical and preclinical advancement of our product candidates, the creation, licensing and protection of related intellectual property rights and the provision of general and administrative support for these operations. We have not yet obtained regulatory approval for any product candidates in any jurisdiction or generated any revenues from any product sales. If any of our current or future product candidates fails in clinical trials or preclinical development, or does not gain regulatory approval, or if our product candidates following regulatory approval, if any, do not achieve market acceptance, we may never become profitable or sustain profitability.

We commenced our first clinical trials with our oral PTH candidates in osteoporosis and hypoparathyroidism, and we have a limited operating history of developing products upon which our business and prospects can be evaluated. In addition, our Phase 2 clinical trial for EB613 for osteoporosis was the largest clinical trial we have conducted to date, and we have never conducted clinical trials of a size required for regulatory approvals. Furthermore, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in rapidly evolving fields, such as the oral delivery of protein therapeutics.

To become and remain profitable, we must succeed in developing and commercializing products that generate significant 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:

- the completion of future development efforts for EB613, EB612 or other product candidates;
- securing additional funding as may be needed to continue the development of EB613 or any other product candidates;

the completion of future development efforts for EB613, EB612 or other product candidates;

- obtaining required regulatory and marketing approvals for the clinical development, manufacturing and commercialization of EB613, EB612 and any other product candidates we may develop;
- obtaining adequate reimbursement from third-party payors for any product that may be commercialized, if approved;
- managing our spending as costs and expenses increase due to the preparation of regulatory filings, potential regulatory approvals, manufacturing scale-up and potential commercialization;
- continuing to build and maintain our intellectual property portfolio;
- recruiting and retaining qualified executive management and other personnel;
- building and maintaining appropriate research and development, clinical, regulatory, sales, manufacturing, financial reporting, distribution, and marketing capabilities on our own or through third parties;
- gaining market acceptance for our product candidates;
- developing and maintaining successful strategic relationships and collaborations;
- developing a sustainable and scalable manufacturing process for any approved product candidates and maintaining supply and manufacturing relationships with third parties that can support clinical development and market demand for our product candidates, if approved;
- establishing sales, marketing, and distribution capabilities in the United States and the EU independently or in collaboration with strategic partners;
- 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;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter; and
- attracting, hiring and retaining qualified personnel.

securing additional funding as may be needed to continue the development of EB613 or any other product candidates;

- obtaining required regulatory and marketing approvals for the clinical development, manufacturing and commercialization of EB613, EB612 and any other product candidates we may develop;
- obtaining adequate reimbursement from third-party payors for any product that may be commercialized, if approved;
- managing our spending as costs and expenses increase due to the preparation of regulatory filings, potential regulatory approvals, manufacturing scale-up and potential commercialization;
- continuing to build and maintain our intellectual property portfolio;
- recruiting and retaining qualified executive management and other personnel;
- building and maintaining appropriate research and development, clinical, regulatory, sales, manufacturing, financial reporting, distribution and marketing capabilities on our own or through third parties;
- gaining market acceptance for our product candidates;
- developing and maintaining successful strategic relationships and collaborations;
- developing a sustainable and scalable manufacturing process for any approved product candidates and maintaining supply and manufacturing relationships with third parties that can support clinical development and market demand for our product candidates, if approved;
- establishing sales, marketing, and distribution capabilities in the United States and the EU independently or in collaboration with strategic partners;

- 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;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter; and
- attracting, hiring and retaining qualified personnel.

If we are unsuccessful in accomplishing any of these objectives, we may not be able to develop product candidates, raise capital, expand our business or continue our operations. 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 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 number 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 most advanced programs, EB613 and EB612 may compete with marketed drugs, such as Forteo®, Tymlos®, Evenity®, and osteoanabolic drugs in clinical development for osteoporosis and drugs in clinical development for hypoparathyroidism such as TransCon™ PTH or Eneboparatide. Furthermore, EB612 has orphan drug designation in the United States and in the EU, which means that the potential patient population is limited. 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 development of our product candidates and any potential approvals 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, N-Tab™ , to other product candidates.

An element of our strategy is to combine our oral drug delivery N-Tab™ technology platform with a variety of peptides and therapeutic proteins and large molecule active pharmaceutical ingredients, or APIs, 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. We intend to use our N-Tab™technology in combination with known APIs, to validate our platform and potentially minimize risk and development timelines.

Our initial product candidates combine our oral drug delivery technology, N-Tab™, with PTH, a hormone that has been used in injectable form for many years for the treatment of osteoporosis and hypoparathyroidism. 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 N-Tab™ technology with our PTH product candidates, in particular our lead candidate EB613, we may be unsuccessful in leveraging our oral drug delivery N-Tab™ technology for use with other APIs. In addition, we have modified 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.

In addition, our technology makes use of synthetically bioengineered ingredients. 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 gland. 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, to the extent they are 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.

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

All of our product candidates are still in clinical or non-clinical development and although our product candidates have undergone or will undergo safety testing, 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. While our oral PTH programs have exhibited no serious drug 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 historically been issued with labels that disclose a potential risk of osteosarcoma based on non-clinical studies.

Additionally, the FDA and foreign regulatory agency regulations require that we report certain information about adverse medical events if our products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date on which we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or a foreign regulatory agency could take action including criminal prosecution, the imposition of civil monetary penalties or seizure of our products.

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 these products off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;

regulatory authorities may require us to take these products off the market;

- 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.

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 any potential 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.

We manage our business and develop our technology with a small number of employees and key advisors with deep functional domain expertise, 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 are highly dependent on the biopharmaceutical research and development, clinical, regulatory, CMC and strategic expertise of our core executive team and key advisors across these domains, including Miranda Toledano, our Chief Executive Officer. Officer, Hillel Galitzer, our Chief Operating Officer and Gregory Bushtein, our Head of Research and Development. Our success depends upon the continued contributions of these senior executives, employees and advisors, many of whom have substantial scientific and technical experience with, and have been instrumental to our regulatory, clinical development and technology platform. Furthermore, recruiting and retaining new executive talent and qualified scientific personnel to perform future research and clinical 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 our key employees and consultants 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 do not maintain “key man” life insurance policies for any of our employees.

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 strategic, clinical development and commercialization R&D plans and strategies develop, evolve, we expect to supplement and expand our employee base, particularly in the United States, for clinical development, regulatory, operational, sales, marketing, business development, financial and other capabilities and with senior managers who are either based in the United States 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.

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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 size 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, we have appointed independent directors, which may result in a change in the company's direction over time.

We are increasingly dependent on information technology systems, infrastructure and data, and our internal computer systems, or those of our collaborators, third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

We are increasingly dependent upon information technology systems, infrastructure and data. Despite the implementation of security measures, our internal computer systems and those of our development partners, third-party clinical research organizations, data management organizations and other contractors and consultants are vulnerable to damage from service interruption or destruction, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. In addition, such systems are subject to compromise from internal threats, such as theft, misuse, unauthorized access or other improper actions by employees, third-party service providers and other third parties with otherwise legitimate access to our systems. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, denial-of service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. It is possible that we may not be able to anticipate, detect, appropriately react and respond to, or implement effective preventative measures against all cybersecurity incidents. Our key business partners face similar risks, and a security breach of their systems could adversely affect our security posture.

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While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could cause damage or destroy assets, compromise business systems, or otherwise result in a material disruption of our programs and business operations. Security breaches further pose a risk that sensitive data, including intellectual property, clinical data, trade secrets or personal information may be exposed to unauthorized persons or to the public, altered or lost. For example, the loss of clinical trial data for any of our product candidates could delay our ability to report such data, 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 other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities, damages or damage to our reputation and the further development of our product candidates could be delayed. We do not currently maintain a cyber insurance policy and therefore the successful assertion of one or more large claims against us in connection with a breach or other cybersecurity-related matter could materially adversely affect our business, financial condition and operating results.

We rely on email and other messaging services in connection with our operations. We may be targeted by parties using fraudulent spoofing and phishing emails to misappropriate passwords, payment information or other personal information or to introduce viruses through Trojan horse programs or otherwise through our networks, computers, smartphones, tablets or other devices. Despite our efforts, such as to mitigate the effectiveness of such malicious email campaigns through a variety of control and non-electronic checks, spoofing and phishing may damage our business and increase our costs. Any of these events or circumstances could materially adversely affect our business, financial condition and operating results.

WeTo date, we have regularly engaged consultants to assess our internal cybersecurity programs and compliance, and, in connection with such assessment, have implemented various cybersecurity defense measures we believe are appropriate. However, we may be required to expend significant capital and other resources to protect against, respond to, and recover from any potential, attempted, or existing cybersecurity incidents. As cybersecurity incidents continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. In addition, our remediation efforts may

not be successful. Moreover, there could be public announcements regarding any cybersecurity incidents and any steps we take to respond to or remediate such incidents, and if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a substantial adverse effect on the price of our Ordinary Shares. There can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information or the illegal transfer of funds to unknown persons, which could result in financial, legal, business or reputational harm, and may harm our relationships with third parties.

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA or foreign regulators, failure to provide accurate information to regulatory authorities, failure to comply with manufacturing standards we have established, failure to comply with federal and state health care fraud and abuse laws and regulations in the United States and abroad, failure to report financial information or data accurately, disclose unauthorized activities to us or failure to comply with our own internal company policies. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. We may not be able to prevent a director, executive or employee from trading in our Ordinary Shares on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money and divert attention of our management team from other tasks important to the success of our business.

We are subject to risks related to restrictive data privacy regulations governing the collection, use, processing and cross-border transfer of personal information.

In the ordinary course of our business, we may collect, process, use, store or transfer sensitive data in our data centers and on our networks, including intellectual property, proprietary business information (both ours and that of our customers, suppliers and business partners) and personally identifiable information, including in connection with conducting clinical trials. We are subject to strict data privacy laws and regulations in the United States, the United Kingdom, the EU, Israel and other jurisdictions in which we operate, as well as contractual obligations, governing the collection, transmission, storage and use of personal information. The legislative and regulatory landscape for data privacy and protection continues to evolve around the world and are increasingly rigorous, with new and constantly changing requirements applicable to our business, including the U.S.'s federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, the EU General Data Protection Regulation ((EU) 2016/679), or the GDPR, the Israeli Privacy Protection Law, 5741-1981, and other laws and regulations governing the collection, use, disclosure and transmission of data. The enforcement practices of these laws and regulations are likely to remain uncertain for the foreseeable future. These laws and regulations may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may have a material adverse effect on our results of operations, financial condition and cash flows.

For example, in the United States, various federal and state regulators have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act, or the CCPA, which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. On November 3, 2020, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, which

significantly modifies the CCPA, including by expanding consumers' rights with respect to certain personal information and creating a new state agency to oversee implementation and enforcement efforts. Many of the CPRA's provisions have become effective on January 1, 2023. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in Congress of a new comprehensive federal data privacy law to which we would likely become subject if it is enacted.

In addition, outside the United States, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, the GDPR greatly increased the European Commission's jurisdictional reach of its laws and adds a broad array of requirements for handling personal data. EU member states are tasked under the GDPR to enact, and have enacted, certain implementing legislation that adds to and/or further interprets the GDPR requirements and potentially extends our obligations and potential liability for failing to meet such obligations. The GDPR, together with national legislation, regulations and guidelines of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, use, retain, protect, disclose, transfer and otherwise process personal data. Specifically, the GDPR's requirements including 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 authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater. The U.K. has transposed the GDPR into domestic law, with its version of the GDPR that took effect on January 1, 2021, which could expose us to two parallel regimes, each of which potentially authorizes similar fines for certain violations. As such, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training associates and engaging consultants, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, distract management or divert resources from other initiatives and projects. Any failure or perceived failure to comply with the requirements of privacy laws and regulations, including the CCPA, GDPR and related national data protection laws of the member states of the EU and the U.K., may result in damage to our reputation and our relationship with our customers, as well as proceedings or litigation by governmental agencies or customers, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, penalties or judgments, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

In recent months,During 2023, record levels of inflation have resulted in significant volatility and disruptions in the global economy. In response to rising inflation, central banks in the markets in which we operate, including the United States Federal Reserve, have tightened their monetary policies and raised interest rates, and such measures may continue if there is a period of sustained heightened inflation. Higher interest rates and volatility in financial markets could lead to additional economic uncertainty or recession. Increased inflation rates have increased our and our suppliers' operating costs, including labor costs, raw materials costs, manufacturing costs, freight costs and R&D costs. In addition to rising inflation, the global economy has also been impacted by fluctuating foreign exchange rates and geopolitical tensions, such as the ongoing conflict between Russia and Ukraine, which has spurred rising energy costs and exacerbated disruptions to the global supply chain caused by the COVID-19 pandemic and the government and societal responses to the pandemic. Supply chain disruptions could continue to result in delays in our R&D and clinical initiatives. As we have substantial international operations, fluctuations in exchange rates between the currencies in which we operate, which could increase our operating costs and adversely affect our results of operations, and cash flows. The duration and extent of such macroeconomic developments are uncertain and we cannot accurately predict whether we will be able to effectively and timely mitigate their impact on our business.

Risks Related to Regulatory Approval of Our Product Candidates

Clinical drug development is expensive, time consuming and uncertain. Development programs are subject to regulatory requirements, unanticipated delays and we may ultimately not be able to obtain regulatory approvals for the commercialization of our product candidates.

Our lead most advanced product candidates are orally delivered tablet formulations of the synthetic form of the first 34 amino acids of human PTH, teriparatide. We are developing EB613 to treat osteoporosis and EB612 to treat hypoparathyroidism. These product candidates have not yet reached late-stage clinical development and are subject to the risks of failure inherent in regulatory assessments and drug development. The clinical development, manufacturing, quality assurance, labeling, storage, record-keeping, advertising, promotion, pharmacovigilance, import, export, marketing and distribution of our product candidates is subject to extensive regulation by the FDA in the United States and by comparable authorities in foreign markets. We are not permitted to market our product candidates in the United States until we receive approval of a new drug application, or an NDA or biologics license application, or a BLA from the FDA or in any other country until we receive marketing approval from the applicable regulatory authorities in such countries. We have not yet submitted a marketing application, or received marketing approval, for any of our product candidates and have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals. The process of obtaining regulatory approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity, and novelty of the products involved, as well as the target indications. Approval policies or regulations may change and the regulatory agencies have substantial discretion in the approval process for products, including the ability to delay, limit or deny approval of a product candidate for many reasons. Obtaining approval of an NDA, a BLA, or any other marketing application can be a lengthy, expensive and uncertain process. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the number, design, size, conduct or implementation of our clinical trials or any of our collaborators' clinical trials;
- we or any of our development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe and effective for any indication;

such authorities may disagree with the number, design, size, conduct or implementation of our clinical trials or any of our collaborators' clinical trials;

- 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;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that authority's jurisdiction;
- the data collected from non-clinical studies and clinical trials of our product candidates may not be sufficient to support the submission of an application for regulatory approval;
- the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;
- we or any of our future development partners may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the use of results from studies that served as precursors to our current or future product candidates;
- such authorities may find deficiencies in our manufacturing processes or facilities or those of third-party manufacturers with which we or any of our future development partners contract for clinical and commercial supplies;
- the FDA may require development of a REMS as a condition of approval; and
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our future development partners' clinical data insufficient for approval.

we or any of our development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate 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;

- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that authority's jurisdiction;
- the data collected from non-clinical studies and clinical trials of our product candidates may not be sufficient to support the submission of an application for regulatory approval;
- the results of clinical trials may not demonstrate the safety or efficacy required by such authorities for approval;
- we or any of our future development partners may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the use of results from studies that served as precursors to our current or future product candidates;

- such authorities may find deficiencies in our manufacturing processes or facilities or those of third-party manufacturers with which we or any of our future development partners contract for clinical and commercial supplies;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval; and
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our future development partners' clinical data insufficient for approval.

Each of our oral PTH product candidates, including EB613 and EB612, are still in 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, 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;

future clinical trial results may show that our oral PTH is not effective, 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;46

- 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.

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 or a potential partner are unable to successfully commercialize our oral PTH or any other product candidates we may develop in the future, it would likely have a material adverse effect on our business, prospects, financial condition and results of operations. \

In addition, 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 2 trials in osteoporosis and hypoparathyroidism (with the earlier formulation of EB612). We will also need to agree on a protocol with the FDA for a Phase 3 clinical trial before commencing the trial. Phase 3 clinical trials frequently produce unsatisfactory results even when 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, EMA or other regulatory agencies may require that we conduct additional clinical, nonclinical, manufacturing validation or drug product quality studies beyond those planned and submit data from such trials 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 or other product candidates we may develop in the future.

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 also not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

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

EB613 completed a six-month placebo-controlled Phase 2 double-blind, dose-ranging trial. In November 2018, we had a Pre-Investigational New Drug ("Pre-IND") meeting with the FDA to discuss our EB613 program for the treatment of osteoporosis. In December 2020, we announced that the FDA had reviewed our October 2020 IND Application and informed us that we may proceed with our U.S. clinical pharmacology study. trial in 2021. In December 2021, we held an end-of-Phase 2 meeting with the FDA to review the six-month phase 2 results and a proposed Head-to-Head Non-Inferiority Phase 3 study protocol vs. Forteo®, our nonclinical and clinical development plan and the use of BMD, rather than fracture incidence, as the primary endpoint to support an NDA. Following our End of Phase 2 Meeting with the FDA and pursuant to the FDA's concern that a Head-to-Head study phase 3 design may not be favorable to support an NDA for EB613, we redesigned the pivotal phase 3 study for EB613 based on the FDA's suggestion to explore a placebo-controlled trial. A Type C meeting with the FDA in relation to Entera's proposed Phase 3 registrational study was held in the second half of 2022 and in October 2022, the Company concluded its Type C meeting and the FDA agreed that a single Phase 3 placebo-controlled study could support an NDA submission of EB613 (oral hPTH (1-34), teriparatide tablets) under the 505(b)(2) regulatory pathway. . The FDA also agreed that Total BMD could serve as the primary endpoint of the registrational study in post-menopausal osteoporosis patients. In February 2023, we announced that a Type D meeting protocol review had been accepted by the FDA. The objective of the Type D meeting review was to confirm that the protocol fully meets FDA's expectations, including the analysis of the primary endpoint and the population PK evaluations, ahead of potential initiation of the Phase 3 study. On April 3, 2023, we reported that the FDA would not be opposed to Entera initiating the Phase 3 study under the proposed FNIH BQP pathway and that the Company's proposed PK sampling scheme seemed reasonable. On the same day, we announced that we plan to continue our dialogue with the FDA and await the final qualification of the FNIH-BQP criteria and their guidance on the statistical evaluation of our BMD endpoint before initiating a Phase 3 study for EB613.

In addition, with respect to EB612, we expect have since developed what we believe could be an improved formulation of EB612 based on new intellectual property, tailored to carry out optimize its PK profile and the potential for reduced daily dosing. We initiated a PK study in May 2023, which is testing various potential drug candidates based on our new platform, including several which could be developed for the new formulation treatment of EB612 in the first half of 2023. hypoparathyroidism. We anticipate that the outcome of the PK study will help determine the dosing and design of a Phase 2 or Phase 3 trial of EB612 in patients with hypoparathyroidism. If successful, the phase 2/3 clinical trial of EB612 in hypoparathyroidism may potentially support a submission are also collaborating on an undisclosed peptide for regulatory approval of EB612. this indication using our N-Tab™ Technology.

Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials 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, or CROs, contract manufacturing organizations, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly;

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;

- failure of our third-party contractors, such as CROs 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 ethics committee approval to conduct a clinical trial at a prospective site;
- the FDA, EMA or other regulatory authority may require changes to any of our trial 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 trial, resulting in incomplete data;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- the FDA or other regulatory authorities may impose a clinical hold, or we or our investigators, IRBs, or ethics committees may elect to suspend or terminate clinical research or trials;
- 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 for our product candidates.

delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, 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 CROs 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 may require changes to any of our trial 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 trial, resulting in incomplete data;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- the FDA or other regulatory authorities may impose a clinical hold, or we or our investigators, IRBs, or ethics committees may elect to suspend or terminate clinical research or trials;
- 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 for our product candidates.

If changes in regulatory requirements and guidance occur, 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 CROs or investigators, 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 United States), other regulatory authorities (for trials conducted outside the United States), the IRB /ethics committee overseeing any given clinical trial, 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;
- failing to establish clinical endpoints acceptable to the FDA and other regulatory authorities;
- 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.

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;48

- failing to establish clinical endpoints acceptable to the FDA and other regulatory authorities;
- 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, including the Physician Payments Sunshine Act, we are required to report some of these relationships to the FDA. FDA and other regulatory authorities. The FDA and other regulatory authorities 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 and other regulatory authorities may therefore question the integrity of the data generated at the applicable clinical

trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and other regulatory authorities 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 other 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 or completed. In addition, we or our investigators 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 impact 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 we have not had any serious adverse events in our clinical trials to date that are believed to be related to our oral PTH product candidates, we may need to change future trial designs 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.

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 for our product candidates, 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 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;

issue warning letters or untitled letters or take similar enforcement actions;

- 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.

seek an injunction or impose civil or criminal penalties or monetary fines;

- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications;

- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products, exclude products from federal healthcare programs, or request that we initiate a product recall; or
- refuse to allow us to enter into supply contracts, including government contracts.

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

Healthcare legislative changes may harm our business and future prospects.

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

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

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The 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 75% 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 ACA 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. In 2011, the U.S. Congress enacted the Budget Control Act of 2011, or the Budget Control Act, which included provisions intended to reduce the federal deficit. The Budget Control Act resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 absent additional congressional action. However, pursuant to the CARES Act, and subsequent legislation, these reductions are were suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. 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. If government spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels, which may impact the ability of relevant agencies to timely review and approve research and development, manufacturing and marketing activities, which may delay our ability to develop, market and sell any product candidates we may develop. In addition, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our anticipated product revenues.

There have been changes and modifications to certain aspects of the ACA, and we expect such changes and modifications to continue. In 2017, the U.S. Congress enacted the Tax Cuts and Jobs Act, or the 2017 Tax Act, which eliminated 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. mandate". The Bipartisan Budget Act of 2018, or the BBA, among other things, amended 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 January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. . Changes and modifications to the ACA are likely to continue, with unpredictable and uncertain results.

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. On September 24, 2020, the FDA released a final rule providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. 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.

On November 20, 2020, the HHS Office of Inspector General finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, the HHS Office of Inspector General added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others, yet removed safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. This rule (with exceptions) became effective on January 19, 2021. We continue to evaluate what effect, if any, these rules will have on our business. CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer 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 if it is equal to or greater than $35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a

public list. Any adopted health reform measure could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future.

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

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

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

- the federal Anti-Kickback Statute prohibits, among other things, the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (i) the referral of a person, (ii) the furnishing or arranging for the furnishing of items or services reimbursable under the Medicare, Medicaid or other governmental programs, or (iii) the purchase, lease or order or arranging or recommending purchasing, leasing or ordering of any item or service reimbursable under the Medicare, Medicaid or other governmental programs. 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 Anti-Kickback Statute prohibits, among other things, the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, (i) the referral of a person, (ii) the furnishing or arranging for the furnishing of items or services reimbursable under the Medicare, Medicaid or other governmental programs, or (iii) the purchase, lease or order or arranging or recommending purchasing, leasing or ordering of any item or service reimbursable under the Medicare, Medicaid or other governmental programs. 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 Physician Self-Referral Law, or “Stark Law”, prohibits, among other things, a physician (defined to include a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor) from referring Medicare and Medicaid patients to certain types of entities with which the physician or any of the physician’s immediate family members have a financial relationship, unless an exception to the law’s prohibition is met. In addition, the government may assert that a claim including items or services resulting from a violation of the Stark Law constitutes a false or fraudulent claim for purposes of the False Claims Act;

- 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 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 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 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 CMS information related to payments or other "transfers of value" made to physicians. All such reported information is publicly available;
- analogous state and non-U.S. laws and regulations, such as certain state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and
- regulation by the CMS and enforcement by the HHS Office of Inspector General or the U.S. Department of Justice.
    - 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 Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require 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 CMS information related to payments or other "transfers of value" made to physicians. All such reported information is publicly available;
    - analogous state and non-U.S. laws and regulations, such as certain state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and
    - regulation by the CMS and enforcement by the HHS 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, drug candidates, 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, N-Tab™, for peptides, therapeutic protein and other large molecules replacement therapies in small tablet form. If another company develops an alternative technology for oral delivery of such molecules in small tablet form that is equal to or better than our technology, we may be unable to compete.

The osteoporosis market is already served by a variety of competing products based on a number of APIs. products. Many of these existing products have achieved widespread acceptance among physicians, patients and payors for the treatment of osteoporosis. We anticipate that our product candidate EB613, if approved, will compete with other osteoanabolic drugs such as daily subcutaneous Forteo®, generic teriparatide daily subcutaneous injections, daily subcutaneous injectable Tymlos® and EVENITY® which requires monthly injections, and the rest of the pharmacological treatments for osteoporosis which include anti-resorptive agents such as the bisphosphonates and Prolia®. Many of these products are available on a generic basis, and EB613 may not demonstrate sufficient additional clinical benefits to physicians and patients or be priced adequately to support reimbursement. In many cases, insurers or other third-party payors, particularly Medicare, seek to encourage the use of generic products. Furthermore, our competitors in this market are large pharmaceutical companies and the alternatives have been on the market for many years and have widespread market acceptance.

Ascendis Pharma has reported that it is developing developed a long-acting, oral prodrug formulation of PTH for the treatment of hypoparathyroidism. In 2022, Ascendis reported top-line results hypoparathyroidism, which was approved in the European Union in November 2023 and has a PDUFA date of May 14, 2024 from its Phase 3 trial. In addition, Ascendis submitted an NDA to the FDA and a Marketing Authorisation Application ("MAA") to the EMA. FDA. We believe that our key competitor competitors in hypoparathyroidism treatment if approved, could be include TransCon™ PTH and eneboparotide, a peptide in Phase 3 development, both of which requires require daily subcutaneous injections. If we obtain regulatory approval for EB612, it may compete with TransCon(TM TransCon™ PTH and eneboparotide which by that time will may have been marketed for several years and may have wide-spread market acceptance that may be difficult to overcome. 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.

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 final manufacturing 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.
    - We do not have experience in manufacturing our product candidates at commercial scale. We may not succeed in the scaling up of our final manufacturing 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 large molecules is more complex and subject to greater regulation than that of other drugs. The process of manufacturing large molecules, 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 process for large molecules is more complex and subject to greater regulation than that of other drugs. The process of manufacturing large molecules, 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, outbreaks of an infectious disease such as COVID-19, geopolitical tensions such as the ongoing conflict between Russia and Ukraine and numerous other factors.
    - The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures, outbreaks of an infectious disease such as the duration and intensity of the ongoing Israel-Hamas War, other geopolitical tensions such as the ongoing conflict between Russia and Ukraine, and numerous other factors.

- We and our contract manufacturing organizations, or CMOs, must comply with applicable current cGMP regulations and guidelines. We and our CMOs may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We and our CMOs 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 and our contract manufacturing organizations, or CMOs, must comply with applicable cGMP regulations and guidelines. We and our CMOs may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We and our CMOs 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 no established sales, marketing or distribution operations. If our product candidates are approved and we were to commercialize these products, such activities 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 our oral PTH candidates globally or in selected regions. Any such collaborator would could be responsible for, or substantially support, late stage clinical trials of our oral PTH product candidates, as well as regulatory approvals and registrations. These arrangements are typically complex and time consuming to negotiate. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed and sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third-party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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

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

- limitations or warnings contained in the approved labeling for a product candidate;
- changes in the standard of care for the targeted indications for any of our product candidates;

limitations or warnings contained in the approved labeling for a product candidate;

- limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;

changes in the standard of care for the targeted indications for any of our product candidates;55

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

limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability and extent of coverage and reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness of our product candidates;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;

- the extent to which the product candidate is approved for inclusion on formularies of hospitals and third-party payors, including managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular diseases;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- convenience and ease of administration of our products; and
- potential product liability claims.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients and the medical community, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

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

In order to market any products in a country or territory, we must establish and comply with numerous and varying regulatory requirements of such countries or territories regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in all major markets could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

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

The successful commercialization of our product candidates, if approved, will depend, in part, on the extent to which coverage and reimbursement for our products will be available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new technologies and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. In light of such challenges to prices and increasing levels of evidence of the benefits and clinical outcomes required of new technologies, we cannot be sure that coverage will be available for our oral PTH product peptide candidates, if approved, 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 payors 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 payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;

- a covered benefit under its health plan;
- safe, effective and medically necessary;

safe, effective and medically necessary;

- appropriate for the specific patent;
- cost-effective; and
- neither experimental nor investigational.

appropriate for the specific patent;
- cost-effective; and
- neither experimental nor investigational.

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

The unavailability or inadequacy of third-party coverage and reimbursement could have a material adverse effect on the market acceptance of our product candidates and the future revenues we may expect to receive from those product candidates. 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 payors is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. 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;

decreased demand for any of our product candidates or products we develop;

- 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;

injury to our reputation and significant negative media attention;57

- loss of revenue; and
- the inability to commercialize any products we develop.

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- 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 revenue; 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 funding, research support, and other milestone payments. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend upon, among other things, 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.

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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, and are unable to raise supplemental capital otherwise, we may have to delay, 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 or 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 may have significant discretion in determining the efforts and resources that they will apply to these collaborations;58

- 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.
- 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.
- The Israel-Hamas War may cause us to fail to meet contractually obligated deadlines with our collaboration partners or otherwise strain our relationships with current collaborators or other business partners.

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.
- 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.

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.

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, if any resulting agreement is terminated, if research institutions are closed down by public authorities for reasons outside of our control, or if we cannot fulfill contractual commitments, 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 can 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 and 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 an NDA 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 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.

- 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.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

A portion of our cash may be held in accounts at U.S. banking institutions. Cash held in non-interest-bearing and interest-bearing operating accounts may exceed the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. The FDIC took control of Silicon Valley Bank ("SVB"), on March 10, 2023. We maintained certain operating accounts with SVB prior to its closure and have since transferred all of our deposits previously held with the bank to other banking institutions. The FDIC also took control of Signature Bank ("Signature Bank") on March 12, 2023. We did not maintain any accounts with Signature Bank. The Federal Reserve announced that account holders with Signature Bank would be made whole. However, as the FDIC continues to address the situation with SVB, Signature Bank and other banking institutions, the risk of loss in excess of insurance limitations and otherwise has increased

across financial institutions. Any loss that we may experience in the future could have a material and adverse effect on our ability to pay our operational expenses or make other payments and may require us to move our accounts to other banks, which could cause delays in making payments to our vendors and employees, among other counterparties, and cause other business and operational disruptions.

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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 and know-how relating to the oral delivery of large molecules for the treatment of certain conditions with oral PTH. PTH and other targeted peptides. 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 with claims generally 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 EU, Hong Kong, Brazil China and India. We have also filed patent applications derived from seven six patent families in various jurisdictions 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. Certain of these patent applications have already matured into patents in the United States, Israel, India, China, Canada, New Zealand, Brazil and Japan. Other applications are in prosecution. We have also recently filed seven additional seven international patent applications (patent families) with claims pertaining to a novel oral delivery platform, with claims directed at compositions comprising a protein, an absorption enhancer and an alkaline polymer, and methods of oral administration these compositions. 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.

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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.

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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, or the Patent Transfer Agreement with Oramed Ltd., or Oramed, pursuant to which we have granted Oramed 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 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.

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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.

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. 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 certain 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.

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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. 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.

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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.

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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 are currently own or use any registered trademarks in the process of registering the trademark N-Tab™ for our product candidates. oral drug delivery platform technology, globally. 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 IPO Warrants

The price of our Ordinary Shares and IPO Warrants may be volatile, and holders of our Ordinary Shares and IPO 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 IPO 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:

- our 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;

our clinical trial results and the timing of the release of such results;

- the announcement of research activities, business developments, technological innovations or new products, or acquisitions or expansion plans by us or our competitors;
- the 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;

the amount of our cash resources and our ability to obtain additional funding;

- actual or anticipated fluctuations in our and our competitors' results of operations and financial condition;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products and plans for clinical development;
- the departure of our key personnel;
- disputes related to intellectual property and proprietary rights, including patents, litigation matters and our ability to obtain intellectual property protection for our technologies;

the announcement of research activities, business developments, technological innovations or new products, or acquisitions or expansion plans by us or our competitors;

- our sale, or the sale by our significant shareholders, of Ordinary Shares or other securities in the future;
- public concern regarding the safety, efficacy or other aspects of the products or methodologies we are developing;
- 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 success or failure of our research and development projects or those of our competitors;

- 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;
- the publication of the results of preclinical or clinical trials for EB613, EB612 or any other oral peptide product candidates we may develop, including the oral GLP-2 and OXM programs we are developing with OPKO;

our entering into or terminating strategic relationships;

- changes in laws or government regulation;
- actual or anticipated fluctuations in our and our competitors' results of operations and financial condition;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products and plans for clinical development;
- the departure of our key personnel;
- disputes related to intellectual property and 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, IPO Warrants or other securities in the future;
- public concern regarding the safety, efficacy or other aspects of the products or methodologies we are developing;
- 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;
- the publication of the results of preclinical or clinical trials for EB613, EB612 or any other product candidates we may develop, including a new Oral GLP-2 analog research program;
- the 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;

- the 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;

variances in our financial performance from the expectations of market analysts;

- 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;
- variances in our financial performance from the expectations of market analysts;
- the limited trading volume of our Ordinary Shares; and

the limited trading volume of our Ordinary Shares and IPO Warrants; and

- general economic and market conditions, including factors unrelated to our industry or operating performance, such as geopolitical tensions.
  - general economic and market conditions, including factors unrelated to our industry or operating performance, such as the duration and intensity of the ongoing Israel-Hamas War, and other geopolitical tensions.

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, stocks, including ours, regardless of actual operating performance.

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

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

Our stock price may continue to be volatile, and securities class action litigation has often been instituted against companies following periods of volatility of their stock price. Any such litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

In the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. Although there is no such shareholder litigation currently pending or threatened against the Company, such litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

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

The value of the IPO 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 IPO Warrants during the period the IPO Warrants are exercisable, and if a public market for our IPO Warrants does not develop, the IPO Warrants may not have any value, and you may be unable to recover any or all of your investment in the IPO Warrants. There can be no assurance that the market price of the Ordinary Shares will ever equal or exceed the exercise price of the IPO Warrants, and consequently, whether it will ever be profitable for holders of the IPO Warrants to exercise the IPO Warrants.

Holders of the IPO Warrants will have no rights as shareholders until they acquire our Ordinary Shares.

Until a holder of an IPO Warrant acquires our Ordinary Shares upon exercise of the IPO Warrants, the holder will have no rights with respect to our Ordinary Shares issuable upon exercise of the

IPO Warrants, except as set forth in the IPO Warrants. Upon exercise of your IPO Warrants, the holder 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 IPO 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 in our Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on June 27, 2018, under "Description of IPO 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 IPO Warrants in the public market could lower the market price of our Ordinary Shares or IPO Warrants. Shares. 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 IPO Warrants are not restricted from resale. In the event of a sale of Ordinary Shares or IPO Warrants offered by selling shareholders, the price of our Ordinary Shares or IPO Warrants could decline, and such decline could be material.

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

If our shareholders, particularly our directors or our executive officers and their affiliates, sell substantial amounts of our Ordinary Shares or IPO 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 IPO Warrants may decline. The perception in the public market that our shareholders might sell our Ordinary Shares or IPO Warrants could also depress the market price of our Ordinary Shares or IPO 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 other similar securities in order to raise capital might have a similar negative impact on the share price of our Ordinary Shares or IPO Warrants. Shares. A decline in the price of our Ordinary Shares may impede our ability to raise capital through the issuance of additional Ordinary Shares IPO Warrants or other equity securities, and may cause holders of our Ordinary Shares or IPO 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 may not have sufficient insurance to cover our liability in any current or future litigation claims either due to coverage limits or as a result of insurance carriers seeking to deny coverage of such claims.

We may face a variety of litigation-related liability risks. Our amended Articles of Association, or Articles, other applicable agreements and/or Israeli law may require us to indemnify (and advance expenses to) our current and past directors and officers and employees from reasonable expenses related to the defense of any action arising from their service to us, including circumstances under which indemnification is otherwise discretionary. While our directors and officers are included in a director and officer liability insurance policy, which covers all our directors and officers in some circumstances, our insurance coverage does not cover all of our indemnification obligations and may not be adequate to cover any indemnification or other claims against us. In addition, the underwriters of our present coverage may seek to avoid coverage in certain circumstances based upon the terms of the respective policies. If we incur liabilities that exceed our coverage under our directors and officers insurance policy or incur liabilities not covered by our insurance, we would have to self-fund any indemnification amounts owed to our directors and officers and employees in which case our results of operations and financial condition could be materially adversely affected. Further, if D&O insurance becomes prohibitively expensive to maintain in the future, we may be unable to renew such insurance on economic terms or unable renew such insurance at all. The lack of D&O insurance may make it difficult for

us to retain and attract talented and skilled directors and officers to serve our company, which could adversely affect our business.

There is a risk that we may 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.

There is a risk that we may be treated as a passive foreign investment company, or PFIC, for any taxable year. The application of the PFIC rules to a company like us is subject to uncertainties, and for the reasons described below, we cannot express a view as to whether we will 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 value of its assets consists of assets (generally determined on a quarterly basis) 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 generally treated as a passive asset that produces passive income for PFIC purposes. The assets shown on our balance sheet consist, and are expected to continue 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 has been, and may continue to 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 like us, which is still developing its key intangible assets and whose overall losses from research activities significantly exceed the amount of its income (including passive income). If our losses from research and development activities are disregarded for purposes of the income test, we may be a PFIC for any taxable year if 75% or more of our gross income (as determined for U.S. federal income tax purposes) for the relevant year is from interest and financial investments. Because the revenue shown on our financial statements is not calculated based on U.S. tax principles, and because for any taxable year we may not have sufficient (or any) non-passive revenue, there is a risk that we may be or become a PFIC under the income test for any taxable year. If we were a PFIC for any taxable year during which a U.S. investor owned our Ordinary Shares (or under proposed Treasury regulations, IPO 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 IPO Warrants) and certain distributions and a requirement to file annual reports with the Internal Revenue Service. U.S. investors should consult with their tax advisers regarding the application of the PFIC rules as they may relate to an investment in our company.

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We are an emerging growth company and a smaller reporting company and non-accelerated filer, and our compliance with the reduced reporting and disclosure requirements applicable to emerging growth smaller reporting companies and smaller reporting companies non-accelerated filers could make our Ordinary Shares less attractive to investors and may make it more difficult to raise capital as and when we need it.

We are an emerging growth qualify as a "smaller reporting company, as defined in the Jumpstart our Business Startups Act of 2012, referred to as the JOBS Act," and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth smaller reporting companies, including the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved and extended adoption period for accounting pronouncements.

Even after statements. In addition, we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company, "non-accelerated filer," which would allow us to continue and we expect to take advantage of many of the same certain exemptions from disclosure various reporting requirements including that are applicable to other public companies that are not being required to comply with non-accelerated filers, including the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. 404.

We cannot predict whether investors will find our Ordinary Shares less attractive as a result of our reliance on these exemptions. If some investors find our ordinary shares Ordinary Shares less attractive as a result, there may be a less active trading market for our ordinary shares Ordinary Shares and our stock price may be more volatile.

Additionally, because of the exemptions from various reporting requirements provided to us as an emerging growth a smaller reporting company and non-accelerated filer, we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as the reporting of other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

Our Ordinary Shares may be delisted from the Nasdaq Capital Market if we are unable to maintain compliance with Nasdaq's continued listing standards.

Nasdaq imposes, among other requirements, continued listing standards, including a minimum bid requirement. The price of our Ordinary Shares must trade at or above $1.00 to comply with the minimum bid requirement for continued listing on the Nasdaq Capital Market. On November 21, 2022, the Company received a notice (the "Notice") from the Nasdaq Stock Market LLC ("Nasdaq"), stating that the Company's Ordinary Shares fail to comply with the $1.00 minimum bid price requirement for continued listing on Nasdaq in accordance with Nasdaq Listing Rule 5550(a)(2) based upon the closing bid price of the ordinary shares for the 30 consecutive business days prior to the date of the Notice. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided an initial compliance period of 180 calendar days, or until May 22, 2023, to regain compliance with the minimum bid price requirement.

On March 23, 2023, Nasdaq notified us that we had regained compliance with the minimum bid price requirement given that the closing bid price for our Ordinary Shares had been at or above $1.00 for 14 consecutive trading days, from March 3rdMarch 3, 2023 through March 22, 2023.

ThereOn June 29, 2023, the Company received an additional notice (the "Additional Notice") from Nasdaq, stating that the Company's Ordinary Shares fail to comply with the minimum bid price requirement based upon the closing bid price of the ordinary shares for the 30 consecutive business days prior to the date of the Additional Notice. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided an initial compliance period of 180 calendar days to regain compliance with the minimum bid price requirement. On December 27, 2023, we received an extension of 180 calendar days, or until June 24, 2024, from Nasdaq, to regain compliance with the minimum bid price requirement. On March 1, 2024, Nasdaq notified us that we had regained compliance with the minimum bid price requirement given that the closing bid price for our Ordinary Shares had been at or above $1.00 for 10 consecutive trading days, from February 15, 2024 through February 29, 2024.
However, there can be no assurance that we will maintain compliance with the $1.00 minimum bid price requirement or comply with Nasdaq's other continued listing standards in the future.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Ordinary Shares.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud among other objectives. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also subject us to regulatory scrutiny and sanctions, impair our ability to raise revenue and cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our Ordinary Shares.

We are required to disclose changes made in our internal controls and procedures and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

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 1-Business-The Israeli Innovation Authority (IIA) 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.

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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, the Board, are required to sign an undertaking towards the IIA in which they would undertake to comply with the Research Law. Shareholders that purchased Ordinary Shares in our IPO would not be required to sign such an undertaking.

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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.

Legislative developments in Israel may have an adverse effect on the Company's business.

The Israeli government is currently pursuing extensive changes to Israel's judicial system. In response to the foregoing developments, certain leading international financial institutions, including investment banks, investors and key economists, have indicated several causes for concern, including that such proposed changes, if adopted, may cause a downgrade to Israel's sovereign credit rating and Israel's international standing, which would adversely affect the macroeconomic condition in which we operate, and also potentially deter foreign investment into Israel or Israeli companies, which may hinder our ability to raise additional funds, if deemed necessary by our management and board of directors, the Board.

Security, political and economic instability in the Middle East may harm our business. business, including the duration and intensity of the ongoing Israel-Hamas War and its impact on our operations and workforce.

Our principal research and development facilities are located in Israel. In addition, part some 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
In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on the Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in thousands of deaths and injuries, and Hamas additionally kidnapped many Israeli civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and commenced a military campaign against Hamas.
While we have a few employees who are in active military service, the ongoing war with Hamas has not, since its inception, materially impacted our business or operations. Furthermore, we do not expect any delays to any of our programs as a result of the situation. However, we cannot currently predict the intensity or duration of Israel's war against Hamas, nor can we predict how this war will ultimately affect our business and operations or Israel's economy in general.
Additionally, political uprisings, social unrest and violence in various other countries in the Middle East, including Israel's neighbor 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 have a material adverse impact on our business in the past, 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 such conflicts result in any serious damage to our facilities. Furthermore, several countries, as well as certain companies and organizations, continue to restrict business with Israel and Israeli companies, which could have an adverse effect on our business and financial condition in the future. 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, generally, may be called upon to perform up to 42 days (and in some cases more) of annual military reserve duty until they generally reach the age of 45 (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. In October 2023, Hamas terrorists invaded southern Israel and launched thousands of rockets in a widespread terrorist attack on Israel. As a result, the Israeli government declared that the country was at war and the Israeli military began to call-up reservists for active duty. To date, several employees were called for duty, but it is possible that there will be additional further or longer military reserve duty call-ups in the future. future, which may affect our business due to a shortage of skilled labor and loss of institutional knowledge, and necessary mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, which may materially adversely affect our operations, business and results of operations. Our operations could also 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 service in connection with other military and results of operations. security matters.

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 NIS against the U.S. dollar. If the dollar cost of our operations in Israel increases, our dollar-measured results of operations will be adversely affected. For example, in 2021, 2023, the value of the NIS appreciated depreciated against the U.S. dollar by 3.27% 3.1%, which appreciation was partially offset potentially computed by inflation in Israel of 02.8% 3%. In 2020, 2022, the value of the NIS appreciated depreciated against the U.S. dollar by 6.97% 13.3%, the effect of which was partially offset potentially computed by inflation in Israel at a rate of approximately 0.7% 5.5%. As a result of these fluctuations, our NIS denominated expenses were 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, to assert U.S. securities laws claims in Israel or to serve process on our officers and directors.

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, a significant number 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 several 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 also be difficult for an investor to effect service of process on these persons in the U.S. or 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.

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Provisions of Israeli law and our 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 Israel’s Companies Law, 5759-1999, as currently amended, or the Companies Law, upon the request of a creditor of either party to a proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that as a result of the merger the surviving company will be unable to satisfy the obligations of any of the parties to the merger. 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.

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 Articles provide that our directors are elected on a staggered basis such that a potential acquirer cannot readily replace our entire board of directors Board 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 are 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 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.

Our business could be negatively affected as a result of actions of activist shareholders, and such activism could impact the trading value of our securities.

In recent years, certain Israeli issuers listed on United States exchanges have been faced with governance-related demands from activist shareholders, unsolicited tender offers and proxy contests. Responding to these types of actions by activist shareholders could be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees. Such activities could interfere with our ability to execute our strategic plan. In addition, a proxy contest for the election of directors at our annual meeting would require us to incur significant legal fees and proxy solicitation expenses and require significant time and attention by management and our board of directors.Board. The perceived uncertainties as to our future direction also could affect the market price and volatility of our securities.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1B.UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C.CYBERSECURITY.

We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats, as such term is defined in Item 106(a) of Regulation S-K. These risks include, among other things: operational risks, intellectual property theft, fraud, extortion, harm to employees or customers and violation of data privacy or security laws.

Identifying and assessing cybersecurity risk is integrated into our overall risk management systems and processes. Cybersecurity risks related to our business, technical operations, privacy and compliance issues are identified and addressed through a multi-faceted approach including third party assessments, internal IT Audit, IT security, governance, risk and compliance reviews. Our IT policies, processes and practices are based on recognized frameworks established by our external IT service provider and other applicable industry standards. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

As part of the above processes, we regularly engage consultants to assess our internal cybersecurity programs and compliance with applicable practices and standards.

As part of our cybersecurity defense measures, we enforce the use of the following security systems:

- EDR System (Endpoint Detection & Response)
- Two-factor authentication for email (Office 365) and cloud-stored information
- We protect our mail system against spam, phishing, spoofing, and malware using a (Mail Relay system).

Additionally, we enforce a real-time threat notification mechanism and activate alerts and reports for failures in our backup system.

We do not believe that there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations or financial condition. We also describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading "We are increasingly dependent on information technology systems, infrastructure and data, and our internal computer systems, or those of our collaborators, third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs." included as part of our risk factor disclosures at Item 1A of this Annual Report on Form 10-K.

Our Audit Committee of the Board of Directors, or the Audit Committee, is responsible for overseeing cybersecurity risk and periodically updates our Board of Directors on such matters. The Audit Committee receives periodic updates from management regarding cybersecurity matters and is notified between such updates regarding any significant new cybersecurity threats or incidents.

Management is responsible for the operational oversight of company-wide cybersecurity strategy, policy, and standards across relevant departments to assess and help prepare us to address cybersecurity risks.

ITEM 2. PROPERTIES.

Our facilities in Israel, which house our research and development and certain production and management functions, are located in Jerusalem, Israel. Most of our clinical development, clinical operations and regulatory functions are located in the United States. Under a Lease Agreement lease agreement with Unihead Biopark Ltd. as of December 31, 2022, that extends through 2028, we are leasing lease approximately 622 square meters of office and laboratory space pursuant space. We have the option to a terminate the lease agreement that will expire on June 30, 2023. Of early in December 2024 and in June 2026. The average rent over the 622 square meters leased, we utilize approximately 527 square meters for our operations and have agreed to sublease the remaining approximately 95 square meters to a third-party until June 2023. current term is $180,000 per year.

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 3. LEGAL PROCEEDINGS. PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market for our Ordinary Shares and IPO Warrants

Our Ordinary Shares and IPO Warrants are listed on the Nasdaq Capital Market under the symbols symbol "ENTX" and "ENTXW," respectively. .

As of March 27, 2023 March 1, 2024, there were approximately 44 89 holders of record of our Ordinary Shares. This number does not include the number of persons whose shares are in

nominee or in “street name” accounts through brokers.

Dividends

The Company has never declared or paid cash dividends on its Ordinary Shares and has no intention to pay any cash dividend for the foreseeable future. The Company currently plans to retain future earnings, if any, to finance the development of its business and for other corporate purposes.

The actual amount, timing, and frequency of future dividends, if any, will be at the sole discretion of the board of directors and will be declared based upon various factors, many of which are beyond our control.

If the Company decides to distribute a cash dividend, Israeli residents who are individuals are generally subject to Israeli income tax at a rate of either 25% or 30%, if the recipient of such dividend is a “substantial shareholder” at the time of distribution or at any time during the preceding 12-month period, unless the cash dividend is paid out of income that has been tax exempt due to an “approved enterprise” status under the Law for the Encouragement of Capital Investments, 5719-1959, in which case the Company will be subject to corporate tax at a rate then in effect under Israeli law on the amount of cash dividend and in addition, an Israeli shareholder, corporation or individual, will be subject to a tax rate of 20% on such cash dividend distribution. In addition, Israeli resident corporations are generally exempt from Israeli corporate tax for dividends paid on our Ordinary Shares. Pursuant to the Convention Between the Government of the United States of America and the Government of Israel with Respect to Taxes on Income, as amended (the “U.S.-Israel Tax Treaty”), the maximum tax on dividends paid to a holder of our Ordinary Shares who qualifies as a resident of the United States within the meaning of the U.S.-Israel Tax Treaty is 25% or 15% in case of dividends paid out of the profits of an “approved enterprise”, subject to certain conditions. Furthermore, dividends not generated by an “approved enterprise” paid to a U.S. corporation holding at least 10% of our issued voting power during the part of the tax year which precedes the date of payment of the dividend and during the whole of its prior tax year (if any), are generally taxed at a rate of 12.5%, subject to certain conditions. The Company has never declared or paid cash dividends on its Ordinary Shares.

The actual amount, timing, and frequency of future dividends, if any, will be at the sole discretion of the board of directors and will be declared based upon various factors, many of which are beyond our control. The Company’s current plans are to retain future earnings primarily to finance the development of its business and for other corporate purposes.

ITEM 6. [Reserved]

[Reserved]

ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (“PSLRA”), PSLRA, Section 27A of the Securities Act, of 1933, as amended, (the “Securities Act”), and Section 21E of the Securities Exchange Act, of 1934, as amended, (the “Exchange Act”), about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies and prospects. You can identify forward-looking statements by the fact that these statements do not relate to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those contained in “Item 1A - Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” of this Annual Report on Form 10-K. Report. We do not undertake any obligation to update forward-looking statements except as required by applicable law. We intend that all forward-looking statements be subject to the safe harbor provisions of PSLRA. These forward-looking statements reflect our views only as of the date they are made.

For purposes of this Item 7, references to the “Company,” “we,” “us” and “our” refer to Entera Bio Ltd. and its consolidated subsidiary.Overview

Overview

Entera is a clinical stage biopharmaceutical company and focused on developing first-in-class oral tablet formats of peptides or protein replacement therapies. We focus on underserved, chronic medical conditions for which oral administration of a leader in protein therapy has the development of orally delivered macromolecule therapeutics, including peptides and therapeutic proteins. potential to significantly shift a treatment paradigm.

Currently, most protein therapies are administered via frequent intravenous, subcutaneous, or intramuscular injections. In chronic diseases where patients require persistent management, these cumbersome, often painful and high-priced injections can create a major treatment gap. Furthermore, from
From a technical standpoint, oral delivery of therapeutic proteins has historically been is challenging due to the enzymatic degradation within the gastrointestinal tract and poor absorption into the blood stream due to the proteins' polarity and variable drug exposures. Entera's proprietary molecular weight. We leverage our N-Tab™ oral delivery technology which is designed to deliver orally administered proteins with sufficient bioavailability to meet treatment goals, using white mini tablets (around 6mm simultaneously stabilize the peptide in diameter) of the desired protein. gastrointestinal tract and promote its absorption into the bloodstream.

We strategically focus on underserved, chronic medical conditions whereOur most advanced product candidate, EB613 (oral PTH (1-34), teriparatide), is being developed as the first oral, administration osteoanabolic (bone building) once-daily tablet treatment for post-menopausal women with low BMD and high-risk osteoporosis with no prior fracture. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (pharmacodynamic/bone turnover biomarker) and secondary endpoints (BMD). Following the completion of a mini Type C and a Type D meeting with the U.S. Food and Drug Administration's (FDA), we announced the FDA's concurrence that a 2-year, placebo-controlled phase 3 (registrational) study with Total Hip BMD as primary endpoint could support a new drug application ("NDA") for EB613.
The EB612 program is being developed as the first oral PTH(1-34) tablet peptide replacement tablet therapy for hypoparathyroidism. With respect to our EB612 program we are currently testing new generations of our N-Tab™ Technology with the naked PTH(1-34) peptide to assess the effectiveness once or twice a day dosing regimens as well as collaborating with a third party on another peptide replacement therapy has the potential to significantly shift a treatment paradigm.
We currently have two product candidates in the clinical stage of development: EB613 and EB612. Both candidates are first-in-class daily mini tablets of human parathyroid hormone (hPTH (1-34), teriparatide). this field. To date, Entera's proprietary PTH tablets have been safely administered to a total of 72 102 healthy subjects in Phase 1 studies and 153 patients across in Phase 2 studies in osteoporosis and hypoparathyroidism, two diseases that remain underserved with the current standard of care and which disproportionately affect women. In addition to We believe these product candidates, if approved, hold the potential to become standards of care for patients with osteoporosis and hypoparathyroidism. Additionally, we have various internal early stage research programs are exploring the use of our PTH(1-34) tablets for the treatment of stress fractures in other approved peptides such as GLP-2 athletes and hGH, as well as outside early stage collaborations expect to potentially diversify our revenue stream. collaborate with an investigator sponsored study in this area. We expect to initiate a phase 2 trial for this indication in the second half of 2024.

In May 2023, the results from our oral GLP-2 program were published in the International Journal of Peptide Research and Therapeutics, "Oral Delivery Technology Enabling Gastro-Mucosal Absorption of Glucagon-Like-Peptide-2 Analog (Teduglutide) - A Novel Approach for Injection-Free Treatment of Short Bowel Syndrome." We believe GLP-2 represents a strong candidate for our N-Tab™ Technology and warrants further development as an injection-free alternative to patients suffering from short bowel syndrome and other gastrointestinal disorders where GLP-2 plays a role.
In September 2023, we entered into a research collaboration agreement with OPKO. Under the terms of this agreement, OPKO has agreed to supply its proprietary long-acting GLP-2 peptide and certain Oxyntomodulin analogs for the development of oral tablet formulations using our proprietary N-Tab™ technology. Oxyntomodulin (OXM) is a naturally occurring peptide hormone found in the colon, with glucagon-like-peptide 1 (GLP-1) and glucagon dual agonist activity which suppresses appetite and induces weight loss. OPKO has developed several proprietary, modified OXM analogs as potential candidates for treating obesity, including an injectable pegylated peptide which demonstrated significant reductions in weight loss and decreased plasma triglyceride levels in over 430 patients in phase 2/2B studies. We expect in vivo PK/PD data from both the oral GLP-2 tablet program and the oral OXM tablet program in 2024. We and OPKO have each agreed to be responsible for specific phases of development of the two oral peptides to the point of demonstrated *in vivo* feasibility.
Since our inception, we have raised a total of $84.7 million $91.3 million from a combination of public and private equity offerings, grants and the exercise of options and warrants. Since inception, we have incurred significant losses. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, our operating losses were $13.0 million $8.9 million and $12.2 million $13.0 million,

respectively, and we expect to continue to incur significant expenses and losses for the foreseeable future. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $95.5 million $104.4 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 research and development activities, and payments under any future collaborations into which we may enter.

As a result of our recurring losses from operations, negative cash flows and lack of liquidity, management is of the opinion that there is substantial doubt as to the Company's ability to continue as a going concern. 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, 2022 December 31, 2023, expressing the existence of substantial doubt about our ability to continue as a going concern. 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 delay certain program initiation, curtail or cease operations. See “Item 1A-Risk Factors-Risks Related to Our Financial Position and Need for Additional Capital.”

As of December 31, 2022 December 31, 2023, we had cash and cash equivalents of $12.3 million $11.0 million. We believe that our existing cash resources will be sufficient to meet our projected operating requirements into through the third second quarter of 2024, 2025, which include the capital required to fund our ongoing operations, including R&D, and the completion of the Phase 1 PK study related to the new formulation EB612. generation platform and the GLP-2/OXM collaborative research we are conducting with OPKO. However, this does not include the capital required to fund our proposed Phase 3 pivotal study for EB613 in osteoporosis and comparative PK study of EB613 and Forteo®. osteoporosis. We currently do not have funding sufficient for such this Phase 3 or PK studies, study, and our ability to commence such studies the study requires additional funding, which may not be available on reasonable terms, or at all. Any delay or our inability to secure such funding will delay or prevent the commencement of these studies. this study.

In order to fund further operations, we will need to raise additional capital. We may raise these funds through a variety of means, including private or public equity offerings, debt financings, 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.

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 with Oramed, pursuant to which Oramed assigned to us all of its rights, title and interest in the patent rights that Oramed licensed to us when we were originally organized, subject to a worldwide, royalty-free, exclusive, irrevocable, perpetual and sub-licensable 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.

Amgen Research Collaboration and License Agreement

On December 10, 2018, we entered into a research collaboration and license agreement with Amgen, which we refer to as the Amgen Agreement, with respect to inflammatory disease and other serious illnesses. Pursuant to the Amgen Agreement, we and Amgen have agreed to use our proprietary drug delivery platform to develop oral formulations for one preclinical large molecule program that Amgen has selected. In exchange for entering into the agreement, Amgen paid us a non-refundable and non-creditable initial access fee of $725,000 in the first quarter of 2019, of which $500,000 was attributed to the right to use the intellectual property and $225,000 was attributed to the pre-clinical R&D services that we are obligated to perform under the Amgen Agreement. In addition, under the Amgen Agreement, Amgen reimburses us for additional expenses that we incur for any work we do under the collaboration. Thus far during our collaboration, Amgen has paid $968,000 for pre-clinical R&D services by the end of 2022.

Amgen is responsible for the clinical development, regulatory approval, manufacturing and worldwide commercialization of the programs. 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 the additional two programs to include in the collaboration. In addition, Amgen is required to make tiered royalty payments ranging from the low to mid-single digits as a percentage of Amgen's net sales of the applicable products covered by the Amgen Agreement. 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.

Under the Amgen Agreement, we granted Amgen an exclusive, worldwide, sub-licensable license to certain of our intellectual property relating to our drug delivery technology to develop, manufacture and commercialize the applicable products. We have retained 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.

During certain periods covered by the Amgen Agreement, we may not alone, or with a third party, research, develop, manufacture or commercialize certain products that interact 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 pre-defined issues.

The term of the Amgen Agreement commenced on December 10, 2018, and unless earlier terminated, continues 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.

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 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 EB613, EB612 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 up to six times the amount of the grant received and the interest. The rate of royalties may be accelerated and the royalty liability may increase (up to three times the amount of the grant amount and the interest), 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. We signed a contract with a U.K.-based contract manufacturing organization to produce and supply pills for trials performed worldwide. We believe that, because this production is not for commercial purposes, it will not affect the royalty rates to be paid to the IIA. Should the IIA successfully take a contrary position, the maximum royalties to be paid to the IIA will be approximately $1.5 million, which is three times the amount of the original grant (three times of the interest will also be added). Following Under a collaboration agreement that was previously mutually terminated in May 2023, from 2019 through March 31, 2023, we recognized an aggregate amount of $1.7 million of revenue in accordance with ASC 606, ""Revenues from Contracts with Customers" With respect to revenue generated from the signing of the Amgen Agreement, collaboration agreement. Prior to its termination, we have had been required to pay to the IIA 5.38% of each payment by Amgen and made to us under the collaboration agreement with an ultimately liability of up to 600% of the grant received and the plus interest. As of

December 31, 2022December 31, 2023, we had paid royalties to the IIA in the amount of $83,000 related to a collaboration agreement and other material transfer agreements ("MTAs").As of December 31, 2023, we owed $13,000 to the Amgen Agreement.IIA, which was paid in February 2024.

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.

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.

Under the Amgen Agreement, through December 31, 2022, we had received an additional aggregate amount of $968,000 for research and development services.
Revenues including revenues under the Amgen Agreement, are recognized according to ASC 606, "Revenues "Revenues from Contracts with Customers".

According to ASC 606, a performance obligation is a promise to provide a distinct good or service or a series of distinct goods or services. Goods and services that are not distinct are bundled with other goods or services in the contract until a bundle of goods or services that is distinct is created. A good or service promised to a customer is distinct if the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. Options granted to the customer that do not provide a material right to the customer that it would not receive without entering into the contract do not give rise to performance obligations. We identified two performance obligations in the agreement: the license to use the Company's proprietary drug delivery platform and pre-clinical research and development services ("pre-clinical R&D services"). The license to our intellectual property has significant standalone functionality, 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, we recognized the revenues related to this performance obligation in December 2018 at the point in time that control of the license was transferred to Amgen. The preclinical R&D services include discovery, research and design preclinical activities relating to the programs selected by Amgen. Revenues attributed to the preclinical R&D services are recognized during the period the pre-clinical R&D services are provided according to the input model method on a cost-to-cost basis. Each of these items met the definition of distinct performance obligation. The Company evaluated the standalone selling price of the pre-clinical R&D services at $225,000 and the right to use the intellectual property at $500,000.

Under ASC 606, 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 milestone-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. Variable consideration is included in the transaction price if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of our anticipated performance and all information (historical, current and forecasted) that is reasonably available. We did not recognize any revenues from milestone payments.

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).

- The subsequent sale or usage occurs; and

We did not recognize any revenues from royalties because royalties are payable based on future commercial sales, as defined in the Amgen Agreement, and there have been no commercial sales.

- 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).

For the years ended December 31, 2022 and 2021, we recognized revenues from the Amgen Agreement and other material transfer agreements ("MTA") in the total amounts of $134 thousand and $571 thousand, respectively.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development ofWe primarily focus on 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 the research and development function;
- expenses incurred in operating our laboratories including our small-scale manufacturing facility;
- expenses incurred under agreements with CROs, and investigative sites that conduct our clinical trials;
- expenses related 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 increase significantly in future periods as we advance EB613, EB612 and EB612 other product candidates into later stages of clinical development and invest in additional preclinical candidates.

Research and development expenses consist of costs incurred for the development of our drug delivery technology and our product candidates, including:

- employee-related expenses, including salaries, bonuses and share-based compensation expenses for employees and service providers in the research and development function;
- expenses incurred in operating our laboratories including our small-scale manufacturing facility;
- expenses incurred under agreements with CROs, and investigative sites that conduct our clinical trials;
- expenses related 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.

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 the timing of initiation of clinical trials and the enrollment of patients in clinical trials. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, our research and development expenses were $5.8 million $4.5 million and $6.8 million $5.8 million, respectively. Research and development expenses for the years ended December 31, 2022 December 31, 2023 and 2021 2022 were primarily for the development of EB613, EB612, and EB612. development of our new generation platform. 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 any 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.

- 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 any 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 that we currently anticipate will be required as necessary 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, then 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, benefits, share-based compensation and related costs for directors and personnel in executive and finance functions. Other general and administrative expenses include D&O insurance and other insurance, communication expenses, professional fees for legal and accounting services, patent counseling costs associated with maintaining and prosecuting our intellectual property portfolio maintenance and business development expenses.

We expect that our general and administrative expenses will increase in the future as we increase our headcount and expand our administrative function to support our operations.

Financial Expenses (Income), Net

Financial expenses (income), net are composed primarily of interest income from bank deposits and exchange rate differences of certain currencies against our functional currency.

Income Tax Expenses (Benefit)

We have not generated taxable income since our inception, and as of December 31, 2022 December 31, 2023, we had carry-forward tax losses of $67.1 million $75.8 million. We anticipate that we will be able to carry forward these tax losses indefinitely to future tax years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carryforward tax losses. We provided a full valuation allowance with respect to the deferred tax assets related to these carry forward losses of the Company.

The Company's subsidiary, Entera Bio, Inc., is taxed separately under the U.S. tax laws. As of December 31, 2022 December 31, 2023, Entera Bio Inc. has had tax loss carry-forwards of $98 $156 thousand.

Results of Operations

Comparison of Years Ended December 31, 2022 December 31, 2023 and 2021 2022

	Year Ended December 31,		Increase (Decrease)	
	2022	2021	$	%
	(In thousands, except for percentage information)			
Revenues	$ 134	$ 571	$ (437)	(77)%
Cost of revenues	$ 101	$ 373	(272)	(73)%
Operating expenses:				
Research and development expenses	$ 5,848	$ 6,771	$ (923)	(14)%
General and administrative expenses	$ 7,253	$ 5,690	$ 1,563	27 %
Other income	$ (51)	$ (46)	$ (5)	11 %
Operating loss	$ 13,017	$ 12,217	$ 800	7 %
Financial expenses (income), net	$ (83)	$ 29	$ (112)	(386)%
Income tax expenses (benefit)	$ 137	$ (59)	$ 196	(332)%
Net loss	$ 13,071	$ 12,187	$ 884	7 %

Revenue

	Year Ended December 31,		Increase (Decrease)	
	2023	2022	$	%
	(In thousands, except for percentage information)			
Revenues	$ -	$ 134	$ (134)	(100)%
Cost of revenues	$ -	$ 101	(101)	(100)%
Operating expenses:				
Research and development expenses	$ 4,510	$ 5,848	$ (1,338)	(22.8)%
General and administrative expenses	$ 4,430	$ 7,253	$ (2,823)	(38.9)%
Other income	$ (49)	$ (51)	$ 2	(3.9)%
Operating loss	$ 8,891	$ 13,017	$ (4,126)	(31.6)%
Financial income, net	$ (31)	$ (83)	$ 52	(62.6)%
Income tax expenses	$ 29	$ 137	$ (108)	(78.8)%
Net loss	$ 8,889	$ 13,071	$ (4,182)	(32.0)%

Revenue

Revenues for the years ended December 31, 2022 and 2021 were $134,000 and $571,000, respectively. For 2022 and 2021, the majority of our revenues were attributable to research and development, or R&D, services provided to Amgen under the Amgen Agreement and other MTA agreements. The decrease in revenue for the year ended December 31, 2022 as comparedwere mainly attributable to the prior year period was primarily due to finalization of third year pre-clinical R&D services. services provided under our previously terminated collaboration agreement. We did not generate recognize any revenues prior revenue for the year ended December 31, 2023 due to entering into the Amgen Agreement. termination of the collaboration agreement, effective May 2, 2023.

Cost of Revenues

Cost of revenues for the year ended December 31, 2022 were $101,000 compared mainly attributable to $373,000 pre-clinical R&D services provided under our previously terminated collaboration agreement. The decrease in cost was due to the lack of revenue, as described above, for the year ended December 31, 2021 and were primarily attributed to salaries and related expenses in connection with the R&D services provided under the Amgen Agreement and other MTA agreements. The decrease in cost of revenues for the year ended December 31, 2022 was primarily due to decreased revenues under the Amgen Agreement, as described above. December 31, 2023.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2022 December 31, 2023 were $5.8 million $4.5 million, as compared to $6.8 million $5.8 million for the year ended December 31, 2021 December 31, 2022. The decrease of $1.0 million $1.3 million was primarily attributed due to a decrease of $0.6 million related to the completion of our Phase 2 trial for EB613 $1.5 million in September 2021, pre-clinical activity and materials costs, a decrease of $0.9 million $0.6 million in pre-clinical activities related employee compensation, including a one-time payment made to our planned Phase 3 clinical trial for EB613, which were a former employee pursuant to the terms of his separation agreement. The decrease was partially offset by an increase of $0.3 million $0.8 million in continued materials and production costs, strengthening the R&D organization in preparation clinical expenses for EB613's

proposed phase 3 study and EB612's proposed new formulation our Phase 1 PK study and an increase of $0.2 million in employee compensation, primarily related to a one-time payment to our former President of R&D. new generation platform and new formulations for EB612.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2022 December 31, 2023 were $7.3 million $4.4 million, compared to $5.7 million $7.3 million for the year ended December 31, 2021 December 31, 2022. The increase decrease of $1.6 million $2.8 million was primarily mainly attributable to an increase a decrease of $0.4 million $1.1 million in non-cash share-based employee compensation, granted to directors and executive officers and an increase of $0.4 with respect to including a one-time payment to our former Chief Executive Officer. Additionally, there was an increase employee pursuant to the terms of $0.5 million in his separation agreement, a decrease of $0.8 million as part of a restructuring of professional fees and an increase other advisor expenses, a decrease in Board fees of $0.3 million $0.2 million due to the Board's forfeiture of their fees for the third and fourth quarters of 2023 and a decrease of $0.7 million in D&O insurance costs.

Financial Expenses (Income), Net

Financial Income, Net

Financial income, net for the year ended December 31, 2022 December 31, 2023 was $83,000, $31,000, compared to $29,000 financial expenses, net $83,000 for the year ended December 31, 2021 December 31, 2022. Our financial expenses (income) is income for 2023 was composed primarily of interest income from bank deposits and exchange rate differences of certain currencies against our functional currency, which is the U.S. Dollar.

Liquidity and Capital Resources

Since inception, we have incurred significant losses. As a result of our recurring losses from operations, negative cash flows from operating activities 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, 2022 December 31, 2023, expressing the existence of substantial doubt about our ability to continue as a going concern. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, our operating losses were $13.0 million $8.9 million and $12.2 million $13.0 million, respectively. We expect to continue to incur significant expenses and losses for the next several years as we advance our products through development and provide administrative support for our operations. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $95.5 million $104.4 million. Since our inception, we have raised a total of $84.7 million $91.3 million, including $25.3 million through at-the-market-offering ("ATM") programs, $6.6million in our December 2023 Private Placement (as defined below), $14.3 million in our December 2019 private placement, $11.2 million in our IPO in 2018 and $33.9 million in aggregate funding from a combination of grants, exercise of options and warrants and private placements of Ordinary Shares, preferred shares and debt prior to our IPO. In addition, as of December 31, 2022 December 31, 2023, we had received approximately $1.4 million $1.7 million under the Amgen Agreement. our previously terminated collaboration agreement.

As of December 31, 2022 December 31, 2023, we had cash and cash equivalents of $12.3 million $11.0 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.

In July 2020, we entered into an equity distribution agreement with Canaccord Genuity LLC, as sales agent, to implement an at-the-market offering program under which we, from time to time, were able to offer and sell our Ordinary Shares, having an aggregate offering amount of up to $13.9 million. This ATM program terminated in accordance with its terms following our sale of the full dollar amount of ordinary shares permitted thereunder. On May 7, 2021 we entered into an At Market Issuance Sales Agreement with B. Riley Securities, Inc., as sales agent, under which we, from time to time, had been able to offer and sell up to 5,000,000 Ordinary Shares . For the year ended December 31, 2021, we sold an aggregate of 4,386,728 ordinary shares under the foregoing ATM programs for aggregate proceeds of $21.8 million, net of issuance costs.

84Equity Offerings

Following our loss of foreign private issuer status on January 1, 2022, we were no longer able to use our then-current ATM program, as offers and sales under which had been registered on our registration statement on Form F-3, which may be used only by a foreign private issuer; therefore, we filed a new shelf registration statement on Form S-3 (file no. 333-365286) on May 27, 2022 to, among other things, facilitate

our use of the Amended B. Riley ATM Program and SVB ATM Program (each as defined below). On May 27,2022 we entered into an Amended and Restated at Market Issuance Sales Agreement with B. Riley Securities, Inc., as sales agent, under which we were able, from time to time, to offer and sell up to 5,000,000 Ordinary Shares (the "Amended B. Riley ATM Program"). Effective August 30, 2022, we terminated the Amended B. Riley ATM Program, and we had not sold any shares under such agreement.

On September 2, 2022, we entered into a Sales Agreement with SVB Securities LLC, as sales agent, to implement an ATM program under which we may from time to time offer and sell up to 5,000,000 Ordinary Shares (the "SVB ATM Program") under our currently effective Registration Statement on Form S-3 and a related prospectus supplement forming a part thereof. The sales agent is entitled to a fixed commission of 3% of the aggregate gross proceeds as well as and reimbursement of expenses. As of December 31, 2022 December 31, 2023, we had not sold any 4,030 shares under the SVB ATM Program. Program for aggregate proceeds of $5 thousand, net of issuance costs.

Funding RequirementsOn December 20, 2023, we entered into a securities purchase agreement with certain investors (the "Purchasers"), providing for the private placement (the "December 2023 Private Placement") to the Purchasers of an aggregate of 7,916,879 units (collectively, the "Units"), each Unit consisting of (i) one Ordinary Share (or, in lieu thereof, one pre-funded warrant to purchase one Ordinary Share (the "Pre-Funded Warrants")) and (ii) one warrant to purchase one Ordinary Share (the "Ordinary Share Warrant"), for aggregate proceeds of approximately $6.6 million (or $0.835 per Unit, which represented the aggregate of the Nasdaq closing price on December 20, 2023 plus $0.125 per Ordinary Share Warrant). The Private Placement was priced at the market under applicable Nasdaq rules and closed on December 22, 2023.

Each Ordinary Share Warrant has an exercise price of $1.00 per share (a premium of 41% to the closing price per Ordinary Share on Nasdaq on December 20, 2023), is immediately exercisable, and expires five years from the date of issuance, and is subject to customary adjustments for dividends, splits, combinations and fundamental transactions, such as a merger of the Company. None of the warrants contain any "ratchet", "reset" or other adjustments related to financial antidilution.
If all Ordinary Share Warrants were exercised for cash, then the Company would receive additional proceeds of approximately $7.9 million. There can be no assurance that the holders of the Ordinary Share Warrants exercise their respective warrants for cash, or at all.
Funding Requirements
We believe that our existing cash resources will be sufficient to meet our projected operating requirements into through the third second quarter of 2024, 2025, which include the capital required to fund our ongoing operations, including R&D, and the completion of the Phase 1 PK study related to the new formulation EB612. generation platform and the GLP-2/OXM collaborative research we are conducting with OPKO. However, this does not include the capital required to fund our proposed Phase 3 pivotal study for EB613 in osteoporosis and comparative PK study of EB613 and Forteo®. osteoporosis. We currently do not have funding sufficient for such Phase the pivotal phase 3 or PK studies, study, and our ability to commence such studies requires the study will require additional funding, which may not be available on reasonable terms, or at all. Any delay or our inability to secure such funding will delay or prevent the commencement of these studies.

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; and
- our ability to establish collaborations on favorable terms, if at all.
- the costs, timing and outcome of clinical trials for, and regulatory review of our five oral peptide programs, including EB613 and 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; and
- our ability to establish collaborations on favorable terms, if at all.

We are in the process of evaluating various financing alternatives in the public or private equity markets or through license of our N-Tab™ technology to additional external parties through partnerships or research collaborations as we 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 our ability to obtain such funding.

Other than the SVB ATM Program, 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 our existing shareholders' rights as shareholders. 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 and may include requirements to hold minimum levels of funding. 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 or collaborations, 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, 2022 December 31, 2023, included elsewhere in this Annual Report, on Form 10-K, 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 our cash outflows from operating activities 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, 2022 December 31, 2023 Compared to Year Ended December 31, 2021 December 31, 2022

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,	
	2022	**2021**
	(in thousands)	
Net Cash used in operating activities	$ (12,499)	$ (9,063)
Net Cash used in investing activities	(102)	(17)
Net Cash provided by financing activities	13	25,381
Net increase (decrease) in cash and cash equivalents	$ (12,588)	$ 16,301

	(audited) Year ended December 31,	
	2023	**2022**
	(in thousands)	
Net Cash used in operating activities	$ (7,310)	$ (12,499)

Net Cash used in investing activities	(17)	(102)
Net Cash provided by financing activities	6,036	13
Net decrease in cash and cash equivalents	$ (1,291)	$ (12,588)

Net Cash Used in Operating Activities

Net Cash used in operating activities for the year ended December 31, 2023 was $7.3 million, consisting primarily of our operating loss of $8.9 million, and an increase of $0.2 million in our working capital which was partially offset by approximately $1.8 million of share-based compensation and depreciation expenses.

Net Cash used in operating activities for the year ended December 31, 2022 was $12.5 million, consisting primarily of our operating loss of $13.0 million and an increase of $1.8 million in our working capital, which was partially offset by approximately $2.3 million of share-based compensation and depreciation expenses.

Net Cash used in operating activities for the year ended December 31, 2021 was $9.1 million, consisting primarily of our operating loss of $12.2 million, which was partially offset by $1.7 million of share-based compensation, depreciation and deferred income taxes, and aThe decrease of $1.4 million in our working capital.

The increase of $3.4 million $5.2 million in cash used in operating activities for the year ended December 31, 2022 December 31, 2023 compared to the same period in 2021 2022 was mainly attributed to an increase a decrease of $0.8 million $4.1 million in our operating loss, and an increase a decrease of $3.2 million $1.6 million in working capital primarily due to payments to suppliers and services providers, which was partially offset by an increase a decrease of $0.4 million $0.5 million in share-based compensation and depreciation expenses.

Net Cash Used in Investing Activities

Net Cash used in investing activities for the year years ended December 31, 2023 and December 31, 2022 and 2021 primarily consisted primarily of the purchase of property and equipment and withdrawal of funds in connection with the retirement of certain employees.

equipment.

Net Cash Provided by Financing Activities

Net Cash provided by financing activities for the year ended December 31, 2023 primarily reflects net proceeds of $5.8 million from issuance of the Units in the December 2023 Private Placement.

Net Cash provided by financing activities for the year ended December 31, 2022 primarily derived from reflects net proceeds of $13 thousand from the exercise of options to purchase Ordinary Shares.

Net Cash provided by financing activities for the year ended December 31, 2021 primarily derived from net proceeds of $21.8 million from the issuance of Ordinary Shares under our ATM and $3.6 million from the exercise of warrants and options.

Contractual Obligations

The following tables summarize our contractual obligations and commitments as of December 31, 2022 December 31, 2023 that will affect our future liquidity:

	Payments due by period						Payments due by period					
Contractual Obligations	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**		**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**	
	(In thousands)						(In thousands)					
Operating leases for facility	$ 96	$ 96	$ -	$ -	$ -		$ 454	$ 184	$ 270	$ -	$ -	

Total	$ 96	$ 96	$ -	$ -	$ -	$ 454	$ 184	$ 270	$ -	$ -

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, 2022 December 31, 2023, our severance pay liability, net was immaterial. 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. milestones. 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 IIA.

Critical Accounting Policies and Estimates

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of consolidated financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by our management. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

While our significant accounting policies are more fully described in Note 2 to the consolidated financial statements included elsewhere in this Annual Report, on Form 10-K, we believe that the following accounting policies are the most critical to assist shareholders and investors reading the consolidated financial statements in fully understanding and evaluating our financial condition and results of operations. These policies relate to the more significant areas involving management's judgments and estimates and they require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of the matters that are inherently uncertain.

Revenue RecognitionShare-Based Compensation

With respect to the Amgen Agreement, we used our judgement to identify our deliverables in the agreement and whether the deliverables are distinct performance obligation. In addition, we use our judgement to determine the allocation of the transaction price between our identified distinct performance obligations. We also used 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-Revenue Recognition" of our audited consolidated financial statements for the year ended December 31, 2022, included elsewhere in this Annual Report.

Share-Based Compensation

In 2013 and in 2018, we adopted share-based compensation plans for employees, directors and service providers. Our share-based compensation plan adopted in 2013 governs the issuance of equity incentive awards prior to our initial public offering, and the share-based compensation plan adopted in 2018 governs the 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 and restricted share units. 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.

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

	Year ended December 31,	
	2022	2021
	(in thousands)	
Cost of revenues	$ 14	$ 102
Research and development	708	661
General and administrative	1,525	1,098
Total	$ 2,247	$ 1,861

	Year ended December 31,	
	2023	2022
	(in thousands)	
Cost of revenues	$ -	$ 14
Research and development	424	708
General and administrative	1,265	1,525
Total	$ 1,689	$ 2,247

Recently Issued Accounting Pronouncements

Certain recently issued accounting pronouncements are discussed in Note 2 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Report.

Item 7A. . Quantitative and Qualitative Disclosures about Market Risk

Not required for smaller reporting companies.

ITEMItem 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ENTERA BIO LTD.
CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2022 2023

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Report of Independent Registered Public Accounting Firm

To theBoard of Directors and Shareholders of Entera Bio Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidatedbalance sheetsof Entera Bio Ltd.and its subsidiary(the (the "Company") as of December 31, December 31, 2023 and 2022, and 2021,and the related consolidatedstatements of operations, changes in shareholders' equity and cash flows for the years then ended,,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 December31, December 31, 2023 and 2022,and 2021, and the results ofitsoperations and itscash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

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 1d 1c 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 regarding in regard to these matters are also described in note 1d. 1c. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. uncertainty.

Basis for Opinion

These consolidatedfinancial statements are the responsibility of the Company's Company's management. Our responsibility is to express an opinion on the Company's consolidatedfinancial 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 consolidatedfinancial 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.The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion opinion..

Our audits included performing procedures to assess the risks of material misstatement of the consolidatedfinancial 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 consolidatedfinancial 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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. We determined there are no critical audit matters.

/s/Kesselman & Kesselman

Certified Public Accountants (lsr.)

A member firm of PricewaterhouseCoopers International Limited

Tel-Aviv, Israel

March 31, 2023 8, 2024

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

ENTERA BIO LTD.

CONSOLIDATED BALANCE SHEETS

(U.S. (U.S. dollars in thousands, except share data)

A s s e t s	December 31	
CURRENT ASSETS:	**2023**	**2022**
Cash and cash equivalents	11,019	12,309
Accounts receivable	-	246
Other current assets	238	294

TOTAL CURRENT ASSETS	11,257	12,849
NON-CURRENT ASSETS:		
Property and equipment, net	100	139
Operating lease right-of-use assets	388	90
Deferred income taxes	14	43
Funds in respect of employee rights upon retirement	6	6
TOTAL NON-CURRENT ASSETS	508	278
TOTAL ASSETS	11,765	13,127
L i a b i l i t i e s and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	83	17
Accrued expenses and other payables	874	1,233
Current maturities of operating lease	134	91
TOTAL CURRENT LIABILITIES	1,091	1,341
NON-CURRENT LIABILITIES:		
Operating lease liabilities	256	-
Liability for employee rights upon retirement	32	32
TOTAL NON-CURRENT LIABILITIES	288	32
TOTAL LIABILITIES	1,379	1,373
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.0000769 par value: Authorized - as of December 31, 2023 and December 31, 2022, 140,010,000 shares; issued and outstanding as of December 31, 2023, and December 31, 2022, 35,476,341 and 28,809,922 shares, respectively	1	*
Additional paid-in capital	114,730	107,210
Accumulated other comprehensive income	41	41
Accumulated deficit	(104,386)	(95,497)
TOTAL SHAREHOLDERS' EQUITY	10,386	11,754
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	11,765	13,127

	December 31	
	2022	**2021**
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	12,309	24,892
Accounts receivable	246	183
Other current assets	294	254
TOTAL CURRENT ASSETS	12,849	25,329
NON-CURRENT ASSETS:		
Property and equipment, net	139	156
Operating lease right-of-use assets	90	239
Deferred income taxes	43	217
Funds in respect of employee rights upon retirement	6	46
TOTAL NON-CURRENT ASSETS	278	658
TOTAL ASSETS	13,127	25,987
L i a b i l i t i e s and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	17	166

Accrued expenses and other payables	1,233	2,801
Current maturities of operating lease	91	179
Contract liabilities	-	15
TOTAL CURRENT LIABILITIES	1,341	3,161
NON-CURRENT LIABILITIES:		
Operating lease liabilities	-	123
Liability for employee rights upon retirement	32	138
TOTAL NON-CURRENT LIABILITIES	32	261
TOTAL LIABILITIES	1,373	3,422
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.0000769 par value: Authorized - as of December 31, 2022 and December 31, 2021, 140,010,000 shares; issued and outstanding as of December 31, 2022, and December 31, 2021 28,809,922 and 28,804,411 shares, respectively	*	*
Additional paid-in capital	107,210	104,950
Accumulated other comprehensive income	41	41
Accumulated deficit	(95,497)	(82,426)
TOTAL SHAREHOLDERS' EQUITY	11,754	22,565
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	13,127	25,987

* Represents an amount less than one thousand US dollars

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

ENTERA BIO LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S.(U.S. dollars in thousands, except share and per share data)

	Year ended December 31		Year ended December 31	
	2022	2021	2023	2022
REVENUES	134	571	-	134
COST OF REVENUES	101	373	-	101
GROSS PROFIT	33	198	-	33
OPERATING EXPENSES:				
Research and development	5,848	6,771	4,510	5,848
General and administrative	7,253	5,690	4,430	7,253
Other income	(51)	(46)	(49)	(51)
TOTAL OPERATING EXPENSES	13,050	12,415	8,891	13,050
OPERATING LOSS	13,017	12,217	8,891	13,017
FINANCIAL EXPENSES (INCOME), net	(83)	29		
FINANCIAL INCOME, net			(31)	(83)
LOSS BEFORE INCOME TAX	12,934	12,246	8,860	12,934
INCOME TAX EXPENSE (BENEFIT)	137	(59)		
INCOME TAX EXPENSES			29	137
NET LOSS	13,071	12,187	8,889	13,071
LOSS PER SHARE BASIC AND DILUTED	0.45	0.47	0.31	0.45
WEIGHTED-AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	28,808,090	26,133,770	29,007,794	28,808,090

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

ENTERA BIO LTDLTD.

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

(U.S.

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

	Ordinary shares				
	Number of shares issued	Amounts	Additional paid-in capital	Accumulated other Comprehensive income	Acc
BALANCE AT JANUARY 1, 2021	21,057,922	*	77,708	41	
Net loss	-	-	-	-	
Exercise of warrants to ordinary shares	3,175,050	*	3,158	-	
Issuance of shares due to the ATM program, net of issuance costs	4,386,728	*	21,805	-	
Exercise of options to ordinary shares	177,711	*	418	-	
Share-based compensation	-	-	1,861	-	
Vested restricted share units	7,000	*	-	-	
BALANCE AT DECEMBER 31, 2021	28,804,411	*	104,950	41	
BALANCE AT JANUARY 1, 2022					
Net loss	-	-	-	-	
Exercise of options to ordinary shares	5,511	*	13	-	
Share-based compensation	-	-	2,247	-	
BALANCE AT DECEMBER 31, 2022	28,809,922	*	107,210	41	
Net loss					
Issuance of ordinary shares, warrants and pre-funded warrants due to a private placement, net of issuance costs					
Issuance of shares under the ATM program, net of issuance costs					
Share-based compensation					
BALANCE AT DECEMBER 31, 2023					

* Represents an amount less than one thousand US dollars.

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

ENTERA BIO LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31		Year ended December 31	
	2022	2021	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	**(13,071)**	**(12,187)**	**(8,889)**	**(13,071)**
Adjustments required to reconcile net loss to net cash used in operating activities:				
Depreciation	**64**	**53**	**56**	**64**
Deferred income taxes	**174**	**(217)**	**29**	**174**
Share-based compensation	**2,247**	**1,861**	**1,689**	**2,247**
Finance expenses (income), net	**(78)**	**18**		
Finance income, net				**(78)**
Changes in operating asset and liabilities:				
Decrease (increase) in accounts receivable	**(63)**	**72**	**246**	**(63)**

Decrease (increase) in other current assets	(40)	7	56	(40)
Increase (decrease) in accounts payable	(149)	2	66	(149)
Increase (decrease) in accrued expenses and other payables	(1,568)	1,471		
Decrease in accrued expenses and other payables			(563)	(1,568)
Decrease in contract liabilities	(15)	(143)	-	(15)
Net cash used in operating activities	(12,499)	(9,063)	(7,310)	(12,499)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Funds with respect to employee rights upon retirement	(55)	-	-	(55)
Purchase of property and equipment	(47)	(17)	(17)	(47)
Net cash used in investing activities	(102)	(17)	(17)	(102)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from issuance of shares through ATM programs, net of issuance costs	-	21,805	5	-
Exercise of options and warrants into shares	13	3,576		
Issuance of ordinary shares and warrants due to a private placement			6,611	-
Issuance costs			(580)	
Exercise of options into shares			-	13
Net cash provided by financing activities	13	25,381	6,036	13
INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS	(12,588)	16,301		
DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS			(1,291)	(12,588)
CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS AT BEGINNING OF THE YEAR	24,964	8,663	12,376	24,964
CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS AT END OF THE YEAR	12,376	24,964	11,085	12,376
Reconciliation in amounts on consolidated balance sheets:				
Cash and cash equivalents	12,309	24,892	11,019	12,309
Restricted deposits included in other current assets	67	72	66	67
Total cash and cash equivalents and restricted deposits	12,376	24,964	11,085	12,376
SUPPLEMENTAL DISCLOSURE OF CASH FLOW TRANSACTIONS:				
Interest received			18	-
Income taxes paid in cash during the year	165	2	-	165
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:				
Issuance costs			470	-
Operating lease right of use assets obtained in exchange for new operating lease liabilities	-	31	449	-

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

ENTERA BIO LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share amounts)

NOTE 1 - GENERAL

a. Entera Bio Ltd. (collectively with its subsidiary, the "Company") "Company) was incorporated on September 30, 2009 and commenced operation on June 1, 2010. On January 8, 2018, the Company incorporated its wholly owned subsidiary, Entera Bio Inc., a wholly owned subsidiary incorporated in Delaware, United States. The Company is focused on developing first-in-class oral tablet formats of peptides or protein replacement therapies. The Company focuses on underserved, chronic medical conditions for which oral administration of a leader in protein therapy has the development and commercialization of orally delivered large molecule therapeutics for use in areas with significant unmet medical need where adoption of injectable therapies is limited due potential to cost, convenience and compliance challenges for patients. significantly shift a treatment paradigm.

The Company's most advanced product candidates, candidate, EB613, oral PTH (1-34), is being developed as the first oral, osteoanabolic (bone building) once-daily tablet treatment for the treatment of post-menopausal women with low bone mineral density ("BMD") and high-risk osteoporosis and EB612 for the treatment of hypoparathyroidism, are based on its proprietary technology platform and are both in clinical development. Additionally, the Company intends to license its oral delivery technology to biopharmaceutical companies for use with their proprietary compounds.no prior fracture.

The Company is preparing to initiate a Phase 3 registrational study for EB613 pursuant to the FDA's qualification of a quantitative BMD endpoint. The EB612 program is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for hypoparathyroidism. Additionally, the Company intends to license its N-Tab™ technology to biopharmaceutical companies for use with their proprietary compounds.

b. The Company's ordinary shares, NIS 0.0000769 par value per share ("ordinary shares"), are have been listed on the Nasdaq Capital Market since July 2018 under the symbol "ENTX".

c. On December 10, 2018, the Company entered into a research collaboration and license agreement with Amgen (the "Amgen Agreement") for the use of the Company's oral delivery platform in the field of inflammatory disease and other serious illnesses. Pursuant to the Amgen Agreement, the Company and Amgen have agreed to use the Company's proprietary drug delivery platform to develop oral formulations for one preclinical large molecule program that Amgen has selected. Amgen is responsible for the clinical development, regulatory approval, manufacturing and worldwide commercialization of the programs.

The Company granted Amgen an exclusive, worldwide, sublicensable 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 agreement is to be determined by U.S. patent law.

d. Because the Company is engaged in research and development activities, it has not derived significant income from its activities and has incurred an accumulated deficit in the amount of $95.5 million through December 31, 2022 $104.4 million as of December 31, 2023 and negative cash flows from operating activities. The Company's management is of the opinion that its available funds as of December 31, 2022 December 31, 2023 will allow the Company to operate under its current plans into through the third second quarter of 2024. 2025. This assumes the use of the Company's capital to fund its ongoing operations, including R&D research and development, the completion of the Phase 1 study related to the new formulation EB612. This does generation platform and the GLP-2/OXM collaborative research the Company is conducting with OPKO Biologics, Inc., a subsidiary of OPKO Health Inc. ("OPKO"). The Company's current capital resources do not include the capital required to fund the Company's proposed Phase 3 study for EB613 in osteoporosis and comparative study. osteoporosis. 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 and private equity markets, debt financing and strategic collaborations, as the Company will need to finance future research and development activities, general and administrative expenses and working capital through fund capital raising. However, there is no certainty about the Company's ability to obtain such funding. The These consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

d. In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on the Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in thousands of deaths and injuries, and Hamas additionally kidnapped many Israeli civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and commenced a military campaign against Hamas. While the Company has a few employees who are in active military service, the ongoing war with Hamas has not, since its inception, materially impacted the Company's business or operations. Furthermore, the Company does not expect any delays to any of its programs as a result of the situation. However, the Company cannot currently predict the intensity or duration of Israel's war against Hamas, nor can predict how this war will ultimately affect its business and operations or Israel's economy in general.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation of the financial statements

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). Prior to 2021, the Company prepared its financial statements in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"), as permitted in the United States ("U.S.") based on the Company's status as a foreign private issuer as defined in the rules promulgated by the U.S. Securities and Exchange Commission (the "SEC"). During 2021, the Company determined that it is no longer qualified as a foreign private issuer under the SEC rules. As a result, since January 1, 2022, the Company has been required to comply with all of the disclosure and reporting requirements applicable to U.S. domestic issuers, including preparing its financial statement in accordance with U.S. GAAP.

b. Use of estimates in the preparation of financial statements

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates.

c. Functional currencyc. **Functional 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 are conducted. The consolidated financial statements are presented in U.S. dollars.
The functional currency of the subsidiary is the U.S. dollar.

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 are conducted. The consolidated financial statements are presented in U.S. dollars.
The functional currency of the subsidiary is the U.S. dollar.

2) Transactions and balances

Transactions and balances originally denominated in U.S. dollars are presented at their original amounts. Balances in non- U.S. dollar currencies are translated into U.S. dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-U.S. dollar transactions and other items in the statements of income (indicated below), the following exchange rates are used: (i) for transactions – exchange rates at transaction dates or average exchange rates; and (ii) for other items (derived from non-monetary balance sheet items such as depreciation and amortization) – historical exchange rates. Currency transaction gains and losses are presented in financial income (expenses), as appropriate.

Transactions and balances originally denominated in U.S. dollars are presented at their original amounts. Balances in non- U.S. dollar currencies are translated into U.S. dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-U.S. dollar transactions and other items in the statements of income (indicated below), the following exchange rates are used: (i) for transactions – exchange rates at transaction dates or average exchange rates; and (ii) for other items (derived from non-monetary balance sheet items such as depreciation and amortization) – historical exchange rates. Currency transaction gains and losses are presented in financial income (expenses), as appropriate.

Principles of consolidation

d.

The consolidated financial statements include the accounts of the Company and its subsidiary Entera Bio Inc. All inter-company transactions and balances have been eliminated in consolidation.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)(continued)

d. Principles of consolidatione. The consolidated financial statements include the accounts of the Company and its subsidiary Entera Bio Inc. All inter-company transactions and balances have been eliminated in consolidation.

e. Cash and cash equivalents

The Company considers as cash equivalents all short-term, highly liquid investments, which include short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

The Company considers as cash equivalents all short-term, highly liquid investments, which include short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

f. Bank deposits

Bank deposits with original maturity dates of more than three months but less than one year are included in short-term deposits. Such short-term deposits bore interest at an average annual rate of approximately 6% for the year ended December 31, 2023.

Bank deposits with maturity of more than one year are considered long-term.

Restricted Restricted cash deposited in an interest-bearing saving account which is used as a security for the Company's cashg. office rent and credit card.

Restricted cash deposited in an interest-bearing saving account which is used as a security for the Company's office rent and credit card.

g.h. Concentrations of credit risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains cash held in checking accounts and deposits at financial institutions in major Israeli and U.S. banks. Management believes the Company is not exposed to significant credit risk to its current financial institution, but will continue to monitor regularly and adjust, if needed, to mitigate risk. The Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain principal and maximize liquidity. To date, the Company has not experienced any losses associated with this credit risk and continues to believe that this exposure is not significant.

h.i. Fair value measurement

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable inputs that are based on inputs not quoted on active markets but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

ENTERA BIO LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)(continued)

i. j. Employee severance benefits

Under the Israeli Severance Pay Law, 1963, the Company is required to make severance payments upon dismissal of an Israeli employee or upon termination of employment in certain other circumstances. The severance payment liability to the employees located in Israel (based upon length of service and the latest monthly salary - one month's salary for each year employed) is recorded on the Company's balance sheet under "Liability for employee rights upon retirement." The liability is recorded as if it was had been payable at each balance sheet date on an undiscounted basis.

In accordance with Section 14 of the Israeli Severance Pay Law, 1963, the Company makes regular deposits with certain insurance companies for accounts controlled by each applicable employee in order to secure the employee's retirement benefit obligation. The Company is fully relieved from any severance pay liability with respect to each such employee after it makes the payments on behalf of the employee. The liability accrued in respect of these employees and the amounts funded, as of the respective agreement dates, are not reflected in the Company balance sheet, as the amounts funded are not under the control and management of the Company and the pension or severance pay risks have been irrevocably transferred to the applicable insurance companies (the "Contribution Plan").

With regard For periods prior to the period before December 2013, the liability is was funded in part from the purchase of insurance policies or by the establishment of pension funds with dedicated deposits in the funds. The amounts used to fund these liabilities are included in the balance sheets under "Funds in respect of employee rights upon retirement". These policies are the Company's assets.

The amounts of severance payment expenses were $132 $128 and $137 $132 for the years ended December 31, 2022 December 31, 2023 and 2021. 2022, respectively.

The Company expects to contribute to insurance companies approximately $132 $128 for the year ending December 31, 2023 December 31, 2024 in connection with its expected severance liabilities for that year.

ENTERA BIO LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

j. Leases k. Leases

The Company determines if an arrangement is a lease at inception. Balances related to operating leases are included in operating lease right-of-use ("ROU") assets and current and non-current operating lease liabilities in the consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized as of the commencement date based on the present value of lease payments over the lease term. Lease terms will include options to extend or terminate the lease when it is reasonably certain that the Company will either exercise or not exercise the option to renew or terminate the lease.

The discount rate for the lease is the rate implicit in the lease unless that rate cannot be readily determined. As the Company's leases do not provide an implicit rate, the Company's uses its estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Sublease income is recognized on a straight-line basis over the expected lease term and is included in other income in our consolidated statements of operations. operations.

k. l. Property and equipment

1) Property and equipment are stated at cost, net of accumulated depreciation and amortization.

2) The Company's property and equipment are depreciated using the straight-line method, which approximates the pattern of usage, over the term of the estimated useful life, as follows: follows:

	Years
Computer equipment	3-5
Office furniture	10
Laboratory equipment	7-10

Leasehold improvements are amortized by the straight-line method over the shorter of (i) the expected lease term and (ii) the estimated useful life of the improvements.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

l. m. Impairment of long-lived assets

The Company tests long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may no longer be recoverable. Recoverability of long-lived assets is measured by comparing the carrying amount of the long-lived asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the sum of the expected undiscounted cash flow is less than the carrying amount of the asset, the Company recognizes an impairment loss, which is the excess of the carrying amount over the fair value of the asset, using the expected future discounted cash flows. flows

As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company did not recognize an impairment loss on its long-lived assets.

m. Share-based compensationn.

Share-based compensation

The Company grants share options and restricted share units ("RSU") (together "Share-Based Compensation") to its employees, directors and non-employees in consideration for services rendered. rendered.

The Company accounts for Share-Based Compensation awards classified as equity awards, including share-based option awards and RSUs, using grant-date fair value. The Company recognize the value of the award as an expense over the requisite service period. period.

The Company applies ASU 2018-07 (Topic 718) that expands the scope of Topic 718 to include Share-Based Compensation transactions for acquiring goods and services from non-employees. Under the provision of the amendment, the Company measures share-based compensation to non-employees in the same manner as share-based compensation to employees.

The Company calculates the fair value of stock-based option awards on the date of grant using the Black-Scholes option pricing model. The option-pricing model requires a number of assumptions, of which the most significant are the expected share price volatility and the expected option term. The computation of expected volatility is based on the historical volatility of the Company's ordinary shares. The expected option term is calculated using the simplified method, as the Company has concluded that its historical share option exercise experience does not provide a reasonable basis to estimate expected option terms. The interest rate for periods within the expected term of an award is based on the U.S. Treasury yield curve in effect at the time of grant. The Company's expected dividend rate is zero because the Company does not currently pay cash dividends on its shares and does not anticipate doing so in the foreseeable future. future.

The Company elected to recognize compensation costs for awards granted to employees and directors conditioned only on continued service that have a graded vesting schedule using the accelerated method based on the multiple-option award approach. The Company has elected to account for forfeitures as they occur. occur.

ENTERA BIO LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

n. o. Research and development expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, lab expenses, consumable equipment and consulting fees. All costs associated with research and developments development are expensed as incurred. incurred.

Grants received from the Israel Innovation Authority (the "IIA") are recognized when the grant becomes receivable, provided there is reasonable assurance that the Company will comply with the conditions attached to the grant and there is reasonable assurance the grant will be received. At the time grants are received, successful development of the related projects is not assured, therefore, grants are deducted from the research and development expenses as the applicable costs are incurred, and presented in R&D expenses, net.

o. Revenue recognitionp. Revenue recognition

On December 10, 2018, the Company entered into a research collaboration and license agreement with Amgen (the "Amgen Agreement") for the use of the Company's oral delivery platform in the field of inflammatory disease and other serious illnesses. Pursuant to the Amgen Agreement, the Company and Amgen had agreed to use the Company's proprietary drug delivery platform to develop oral formulations for one preclinical large molecule program that Amgen had selected. Additionally, the Company had granted Amgen an exclusive, worldwide, sublicensable license under certain of its intellectual property relating to its drug delivery technology to develop, manufacture and commercialize the applicable products.

On May 2, 2023, the Company and Amgen agreed to terminate the Amgen Agreement in accordance with its terms, effective on such date. Neither party incurred any termination penalty or fees in connection with the termination of the Amgen Agreement.

ThePrior to its termination, the Company recognized revenue from the Amgen Agreement according to ASC 606, "Revenues from Contracts with Customers". Prior The Company recognized no revenue prior to the signing of entering into the Amgen Agreement in 2018, the Company did not have revenue transactions. Agreement.

ASC 606 Revenue from Contracts with Customer introduces a five-step model for recognizing revenue from contracts with customers, as follows:

1. Identify the contract with a customer.
2. Identify the performance obligations in the contract.
3. Determine the transaction price.
4. Allocate the transaction price to the performance obligations in the contract.
5. Recognize revenue when (or as) the entity satisfies a performance obligation.

According to ASC 606, a performance obligation is a promise to provide a distinct good or service or a series of distinct goods or services. Goods and services that are not distinct are bundled with other goods or services in the contract until a bundle of goods or services that is distinct is created. A good or service promised to a customer is distinct if the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

Options granted to the customer that do not provide a material right to the customer that it would not receive without entering into the contract do not give rise to performance obligations.(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

q. Income taxes

1) Deferred taxes

Deferred income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future.

2) Uncertainty in income taxes

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained based on technical merits. If this threshold is met, the second step is to measure the tax position as the largest amount that has more than a 50% likelihood of being realized upon ultimate settlement.

r. Loss per share

Basic loss per share is computed on the basis of the net loss, adjusted to recognize the effect of a down-round feature when it is triggered, for the period, divided by the weighted average number of outstanding ordinary shares during the period.

Diluted loss per share is based upon the weighted average number of ordinary shares and of ordinary shares equivalents outstanding when dilutive. Ordinary share equivalents include outstanding stock options and warrants, which are included under the treasury stock method when dilutive. The calculation of diluted loss per share does not include options, and warrants, exercisable into an aggregate of 7,458,542 shares and 6,255,235 shares for the years ended December 31, 2023 and 2022, respectively, because the effect would have been anti-dilutive.

s. Legal and other contingencies

Management applies the guidance in ASC 450-20, "Loss Contingencies" when assessing losses resulting from contingencies. If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability is recorded as accrued expenses in the Company's consolidated financial statements.

Legal costs incurred in connection with loss contingencies are expensed as incurred.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

t. Warrants

When the Company issues freestanding instruments, it first analyzes the provisions of ASC 480, "Distinguishing Liabilities From Equity" ("ASC 480") in order to determine whether the instrument should be classified as a liability, with subsequent changes in fair value recognized in the consolidated statements of operations in each period. If the instrument is not within the scope of ASC 480, the Company further analyzes the provisions of ASC 815-10 in order to determine whether the instrument is considered indexed to the entity's own stock, and qualifies for classification within equity. All warrants issued by the Company have been classified within stockholders' equity as "Additional paid-in capital".

u. Newly issued and recently adopted accounting pronouncements:

Recently issued accounting pronouncements, not yet adopted

In December 2023, the FASB issued ASU 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures". This guidance is intended to enhance the transparency and decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the United States and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis. Early adoption is permitted, with the option to apply the standard retrospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

In November 2023, the FASB issued ASU 2023-07 "Segment Reporting: Improvements to Reportable Segment Disclosures". This guidance expands public entities' segment disclosures primarily by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

NOTE 3 - OPERATING LEASES

1) The Company leases office and research and development space under several agreements. The annual lease consideration is a total of $172 and is linked to the Israeli consumer price index. In April 2023, the Company extended the period of the lease agreement for an additional five years, expiring on June 30, 2028, with two options for early termination by the Company subject to a notice period. The annual lease consideration is a total of $180.

The Company recorded the related asset and obligation at the present value of lease payments over the expected terms, discounted using the lessee's incremental borrowing rate, which was 13.84%. The Company lease agreements do not provide a readily determinable implicit rate. Therefore, the Company estimated the incremental borrowing rate to discount the lease payments based on information available at lease commencement.

As of December 31, 2023, the Company provided bank guarantees of approximately $52, in the aggregate, to secure the fulfillment of its obligations under the lease agreements.

NOTE 3 - OPERATING LEASES (continued)

2) The Company has entered into operating lease agreements for vehicles used by its employees. The lease periods are generally for three years, and the payments are linked to the Israeli consumer price index. To secure the terms of the lease agreement, the Company has made certain deposits to the leasing company, representing approximately three months of lease payments. The annual lease consideration is a total of $22.

The lease cost was as follows:

	Year ended December 31, 2023	Year ended December 31, 2022
Operating lease cost	196	197

Supplemental cash flow information related to leases was as follows:

	Year ended December 31, 2023	Year ended December 31, 2022
Operating cash flows from operating leases	196	197

Supplemental balance sheet information related to operating leases was as follows:

	December 31, 2023	December 31, 2022
Operating Leases		
Operating lease right-of-use assets	388	90
Current lease liabilities	134	91
Non-current lease liabilities	256	
Total lease liabilities	390	91
Weighted-average remaining lease term (in years)	2.5	0.52
Weighted-average discount rate	14 %	16 %

As of December 31, 2023, the maturity of lease liabilities under our non-cancelable operating leases are $390 to be paid in 2024- 2026.

As of December 31, 2023, the maturity of lease liabilities under our non-cancelable operating leases were as follows:

2024	184
2025	184
2026	86
Total future minimum lease payments	454
Less: interest	(64)
Present value of operating lease liabilities	390

ENTERA BIO LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

o. Revenue recognition (continued)

The Company determined the license to the intellectual property to be a right to use that has significant standalone functionality separately from the pre-clinical 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 was transferred to Amgen on December 10, 2018.

Revenues attributed to the preclinical R&Ds services are recognized during the period of the pre-clinical R&D services, over time according to the input model method on a cost-to-cost basis, since the customer benefits from the research and development services as the entity performs the service.

The Company evaluated the standalone selling price of the pre-clinical R&D services at $225 and the right to use the intellectual property at $500.

The transaction price was comprised of fixed consideration and variable consideration (capped research and development reimbursements). Under ASC 606, 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. Variable consideration is included in the transaction price if, in the Company's judgment, it is highly probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available. As of December 31, 2022, the Company did not recognize any revenues from any potential milestone payments.

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.

Revenues attributed to preclinical R&D services are recognized during the period of the pre-clinical R&D services according to the input model method on a cost-to-cost basis.

In 2022 and 2021, the Company recorded revenues of $89 and $502, respectively, related to services provided under the Amgen Agreement.

ENTERA BIO LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

p. Income taxes

1) Deferred taxes

Deferred income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future.

2) Uncertainty in income taxes

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained based on technical merits. If this threshold is met, the second step is to measure the tax position as the largest amount that has more than a 50% likelihood of being realized upon ultimate settlement.

q. Loss per share

Basic loss per share is computed on the basis of the net loss, adjusted to recognize the effect of a down-round feature when it is triggered, for the period, divided by the weighted average number of outstanding ordinary shares during the period.

Diluted loss per share is based upon the weighted average number of ordinary shares and of ordinary shares equivalents outstanding when dilutive. Ordinary share equivalents include outstanding stock options and warrants, which are included under the treasury stock method when dilutive. The calculation of diluted loss per share does not include options, RSUs and warrants, exercisable into an aggregate of 6,255,235 shares and 6,517,102shares for the years ended December 31, 2022 and 2021, respectively, because the effect would have been anti-dilutive.

r. Legal and other contingencies

Management applies the guidance in ASC 450-20, "Loss Contingencies" when assessing losses resulting from contingencies. If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability is recorded as accrued expenses in the Company's consolidated financial statements.

Legal costs incurred in connection with loss contingencies are expensed as incurred.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)

s. Newly issued and recently adopted accounting pronouncements:

Recently issued accounting pronouncements adopted

1) In November 2021, the FASB issued ASU 2021-10 "Government Assistance (Topic 832)", which requires annual disclosures that increase the transparency of transactions involving government grants, including (1) the types of transactions, (2) the accounting for those transactions, and (3) the effect of those transactions on an entity's financial statements. The amendments in this update are effective for financial statements issued for annual periods beginning after December 15, 2021. The adoption of this guidance did not have material impact on the Company's consolidated financial statements.

2) In August 2020, the FASB issued ASU 2020-06 "Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)." This guidance simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The amendments to this guidance are effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. The Company early adopted this guidance effective January 1, 2022 and the impact of the adoption on the Consolidated financial statements was immaterial.

Recently issued accounting pronouncements, not yet adopted

1) In June 2016, the FASB issued ASU 2016-13 "Financial Instruments—Credit Losses—Measurement of Credit Losses on Financial Instruments." This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance will be effective for Smaller Reporting Companies (SRCs, as defined by the SEC) for the fiscal year beginning on January 1, 2023, including interim periods within that year. The adoption of this guidance will not have material impact on the Company's consolidated financial statements.

NOTE 3 - OPERATING LEASES

1) The Company leases office and research and development space under several agreements. The annual lease consideration is a total of $166 and is linked to the Israeli CPI. The lease agreement expires on June 30, 2023.

As of December 31, 2022, the Company provided bank guarantees of approximately $37, in the aggregate, to secure the fulfillment of its obligations under the lease agreements.

2) The Company has entered into operating lease agreements for vehicles used by its employees. The lease periods are generally for three years and the payments are linked to the Israeli CPI. To secure the terms of the lease agreements, the Company has made certain deposits to the leasing company, representing approximately three months of lease payments. The annual lease consideration is a total of $21.

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

The lease cost was as follows:

	Year ended December 31, 2022	Year ended December 31, 2021
Operating lease cost	197	216

Supplemental cash flow information related to leases was as follows:

	Year ended December 31, 2022	Year ended December 31, 2021
Operating cash flows from operating leases	197	216

Supplemental balance sheet information related to operating leases was as follows:

	December 31, 2022	December 31, 2021
Operating Leases		
Operating lease right-of-use assets	90	239
Current lease liabilities	91	179
Non-current lease liabilities	-	123
Total lease liabilities	91	302
Weighted-average remaining lease term (in years)	0.52	1.53
Weighted-average discount rate	16 %	16 %

As of December 31, 2022, the maturity of lease liabilities under our non-cancelable operating leases are $91 to be paid in 2023.

NOTE 4 - COMMITMENTS AND CONTINGENCIES

a. **Commitment to pay royalties to the government of Israel**

The Company is committed to pay royalties to the IIA Israel Innovation Authority (the "IIA") on proceeds from sales of products in for which the government provided grants with respect to the research and development of which the Government participates by way of grants. underlying such products. 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 IIA, the Company is not obligated to pay any such royalties.

Under the terms of the Company's funding from the IIA, royalties are payable on sales of products developed from IIA funded projects in the amount of 3% of sales during the first three years from following 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) plus annual interest based on LIBOR. SOFR. The interest had been based on LIBOR and it changed to SOFR. 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. In addition, if the Company undergoes a change of control or otherwise transfers the technology "know-how" (as defined under the Research Law) in or outside of Israel, the amount that must be repaid will be increased up to six times.

The IIA has not yet declared the alternative benchmark rate to replace LIBOR. However, the Company does not believe it will have significant impact on the Company's financial position or results of operations.
As of December 31, 2022 December 31, 2023, the total royalty amount that would be payable by the Company to the IIA, before the interest and payments potential increases as described above, was approximately $460. These grants were allocated to research and development. development in prior periods.

Following the signing of the Amgen Agreement, the IIA determined that the Company should was required to pay 5.38% of each payment received by the Company from Amgen on under the license of Intellectual Property agreement in an amount up to six times the grant received. As of December 31, 2022 December 31, 2023, the Company had paid a total amount of $83 to the IIA. As of December 31, 2023, we had liability of $13 thousand to the IIA, which were paid in February 2024.

b. 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 in the Company, and Oramed and the Company entered into a Patent License Agreement pursuant to which Oramed licensed to the Company one of Oramed's patents (the "IPR&D").

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 in 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).

c. In September 2023, the Company entered into a research collaboration agreement with OPKO Biologics, Inc., a subsidiary of OPKO. Under the terms of this agreement, OPKO has agreed to supply its proprietary long-acting GLP-2 peptide and certain Oxyntomodulin (OXM) analogs for the development of oral tablet formulations using the Company's proprietary oral delivery technology. The Company and OPKO have each agreed to be responsible for specific phases of development of the two oral peptides to the point of demonstrated in vivo feasibility. Work under this agreement commenced in the fourth quarter of 2023; therefore there was no material financial impact as of December 31, 2023.

NOTE 5 - SHARE CAPITAL

1) **Rights of the Company's ordinary shares**

Each ordinary share is entitled to one vote. The holder of an ordinary shares is also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors.

A holder of an ordinary share also has the right to receive upon liquidation of the Company, a sum equal to the nominal value of such share, and if a surplus per share remains, to receive such surplus, subject to the rights conferred on any class of shares which may be issued in the future. Since its inception, the Company has not declared any dividends.

2) **Changes in share capital:**

a. In connection with the Company's initial public offering ("IPO") in July 2018, the Company issued 1,400,000 IPO warrants to purchase 700,000 ordinary shares, and these warrants were listed for trading on Nasdaq Capital Market ("Nasdaq") on August 12, 2018. The IPO warrants were immediately exercisable at an initial exercise price of $8.40 per ordinary share for a period of five years, unless earlier repurchased by the Company as described in the warrant agreement. The IPO warrants expired on July 2, 2023, in accordance with their original terms, and Nasdaq removed them from listing.

b. On September 2, 2022, the Company entered into a sales agreement with SVB Securities LLC, as sales agent, to implement an ATM program under which the Company may from time to time offer and sell up to 5,000,000 Ordinary Shares (the "SVB ATM Program").
Duringthe year ended December 31, 2023, the Company issued 4,030 ordinary shares pursuant to the SVB ATM Program for net proceeds of $5 at a weighted average price of $1.16 per ordinary share.

a.c. On December 20, 2023, the Company entered into a securities purchase agreement in connection with a private offering (the "2023 PIPE") with certain existing and new investors, including the Company's Chairman of the Board and the Chief Executive Officer (collectively, the "Investors") for the private placement of 7,916,879 units at a purchase price of $0.835 per unit, each unit consisting of (i) one ordinary share and (ii) one warrant to purchase one ordinary share (each an " Investor Warrant"). The Company received aggregate proceeds of approximately $6.6 million before expenses. Certain Investors elected to receive pre-funded warrants (the "Pre-Funded Warrants") in lieu of ordinary shares, as such warrants may not be exercised if the aggregate number of ordinary shares beneficially owned by the holder thereof would exceed 4.99% or 9.99%, as applicable, immediately after exercise thereof.
IPO warrants

In connection with the Company's initial public offering ("IPO") in July 2018, the Company issued 1,400,000 IPO warrants to purchase 700,000 ordinary shares, and these warrants have been listed for trading on the Nasdaq Capital Market since August 12, 2018. The IPO warrants were immediately exercisable at an initial exercise price of $8.40 per ordinary share for a period of five years, unless earlier repurchased by the Company under "Fundamental Transactions" as described in the warrant agreement or earlier expired as described in the warrant agreement.

The exercise price and number of ordinary shares issuable upon exercise of each warrant are subject to standard

adjustments. In addition, subject to certain exceptions, the exercise price was subject to reduction if, within two years following the date of original issuance of the warrants, which ended in July 2020, the Company sold or granted any warrant or option at an effective price per share of less than $8.00 (as adjusted in proportion with any adjustments made from time to time), based on a weighted average, as described in the warrant agreement. As described in note 5b below, the Company completed a financing round during such two-year period at a price per share lower than the $8.00, therefore, the exercise price of these warrants adjusted to $5.85 per share.

At the IPO completion date, both of the instruments (warrants and shares) were classified as equity instruments as the warrants are considered indexed to the entity's own stock based on the provision of ASC 815.

In March 2021, 4,500 IPO warrants were exercised into 2,250 ordinary shares for total consideration of $13 at an exercise price of $5.85 per ordinary share.

As of the December 31, 2022 there were 1,395,500 traded warrants to purchase 697,750 ordinary shares outstanding with an exercise price of $5.85.The 2023 PIPE closed on December 22, 2023, and the Company issued 6,662,389 ordinary shares, 1,254,490 Pre-Funded Warrants and 7,916,879 Investors Warrants.

Each Pre-Funded Warrant has an exercise price of NIS 0.0000769 per ordinary share, is immediately exercisable and may be exercised at any time and has no expiration date and is subject to customary adjustments.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 5 - SHARE CAPITAL (continued)

Each Investor Warrant has an exercise price of $1.00 per share, is immediately exercisable, and expires five years from the date of issuance, and is subject to customary adjustments. The Company accounted for the Investors Warrant as a component of permanent equity, as part of Additional Paid in Capital. The Investor Warrants are considered a separate instrument and they are indexed to the entity's own stock based on the provision of ASC 815.

The Chairman of the Board and the Chief Executive Officer participated in the 2023 PIPE on the same terms and subject to the same conditions as all other Investors.

In connection therewith, the Company entered into a placement agency agreement with a registered U.S. broker-dealer (the "Broker"), pursuant to which the Broker was entitled to the following consideration:

b.1. A cash fee equal to 10% of the total proceeds paid by subscribers introduced by the Broker.

In December 2019 and February 2020, 2. A cash fee equal to 5% of the Company entered into subscription agreement with a selected group of accredited investors for total proceeds paid by other subscribers that participated in the private placement of 6,047,706 placement.

3. Five-year warrants to purchase 487,496 ordinary shares, for aggregate subscription proceeds representing 10% of the ordinary shares issued to subscribers introduced by the Company of $14.3 million at a price of $2.37 per share. In addition, the Company granted 3,023,871 warrants, exercisable over a three-year period from the date of issuance to purchase up to 3,023,871 ordinary shares Broker, at a per share exercise price of $2.96 ("Investors Warrants"). In addition, the exercise price was subject to reduction if, within one year of the date of original issuance of the warrants which ended in December 2020, the Company issued ordinary shares at an effective price per share less than $2.96.

   Following the closing of the offering, the Company issued to a broker-dealer 184,515 warrants and 92,257 warrants with per share exercise prices of $2.37 to $2.96, respectively ("Broker $0.71 (the "Broker Warrants").

During 2020, upon issuance In addition, the Company entered into a finder agreement with a private non-U.S. finder (the "Finder"), pursuant to which the Finder was entitled to a cash fee equal to 5% of total proceeds paid by subscribers introduced by the Finder, as well as five-year warrants to purchase 179,640 ordinary shares, through representing 10% of the Company's At-the-market equity program ordinary shares issued to the subscribers introduced by the Finder, at a price per share lower than the exercise price, the exercise price of the Investors Warrants and the Broker Warrants adjusted to $1.05. See note 5c.

On April 21, 2021, upon satisfaction of the sale price condition pursuant to the subscription agreement, the Company's Board of Directors elected to accelerate the termination date of the Investors Warrants and Broker Warrants. In accordance with the terms of the applicable agreements, the holders had the opportunity to exercise their warrants until June 23, 2021, following which any unexercised warrants would terminate.

Through June 23, 2021, all warrants holders exercised 3,300,645 warrants into 3,172,800 ordinary shares, either through purchase or a cashless exercise. The total consideration from the exercise of these warrants was $3,145 at an exercise price of $1.05 per share.$0.71 (the "Finder Warrants").

As of December 31, 2021, all The Pre-Funded Warrants, Investors Warrants, and Broker Warrants had been exercised and none remain outstanding.

Finder Warrants (collectively, the “Warrants”) were classified as a component of permanent equity and recorded as part of the Additional Paid in Capital based on the provision of ASC 815. The Warrants are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the Investor to receive a fixed number of shares of common stock upon exercise.

c. On July 4, 2020, the Company filed a primary registration statement on form F-3 and established an at-the-market equity program (the " 2020 ATM Program") that allowed the Company to issue up to $13.9 million of ordinary shares, at the Company’s discretion. Distributions of the ordinary shares through 2020 ATM Program were made pursuant to the terms of an equity distribution agreement dated July 13, 2020, among the Company and Canaccord Genuity LLC (the "Agent").

In 2020, the The Company issued 2,802,731 ordinary shares pursuant had transaction costs of approximately $1.0 million, out of which $267 was stock-based compensation expenses due to the 2020 ATM Program for net proceeds issuance of $3.2 million at a weighted average price of $1.27 per ordinary share.

In 2021, the Company issued an additional 2,546,265 ordinary shares pursuant to the 2020 ATM Program for net proceeds of $9.9 million at a weighted average price of $3.99 per ordinary share.

d. On May 7, 2021, the Company entered into a new at-the-market equity program (the "2021 ATM Program") that allowed the Company to issue up to additional five million ordinary shares, at the Company's discretion.

NOTE 5 - SHARE CAPITAL (continued)

Distributions of the ordinary shares through the 2021 ATM Program were made pursuant to the terms of an equity distribution agreement dated May 7, 2021 among the Company and B. Riley Securities, Inc.

e. In June and July 2021, the Company issued an aggregate of 1,840,463 ordinary shares pursuant to the 2021 ATM Program for net proceeds of $12.1 million at a weighted average price of $6.74 per ordinary share.

f. During the year ended December 31, 2021, several employees and service providers exercised 177,711 options into 177,711 ordinary shares for a total consideration of $418 at a weighted average price of $2.54 per ordinary share.

g. During the year ended December 31, 2022, one employee exercised 5,511 options into 5,511 ordinary shares for a total consideration of $13 at a price of $2.14 per ordinary share.

NOTE 6 - SHARE-BASED COMPENSATION

1) Share-based compensation 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 reserves specified number of ordinary shares for allocation to stock options (each, an “Option”), restricted share units, restricted share awards and performance-based awards, that had been awarded to employees and non-employees under the 2013 Plan. Each Option is exercisable for 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. Since adopting the 2018 Plan (as defined below), the Company has not granted any awards under the 2013 Plan.

On July 2, 2018, the Company's Board of Directors and shareholders of the Company approved a new Share Incentive Plan (the “2018 Plan”) and reserved 1,371,398 ordinary shares for allocation to stock options (each, a "2018 Plan Option"), restricted share units, restricted share awards and performance-based awards, to employees and non-employees for issuance under the 2018 Plan. Each 2018 Plan Option is exercisable for one ordinary share.

Any 2018 Plan Option that is not exercised within 10 years from the date of grant will expire.

The 2018 Plan 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.

2018 Plan Options granted to related parties or non-employees of the Company are governed by Section 3(i) of the Ordinance or Non-Qualified Share Options ("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.

As of December 31, 2022 December 31, 2023, 922,080 638,598 ordinary shares remain remained available for future grants under the 2018 Plan.

On January 2, 2023 January 1, 2024, the Company's Board of Directors approved an increase of 1,440,496 1,773,817 ordinary shares that may be issued under the Company's 2018 Plan pursuant of the terms of the 2018 Plan, Plan.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 6 - SHARE-BASED COMPENSATION (continued)

2) share-based compensation grants to employees and directors:

a) On January 4, 2021, options to purchase 1,314,218 ordinary shares were granted to the Company's former Chief Executive Officer, Dr. Spiros Jamas with an exercise price of $1.24 per share. Prior to the terms of Dr. Jamas' separation agreement (as described below), The below table summarizes the options were grants to vest over four employees and directors during the years from the date of grant; 25% vest on the first anniversary of the date of grant ended December 31, 2023 and the remaining 75% of the option to vest in twelve equal quarterly installments following the first anniversary of the grant date. 2022: The grant was subject to the approval by the Company's shareholders, which approved the grant in March 2021. The fair value of the options at the date of grant was $1,320.

Period	Grantee	Number of options	Exercise price	Vesting period	Fair value at the grant date	Expiration period
For the year ended December 31, 2023	Employees and Executive Officers	1,201,000	$0.80	(1)	$629	10 years
	Directors	534,246	$ 0.73	Quarterly over a period of one year	$ 253	10 years
	Directors	33,638	$ 0.89	Quarterly over a period of three years	$ 15	10 years
	Consultant	30,000	$ 0.80	Immediate	$ 17	10 years
For the year ended December 31, 2022	Employees and Executive Officers	1,455,000	$ 1.40- $2.86	(1)	$1,462	10 years
	Directors	250,964	$ 2.815	Quarterly over a period of one year	$ 455	10 years
	Directors	752,899	$ 2.815	Quarterly over a period of three years	$ 1,365	10 years

On July 15, 2022, (1) 25% vest on the Company entered into a mutual separation agreement with Dr. Jamas. Pursuant to the separation agreement, Dr. Jamas received the following benefits: (i) a one-time lump sum payment of his annual base salary for a period of 13 months, for a total gross amount equal to $412; and (ii) an extension first anniversary of the exercise period for date of grant and the vested portion remaining 75% of the options granted on January 4, 2021, based on option vest in twelve equal quarterly installments following the award original terms, representing an aggregate of 492,832 ordinary shares, through the end of a two-year period commencing on July 15, 2022. Effective July 15, 2022, upon termination first anniversary of the employment agreement with Dr. Jamas, the remaining 821,386 unvested options were forfeited and recognized as a reverse of expense of $457 in general and administrative expenses. grant date.

b) On April 7, 2021, Upon the Company's Board occurrence of Directors approved the following option grants:

i. Option grants to purchase 213,000 ordinary shares to certain employees a Triggering Event (as defined below) and 70,000 options granted to service providers, with an exercise price of $3.61 per share. The options vest over four years from the date of grant; 25% vest on the first anniversary of the date of grant and the remaining 75% of the option will vest in twelve equal quarterly installments following the first anniversary of the grant date. The fair value of the options at the date of grant was $646.

ii. Options grant to purchase 33,368 ordinary shares to a non-executive director of the Company, with an exercise price of $3.61. The options will vest over three years in twelve equal quarterly instalments starting on the vesting commencement date. These options were subject to the approval of the shareholders of the Company, which was approved on October 4, 2021. The fair value of the options at the shareholders' approval date was $104.

c) On April 21, 2021, options to purchase 345,000 ordinary shares were granted to several executive officers of the Company, with an exercise price of $3.15. The options vest over four years from the date of grant; 25% vest on the first anniversary of the date of grant and the remaining 75% of the option will vest in twelve equal quarterly installments following the first anniversary of the grant date. These options were subject to the approval of the shareholders of the Company, which was approved on October 4, 2021. The fair value of the options at the shareholders' approval date was $1,140.

NOTE 6 - SHARE-BASED COMPENSATION (continued)

d) On August 23, 2021, the Company's Board of Directors, approved the following option grants which were approved by the shareholders of the Company on October 4, 2021.

i. Grants of options to purchase ordinary shares with a total fair value 0f $195 for each of the seven non-executive board members on January 1, 2022. The options will vest over three years in twelve equal quarterly instalments starting on January 1, 2022 the vesting commencement date. On January 1, 2022, which is considered the awards grant date, the Company granted 752,899 ordinary shares to non-executive directors with an exercise price of $2.815 per share.

ii. Grants of options to purchase ordinary shares with a total fair value 0f $65 for each of the seven non-executive board members on January 1, 2022. The options will vest over one year in four equal quarterly instalments starting on January 1, 2022 the vesting commencement date. On January 1, 2022, which is considered the awards grant date, the Company granted 250,964 ordinary shares to non-executive directors with an exercise price of $2.815 per share.

e) On March 31, 2022, the Company's Board of Directors approved the following option grants:

i. Options to purchase 80,000 ordinary shares to an executive officer and a service provider, in each case, with an exercise price of $2.86 per share. The fair value of the options was $147.

ii. Options to purchase 55,000 ordinary shares to certain executive officers with an exercise price of $2.86 per share. This grant was subject to shareholders' approval, which was obtained at a meeting of the Company's shareholders held on September 7, 2022. The fair value of the options was $37.
The options vest over four years from the date of grant; 25% vest on the first anniversary of the date of grant and the remaining 75% of the option will vest in twelve equal quarterly installments following the first anniversary of the grant date.

f) On April 28, 2022, the Company's Board of Directors approved option grants to purchase 220,000 ordinary shares to employees with an exercise price of $2.57 per share. The options vest over four years from the date of grant; 25% vest on the first anniversary of the date of grant and the remaining 75% of the option will vest in twelve equal quarterly installments following the first anniversary of the grant date. The fair value of the options was $364.

g) On May 11, 2022, the Company's Board of Directors approved a grant of options to purchase 500,000 ordinary shares to Ms. Miranda Toledano, who was serving as the Company's Chief Financial Officer at the time of the grant. Ms. Toledano has since been appointed the Company's Chief Executive Officer (as described in Note 6(2)l below). This grant was subject to shareholders' approval, which was obtained at a meeting of the Company's shareholders held on September 7, 2022. These options have an exercise price of $2.00 per share and vest over four years from the date of grant; 25% vest on the first anniversary of the date of grant and the remaining 75% of the option will vest in twelve equal quarterly installments following the first anniversary of the grant date. The fair value of the options was $390.

NOTE 6 - SHARE-BASED COMPENSATION (continued)

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

h) On July 15, 2022, the Company's Board of Directors appointed Ms. Miranda Toledano as the Company's Chief Executive Officer and approved a grant of options to purchase 600,000 ordinary shares at an exercise price of $1.40 per share, which are in addition to the options described in note 6(2)k above. This grant was subject to shareholders' approval, which was obtained at a meeting of the Company's shareholders held on September 7, 2022. The options vest over four years from the date of grant; 25% vest on the first anniversary of the date of grant and the remaining 75% of the option will vest in twelve equal quarterly installments following the first anniversary of the applicable grant date. The fair value of the options was $524.

In addition, upon the occurrence of a Triggering Event (as defined below) and subject to the approval of the Board of Directors, Ms. Toledano our CEO will be granted additional options to purchases 200,000 ordinary shares. The exercise price will be determined at the time of the Board of Directors' approval.

"Triggering Event" means the earlier of the following events: (i) the execution by the Company of a binding strategic or partnership agreement with a strategic partner to fund the Company's Phase III FDA Trial; or (b) raising sufficient funding to complete the Company's Phase III FDA Trial, in each case as such event is approved by the Board of Directors.

As of December 31, 2023, none of these events occurred.

i) c) On July 15, 2022, the Company entered into a mutual separation agreement with the Company's former Chief Executive Officer, Dr. Jamas. Pursuant to the separation agreement, Dr. Jamas received the following benefits: (i) a one-time lump sum payment of his annual base salary for a period of 13 months, for a total gross amount equal to $412; and (ii) an extension of the exercise period for the vested portion of the options granted on January 4, 2021, based on the award original terms, representing an aggregate of 492,832 ordinary shares, through the end of a two-year period commencing on July 15, 2022. Effective July 15, 2022, upon termination of the employment agreement with Dr. Jamas, the remaining 821,386 unvested options were forfeited and recognized as a reverse of expense of $457 in general and administrative expenses.

NOTE 6 - SHARE-BASED COMPENSATION (continued)

d) On June 15, 2022, the Company entered into a separation agreement with Dr. Phillip Schwartz, a former executive officer of the Company's former President of R&D, Company, under which Dr. Schwartz agreed to continue to provide services to the Company until July 21, 2022 (the "Separation Date"). Pursuant to the terms of the separation agreement, which were approved by the Company's shareholders on September 7, 2022, Dr. Schwartz received a full acceleration of his unvested options, as of the Separation Date, to purchase 68,750 ordinary shares granted in April 2021 that otherwise would have been forfeited. These options, together with 31,250 already vested options granted in April 2021 and 357,500 already vested options to purchase ordinary shares granted in 2017, will be exercisable for a period of 10 years from their respective initial grant dates.dates.

The acceleration described above was recognized as a "Type III" modification; therefore, on the shareholder approval date, the Company recognized the incremental costs of unvested options based on the fair value of the options on such date. In addition, the extension of the exercise period for the vested awards was recognized as a "Type I" modification. The total expense amount was $112 thousand, which was classified as additional share-based compensation costs in the research and development expenses.

In addition, the separation agreement provides for the following payments to Dr. Schwartz, all of which would have otherwise been payable in accordance with either Israeli law or pursuant to his existing employment agreement: a one-time cash separation payment in an amount equal to NIS 537,600 (approximately $156) and additional payments of NIS 737,771 (approximately $214) in respect of all other ongoing accrued benefits, subject to any mandatory deductions. The foregoing payments were recognized in the research and development expenses.

e) The fair value of each option granted is estimated at the date of grant using the Black-Scholes option-pricing model, with the following weighted average assumptions:

	2023	2022
Exercise price	$0.73-$0.89	$1.40-$2.86
Dividend yield	-	-
Expected volatility	74%-76%	69%-70.2%
Risk-free interest rate	3.58%-4.37%	1.35%-3.36%
Expected life - in years	5.3-6.11	5.5-6.5

	2023	2022

	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of the year	5,733,087	$ 3.30	4,316,859	$ 3.63
Granted	1,798,884	0.78	2,458,863	2.29
Exercised	-	-	(5,511)	2.14
Forfeited	(34,313)	2.27	(902,009)	1.41
Expired	(392,244)	4.97	(135,115)	3.80
Outstanding at end of the year	7,105,414	$ 2.57	5,733,087	$ 3.30
Exercisable at end of the year	4,208,325	$ 3.26	3,165,677	$ 4.06

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NOTE 6 - SHARE-BASED COMPENSATION (continued)

The fair value of each option granted is estimated at the date of grant using the Black-Scholes option-pricing model, with the following weighted average assumptions:

	2022	2021
Exercise price	$1.40-$2.86	$1.24-$3.61
Dividend yield	-	-
Expected volatility	69%-70.2%	68%-71%
Risk-free interest rate	1.35%-3.36%	1.11%-0.94%
Expected life - in years	5.5-6.5	6.1-5.8

	2022		2021	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of the year	4,316,859	$ 3.63	2,570,109	$ 4.85
Granted	2,458,863	2.29	1,975,586	1.95
Exercised	(5,511)	2.14	(177,710)	2.37
Forfeited	(902,009)	1.41	(16,660)	2.37
Expired	(135,115)	3.80	(34,466)	4.00
Outstanding at end of the year	5,733,087	$ 3.30	4,316,859	$ 3.63
Exercisable at end of the year	3,165,677	$ 4.06	2,068,067	$ 5.39

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NOTE 6 - SHARE-BASED COMPENSATION (continued)(continued)

The following tables summarizes information concerning outstanding and exercisable options as of December 31, 2022 December 31, 2023, in terms of ordinary shares: shares for which the options may be exercised:

December 31, 2022					December 31	
December 31, 2023						
Options outstanding	Options outstanding		Options exercisable		Options outstanding	
	Number of options	Weighted Average	Number of options	Weighted Average	Number of options	Weighted Average

Exercise prices per share (USD)	Exercise prices per share (USD)	outstanding at end of Year	Remaining Contractual Life	exercisable at end of year	Remaining contractual Life	Exercise prices per share (USD)	outstanding at end of Year	Remainin Contractu Life
	-	1,560	0.09	1,560	0.09	0.73	534,244	9.0
	1.24	492,831	1.54	492,831	1.54	0.79	1,223,000	9.3
	1.40	600,000	9.54	-	-	0.89	33,638	9.4
	2.02	500,000	9.37	-	-	1.24	492,831	0.5
	2.14	400,775	7.26	277,994	7.26	1.40	600,000	8.5
	2.53	33,638	6.89	33,638	6.89	2.02	500,000	8.3
	2.57	205,500	9.33	-	-	2.14	379,900	6.2
	2.815	1,003,863	9.01	376,447	9.01	2.53	33,638	5.8
	2.86	135,000	9.25	-	-	2.57	187,500	8.3
	3.15	345,000	8.30	123,125	8.30	2.815	1,003,863	8.0
	3.61	250,868	8.27	101,059	8.27	2.86	135,000	8.2
	3.68	294,580	0.26	294,580	0.26	3.15	345,000	7.3
	3.97	247,082	6.05	242,053	6.05	3.61	237,368	7.2
	6.31	1,222,390	3.08	1,222,390	3.08	3.68	147,290	3.2
		5,733,087		3,165,677		3.97	232,552	5.0
						6.31	1,019,590	3.9
							7,105,414	

The aggregate intrinsic value of the total of the outstanding and exercisable options as of December 31, 2022, December 31, 2023 is $1. $0.

The following table illustrates the effect of share-based compensation on the statements of operations:

	2023	2022
Cost of revenues	-	14
Research and development expenses	424	708
General and administrative	1,265	1,525
	1,689	2,247

	2022	2021
Cost of revenues	14	102
Research and development expenses	708	661
General and administrative	1,525	1,098
	2,247	1,861

ENTERA BIO LTD.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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

NOTE 7 - INCOME TAX

A. Corporate tax rate

1) Ordinary taxable income in Israel is subject to a corporate tax rate of 23%.

1) Ordinary taxable income in Israel is subject to a corporate tax rate of 23%.

2) The Company's subsidiary Entera Bio, Inc. is taxed separately under the U.S. tax laws at a tax rate of 29% (federal and state tax)

2) The Company's subsidiary Entera Bio, Inc. is taxed separately under the U.S. tax laws at a tax rate of 29% (Federal and state tax)

B.

B. Losses for tax purposes carried forward to future years

The balance of carryforward losses as of December 31, 2023 and 2022 are approximately $75.8 million and $67.1 million, respectively. Under Israeli tax law, tax loss carry-forward have no expiration date.

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

The balance of carryforward losses as of December 31, 2022 and 2021 are approximately $67.1 million and $56.1 million, respectively.

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

C. **C.** **Tax assessments**

The Company and its subsidiary have tax assessments that are considered to be final through tax year 2017.

The Company and its subsidiary have tax assessments that are considered to be final through tax year 2018.

D. **Loss (income) before income taxes is composed of the followingfollowing:**

	Year ended December 31	
	2022	**2021**
Entera Bio Ltd.	12,997	12,362
Entera Bio Inc.	(65)	(116)
Total loss before taxes	12,934	12,246

	Year ended December 31	
	2023	2022
Entera Bio Ltd.	8,868	12,997
Entera Bio Inc.	(8)	(65)
Total loss before taxes	8,860	12,934

E. **Income tax expense (benefit): expense:**

	Year ended December 31	
Current:	2023	2022
Subsidiary:	-	(37)
Total current income tax	-	(37)
Deferred income taxes - subsidiary	29	174
Total deferred income taxes	29	174
Total income tax expense	29	137

	Year ended December 31	
	2022	**2021**
Current:		
Subsidiary:	(37)	158
Total current income tax	(37)	158
Deferred income taxes	174	(217)
Total deferred income taxes	174	(217)
Total income tax expense (benefit)	137	(59)

NOTE 7 - INCOME TAX (continued)(continued)

F. **F.** **Deferred income taxes**

	December 31,	
	2022	**2021**
Deferred tax assets:		
Net operating loss carry forward	**15,428**	**12,895**

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

Research and development	**1,225**	**1,319**
Share-based compensation	**877**	**876**
Other	**158**	**152**
Net deferred tax assets before valuation allowance	**17,688**	**15,242**
Valuation allowance	**(17,645)**	**(15,025)**
Net deferred tax assets	**43**	**217**

	December 31,	
Deferred tax assets:	**2023**	**2022**
Net operating loss carry forward	**17,427**	**15,428**
Research and development	**983**	**1,225**
Share-based compensation	**855**	**877**
Other	**220**	**158**
Net deferred tax assets before valuation allowance	**19,485**	**17,688**
Valuation allowance	**(19,471)**	**(17,645)**
Net deferred tax assets	**14**	**43**

In assessing the likelihood of realizing deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences and carry forward losses become deductible. Based on the taxable loss in the Israel, management believes it was more likely than not that the deferred tax assets will not be realized in the Israel and believes it was more likely than not that deferred tax assets will be realized for the U.S. subsidiary.

The Company has classified the net deferred tax assets as long-term. In assessing the likelihood of realizing deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences and carry forward losses become deductible. Based on the taxable loss in the Israel, management believes it was more likely than not that the deferred tax assets will not be realized in the Israel and believes it was more likely than not that deferred tax assets will be realized for the U.S. subsidiary.

G. **Rollforward Roll-forward of valuation allowance:**

Balance at January 1, 2021	**12,420**
Additions	2,605
Balance at January 1, 2022	**15,025**
Additions	2,620
Balance at December 31, 2022 January 1, 2023	**17,645**
Additions	1,826
Balance at December 31, 2023	**19,471**

H. **Reconciliation of theoretical tax expenses to actual expenses**

The primary difference between the statutory tax rate of the Company and the effective rate results virtually from the changes in valuation allowance in respect of carry forward tax losses and research and development expenses due to the uncertainty of the realization of such tax benefits.

I. **Uncertain tax positions**

As of December 31, 2023 and 2022, the Company does not have a provision for uncertain tax positions as existing uncertain tax positions as, based on the technical merits, they are not more likely than not to be sustained.

NOTE 7 - INCOME TAX (continued)

H. **Reconciliation of theoretical tax expenses to actual expenses**

The primary difference between the statutory tax rate of the Company and the effective rate results virtually from the changes in valuation allowance in respect of carry forward tax losses and research and development expenses due to the uncertainty of the realization of such tax benefits.

I. **Uncertain tax positions**

As of December 31, 2022 and 2021, the Company does not have a provision for uncertain tax positions.

NOTE 8 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

	December 31,		December 31,	
	2022	**2021**	**2023**	**2022**
Accrued expenses and other payables:				
Employees and employees related	154	147	159	154
Income tax	-	134		
Provision for vacation	146	308	215	146
Accrued expenses	933	2,212	500	933
	1,233	2,801	874	1,233

NOTE 9 - SUBSEQUENT EVENT EVENTS

a. On January 2, 2023 January 1, 2024, 534,246 an aggregate of 758,331 options to purchase ordinary shares were granted to six seven non-executive board members with an exercise price of $0.73 $0.60 per share. The options will vest over one year in four equal quarterly installments starting on January 1, 2023 January 1, 2024. This grant was approved by the shareholders of the Company on October 4, 2021.

b. On February 1, 2024, the Company entered into a consulting agreement. Under the terms of the agreement, the Company agreed to pay a monthly fee of $5 and to issue the consultant 25,000 RSUs. The RSUs vest over five months in five equal monthly installments starting on February 1, 2024.

c. On February 15, 2024, the Company entered into an investor relations consulting agreement. Under the terms of the agreement, the Company agreed to issue the consultant 50,000 RSUs. The RSUs vest over five months in five equal monthly installments starting on February 15, 2024.

ITEM 9. 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. 9A. CONTROLS AND PROCEDURES

Evaluation of 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) Act) as of December 31, 2022, which we refer to as the Evaluation Date. December 31, 2023. Based on such evaluation, those officers have concluded that as of the Evaluation Date, our disclosure controls and procedures were effective. effective as of December 31, 2023.

Management's Report on Internal Control over Financial Reporting

Our management, under the supervision of our Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and asset dispositions;

- provide reasonable assurance that transactions are recorded as necessary to permit the preparation of our financial statements in accordance with generally accepted accounting principles;

- provide reasonable assurance that receipts and expenditures are made only in accordance with authorizations of our management and board of directors the Board (as appropriate); and

- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2022 December 31, 2023 based on criteria established in Internal Control-Integrated Framework (2013) by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on such assessment, our management concluded that the Company's internal control over financial reporting was effective as of December 31, 2022 December 31, 2023.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. 9B. OTHER INFORMATION

None. During the quarter ended December 31, 2023, none of our officers or directors adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any "non-Rule 10b5-1 trading arrangement", as defined in Item 408 of Regulation S-K.

ITEM 9C. 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The names of our directors and executive officers as of the date of this Annual Report and their respective ages, positions and biographies are set forth below.

Name	Age	Position
Executive Officers		
Miranda J. Toledano(5)	46 47	Chief Executive Officer and Director
Dana Yaacov-Garbeli	39 40	Chief Financial Officer
Dr. Hillel Galitzer	44 45	Chief Operating Officer
Dr. Arthur Santora	72 73	Chief Medical Officer
Non-Employee Directors		
Gerald Lieberman (1)	76 77	Director, Chairman of the Board of Directors
Dr. Roger J. Garceau (5)	69 70	Director, Chairman of the Scientific Advisory Committee
Ron Mayron (1) (2)	59 60	Director, Chairman of the Compensation Committee
Gerald M. Ostrov (1) (2) (3)	73 74	Director, Chairman of the Audit Committee
Sean Ellis(1) (3) (4)	48 49	Director
Haya Taitel (1) (5)	61	Director
Yonatan Malca(1)(2) (3) (4) (5)	56 57	Director, Chairman of the Nominating and Corporate Governance and Nomination Committee

(1) Independent in accordance with SEC regulations and Nasdaq rules requirements applicable to us.

(2) Member of the Compensation Committee.
(3) Member of the Audit Committee.
(4) Member of the Nominating andCorporate Governance and Nomination Committee.
(5) Member of the Scientific Advisory Committee.
Executive Officers

Miranda J. Toledano has served as the Company's Chief Executive Officer, or CEO, since July 2022. Prior to her appointment as CEO, Ms. Toledano served as the Company's Chief Business Officer, Chief Financial Officer and Head of Corporate Strategy since from May to June 2022. Ms. Toledano has over 20 years of C-level leadership, principal investment and Wall Street/capital market experience in the biotech sector. Ms. Toledano has served as a member of our Board of Directors (the "Board") since 2018, and as Member of the Scientific Advisory Committee since February 2022. Ms. Toledano has over 20 years of C-level leadership, principal investment and Wall Street/capital market experience in the biotech sector. Previously, Miranda served as Chief Operating Officer, Chief Financial Officer, and Director of TRIGR Therapeutics, an oncology focused, clinical stage bispecific antibody company, from August 2018 until its acquisition by Compass Therapeutics (Nasdaq: CMPX) in June 2021. At TRIGR, Miranda oversaw the clinical development of lead asset TR009 (now CTX-009) and led strategic execution, including a $117 million China License Transaction and acquisition by CMPX. Previously, Ms. Toledano served as Head of Healthcare Investment Banking at MLV & Co. (acquired by B. Riley FBR & Co.), where she completed biotech equity financings (IPOs, ATMs, and follow-ons) totaling over $4 billion in aggregate value. Earlier in her career, Ms. Toledano served as vice president in the investment group of Royalty Pharma (Nasdaq: RPRX) from 2004 to 2010. Ms. Toledano is also a member of the board of directors of Journey Medical (Nasdaq: DERM) and NEXGEL (Nasdaq: NXGL). Ms. Toledano holds a B.A. in Economics from Tufts University and an MBA in Finance and Entrepreneurship from the NYU Stern School of Business.

Dana Yaacov-Garbeli has served as our Chief Financial Officer since July 2022. Prior that, Ms. Yaacov-Garbeli served as our Israel-based Chief Financial Officer from June 2019 through July 2022. Ms. Yaacov-Garbeli has over 15 years of chief finance and accounting experience. She previously served as Senior Manager at PwC Israel overseeing audits of public and private companies. She has significant experience in financial planning, operations management, external and internal audit for public multinational companies under US GAAP, IFRS and PCAOB standards. Ms. Yaacov-Garbeli is also a partner at A2Z-Finance, a company that provides financial and accounting services. Ms. Yaacov-Garbeli holds a B.A in accounting and business management and an MBA in financial management from The College of Management and Academic studies. Ms. Yaacov-Garbeli is a Certified Public Accountant in Israel.

Dr. Hillel Galitzer has served as our Chief Operating Officer since February 2014, prior to which he 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 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 April 2017, where he was the lead clinical research physician responsible for much of the clinical development of Fosamax®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 Dr. Santora completed a clinical fellowship in Internal Medicine at Emory, and its Endocrinology and Metabolism subspecialty endocrinology at the NIH in Bethesda. Dr. Santora Bethesda and received his M.D. and Ph.D. in biochemistry from Emory University in Atlanta. Atlanta, where he also received graduate training in Internal Medicine.

Non-Employee Directors

Gerald LiebermanMr. Lieberman has served as a member of our Board since April 2014 and became our Chairman in July 2019. Mr. Lieberman is also a member of the board of directors of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), a global leader in pharmaceuticals and the world's largest generic drug developer and manufacturer, where he chairs the Audit Committee and serves on both the Human Resources and Compensation Committee and the Finance Committee. He also serves as Chairman of the Board of Directors of DosenRx, DosentRx, Ltd., a Digital digital health company that has developed a personalized, patient-controlled device for delivering medication. He is also currently a special advisor at Reverence Capital Partners, a private investment firm focused on the middle-market financial services industry. From 2000 to 2009, Mr. Lieberman was an executive at Alliance Bernstein L.P., where he served as President and Chief Operating Officer from 2004 to 2009, as Chief Operating Officer from 2003 to 2004 and as Executive Vice President, Finance and Operations from 2000 to 2003. From 1998 to 2000, he served as Senior Vice President, Finance and Administration at Sanford C. Bernstein &

Co., Inc., until it was acquired by Alliance Capital in 2000, forming Alliance Bernstein L.P. Prior to that, he served in various executive positions at Fidelity Investments and at Citicorp. Prior to joining Citicorp he was a certified public accountant with Arthur Andersen. He previously served on the board of directors of Forest Laboratories, LLC from 2011 to 2014, Computershare Ltd. from 2010 to 2012 and Alliance Bernstein L.P. from 2004 to 2009. Mr. Lieberman received a B.S. Beta Gamma Sigma with honors in business from the University of Connecticut. Our Board believes that Mr. Lieberman is qualified to serve as director based upon his experience on boards of other pharmaceutical companies and his years of experience working with healthcare and pharmaceutical companies.

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Dr. Roger J. Garceau has served as a member of our Board since March 2016, and he served as our interim CEO From August 2020 to January 4, 2021. Dr. Garceau served also served as our Chief Development Advisor from December 2016 to December 2021 (excluding the period he served as our interim CEO). 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 Protara Therapeutics, Inc. since January 2019. Prior to joining Entera, Dr. Garceau served as Chief Medical Officer and Executive Vice President of NPS Pharmaceuticals, Inc. from 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. Our Board believes that Dr. Garceau is qualified to serve as director based upon his experience with the Company and his years of experience working with healthcare and pharmaceutical companies.

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Ron Mayron has served as a member of our Board since April 2021 and is a global healthcare specialist who serves on the boards of numerous public and privately-held pharma and medical device companies in Israel, including InnoCan Pharma Ltd., IceCure Medical Ltd., BioLight Life Sciences Investments Ltd., IR-Med Inc., G-Med Ltd., Kaizen Bio Tec Ltd., and Simplivia Ltd. He previously served on the boards of DNA BioMedical Biomedical Solutions Innocan Pharma, Ltd. from March 2021 to May 2023, Kadimastem, Ltd. from December 2020 to December 2023, WizePharma Inc. (now Mawson Infrastructure Group Inc. (NASDAQ: MIGI)) from April 2015 to November 2018 and IceCure Medical. NurExone Biologic Inc. from December 2021 to August 2023. His prior executive experience includes several leadership positions culminating in CEO of Teva Israel & Africa from 2009 until 2013 and CEO of S.L.E from 1999 and until 2007. His Mr. Mayron's expertise within healthcare includes M&A, integration and implementation, global business development, global operations, and supply chain management. He earned a B.Sc. from Ben-Gurion University, and an MBA from the University of Tel Aviv, and attended several programs at Insead University Fontainebleu, France and the Massachusetts Institute of Technology, Boston. Our Board believes that Mr. Mayron is qualified to serve as a director based upon his pharmaceutical industry experience in multiple capacities from operations to chief executive positions as well as his experience on multiple boards of pharmaceutical and medical device companies in Israel.

Gerald M. Ostrov has served as a member of our Board 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, Synergio, a natural products company working with industry giants, Addon Optics, an innovative technology company, and Nuvo Group Ltd., 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. Our Board believes that Mr. Ostrov is qualified to serve as a director based upon his years as an investor in healthcare related companies.

Sean Ellis has served as a member of our Board since June 2019. Mr. Ellis brings extensive knowledge of both life science industries and the U.S. financial markets, with a longstanding history in asset management. Mr. Ellis is a fund manager of Centillion Fund, a venture capital fund dedicated to Israeli investments, with a primary focus on investments in the biotech and healthcare industries. Centillion is one of Entera Bio's earliest investors and largest shareholders. He holds a BA from New York University and MBA from Columbia University. Our Board believes that Mr. Ellis is qualified to serve as a director based upon his years as an investor in healthcare related companies.

Yonatan Malca has served as a member of our Board since 2011. Mr. Malca currently serves as a Chief Executive Officer and director of NanoGohst Ltd. Since 2010 until From 2009 to 2021, he served as a Chief Executive Officer and director of D.N.A DNA Biomedical Solutions Ltd. (TASE: DNA). Mr. Malca also serves as a director of Nextgen-Biomed LTD. (TASE: NXGN) and Jungo Connectivity Ltd. (TASE: JNGO) and Unicorn Technologies (TASE: UNCT), each of which is an Israeli public company. He also serves as director of BeamMed Ltd, a private medical device company. He previously served as a director of Nextgen-Biomed LTD. (TASE: NXGN) from July 2018 to April 2019, ARKO Holdings Ltd. from August 2014 to December 2020, and Tamda Ltd. from July 2016 to September 2020. 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. Our Board believes that Mr. Malca is qualified to serve as a director based upon his pharmaceutical industry experience as an executive as well as his experience on boards of multiple pharmaceutical companies.

122 Haya Taitel was appointed in June 2023 to serve as a member of our Board. Ms. Taitel has over 30 years of global C-level biopharma commercial and strategic executive experience. She currently serves as the Head of Sanofi's Global Transplant Franchise where she is responsible for increasing franchise growth and profitability. Prior to her role at Sanofi, Ms. Taitel served as the Chief Commercial Officer of Kadmon Pharmaceuticals, LLC, where she contributed to the launch of Rezurock®, from 2013 until the company was acquired by Sanofi for $1.9 billion in November 2021. Ms. Taitel also led Kadmon Board's Executive Commercial Committee. Beginning in 1997, Ms. Taitel had held various commercial leadership positions of increasing seniority at Johnson and Johnson in multiple therapeutic areas, including oncology,

immunology, neurology and women's healthcare. Ms. Taitel holds a Master of Science, Pharmacology, (PharmD equivalence) from Temple University and a Bachelor of Science, Pharmacy and Biology from the Hebrew University School of Pharmacy in Jerusalem, Israel. Our Board believes that Ms. Taitel is qualified to serve as a director based upon her extensive biopharmaceutical industry experience and specific commercial domain expertise in women's health.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Involvement in Certain Legal Proceedings

Our directors and executive officers are not parties to any material legal proceedings.

Overall Role of the Board and Board Leadership Structure

Under the Israeli Companies Law, 1999 and the regulations promulgated thereunder (together, the "Companies Law"), our Board is responsible for setting our general policies and supervising the performance of management. Our Board may exercise all powers and may take all actions that are not specifically granted by the Companies Law or our Amended and Restated Articles of Association ("Articles") 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. Our chief executive officer CEO is appointed by, and serves at the discretion of, our Board, subject to the terms of the employment agreement that we have entered into with him. Board. All other executive officers are also appointed by our Board, and are subject to the terms of any applicable employment agreements that we may enter into with them. Board.

Our Board currently consists of seven directors. According to Under our Articles, the number of members of our Board must be consist of at least three and cannot be no more than ten. ten persons. Currently, our Board consists of eight directors. Our Board is divided into three classes, with staggered three-year terms and with one class comes up for election each year. The Class I directors were re-elected at our 2021 annual meeting of shareholders to serve until our annual meeting of shareholders in 2024. The Class II director was re-elected at our 2022 annual meeting of shareholders to serve until our annual meeting in 2025. Our Class III directors have terms expiring at our annual meeting of shareholders in 2023. 2024, and the Class II and Class III directors have terms expiring at our annual meetings in 2025 and 2026, respectively. The members of the classes as of the date hereof are as follows:

- the Class I directors are Miranda J. Toledano, Roger Garceau and Ron Mayron;
- the Class II director is directors are Yonatan Malca; Malca and Haya Taitel;
- the Class III directors are Gerald Lieberman, Gerald M. Ostrov and Mr. Sean Ellis.

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 could have the effect of increasing the length of time necessary to change the composition of a majority of the Board. 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.

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). Officer. Subject to any requirements under the Companies Law, to be considered timely and thereby be added to such agenda, such a request must be delivered, either in person or by certified mail, postage prepaid, and received at the Company's offices, (i) in the case of an annual meeting, no less than sixty (60) days nor more than one-hundred twenty (120) days prior to the date of the first anniversary of the preceding year's annual meeting, provided, however, that, in the event that the date of the annual meeting is advanced more than thirty (30) days prior to or delayed by more than thirty (30) days after the anniversary of the preceding year's annual meeting, notice by the proposing shareholder, in order to be timely, must be received no earlier than the close of business one-hundred twenty (120) days prior to such annual meeting and no later than the close of business on the later of ninety (90) days prior to such annual meeting or the tenth (10th) (10th) day following the day on which public announcement of the date of such meeting is first made, and (ii) in the case of a Company meeting of shareholders that is an extraordinary meeting, no earlier than one-hundred twenty (120) days prior to such extraordinary meeting and no later than the close of business on the later of sixty (60) days prior to such extraordinary meeting or the tenth (10th) (10th) day following the day on which public announcement of the date of such meeting is first made, subject to applicable law. Any such notice must include certain information, including, inter alia, among other things, 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 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. vacancies. Each of our directors, other than our external directors will serve from the date of election or appointment until the next annual meeting of shareholders for which such director's class is due for reelection. The approval of at least a majority of the voting power in the Company is generally required to remove any of our directors from office (other than external directors) directors appointed according to the Companies Law, to the extent then in office).

Under the Companies Law, our Board 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 must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our Board has determined that the minimum number of directors of our company who are required to have we require one director with accounting and financial expertise is one. expertise. Our Board has determined that Mr. Gerald Lieberman M. Ostrov and Ms. Miranda J. Toledano Mr. Yonatan Malca each have financial and accounting expertise as defined in the regulations promulgated under the Companies Law, or Financial and Accounting Expertise. Law.

Other than with respect to our directors that who are also executive officers or employees, there are no arrangements or understandings between us, on the one hand, and any of our directors, on the other hand, providing for benefits upon termination of their service as directors of our Company. For information with respect to compensation arrangements with our directors that are also executive officers or employees, see the sections entitled "Item 11. Executive Compensation"" and "Item 13. Certain Relationships and Related Party Transactions" included in this Annual Report.

Alternate Directors

Our Articles provide that, as permitted under the Companies law, 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, excluding such director. The term of an alternate director could be terminated at any time by the appointing director or our Board 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.

Board Leadership Structure

The Board currently separates the roles of Board Chairperson and Chief Executive Officer. We believe that separation of the positions of Chairperson of the Board and Chief Executive Officer reinforces the independence of the Board in its oversight of our business and affairs, is more conducive to objective evaluation and oversight of management's performance, increases management accountability, and improves the Board's ability to monitor whether management's actions are in the best interests of the Company and its shareholders.

Role of the Board in Risk Oversight

Our Board is responsible for overseeing our risk management process. Our Board focuses on our general risk management strategy, the most significant risks facing us, and oversees the implementation of risk mitigation strategies by management. Our Board is also apprised by management of particular risk management matters in connection with its general oversight and approval of corporate matters and significant transactions. The Board's independent oversight function is further enhanced by the fact that all of the Board's Committees are composed entirely of independent directors, the directors have complete access to management and the Board and its committees may retain their own respective advisors.

Corporate Governance Guidelines

Our Board strongly supports effective corporate governance and has developed and followed a program of strong corporate governance. Our Nominating and Corporate Governance Committee is responsible for overseeing our guidelines and reporting and making recommendations to the Board concerning corporate governance matters. Our guidelines are published on our website at www.enterabio.com and are available in print to any shareholder who requests them from our Secretary.

Director Independence

Our Board undertook a review of the independence of each director. Based on information provided by each director concerning his or her background, employment, and affiliations, our Board has determined that the Board meets the independence standards under the applicable rules and regulations of the SEC and the listing standards of Nasdaq. The Board has affirmatively determined that the following Directors are "independent" as of the date of this Annual Report, as defined in the listing standards of Nasdaq: Gerald Lieberman, Ron Mayron, Gerald M. Ostrov, Sean Ellis, Yonatan Malca, and Yonatan Malca.Haya Taitel. In making these determinations, our Board considered the current and prior relationships that each non-employee director has or had with our Company and all other facts and circumstances our Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled Item 13 "Certain "Item 13. Certain Relationships and Related Party Transactions, and Director Independence" contained in this Annual Report on Form 10-K. Report.

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. 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 Annual 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 as required by the rules and regulations of the SEC.

Board Committees

Our Board has established the following committees:

Audit Committee

Composition and Quorum

Under the Nasdaq rules and SEC regulations, we are required to maintain an Audit Committee consisting of at least three independent directors, each of whom is financially literate and one of whom has accounting or related financial management expertise and would qualify as an "audit committee financial expert" as such term is defined in Item 407(d)(5) of Regulation S-K.
Our Audit Committee consists of Gerald M. Ostrov, who also serves as chairman of the committee, Yonatan Malca, and Sean Ellis. The Board has determined that each of the members of our Audit Committee is an independent director in accordance with SEC regulations and additionally satisfies the independent director requirements heightened standards for audit committee service under the applicable SEC and Nasdaq rules. All designated members of our Audit Committee meet the requirements for financial literacy under the applicable Nasdaq rules and SEC regulations. Our Board has determined that Gerald M. Ostrov is an "audit audit committee financial expert," as such term is defined under applicable SEC rules.

Roles, responsibilities and procedures expert.

Roles, Responsibilities and Procedures
Our Audit Committee provides assistance to assists our Board in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, cybersecurity, internal control and legal compliance functions by, among other things, 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 has adopted an Audit Committee charter setting forth the responsibilities of the Audit Committee consistent with the applicable rules and regulations of the SEC and Nasdaq, as well as the requirements for such committee under the Companies Law, including (a) oversight of our independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to the Board in accordance with the Companies law; Law; (b) recommending the engagement or termination of our internal auditor; (c) recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by our Board; (d) identifying deficiencies in the business management practices of our Company, including, inter alia, in consultation with our internal auditor or the independent auditor, and making recommendations to the Board as to how to correct such practices; (e) reviewing and considering the approval of related party transactions; (f) determining whether related party transactions are extraordinary or material under the Companies Law, including transactions in which an office holder Office Holder (as defined under the Companies Law, which includes directors, the CEO, other executive officers and any other managers directly subordinate to the CEO) has a "personal interest", under the Companies Law, and whether to approve such transactions; (g) establishing the approval process for certain transactions with a controlling shareholder or in which the controlling shareholder has a "personal interest"; (h) examining and approving the working plan of the internal auditor, subject to any modifications in its discretion; (i) examining our internal audit controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to fulfill his or her responsibilities; (j) examining the scope of our auditor's work and compensation and submitting its recommendations with respect thereto to our Board or shareholders, depending on which of them is considering the appointment of our auditor; (k) establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees; and (l) reviewing the 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" sections.
A copy of the Audit Committee Charter is available on our website at www.enterabio.com.

A "personal interest" under the Companies Law 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, sibling, parent, grandparent, descendant, spouse's descendant, sibling or parent 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, "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.

Compensation Committee

Composition and quorum

We have a Compensation Committee, the members of which are Ron Mayron, who also serves as chairman of the committee, Gerald M. Ostrov and Yonatan Malca. Each member of our Compensation Committee is independent under Nasdaq rules.

Roles, responsibilities Responsibilities and procedures Procedures

Our Board has adopted a charter setting forth the Compensation Committee's roles and responsibilities, which include (a) recommending a compensation policy regarding the terms of engagement of office holders, Office Holders, which is recommended to the Board for approval and subsequently to shareholders for their approval, in accordance with the Companies Law, and reviewing such policy from time to time, (b) recommending to the Board periodic updates to the compensation policy and whether the compensation policy should continue in effect every three years; (c) assessing the implementation of the compensation policy; (d) reviewing and approving the granting of options, restricted share units, or RSUs, and other incentive awards to the extent such authority is delegated by the Board; (e) reviewing, evaluating and making recommendations regarding the compensation and benefits for non-executive directors, (f) determining whether to approve and recommend to the Board and shareholders to approve transactions with office holders Office Holders relating to their terms of compensation, as required under the Companies Law, (g) determining whether changes to the compensation terms of the Chief Executive Officer of the Company are material and if the changes are required to be brought to the shareholders for approval, (h) overseeing compliance reporting requirements of the SEC, (i) determining whether to recommend to the Board to adopt a share ownership policy for directors and executive officers, and (j) performing such other activities as may be required.

A copy of the Compensation Committee Charter is available on our website at www.enterabio.com.

Under the Companies Law, the compensation policy must be adopted by the Board after considering the recommendations of the Compensation Committee and needs then presented to, be further brought before and approved by, the company's Company's shareholders for approval by a special majority, if necessary. approval.

The compensation policy must serve as the basis for decisions concerning the terms of employment or engagement of office holders, 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; Office Holder; (b) the office holder's 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; (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, 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 services.

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 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, including bonuses; and (e) maximum limits for severance.

Under the Companies Law, every three years we are required to re-obtain the approval of our must obtain Compensation Committee, Board and shareholders shareholder approval for either the continuation of our existing compensation policy or adoption of a new compensation policy. Our compensation policy was last approved by our shareholders on October 4, 2021, after having been recommended by our Compensation Committee and approved by our Board, and will therefore need to be either re-approved, amended, or replaced by a new policy in 2024.

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 2021 and 2023, in determining the compensation of certain non-executive directors and in determining our compensation policy, the Compensation Committee retained the services of a compensation consultant, Brightman Almagor Zohar & co., or a firm in the Deloitte Touche Tohmatsu Limited network, to conduct a comparative survey of the compensation of such office holders. Office Holders. The 2021 and 2023 comparative study studies consisted of: (i) an executive compensation benchmark analysis analyses which included comparative data of the Company's executive compensation, relative to the peer-group companies in Israel and (ii) an executive compensation benchmark analysis analyses which included comparative data of the Company's executive compensation, relative to the peer-group companies in the United States.

Nominating and Corporate Governance Committee

Composition

Our Nominating and Corporate Governance Committee consists of Yonatan Malca, who also serves as chairman of the committee, and Sean Ellis. Each of the members of our Nominating and Corporate Governance Committee is independent under Nasdaq rules.

Roles, Responsibilities and Procedures

Our Board has adopted a Nominating and Corporate Governance Committee Charter that sets forth the responsibilities of the Nominating and Governance Committee consistent with the rules and regulations of the SEC and Nasdaq, including (a) assisting in identifying, recruiting and, if appropriate, interviewing candidates to fill positions on the Board, including persons suggested by shareholders or others, (b) establishing procedures to be followed by shareholders in submitting recommendations for Board candidates, if appropriate, (c) reviewing the background and qualifications of individuals being considered as director candidates, while considering the candidate's experience, skills, expertise, diversity, personal and professional integrity, character, business judgment, time availability in light of other commitments, dedication, conflicts of interest and such other relevant factors that the committee considers appropriate in the context of the needs of the Board, (d) recommending the Board nominees for election by shareholders or appointment by the Board, as the case may be, in a manner consistent with the criteria for selecting directors, as established by the Board from time to time, (e) reviewing the suitability for continued service as a director of each Board member, when the term of service of the director expires, and when the director has a change in status (including, but not limited to, an employment change) and recommending whether or not the director should be re-nominated, (f) making recommendations to the Board regarding the size and composition of each committee; and (g) overseeing the performance of the Board as a whole.

A copy of the Nominating and Corporate Governance Committee Charter is available on our website at www.enterabio.com.

Our The Nominating and Corporate Governance Committee believes that candidates for director should have certain minimum qualifications, including sufficient scientific and/or medical expertise to review and evaluate appropriately the Company's clinical programs, research and development programs and licensing opportunities.

Scientific Advisory Committee

Our Scientific Advisory Committee consists of Yonatan Malca, Roger Garceau, who also serves as chairman of the committee, along with Yonatan Malca, Miranda Toledano, and Sean Ellis.

Scientific Advisory Committee Haya Taitel.

Our Board has adopted a Scientific Advisory Committee Charter that sets forth the responsibilities of the Scientific Advisory Committee, including (a) reviewing, evaluating and reporting to the Board regarding strategy, plans and goals, as well as progress and performance, of the Company's clinical programs, licensing activities, and research and development activities, (b) meeting with the Company's R&D and licensing teams to evaluate the plans, goals and performance of the Company's clinical programs and research and development projects, and make recommendations to the Board as appropriate in the opinion of the committee to fulfill the company strategic goals, (c) identifying and discussing significant emerging regulatory, research and scientific issues and trends and competitive activity, including their potential impacts on any Company programs, plans, or policies relating to its licensing opportunities, clinical programs and research and development activities. (d) evaluating the performance of the committee, including a review of the committee's compliance with its charter, and review and reassess the charter and submit any recommended changes to the Board for its consideration and approval, (e) form forming external consulting panels to assist the committee in review of specific R&D programs either current or planned and (f) such other duties and responsibilities as may be assigned to the committee, from time to time, by the Board.

A copy of the Scientific Advisory Committee Charter is available on our website at www.enterabio.com.

Our Scientific Advisory Committee consists of Roger Garceau, who also serves as chairman of the committee, along with Yonatan Malca and Miranda Toledano.120

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act and the rules thereunder require that our directors and executive officers and persons who beneficially own more than 10% of a registered class of our equity securities to (collectively, "reporting persons") file reports with the SEC relating to their share ownership and changes in such ownership.

Delinquent Section 16(a) Reports

Based solely upon our review of copies of filings or written representations from the reporting persons, we believe that certain all reporting persons timely filed all reports for our executive officers and directors that were required to be filed by them under Section 16(a) of the

Exchange Act during the year ended December 31, 2022 were not filed on a timely basis. Specifically, (i) Messrs. Garceau, Mayron, Lieberman, Ostrov, Galitzer, Santora II, Malca, Ellis, Jamas, Schwartz and Ratan as well as Mses. Toledano and Yaacov-Garbeli each filed a late Form 3 and (ii) Messrs. Garceau, Mayron, Lieberman, Ostrov, Malca and Ellis as well as Ms. Toledano each filed a late Form 4 disclosing two January 2022 option grants from the Company in connection with their service as directors of the Company, in each case due to the delay in obtaining EDGAR codes in connection with our transition from a foreign private issuer to a domestic reporting company. Other than with respect to the aforementioned forms, we believe that all other reports for our executive officers and directors and persons who beneficially own more than 10% of our common stock that were required to be filed under Section 16(a) of the Exchange Act during the year ended December 31, 2022 were December 31, 2023, other than Ms. Taitel, for whom her Form 3 was filed on a timely basis. late.

ITEM 11. ITEM 11. EXECUTIVE COMPENSATION

Compensation Policy

Our compensation policy was adopted by our shareholders on October 4, 2021, after having been recommended by our Compensation Committee and approved by our Board, and will therefore, under the Companies Law, need to be either re-approved, amended, or replaced by a new policy no later than 2024, and every three years thereafter. The compensation policy includes, among other matters prescribed by the Companies Law, a framework for establishing the terms of office and employment of the directors and officers and guidelines with respect to the structure of the variable pay of officers.

Objectives

Our compensation policy is intended to align our objectives and work plans with appropriate goals and objectives of our officers and directors, and to ensure that the overall financial and strategic objectives of the Company and its shareholders are met. We recognize that strong and effective leadership is fundamental to our continued growth and success. Therefore, our compensation policy recognizes as a primary objective the need to attract, retain, reward and motivate highly talented officers and directors in competitive labor markets.

Officer compensation Compensation

With regard to our executive officers, or "Officers," (which includes our Named Executive Officers, as defined below) our compensation policy is designed to provide a mix of compensation to pay reward Officers for individual and company performance as well as to align their interests with the interests of shareholders. The We have also designed our compensation policy is also designed to provide flexibility in design. flexibility. It must also take into consideration the fact that the appropriate mix of compensation may vary from period to period and from Officer to Officer. To achieve this philosophy, our goal of appropriately rewarding our Officers for their efforts, our compensation policy generally includes: (i) short-term incentives, such as an annual base salary, benefits and perquisites, perquisites; (ii) short to medium-term incentives, such as an annual bonus based on target and above-target performance, performance; and (iii) medium to long-term incentives, such as equity-based compensation termination and retirement benefits.

Base salary Salary

Base salary compensates our Officers for Officers is a fixed compensation element which provides compensation to an Officer for the performance of his or her their standard duties and responsibilities that reflects the each Officer's education, skills, qualifications, expertise, professional experience and accomplishments, as well as the position, areas and scope of responsibilities of such Officer and his or her prior compensation agreements. Officer. Adjustments to base salary are periodically reviewed by the Compensation Committee and the Board.

Bonuses

Monetary Cash bonuses are generally paid annually and are designed intended to reward Officers based on the performance of the Company and their individual results. contributions. The target bonus amount and the performance measures and targets for each Officer are provided and calculated in an annual bonus plan, to the extent it is determined and approved by the Company's Compensation Committee and the Board at the beginning of each calendar year for which the a bonus is may be paid. However, Additionally, the CEO has the power to determine the annual bonus's bonus performance measures and targets for any of the all Officers other Officers. than for herself.

The performance measures and targets for receiving the annual bonus are intended to be measurable and quantifiable and may include, (but are not limited to) without limitation: (i) objectives such as capital investment, cash balance relative to equity, obtaining approval from the authorities in the target markets; and (ii) key performance indicators, determined for each Officer separately, according to the Officer's position. The annual bonus also includes a non-measurable, qualitative component of up to 20% of the an Officer's annual bonus, which is based on the an evaluation of each Officer's, according to such Officer in accordance with qualitative measures provided in the annual bonus plan. grant.

In addition to the annual bonus, the Compensation Committee and the Board may elect to pay each Officer a special bonus, based on non-measurable criteria (e.g., criteria or milestones not based on quantifiable measures), in recognition of a significant achievement or for completion of an assignment, such as completion of a major transaction or achieving a major milestone with material effect over the Company's impact on our business. Our Under our compensation policy, provides for a maximum cap for special bonus payments made is

limited to our Officers. The maximum bonus cap for each of our Officers is six times the monthly base salary and with respect to the for a given Officer, other than our CEO, up for whom a special bonus is limited to three times the monthly base salary, determined by non-measurable criteria.

Equity-based compensation Compensation

Our compensation policy also includes an equity incentive component designed inter alia, to retain Officers, align Officers and shareholders' interests and incentivize Officers to attain high level of business achievements without taking unreasonable risk, under which the Company may grant Officers options to purchase shares, share appreciation rights, restricted shares, restricted share units, performance awards or other share-based awards (collectively referred to as "equity awards"). The equity awards are determined individually by our Compensation Committee and the Board and awarded from time to time inter alia, according to based on, among other elements, each Officer's (a) contribution to the Company's performance; performance, (b) ability to influence the Company's future and performance; performance and (c) the Officer's skills, qualifications, experience, roles and personal responsibilities. Additionally, the Compensation Committee and the Board award equity-based compensation based upon the desired mix of compensation components and the mix of equity awards; (d) the Officer's skills, qualifications, experience, roles and personal responsibilities; and (e) awards, as well as the desired competitive levels and dilution or pool limits.

The Our compensation policy caps limits the annual value of the equity awards to be granted to each an Officer, measured at the applicable grant date, at to 18 times the monthly base salary of each such Officer. The These equity awards must provide for a vesting period shall of not be less than one year. Options shall expire up to year, and options may be granted with terms of not more than 10 years from following the grant date. For option grants and share appreciation rights, the exercise price shall be no less than the fair market value of the underlying ordinary shares Ordinary Shares on the date of grant and subject to applicable law.

The Hedging and Pledging

Pursuant to the terms of our compensation policy provides that and insider trading policy, Officers and directors (to the extent granted equity awards) may be are prohibited from hedging or pledging their equity awards and any other Company securities held by them. securities. The no-hedging policy applies to each director and each Officer until one year following their termination of employment. The compensation policy further provides that such director's term of office or such Officer's termination of employment, as applicable. Furthermore, Officers and directors are subject to certain restrictions on pledging may not pledge or using use their equity awards and or any other Company securities held by them (whether they are subject to transfer restrictions or not) as collateral for loans as unless otherwise approved by the Company's Compensation Committee and Board shall determine. Board.

Benefits and perquisites Perquisites

Under the compensation policy, our Officers are further entitled to certain fringe benefits that we believe are commonly provided to similarly-situated similarly situated executives in the market in which we our industry. These benefits allow us to compete for talent and are therefore are important to our ability to attract and retain top-level executive management. This includes vacation days, paid sick leave, as well as additional benefits such as, but not limited to, health insurance, a company car and cell phone, company-provided health insurance and meals.

For Officers residing in Israel, these benefits may also include contributions to a pension fund, provident fund or insurance policy in accordance with Israeli law, contributions to an education fund of 7.5% of the Officer's monthly salary and recuperation pay as required under applicable law. An 'education fund' is a medium-term savings scheme that takes advantage of a unique tax break granted under Israeli law, whereby a company's contributions to such fund (which, despite its misleading name, may be used by the employee for any purpose), as well as all capital gains accrued on such contributions, are free of tax if (a) the company contributes an amount equal to 7.5% of the employee's salary to such fund, up to a certain limit, and the employee further contributes 2.5% of his salary at his expense, and (b) the fund remains undrawn for a period of at least six years from the time of the first contribution. While some of these contributions and benefits are not mandatory under Israeli law, the nature and amount of the benefits provided to our Israeli Officers are customary and prevalent in the Israeli high-tech and bio-pharma market, especially among executives. Non-Israeli Officers may receive similar, comparable or customary benefits as applicable in the jurisdiction in which they are employed.

Termination

Our Officers are further entitled to certain termination payments and benefits. Officers are entitled to an advance notice period, severance payments and retirement and termination awards. The retirement and termination awards are subject to the Compensation Committee and the Board's approval, and may be provided only if: only: (a) in certain change of control related cases; (b) if the Officer has made a special contribution to the advancement of the Company's business during his employment period as shall be determined by the Compensation Committee; and (d) or (c) in respect of Officers other than the CEO, if the CEO has recommended granting a retirement bonus.

Director compensation Compensation

The compensation policy provides that non-employee and non-executive directors' compensation packages shall be are determined pursuant to the provisions of the Companies Law in accordance with the Company's objective to attract and retain talented directors with excellent

educational background, qualifications, skills, expertise, professional experience and achievements, by providing a fair and competitive compensation program. Such Our non-employee and non-executive directors' directors may be eligible to receive an annual Board membership fee, annual Committee membership fee and equity based equity-based compensation. Notwithstanding, non-employee and non-executive Non-employee directors shall may also be entitled to receive insurance, indemnification and release arrangements. The chair of the Board and the chair chairs of the Board committees may also receive additional annual cash payments for their extra service in such capacities, subject to the provisions of applicable law.

In May 2021, we elected to be governed by an exemption under exempt from the Companies Law regulations requirement that exempts us from appointing we appoint external directors and from complying or otherwise comply with the Companies Law requirements related to the composition of the Audit Committee and Compensation Committee of our Board. Committee. Our eligibility for that exemption is conditioned upon: (i) the continued listing of our Ordinary Shares on the Nasdaq Capital Market (or one of a few select other non-Israeli stock exchanges); (ii) there not being a controlling shareholder of our company under the Companies Law; and (iii) our compliance with the Nasdaq Listing Rules requirements as to the composition of (a) our Board of Directors which requires Directors, which require that we maintain a majority of independent directors, (as defined under the Nasdaq Listing Rules) on our Board of Directors (subject to applicable cure periods under the Nasdaq Listing Rules) and (b) the Audit and Compensation Committees, of our Board of Directors, which rules require that such committees consist solely of independent directors (at least three and two members, respectively). At the time that it was determined to exempt our Company from the external director requirement, our Board affirmatively determined that we met the conditions for exemption from the external director requirement. As of the date hereof, we continue to meet the conditions for exemption from the external director requirement.

As a result of our election to be exempt from the external director requirement under the Companies Law, none of our directors are categorized as external directors and as such directors; therefore, the applicable requirements and restrictions relating to external directors (including certain compensation related provisions) is no longer applicable. do not apply.

Claw-back Clawback Policy

TheOn November 30, 2023, the Board adopted an Executive Officer ClawbackPolicy (the "ClawbackPolicy") in compliance with Rule 10D-1 under the Exchange Act and the appliable Nasdaq rules. In the event of an accounting restatement, under the ClawbackPolicy, the Board, or another committee designated by the Board, is required to recover certain incentive-based compensation packages paid to Officers and directors are also an executive officer of the Company, subject to claw-back provisions, allowing for the Company's recovery terms of any payment made to an Officer or director if the payment was based on incorrect financial statements that subsequently required restatement. The Officer or director will be required to repayClawbackPolicy, to the Company the difference between the original payment and any payment due to the officer or director based on the restatement.

Our Compensation Committee periodically reviews the extent such incentive-based compensation policy, monitors its implementation and recommends to our Board and shareholders amendments to the compensation policy as it deems necessary from time to time. The term was in excess of the compensation policy is that would have otherwise been payable based upon the restated financials. The Clawback period extends for a period of three years prior to the restatement. The ClawbackPolicy is in addition to Section 304 of the Sarbanes-Oxley Act of 2002, which permits the SEC to order the disgorgement of bonuses and incentive-based compensation earned by a registrant issuer's chief executive officer and chief financial officer in the year following the date filing of its adoption, during which, any financial statement that the Board issuer is required to examine restate because of misconduct, and the compensation policy and revise it from time to time if the circumstances under which it had been adopted have materially changed. Following such three-year term, the compensation policy, including any revisions recommended by our Compensation Committee and approved by our Board, as applicable, will be brought once again reimbursement of those funds to the shareholders for approval. issuer. A copy of the Clawback Policy has been filed herewith as Exhibit 97 to this Annual Report.

Summary Compensation Table

The table and summary below outline the compensation granted to our named executive officers ("Named Executive Officers") during our fiscal years ended December 31, 2022 December 31, 2023 and December 31, 2021 December 31, 2022. As a "smaller reporting company," we are required to provide executive compensation information for the following individuals: (i) all individuals who served as the Company's principal executive officer ("PEO"), during the last completed fiscal year, regardless of compensation; (ii) the two most highly compensated executive officers (other than the PEO) who were serving as executive officers of the Company at the end of the last completed fiscal year and whose total compensation was greater than $100,000; and (iii) up to two additional persons who served as executive officers (other than as the PEO) during the last completed fiscal year but who were not serving in that capacity at the end of the fiscal year if their total compensation is higher than any of the other two Named Executive Officers in the preceding group.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Award(s) ($)(1)	All Other Compensation ($)	Total ($)
Miranda Toledano (2)	2022	231	-	382	66	679
Chief Executive Officer and director	2021			17	65	82
Spiros Jamas (3)	2022	255	95	(256)	428	522
Former Chief Executive Officer	2021	392	-	751	-	1,143

Dr. Phillip Schwartz (4)	2022	188	27	196	371	782
Former President of R&D	2021	453	-	183	49	685
Dr. Hillel Galitzer	2022	287	63	234	37	621
Chief Operating Officer	2021	319		260	61	640

The below figures are represented in thousands.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Award(s) ($)(1)	All Other Compensation ($)	Total ($)
Miranda Toledano (2)	2023	338	-	532	80	950
Chief Executive Officer and director	2022	231	-	382	66	679
Dr. Hillel Galitzer	2023	245	-	163	51	459
Chief Operating Officer	2022	287	63	234	37	621
Dana Yaacov-Garbeli	2023	193	-	118	-	311
Chief Finance Officer	2022	193	32	156	-	381

(1) Reflects the associated annual expense recorded in our financial statements for the year ended December 31, 2022, based on the grant date fair value of the share-based compensation granted in exchange for the directors' and officers' services computed in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718, *Compensation - Stock Compensation* ("ASC Topic 718"). The assumptions used in calculating the amounts are discussed in the notes of Note 6 to the Company's audited financial statements for the year ended December 31, 2022 December 31, 2023 included in this Annual Report. The fair value amount is recognized as an expense over the course of the vesting period of the options (subject to any applicable accounting adjustments during that period).

(2) Ms. Toledano was appointed as our Chief Business Officer, Chief Financial Officer and Head of Corporate Strategy in May 2022. Ms. Toledano was then appointed as our Chief Executive Officer in July 2022. The compensation for fiscal year 2021 from January 2022 and until May 2022 represents her compensation as a non-employee board member.

(3) Mr. Jamas served as our Chief Executive Officer from January 4, 2021 until July 13, 2022. Pursuant to the mutual separation agreement entered into between us and Mr. Jamas, he was entitled to a one-time lump sum payment of his annual base salary for a period of 13 months which is included in the table above.

(4) Dr. Schwartz served as the President of R&D during fiscal years 2021 and 2022 through his resignation on July 21, 2022. On June 15, 2022, Dr. Schwartz resigned from his position with the Company, effective July 21, 2022. The compensation for fiscal year 2022 represents his compensation received for services rendered through his resignation date.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth the outstanding equity awards at December 31, 2022 December 31, 2023 for our Named Executive Officers.

	Number of Securities Underlying Unexercised Options		Option Expiration	Number of Securities Underlying Unexercised Options		Option Expiration
Name	Exercisable	Unexercisable	Date	Exercisable	Unexercisable	Date
Miranda Toledano	33,638		17/1/2029	33,638	-	17/1/2029
Chief Executive Officer and director	35,852		1/1/2031	35,852	-	1/1/2031
	35,852	71,705 (1)	1/1/2031	62,741	44,816(1)	1/1/2031
		500,000 (2)	16/05/2032	187,500	312,500(2)	16/05/2032
		600,000 (3)	15/07/2032	187,500	412,500(3)	15/07/2032
Dr. Spiros Jamas						
Former *Chief Executive Officer*	492,832	-	14/7/2023			
Dr. Phillip Schwartz	357,500	-	23/11/2027			
Former President of R&D	100,000	-	21/4/2031			
				-	350,000(4)	24/04/2033
Dr. Hillel Galitzer	143,000	-	15/11/2023	164,062	10,937(5)	16/3/2030
Chief Operating Officer	120,312	54,688 (4)	16/3/2030	78,125	46,875(6)	21/4/2031
	46,875	78,125 (5)	21/4/2031	26,250	33,750(7)	24/3/2032
		60,000 (6)	30/3/2032	-	210,000(8)	24/04/2033
				32,812	2,188(9)	25/06/2030
Dana Yaacov-Garbeli						

Chief Finance Officer	75,000	45,000(10)	21/04/2031
	10,938	24,062(11)	31/03/2032
	-	190,000(12)	24/04/2033

(1) The 71,705 44,816 unexercisable options as of December 31, 2022 December 31, 2023 will vest in eight five equal quarterly installments beginning on March 31, 2023 January 1, 2024.

(2) Of the 500,000 The 312,500 unexercisable options as of December 31, 2022 December 31, 2023 will vest in ten equal quarterly installments beginning on February 16, 2024.

(3) The 412,500 unexercisable options as of December 31, 2023 will vest in eleven equal quarterly installments beginning on March 9, 2024.

(4) Of the 350,000 unexercisable options as of December 31, 2023, 25% vest on May 16, 2023 April 24, 2024, the first anniversary of the grant date, and the remaining 75% begin vesting in 12 equal quarterly installments over the following three years.

(3) Of the 600,000 unexercisable options as of December 31, 2022, 25% vest on July 15, 2023, the first anniversary of the grant date and the remaining 75% begin vesting in 12 equal quarterly installments over the following three years.

(4) (5) The 54,688 10,937 unexercisable options as of December 31, 2022 December 31, 2023 will vest on March 16, 2024.

(6) The 46,875 unexercisable options as of December 31, 2023 will vest in five six equal quarterly installments beginning on March 16, 2023 January 20, 2024.

(5) (7) The 78,125 33,750 unexercisable options as of December 31, 2022 December 31, 2023 will vest in 10 nine equal quarterly installments from January 21, 2023 beginning on March 30, 2024.

(6) (8) Of the 60,000 210,000 unexercisable options as of December 31, 2022 December 31, 2023, 25% vest on March 31, 2023 April 24, 2024, the first anniversary of the grant date, and the remaining 75% will vest in 12 equal quarterly installments over the following three years.

(9) The 2,188 unexercisable options as of December 31, 2023 will vest on March 16, 2024.

(10) The 45,000 unexercisable options as of December 31, 2023 will vest in six equal quarterly installments beginning on January 20, 2024.

(11) The 24,062 unexercisable options as of December 31, 2023 will vest in eleven equal quarterly installments beginning March 8, 2024.

(12) Of the 190,000 unexercisable options as of December 31, 2023, 25% vest on April 24, 2024, the first anniversary of the grant date, and the remaining 75% will vest in 12 equal quarterly installments over the following three years.

Director Compensation Table

Under the Companies Law, our directors can be paid for their services as directors to the extent such payments are in accordance with the compensation policy adopted by the Company after approval by the Compensation Committee, our Board and our shareholders by ordinary majority, or, if their compensation deviates from our compensation policy, after approval by the Compensation Committee, our Board and our shareholders by a special majority, if necessary, provided that (i) the majority of the votes includes at least a majority of all the votes of shareholders who are not controlling shareholders of the Company or who do not have a personal interest in the compensation paid to the directors and participating in the vote or (ii) the total of opposing votes from among the shareholders described in subsection (i) above does not exceed 2% of all the voting rights in the Company.

The table below outlines compensation earned by our non-employee directors for the fiscal year ended December 31, 2022 December 31, 2023, including fees earned in cash and options awarded for services provided as a director. Ms. Toledano served as a In order to help the Company maintain sufficient cash for operations, all non-employee director in 2022 until her appointment as an officer in May 2022. Her compensation received in connection with her service as a director is included in her 2022 compensation described above in "Summary Compensation Table", above. directors agreed to forfeit receipt of all cash fees otherwise payable to them for the third and fourth quarters of 2023.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Gerald Lieberman	61,000	196,000	-	257,000	40,000	90,966	-	130,966
Dr. Roger J. Garceau	41,000	196,000	-	237,000				
Yonatan Malca	56,000	196,000	-	252,000	34,000	90,966	-	127,854
Ron Mayron	50,000	229,000	-	279,000				
Gerald M. Ostrov	56,000	196,000	-	252,000	30,000	90,966	-	120,966
Sean Ellis	52,000	196,000	-	248,000	26,500	90,966	-	117,466
Dr. Roger J. Garceau					25,000	90,966	-	115,966
Ron Mayron					25,000	102,864	-	127,966

Haya Taitel	**3,091**	**5,523**	**-**	**8,613**

(1) **Reflects the associated annual expense recorded in our financial statements for the year ended December 31, 2022, based on the grant date fair value of the share-based compensation granted in exchange for the directors' and officers' services computed in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718, *Compensation - – Stock Compensation* ("ASC Topic 718"). The assumptions used in calculating the amounts are discussed in the notes Note 6 of the Company's audited financial statements for the year ended December 31, 2022 December 31, 2023 included in this Annual Report. The fair value amount is recognized as an expense over the course of the vesting period of the options (subject to any applicable accounting adjustments during that period).**

The table below sets forth the aggregate number of share options of each non-employee director outstanding as of December 31, 2022 December 31, 2023:

Name	Share Options
Gerald Lieberman	**324,337 266,088**
Dr. Roger J. Garceau	**449,739 588,780**
Yonatan Malca	**177,047 266,088**
Ron Mayron	**177,047 266,088**
Gerald M. Ostrov	**177,047 266,088**
Sean Ellis	**177,047 266,088**
Haya Taitel	**33,638**

Employment Agreements

We have entered into employment agreements with our Named Executive Officers. A summary of the material terms of these agreements with each of our Named Executive Officers is set forth below. The below descriptions of employment agreements and separation agreements, as applicable, are only summaries and are qualified in their entirety by reference to the full text of the applicable agreement, which are filed as exhibits to this Annual Report on Form 10-K. Report.

Miranda J. Toledano

In connection with Ms. Toledano's appointment as the Company's Chief Business Officer, Chief Financial Officer and Head of Corporate Strategy in May 2022, Ms. Toledano entered into an employment agreement (the "Original Employment Agreement") with the Company, providing for an annual employer cost of $350,000 inclusive of base salary, pension payments, severance and disability benefits as required under Israeli law. Additionally, Ms. Toledano was entitled to a grant of options pursuant to the Company's 2018 Equity Incentive Plan to purchase 500,000 Ordinary Shares of the Company's Ordinary Shares at an exercise price of $2.02 per share, the closing price of the Ordinary Shares on the date the option was approved by the Board. The options vest over four years, with 25% of the options vesting on May 16, 2023 and the remaining 75% vesting in quarterly increments over the remaining three-year period, subject to Ms. Toledano's continued employment. In addition, Ms. Toledano was eligible to receive an annual bonus in an amount equal to 50% of her annual base salary. Under the Original Employment Agreement, Ms. Toledano also agreed to customary non-disclosure and non-competition covenants, covenants.

In connection with Ms. Toledano's appointment as Chief Executive Officer, on July 15, 2022, Ms. Toledano and the Company entered into an amended and restated employment agreement (the "A&R Employment Agreement"), which amends and restates the Original Employment Agreement. The material terms of the Original Employment Agreement remain unchanged, except that the A&R Employment Agreement provides for (i) Ms. Toledano's service as Chief Executive Officer, (ii) an annual employer cost of $380,000 inclusive of base salary, pension payments, severance and disability benefits as required under Israeli law, (iii) eligibility to receive an annual bonus in an amount equal to 60% of Ms. Toledano's annual base salary, (iv) a one-time separation payment in the total amount of 12 months of salary and an extension of the exercise period with respect to vested options for a period of up to two-years post-termination, in each case in the event of the termination of Ms. Toledano's employment by the Company for any reason other than for Cause (as defined in the A&R Employment Agreement), (v) an additional grant of options (the "Options") pursuant to the Company's 2018 Equity Incentive Plan to purchase 600,000 Ordinary Shares at an exercise price of $1.40, which was the closing price of the Ordinary Shares on the date the Board approved such option grant and (vi), upon the Company's achievement of certain performance or financial milestones, a grant of options (the "Additional Options") to purchase an additional 200,000 Ordinary Shares pursuant to the Company's 2018 Equity Incentive Plan at an exercise price equal to the closing price of the Ordinary Shares on the date the Board approves such option grant. The Options will vest over four years, with 25% of the Options vesting on July 15, 2023 and the remaining 75% vesting in quarterly increments over the remaining three-year period, subject to Ms. Toledano's continued employment. The Additional Options will vest over four years, with 25% of the Additional Options vesting on the first anniversary of the grant date and the remaining 75% vesting in quarterly increments over the remaining three-year period, subject to Ms. Toledano's continued employment.

Spiros Jamas

Employment Agreement

We entered into an employment agreement, effective as of January 2021, with Dr. Spiros Jamas, in connection with his appointment as our Chief Executive Officer and in light of his previous membership in our Board. Pursuant to the agreement, Dr. Spiros Jamas was entitled to an annual base salary of $380,000 and an annual bonus of up to 60% of his base salary (up to $228,000). Additionally, Dr. Jamas was eligible to participate in the Company's standard full-time employment benefits that are offered by the Company from time to time, which currently include medical, short term disability and 401(k) benefits. Mr. Jamas was also generally entitled to reimbursement for travel and other business expenses and other benefits, including, vacation, holidays and sick leave. Subject to applicable law, Dr. Jamas is also covered by our D&O insurance policy. Dr. Jamas was also granted options to purchase 1,314,218 Ordinary Shares under the 2018 Plan, effective as of January 2021, at an exercise price of $1.24. Salary and other benefits (including any bonus) shall immediately terminate upon termination, provided, however, that in case Dr. Jamas's employment would have been terminated by the Company without Cause or if Dr. Jamas resigned for Good Reason ("Cause" and Good Reason" as defined in the proxy statement of the Company's extraordinary general meeting dated March 3, 2021) at any time, he would have been entitled to (i) a one-time lump sum severance payment equal to a period of twelve (12) months of his then-effective annual base salary and (ii) an extension of the exercise period with respect to his vested options to purchase ordinary shares as of the date of termination for up to two (2) years post-termination (provided that in no event shall such extension extend beyond 10 years from the applicable grant date), all subject to his execution and non-revocation of a customary release of claims against the Company, its subsidiary, Entera Bio, Inc., or any applicable affiliates.

Separation Agreement

On July 13, 2022 April 24, 2023, the Company and Dr. Jamas entered into a mutual separation agreement (the "Separation Agreement"), pursuant to which the parties agreed that Dr. Jamas would resign from his position as the Company's Chief Executive Officer, effective July 15, 2022 (the "Jamas Separation Date"). Pursuant to the Separation Agreement, Dr. Jamas' employment agreement, dated November 30, 2020, terminated, other than with respect to those provisions intended to survive termination, including those with respect to confidentiality, non-competition, non-solicitation and intellectual property.

Pursuant to the terms of the Separation Agreement, Dr. Jamas was entitled to receive payment for all accrued but unpaid base salary through the Jamas Separation Date, unused paid time off through the Jamas Separation Date, reimbursement for unreimbursed business expenses properly incurred pursuant to the Company's applicable expense reimbursement policy, and benefits provided under the Company's employee benefit plan. In addition, in consideration for Dr. Jamas' execution of the Separation Agreement and non-revocation of a waiver and release of claims relating thereto, Dr. Jamas was entitled to the following benefits under the Separation Agreement:

- **a one-time lump sum payment of Dr. Jamas' annual base salary for a period of thirteen (13) months, for a total gross amount equal to $411,666.67, after the expiration of the revocation period;**
- **an extension of the exercise period for the vested portion of the share option granted to Dr. Jamas on January 4, 2021 pursuant to the terms of the Company's 2018 Equity Incentive Plan, representing collectively 492,832 ordinary shares, through the end of a two-year period commencing on the Jamas Separation Date.**

Under the Separation Agreement, Dr. Jamas agreed to cooperate with and assist the Company regarding certain matters and transitioning his employment duties and responsibilities. Subject to certain exceptions and limitations, the Separation Agreement included a general release of claims by Dr. Jamas in favor of the Company and certain related persons and parties, and customary non-disparagement provisions. The Separation Agreement also included certain other customary representations, warranties and covenants of Dr. Jamas. The Separation Agreement superseded all other agreements or arrangements between Dr. Jamas and the Company regarding the subject matter of the agreement, including those with respect to severance payments and benefits.

Phillip Schwartz

Dr. Phillip Schwartzwas appointed as our President of Research and Development in August 2019 and served in this capacity until July 21, 2022, (the "Schwartz Separation Date"), and acted as a director from our inception in 2010 until June 15, 2022, and as Chief Executive Officer from 2010 up until August 2019. We entered into an employment agreement with Dr. Schwartz as our Chief Executive Officer dated June 8, 2014 which was amended last and approved on April 6, 2021, and on April 21, 2021, by our Compensation Committee and the Board respectively, voted to approve, and approved accordingly by our shareholders in the last annual meeting of on September 13, 2023, the shareholders of the Company on October 4, 2021. Pursuant ratified and confirmed, (i) a salary increase for Ms. Toledano, according to the agreement as amended, effective as which her annual employer cost would be increased to $480,000, and (ii) a one-time grant of January 1, 2021, Dr. Schwartz was entitled options to purchase 350,000 Ordinary Shares, at an annual gross base salary option exercise price of $312,889. Additionally, Dr. Schwartz was eligible to participate in $0.795 per Ordinary Share, under the Company's standard full-time employment benefits that are offered by the Company from time to time, which currently include medical, short term disability and pension fund benefits. Dr. Schwartz was also generally entitled to reimbursement for travel and other business expenses and other benefits, including, vacation, holidays and sick leave. Subject to applicable law, Dr. Schwartz was also covered by our D&O insurance policy. Dr. Schwartz was granted 357,000 Ordinary Shares under our 2013 2018 Equity Incentive Plan as (the "2018 Plan"), both of November 23, 2017, at an exercise price which were deemed by the Board to be inside the respective ranges set in the Company's compensation policy. For the sake of $6.31, which are as of today considered fully vested. In April 2021, he was also granted options to purchase 100,000 Ordinary Shares of good corporate governance, the Company under the 2018 Plan, at and Ms. Toledano executed an exercise price of $3.15. In addition, amendment to Ms. Toledano's employment agreement in case of termination of Dr. Schwartz's employment, the Company agreed to pay Dr. Schwartz an amount equal to six (6) months salaries as a severance payment, as well as all accrued and unused vacation days and any accrued and unpaid bonuses (to the extent that Dr. Schwartz is entitled to such bonus as of the termination date).

On June 15, 2022, the Company entered into a separation agreement with Dr. Phillip Schwartz, the Company's former President of R&D, January 2024, under which Dr. Schwartz agreed to continue to provide services to the Company until July 21, 2022 (the "Schwartz

Separation Date"). Pursuant to the terms of which the separation agreement, which were approved by the Company's shareholders salary increase became effective on September 7, 2022, Dr. Schwartz received a full acceleration of his unvested options, as of the Shwartz Separation Date, to purchase 68,750 ordinary shares granted in April 2021 that otherwise would have been forfeited. These options, together with 31,250 already vested options granted in April 2021 and 357,500 already vested options to purchase ordinary shares granted in 2017, will be exercisable for a period of 10 years from their respective initial grant dates. The acceleration described above was recognized as a "Type III" modification; therefore, on the shareholder approval date, the Company recognized the incremental costs of unvested options based on the fair value of the options on such date. In addition, the extension of the exercise period for the vested awards was recognized as a "Type I" modification. The total expense amount was $112 thousand, which was classified as additional share-based compensation costs in the research and development expenses.

In addition, the separation agreement provides for the following payments to Dr. Schwartz, all of which would have otherwise been payable in accordance with either Israeli law or pursuant to his existing employment agreement: a one-time cash separation payment in an amount equal to NIS 537,600 (approximately $155.9) and additional payments of NIS 737,771 (approximately $214.0) in respect of all other ongoing accrued benefits, subject to any mandatory deductions. The foregoing payments were recognized in the research and development expenses January 1, 2024.

Hillel Galitzer

We In March 2014, we entered into an employment agreement effective as of June 8, 2014, with Dr. Hillel Galitzer, in connection with his appointment as our Chief Operating Officer, who prior to that served as our Director of Scientific Development from July 2012. Dr. Hillel Galitzer. Pursuant to the agreement as amended most recently terms of his employment, and approved in within the Company's annual meeting of shareholders dated October 4, 2021, discretion granted to the Board, Dr. Galitzer is was entitled to an annual gross base salary of $246,547. $230,725 for both 2022 and 2023, which represents an increase in base salary from the original terms of the employment agreement approved by the Board. In 2024, the Board approved an increase to Dr. Galitzer's annual salary, and he is currently entitled to an annual gross base salary of $246,000. Additionally, pursuant to the terms of his employment agreement, Dr. Galitzer is eligible to participate in the Company's standard full-time employment benefits that are offered by the Company from time to time, which currently include medical, short term short-term disability and pension fund benefits. Dr. Galitzer is also generally entitled to reimbursement for travel and other business expenses and other benefits, including, vacation, holidays, company car and sick leave. Subject to applicable law, Dr. Galitzer is also covered by our D&O insurance policy. In November 2017, Dr. Pursuant to the terms of his employment agreement. Dr Galitzer was granted options is eligible to purchase 143,000 Ordinary Shares of the Company, under the Company's 2013 Equity Incentive Plan, with an exercise price of $6.31, all of which are fully vested.We also granted Dr. Galitzer options to purchase 175,000 Ordinary Shares of the Company, receive equity awards under the Company's 2018 Plan, as existing and future incentive plans. Pursuant to the terms of March 16, 2020, at an exercise price of $2.14. Additionally, his employment agreement, Dr. Galitzer received also agreed to customary non-disclosure and non-competition covenants.

Dana Yaacov-Garbeli

In June 2019, we entered into a grant consulting agreement with A2Z Finance Ltd. ("A2Z"), in connection with the appointment of options to purchase 125,000 Ordinary Shares under Ms. Yaacov-Garbeli as our Chief Financial Officer, which was further amended in June 2020, October 2021 and April 2023 (as amended, the Company's 2018 Plan, as ("consulting agreement"). Under the terms of April 28, 2021, at an exercise price of $3.15, under the 2018 Plan. consulting agreement, both parties may terminate the agreement for any reason upon 30 days' notice. In addition, Dr. Galitzer received a grant the Company has the ability to terminate the agreement immediately upon the occurrence of options certain limited circumstances, such as breach of contract. In 2022 and 2023, pursuant to purchase 60,000 Ordinary Shares the terms of the Company, under consulting agreement, Ms. Yaacov-Garbeli was entitled to an annual payment of $193,200. Ms. Yaacov-Garbeli's annual payment was raised to $225,000 for fiscal year 2024. In addition, Ms. Yaacov-Garbeli is reimbursed for reasonable out of pocket expenses which were pre-approved in writing in connection with her duties as Chief Financial Officer. Pursuant to the Company's 2018 Plan, as of March 31, 2022, at an exercise price of $2.86. terms the consulting agreement, Ms. Yaacov-Garbeli also agreed to customary non-disclosure and non-competition covenants.

Employee Equity Incentive Plan Plans

2013 Share Incentive Plan

On March 17, 2013, our Board 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, 2022 December 31, 2023, 1,518,262 1,166,880 Ordinary Shares were issuable upon the exercise of outstanding awards under the 2013 Plan, at a weighted-average exercise price of$5.71 of $5.98 per share. As of December 31, 2022 December 31, 2023, all of the foregoing outstanding options had vested under the 2013 Plan.

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 or by a committee appointed by our Board. Upon the completion of our initial public offering, the remaining pool of reserved Ordinary Shares under the 2013 Plan was cancelled, and the only reserved Ordinary Shares available for grants to our employees, directors, consultants and service providers in the future are those under the 2018 Plan (which is described below).

2018 Equity Incentive Plan

On July 2, 2018, in connection with the consummation of our initial public offering, our Board approved our 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) have and will become available for issuance under the 2018 Plan. In our shareholders meeting held September 7, 2022, our shareholders approved an amendment to the 2018 Plan to increase the number of Ordinary Shares issuable under the 2018 Plan by a one-time additional amount of 576,188 Ordinary Shares. As of December 31, 2022 December 31, 2023, a total of 922,080 638,598 Ordinary Shares representing 3.2% 1.8% of the total outstanding shares as of that date remained available for issuance under the 2018 Plan. On January 1, 2023 January 1, 2024, pursuant to the annual evergreen provision and following the approval of our Board, an additional 1,440,496 1,773,817 Ordinary Shares, equal to 5% of the total outstanding shares as of January 1, 2023 January 1, 2024, became available for issuance under the 2018 Plan.

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

As of December 31, 2022 December 31, 2023, 4,214,825 5,938,534 Ordinary Shares were issuable upon the exercise of outstanding awards under the 2018 Plan, at a weighted-average exercise price of $2.04 $1.90 per share. Of the foregoing outstanding awards, as of December 31, 2022 December 31, 2023, options to purchase 1,653,531 3,078,715 Ordinary Shares, in the aggregate, had vested under the 2018 Plan, with a weighted-average exercise price of $2.47 $3.63 per share.

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, provided that the Board 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 12.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information known to us with respect to the beneficial ownership of our Ordinary Shares as of March 27, 2023 March 1, 2024 by:

- **each person or entity known by us to own beneficially 5% or more of our outstanding Ordinary Shares;**
- **each of our directors and executive officers individually; and**
- **all of our executive officers and directors as a group.**

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. For purposes of the table and the related footnotes, unless described otherwise within the footnotes, Ordinary Shares issuable pursuant to options or warrants that are currently exercisable will become exercisable within 60 days following March 27, 2023 March 1, 2024 to be outstanding and 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 28,809,922 35,481,341 Ordinary Shares outstanding as of March 27, 2023 March 1, 2024. The beneficial ownership data provided below is based solely on information available to our Company and, in the case of major shareholders who are not otherwise officers or directors, 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, 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)	3,762,960	13.1 %
Gakasa Holdings LLC.(2)	2,484,275	8.6 %
Centillion Fund (3)	2,396,953	8.3 %
Executive Officers and Directors:		
Yonatan Malca(4)	143,798	*
Gerald Lieberman(5)	494,515	1.7 %
Dr. Roger J. Garceau(6)	464,198	1.6 %
Dr. Hillel Galitzer(7)	385,856	1.3 %
Dr. Arthur Santora(8)	60,000	*
Miranda J. Toledano(9)	296,105	1.0 %
Gerald M. Ostrov(10)	146,566	*
Sean Ellis(11)	201,666	*
Dana Yaacov-Garbeli(12)	151,580	*
Ron Mayron(13)	132,353	*
All Directors and Executive Officers as a Group (10 persons)(14)	2,476,637	8.0 %

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)	3,732,540	10.5 %
Gakasa Holdings LLC.(2)	3,524,275	9.9 %
Centillion Fund (3)	2,396,953	6.8 %
Executive Officers and Directors:		
Miranda Toledano(4)	853,612	2.4 %
Dr. Roger J. Garceau(5)	593,914	1.7 %
Gerald Lieberman(6)	541,995	1.5 %
Dr. Hillel Galitzer(7)	385,356	1.0 %

Sean Ellis(8)	368,382	1.0 %
Gerald M. Ostrov(9)	276,282	*
Yonatan Malca(10)	273,514	*
Ron Mayron(11)	273,282	*
Dana Yaacov-Garbeli(12)	246,580	*
Dr. Arthur Santora(13)	381,421	*
Haya Taitel (14)	53,493	*
All Directors and Executive Officers as a Group (11 persons)(15)	3,984,266	10.26 %

* Less than 1%

(1) D.N.A Biomedical Solutions Ltd.'s holdings consisted of 3,762,960 Ordinary Shares. D.N.A's address is at Shimon Hatarsi 43 St., Tel Aviv, Israel.

(2) Based on the Schedule 13G/A filed Beneficial ownership includes 3,534,275 ordinary shares. This consists of: (i) 3,534,275 ordinary shares, (ii) 347,604 ordinary shares underlying Pre-Funded Warrants and (iii) 1,197,604 shares underlying Ordinary Share Warrants. The Pre-Funded Warrants and Ordinary Share Warrants beneficially owned by Gakasa Holdings LLC with prohibit the SEC on June 14, 2021 regarding its holdings as of May 19, 2021 exercise thereof if, after giving effect to such exercise, the holder, including any person whose beneficial ownership would be attributable to the holder, would exceed 9.99%. Gakasa Holdings LLC's address is 201 S. Biscayne Blvd., Suite 800, Miami, Florida.

(3) Based on the Schedule 13G/A filed by Centillion Fund Inc. with the SEC on November 18, 2022 regarding its holdings as of August 31, 2022. Centillion Fund Inc's address is 10 Manoel Street, Castries, Saint Lucia LC04 101

(4) Consists of (i) 110,752 Ordinary Shares and (ii) 23,952 Ordinary Shares underlying warrants to acquire Ordinary Shares (iii) 718,908 Ordinary Shares underlying options to acquire Ordinary Shares

(5) Consists of (i) 4,940 Ordinary Shares and (ii) 588,974 Ordinary Shares underlying options to acquire Ordinary Shares.

(6) Consists of (i) 251,761 Ordinary Shares and (ii) 23,952 Ordinary Shares underlying warrants to acquire Ordinary Shares (iii) 266,282 Ordinary Shares underlying options to acquire Ordinary Shares

(7) Consists of (i) 34,106 Ordinary Shares and (ii) 351,250 Ordinary Shares underlying options to acquire Ordinary Shares.

(8) Consists of (i) 102,100 Ordinary Shares and (ii) 266,282 Ordinary Shares underlying options to acquire Ordinary Shares

(9) Consists of (i) 10,000 Ordinary Shares and (ii) 266,282 Ordinary Shares underlying options to acquire Ordinary Shares.

(10) Consists of (i) 7,232 Ordinary Shares and (ii) 136,566 266,282 Ordinary Shares underlying options to acquire Ordinary Shares.

(5) (11) Consists of (i) 210,659 7,000 Ordinary Shares and (ii) 283,856 266,282 Ordinary Shares underlying options to acquire Ordinary Shares.

(6) (12) Consists of (i) 4,940 56,580 Ordinary Shares and (ii) 459,258 190,000 Ordinary Shares underlying options to acquire Ordinary Shares.

(7) (13) Consists of (i) 34,106 Ordinary Shares and (ii) 351,750 83,750 Ordinary Shares underlying options to acquire Ordinary Shares.

(8) (14) Consists of 60,000 (i) 18,000 ordinary Shares (ii) 35,493 Ordinary Shares underlying options to acquire Ordinary Shares.

(9) (15) Consists of (i) 56,800 Ordinary Shares and (ii) 239,305 Ordinary Shares underlying options to acquire Ordinary Shares.

(10) Consists of (i) 10,000 Ordinary Shares and (ii) 136,566 Ordinary Shares underlying options to acquire Ordinary Shares.

(11) Consists of (i) 62,100 Ordinary Shares (ii) 3,000 Ordinary Shares underlying warrant to acquire Ordinary Shares and (iii) 136,566 Ordinary Shares underlying options to acquire Ordinary Shares.

(12) Consists of (i) 56,580 Ordinary Shares and (ii) 95,000 Ordinary Shares underlying options to acquire Ordinary Shares.

(13) Consists of (i) 7,000 Ordinary Shares and (ii) 125,353 Ordinary Shares underlying options to acquire Ordinary Shares.

(14) Consists of (i) 449,417 602,471 ordinary Shares (ii) 3,000 47,904 Ordinary Shares underlying warrant to acquire Ordinary Shares and (iii) options to acquire 1,899,220 3,299,785 Ordinary Shares.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides certain information as of December 31, 2022 December 31, 2023, with respect to our equity compensation plans under which our equity securities are authorized for issuance:

Plan Category	Number of securities to be issued upon exercise of outstanding options, RSUs, warrants and rights (#)	Weighted-average exercise price of outstanding options, RSUs, warrants and rights ($)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (#)	Number of securities to be issued upon exercise of outstanding options, RSUs, warrants and rights (#)	Weighted-average exercise price of outstanding options, RSUs, warrants and rights ($)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (#)
	(a)	(b)	(c)	(a)	(b)	(c)
Equity compensation plans approved by security holders						
2013 Plan	1,518,262	$ 5.71	-	1,166,880	$ 5.98	-
2018 Plan	4,214,825	$ 2.04	922,080	5,938,534	$ 1.9	638,598
Equity compensation plans not approved by security holders	-	-	-	-	-	-
Total	5,733,087	$ 3.30	922,080	7,105,414	$ 2.57	638,598

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Described below are any transactions occurring since January 1, 2021 January 1, 2022, and any currently proposed transactions to which either the Company was a party and in which:

- **The amounts involved exceeded or will exceed the lesser of (i) $120,000 and (ii) one percent of the average of the Company's total assets at year-end for the last two completed fiscal years; and**
- **A director, executive officer, holder of more than 5% of the outstanding share capital of the Company, or any member of such person's immediate family had or will have a direct or indirect material interest.**

Indemnification Agreements with Directors

Our Articles provide that we may indemnify each of our directors and officers to the fullest extent permitted by the Companies law. Law. Accordingly, we have entered into standard indemnification agreements with each of our directors, whereby we have undertaken to indemnify each such director, in advance, for losses, damages, costs or expenses that such director may suffer or incur as a result of his or her actions or omissions in such capacity on behalf of the Company in certain circumstances and events, subject to the terms, conditions and limitations set out in the indemnification agreement.

Approval of Related Party Transactions

The Companies Law requires that an "office holder" (as defined in the Companies Law) Office Holder of a company promptly disclose any personal interest that he or she may have and all related material information known to him or her, in connection with any existing or proposed transaction of the company.

Pursuant to the Companies Law, any transaction with an office holder Office Holder or in which the office holder Office Holder has a personal interest must be brought before the Audit Committee, in order to determine whether such transaction is an Extraordinary Transaction. Transaction (as defined in the Companies Law).

Pursuant to the Companies Law, our Articles and Entera written policy, in the event that the Audit Committee determines that the transaction is not an Extraordinary Transaction, the transaction will require only Audit Committee approval; if, however, it is determined to be an Extraordinary Transaction, Board approval is also required and, in some circumstances, shareholder approval may also be required. Such a transaction may only be approved if it is determined to be in the best interests of Entera.

A person with a personal interest in the matter generally may not be present at meetings of the Board or certain committees where the matter is being considered and, if a member of the Board or a committee, may generally not vote on the matter.

Transactions with Controlling Shareholders

Under the Companies law, Extraordinary Transactions with a controlling shareholder, or in which the controlling shareholder has a personal interest, and any engagement with a controlling shareholder, or a controlling shareholder's relative, with respect to the provision of services to the company or their Terms of Office and Employment as an office holder Office Holder or their employment, if they are not an office holder, Office Holder, generally require the approval of the Audit Committee (or with respect to Terms of Office and Employment, the Compensation Committee), the Board of Directors and the shareholders. If required, shareholder approval must include (i) at least a majority of the shareholders who do not have a personal interest in the transaction and are present and voting at the meeting (abstentions are disregarded), or, alternatively, that (ii) the total shareholdings of the disinterested shareholders who vote against the transaction do not represent more than two percent of the voting rights in the company. Transactions for a period of more than three years generally need to be brought for approval in accordance with the above procedures every three years. A shareholder who holds 25% or more of the voting rights in a company is considered a controlling shareholder for these purposes if no other shareholder holds more than 50% of the voting rights. If two or more shareholders are interested parties in the same transaction, their shareholdings are combined for the purposes of calculating percentages.

Independent Directors

Our Board undertook a review of the independence of each director. Based on information provided by each director concerning his or her background, employment, and affiliations, our Board has determined that the Board meets independence standards under the applicable rules and regulations of the SEC and the listing standards of Nasdaq. The Board has affirmatively determined that the following Directors are "independent" as of the date of this Annual Report as defined in the listing standards of Nasdaq: Gerald Lieberman, Ron Mayron, Gerald M. Ostrov, Sean Ellis, Yonatan Malca and Yonatan Malca. Haya Taitel. In making these determinations, our Board considered the current and prior relationships that each non-employee director has with our Company and all other facts and circumstances our Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in this Item 13.

ITEM 14. ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Kesselman & Kesselman (a member firm of PricewaterhouseCoopers International Limited, or PwC) Limited) has served as our independent registered public accounting firm for 2022 2023 and 2021. 2022. The following table sets forth fees billed to us by our independent registered public accounting firm during the fiscal years ended December 31, 2022 December 31, 2023 and 2021 2022 for (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements; (ii) services by our independent registered public accounting firm that are reasonably related to the performance of the audit or review of our financial statements and that are not reported as Audit Fees; (iii) (ii) services rendered during the period in connection with tax compliance, tax advice and tax planning; and (iv) all other fees for services rendered. planning.

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Audit fees (1)	$ 194,000	$ 190,000	$ 157,500	$ 194,000
Tax fees(2)	7,500	6,500		
Tax fees (2)			6,700	7,500
Total fees	$ 201,500	$ 196,500	$ 164,200	$ 201,500

(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 certain registration statements.

(2) Tax consulting services.

Audit Committee Pre-approval Policies and Procedures

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.

PART IV.

ITEM EXHIBITS, FINANCIAL STATEMENT SCHEDULES.
15 Item 15. .

(a) Documents filed as part of this report:

(1) Financial statements

See Item 8 for Financial Statements included with this Annual Report.

(2) Financial Statement Schedules

None.

(3) Exhibits: See below.

Exhibit No.	Description
3.1	Amended and Restated Articles of Association of Entera Bio Ltd. (incorporated by reference to Exhibit 1.1 to the Form 20-F, filed with the SEC on March 18, 2021).
4.1	Description of rights of each applicable class of securities registered under Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 2.2 to the Form 20-F filed with the SEC on March 18, 2021).
4.2	Specimen Form of Ordinary Share Certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
4.3	Form of IPO Pre-Funded Warrant (incorporated herein by reference to Exhibit 4.2 10.2 to the Company's Registration Statement on Form F-1 (File No. 333-221472) 8-K filed with the SEC on May 17, 2018 December 26, 2023)
4.4	Form of Underwriter Ordinary Share Warrant issued by the Registrant to Maxim Group LLC (incorporated by reference to Exhibit 4.3 10.3 to the Registration Statement on Form F-1 (File No. 333-221472) 8-K filed with the SEC on May 17, 2018 December 26, 2023)
4.5	Form of Placement Agent Warrant issued by the Registrant to GP Nurmenkari Inc. (and Finder Warrant) (incorporated by reference to Exhibit 4.5 10.4 to the Registration Statement on Form F-1 (File No. 333-221472) 8-K filed with the SEC on November 9, 2017 December 26, 2023)
10.1	Amended and Restated Investor's Rights Agreement, dated as of October 4, 2017, between the Registrant and the other parties thereto (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
10.2	Patent Transfer Agreement, dated as of February 22, 2011, between the Registrant and Oramed Ltd. (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
10.3	Form of Warrant Agency Agreement (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on June 15, 2018)
10.4	Form of Regulation D Private Placement Subscription Agreement (incorporated by reference to Exhibit 4.25 to the Form 20-F filed with the SEC on March 18, 2021).
10.5	Subscription Agreement, dated December 13, 2019, between the Registrant and D.N.A Biomedical Solutions Ltd. (incorporated by reference to Exhibit 4.26 to the Form 20-F filed with the SEC on March 18, 2021).
10.6	Registration Rights Agreement, dated December 10, 2019, between the Registrant and the other parties thereto (incorporated by reference to Exhibit 4.28 to the Form 20-F filed with the SEC on March 18, 2021).
10.7 10.2	Sales Agreement, dated September 2, 2022, between Entera Bio. Ltd. and SVB Securities LLC (incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on September 2, 2022)
10.8†† 10.3	Research Collaboration and License Securities Purchase Agreement, dated as of December 10, 2018 December 20, 2023, between Amgen Inc. by and among Entera Bio Ltd. and the purchasers party thereto (incorporated by reference to Exhibit 4.28 10.1 to the Amended Annual Report on Form 20-F/A (File No. 001-38556) 8-K filed with the SEC on April 17, 2019 December 26, 2023)
10.9† 10.4	Registration Rights Agreement, dated as of December 22, 2023, by and among Entera Bio Ltd. and the purchasers party thereto (incorporated by reference to Exhibit 10.5 to the Form 8-K filed with the SEC on December 26, 2023)
10.5†	Form of indemnification agreement between the Registrant and its directors and executive officers (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 20, 2017)
10.10† 10.6†	The Entera Bio Ltd. Share Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form F-1 (File No. 333-221472) filed with the SEC on November 9, 2017)
10.11† 10.7†	2018 Equity Incentive Plan (incorporated by reference to Exhibit 99 to the Registration Statement on Form S-8 (File No. 333-227488) filed with the SEC on September 24, 2018)
10.12† 10.8†	Form of Stock Option Award Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 4.25 to the Annual Report on Form 20-F (File No. 001-38556) filed with the SEC on March 28, 2019)
10.13† 10.9†	Amended and Restated Employment Agreement, dated July 15, 2022, by and between Entera Bio Ltd. and Miranda Toledano (incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on July 18, 2022)

10.14† 10.10†*	Amendment to Employment Agreement, dated January 30, 2024, by and between Entera Bio Ltd. and Miranda Toledano.
10.11†*	Consulting agreement, dated June 2, 2019, between Entera Bio Ltd. and Dana Yaacov Garbeli (through A2Z Finance Ltd.), as amended.

10.15† 10.12†*	Employment Agreement, dated as of June 8, 2014, between Entera Bio Ltd. and Dr. Hillel Galitzer, as amended.
10.16†	Employment Agreement, dated as of January 4, 2021 between Entera Bio Ltd. and Dr. Spiros Jamas (incorporated by reference to Exhibit 4.30 to the Form 20-F, filed with the SEC on March 18, 2021).
10.17†	Mutual Separation Agreement, dated July 13, 2022, by and between Entera Bio Ltd. and Dr. Spiros Jamas (incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on July 18, 2022)
10.18†	Mutual Separation Agreement, dated June 15, 2022, by and between Entera Bio Ltd. and Dr. Phillip Schwartz (incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on June 17, 2022)
21.1*	List of Subsidiaries
23.1*	Consent of Kesselman & Kesselman, an independent registered public accounting firm in Israel and a member of PricewaterhouseCoopers International Limited.
31.1*	Certification of Principal Executive Officer of Entera Bio Ltd. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial and Accounting Officer of Entera Bio Ltd. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer of Entera Bio Ltd. pursuant to Section 906 of the Sarbanes-Oxley act of 2002
32.2**	Certification of Principal Financial and Accounting Officer of Entera Bio Ltd. pursuant to Section 906 of the Sarbanes-Oxley act of 2002
97*	Entera Bio Ltd. Executive Officer Clawback Policy, effective as of November 30, 2023
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Inline XBRL for the cover page of this Annual Report, on Form 10-K, included in the Exhibit 101 Inline XBRL Document Set.

† Management contract or compensatory plan or arrangement.
*** 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.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 31, 2023 March 8, 2024

ENTERA BIO LTD.

By: /s/ Miranda J. Toledano
Miranda J. Toledano
Chief Executive Officer
and Director

KNOW ALL MEN BY THESE PRESENTS, that each of the undersigned constitutes and appoints each of Miranda J. Toledano and Dana Yaacov-Garbelli, or any of them, each acting alone, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstituting, for such person and in his name, place and stead, in any and all capacities, to sign this Annual Report, on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto

said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that any such attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Miranda J. Toledano Miranda J. Toledano	Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2023 8, 2024
/s/ Dana Yaacov-Garbeli Dana Yaacov-Garbeli	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2023 8, 2024
/s/ Gerald Lieberman Gerald Lieberman	Director	March 31, 2023 8, 2024
/s/ Roger J. Garceau Roger J. Garceau	Director	March 31, 2023 8, 2024
/s/ Ron Mayron Ron Mayron	Director	March 31, 2023 8, 2024
/s/ Yonatan Malca Yonatan Malca	Director	March 31, 2023 8, 2024
/s/ Sean Ellis Sean Ellis	Director	March 31, 2023 8, 2024
/s/ Gerald M. Ostrov Gerald M. Ostrov	Director	March 31, 2023 8, 2024
/s/ Haya Taitel Haya Taitel	Director	March 8, 2024

Exhibit 10.14 10.10

AMENDMENT TO EMPLOYMENT AGREEMENT

This Amendment to Employment Agreement ("Amendment") is made as of January 31, 2024 by and between Entera Bio Ltd. an Israeli company (the "Company") and Miranda Toledano (the "Employee", and together with the Company, the "Parties").

WHEREAS:

A. The Company and the Employee entered into a personal employment agreement, as amended (the "**Agreement**"), pursuant to which the Employee has been employed by the Company effective as of May 16, 2022;

B. The Company has lawfully approved the amendment of the Agreement according to the terms of this Amendment; and

C. The Parties desire to amend the Agreement in accordance with the provisions set forth herein, effective as of January 1, 2024 (the "**Effective Date**");

NOW, THEREFORE, in consideration of the mutual promises, covenants and understandings contained herein, the Parties agree as follows:

1. As of the Effective Date, the Employee shall be entitled to a gross monthly Salary of $33,584 . The payment shall be made in NIS and shall be calculated based on the last official exchange rate of NIS/US$ at the end of each calendar month, as published by the Bank of Israel.

2. All Salary-based benefits due to the Employee under the Agreement shall be adjusted according to the amended Salary as of the Effective date.

3. All other terms and conditions of the Agreement shall remain unchanged. In the event of any inconsistency between the terms of the Agreement and this Amendment, the terms of this Amendment shall prevail.

4. Any capitalized terms not defined in this Amendment shall have the meaning attributable to them in the Agreement.

5. This Amendment may be executed in counterparts, each of which shall be deemed an original.

[Signature Page to Follow]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the date first written above.

/s/ Miranda Toledano	/s/ Dana Yaacov-Garbeli
Miranda Toledano	Entera Bio Ltd.
	By: Dana Yaacov-Garbeli
	Name & Title: CFO

[*Signature Page to the Amendment to Employment Agreement*]

Exhibit 10.11

CONSULTANCY AGREEMENT

This Consultancy Agreement ("Agreement") is entered into effective as of June 2, 2019, by and between Entera Bio Ltd., an Israeli company I.D. No. 514330604 ("Company"), and A2Z Finance Ltd., a company organized under the laws of the State of Israel ("Consultant").

WHEREAS, the Consultant agrees to perform the Services for the interim period until the engagement by the Company of a new chief financial officer for the Company on a permanent basis; and

WHEREAS, the Consultant is ready, qualified, willing and able to carry out her obligations and undertakings towards the Company pursuant hereto; and

WHEREAS, the Services will be provided by the Consultant as an independent contractor, as per the Consultant's and the Designated Service Provider's specific wish and requirement, made as a result of considerations and benefits personal to the Consultant and the Designated Service Provider, that the Services shall be provided to the Company by the Consultant on an independent contractor basis, absent an employment relationship between the Company and the Consultant or the Designated Service Provider; and

WHEREAS, the parties hereto wish to regulate their relationship in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing, the parties do mutually agree as follows:

1. Engagement of Services.

1.1. Consultant will provide to the Company CFO services, which shall include, without limitation, the list of responsibilities described in Exhibit A (the "Services"), in a scope and position expressly stated in Exhibit A. Consultant will perform Services faithfully, diligently and to the best of Consultant's skill and ability. The engagement hereunder is not exclusive, and shall not limit the Company from engaging a third party to provide services which are the same as or similar to the Services.

1.2. Consultant will provide the Services commencing as of June 2, 2019 (the "Commencement Date") until termination of this Agreement in accordance with the terms of this Agreement. The provisions of this Section 1.2 and of Sections 2, and 4 through 9 of this Agreement shall survive any termination of this Agreement indefinitely. Upon termination of this Agreement or at such other time as directed by the Company, the Consultant shall immediately return to the Company all assets in the Consultant's possession or control which belong to, or have been entrusted to, the Company. The Consultant shall neither have, nor retain, any proprietary interest or lien in such assets.

1.3. This Agreement will be in effect commencing on the Commencement Date, until terminated by either party as provided below. Either party may terminate this Agreement immediately without cause upon prior written notice of 30 days to the other party.

1.4. Notwithstanding the above, the Company shall be entitled to terminate this Agreement with an immediate effect if: (i) the Consultant act dishonestly, breach its duties (including the duty of loyalty) towards the Company and/or its subsidiaries (the "Group"), or breach the terms of this Agreement, or other agreement with the Company relating to confidentiality, ownership or protection of proprietary rights, non-solicitation or non-disparagement or in the

event of any act or omission of the Consultant which would have entitled the Company legally to dismiss the Consultant without severance pay, in whole or in part, had the Consultant or the Designated Service Provider been engaged as an employee of the Company; or (ii) the Company has employed a new Chief Financial Officer (the "New CFO") (for the avoidance of doubt, the Company shall be entitled to terminate this Agreement with an immediate effect, at the Company's sole discretion, on the starting date of the New CFO with the Company.

1.5. Designated Service Provider. The Consultant undertakes that all of the Services shall be performed solely and exclusively by Dana Yaacov (the "Designated Service Provider") for the entire term of this Agreement, unless otherwise agreed in writing by the Company.

1.6. Corporate approvals. Notwithstanding anything to the contrary herein, the Consultant agrees and understands that this Agreement is subject to, and shall only enter into effect upon the receipt of the approval by all corporate organs of the Company as required according to the applicable law (as determined by the Company on its sole discretion).

2. Representations and Obligations. Consultant warrants and undertakes as follows:

2.1. Consultant has the ability, experience, expertise and resources to provide the Services and to perform all of its obligations hereunder. Consultant shall perform all duties and obligations under this Agreement with the highest degree of professionalism, loyalty and to the full satisfaction of the Company. Consultant is free to provide the Company with the Services, upon the terms contained in this Agreement, and there are no legal, commercial or contractual restrictions preventing the Consultant from fully performing all duties hereunder. Designated Service Provider is an employee of the Consultant ("Employer"). Consultant represents warrants and covenants that Consultant's performance of the obligations under this Agreement does not and will not violate the terms of any of Designated Service Provider's agreements with Employer or any other party. Neither Consultant nor the Designated Service Provider shall accept any Confidential Information (as defined in Section 5.1 below) if he believes, in her sole discretion, that such acceptance might impair her ability to perform her duties of research and publication under her employment agreement with Employer.

2.2. Consultant shall provide the Company with the Services, in accordance with the directions of the Company's Chief Executive Officer, or such other person as directed.

2.3. Consultant will notify the Company immediately should anything occur or come to its attention which would or might prevent it from providing the Services at the level required by the Company. In these circumstances, the Company may terminate this Agreement immediately, without any advance notice, in respect of which the Consultant will not be entitled to any damages or payment other than the Fee (as defined below) for Services provided to the Company prior to termination. Where the Consultant discovers that it has or might have at some point in the future, any personal interest in Company business, or a conflict of interest arising out of or in connection with the Services then, immediately upon discovery, Consultant shall notify the same to the Company in writing. Without derogating from any other rights under this Agreement or under law, the Company may require the Consultant to cease to have any such personal interest or conflict of interest, as the case may be or to immediately terminate this Agreement as detailed in this Section 1.4.

2.4. Consultant shall be responsible, at its own expense, to obtain all of the equipment necessary for providing the Services, such as car, phone, computer or other communications equipment.

2.5. Consultant shall comply with all of the Company's policies, as effective from time to time, and acknowledges that the Company is a public company and further represents that Consultant shall at all times comply with all applicable laws, including any applicable securities laws.

2.6. The Consultant has, and will have throughout the term of this Agreement, all approvals, permits and licenses required pursuant to any law to provide the Services in accordance with this Agreement (if required).

2.7. The Consultant shall not, directly or indirectly, accept any commission, rebate, discount or gratuity in cash or in kind, from any person who has or is likely to have a business relationship with the Group related in any way to the Services provided by the Consultant.

3. Consideration

3.1. Subject to the fulfillment of the Consultant's obligations hereunder, and contingent upon the performance of the Services by it, the Company shall pay the Consultant a gross service fee (and expense reimbursement, if applicable) as (and only as) expressly stated in Exhibit A ("Fee"). Payment of the Fee by the Company will be made within 30 days following the receipt by the Company of a valid tax invoice issued by the Consultant.

3.2. Subject to and without derogating from Section 2.4, the Company will reimburse the Consultant for reasonable out of pocket expenses which were pre-approved in writing in connection with its duties hereunder (at the Company's sole discretion), all subject to any Company policies as may be in force from time to time and against the provision of proper receipts. For the avoidance of doubt, it is hereby clarified that the Company will not reimburse the Consultant for any car expenses or other similar expenses according to this Section 3.2.

3.3. The Consultant shall not be entitled to any further compensation in connection with the Services except as otherwise stated in this Agreement.

4. Taxes. Consultant shall bear any and all taxes and national insurance contributions (as applicable) which may be payable in connection with any consideration payable to, or benefit receivable by, Consultant and/or Designated Service Provider pursuant to this Agreement. Consultant declares that it maintains financial books in accordance with applicable law and that it is duly registered with the income tax, VAT and national insurance authorities (if and as

applicable). Consultant shall bear and be responsible for, and shall indemnify and hold the Company harmless from, all payments required to be made to any such applicable national insurance institute, taxation body or other third party in consequence of the provision of the Services or the remuneration provided in connection therewith. Notwithstanding the above, the Company shall withhold at source all taxes and compulsory payments on any payment to the Consultant to the extent that such taxes and compulsory payments are required by any applicable law to be withheld at source.

5. Status of Parties

5.1. The relationship between the Consultant and the Designated Service Provider and the Company, in compliance with the Consultant's request, is one of principal and independent contractor. The Consultant declares that he maintains financial books in accordance with the applicable law and that it is duly registered with the income tax, VAT and National Insurance authorities, and that he must perform and continue to perform all actions legally required to establish and maintain its status as an independent contractor with an independent business. The parties expressly declare that no employment relationship exists between the Company and the Consultant and/or the Designated Service Provider.

5.2. If, notwithstanding anything contained in this Agreement any person shall claim, or a judicial authority shall determine, that the Consultant and/or the Designated Service Provider provided the Services under this Agreement as an employee of the Company, then the following provisions shall apply:

(a) For the period as to which it is claimed or determined that an employment relationship existed between the Company and the Consultant (the "Relevant Period"), the Consultant shall not be entitled to the Fee, but only 60% thereof (the "Reduced Fee").

(b) The Reduced Fee shall constitute the full Fee payable to the Consultant as salary in connection with said employment relationship, on which basis any social benefits will be calculated - to the extent that such social benefits are required to be paid to or in respect of the Consultant pursuant to any third party authority's decision reclassifying the Consultant as an employee.

(c) In view thereof, an accounting shall be conducted between the parties, and the Consultant shall immediately return and pay to the Company all amounts paid to him in excess of the Reduced Fee for the Relevant Period, along with linkage differentials and interest from the date of payment of each amount by the Company to the Consultant and up to the date upon which actual return and payment of the funds is made by the Consultant, all based on the Consumer Price Indices known at the relevant dates and as provided by the Adjudication of Interest and Linkage Law, 1961.

5.3. In addition, in the event that the relationship between the Company and the Consultant shall be claimed, regarded or determined by any third party, including any governmental or judicial or tax authority to be an employment relationship, the Consultant shall reimburse and indemnify the Company for any expense and payment incurred by or demanded of the Company as a consequence, no later than seven days of its receipt of such demand.

5.4. The Company shall be entitled to offset any amounts due to it under this Section 5 from any amounts payable to the Consultant under this Agreement.

6. Confidentiality and Assignment of IP. Each of Consultant and Designated Service Provider shall sign and comply with the Company's standard Proprietary Information and Inventions Agreement attached hereto as Exhibit B, which requires, among other things, the assignment of Consultant and Designated Service Provider rights to any intellectual property made during Consultant and Designated Service Provider Services at the Company and the nondisclosure of proprietary information.

7. Non-Competition and Non-Solicitation.

7.1. During the term of this Agreement and for a period of twelve (12) months following its termination, the Consultant and the Designated Service Provider shall not:

7.1.1. directly or indirectly, in any capacity whatsoever, whether independently or as a shareholder, an employee, consultant, an officer or any managerial capacity, carry on, set up, own, manage, control or operate, be employed, engaged or interested in a business, anywhere in the world, which competes with, or proposes to compete with the Group.

7.1.2. directly or indirectly, in any way (i) offer, solicit or attempt to solicit, induce or attempt to induce or endeavor to entice away, any person with whom any member of the Group has or had or shall have any contractual or commercial relationship as a consultant, licensor, joint venturer, supplier, customer, distributor, agent or contractor of whatsoever nature, existing or under negotiation on or prior to date of termination of this Agreement, to cease his, her or its relationship with that member of the Group, or otherwise interfere in any way with the relationship between that member of the Group and such person or (ii) have any business dealings with any such person.

7.1.3. directly or indirectly, in any way (i) offer, solicit or attempt to solicit for employment or other engagement, or otherwise contract or seek to contract the services of, any individual who is, at the effective date of termination of this Agreement, employed or engaged (whether directly or indirectly) by any member of the Group or induce or entice or attempt to induce or entice such individual to leave such employment or other engagement or otherwise interfere in its, his or her relationship with any member of the Group.

7.2. The Consultant acknowledges that its obligations under this Section are reasonable, in light of knowledge it will gain of the Group's Confidential Information and that the consideration it receives hereunder is paid, inter alia, as consideration for its undertaking under this Section.

8. No Conflicting Obligations. The Consultant and the Designated Service Provider will not, at any time during the term of the Agreement, use or disclose any trade secrets or proprietary or confidential information in such manner that may breach any confidentiality or other obligation that the Consultant owes to any third party (including to any other employer or other clients of the Consultant and the Designated Service Provider), without their prior written consent.

9. General. This Agreement inures to the benefit of the parties hereto and their permitted assigns and successors, and will not inure to the benefit of any third party (such as the Designated Service Provider). The Consultant shall not assign any of its rights and obligations hereunder without the prior written consent of the Company, and any attempt to do so shall be null and void. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of Israel, regardless of any conflicts of laws provisions. The competent courts of Tel-Aviv, Israel shall have exclusive jurisdiction to hear any such dispute and no other courts shall have any jurisdiction whatsoever in respect of such disputes. This Agreement contains the entire agreement and understanding between the parties with respect to the subject matter hereof, and supersedes all prior discussions, agreements, representations and understandings in this regard. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the Company and Consultant. Each notice given by one party to the other pursuant to this Agreement shall be given in writing, correctly addressed to the relevant party's address as set forth below (unless another address has been notified in accordance with this clause), and will be deemed to have been duly served with immediate effect at the time of hand delivery (or refusal to receive) or email receipt, on the next business day (being a day in which the banks are open to the public in Israel) following transmission by facsimile (and electronic confirmation of receipt), three business days after posting for delivery with a first class registered or recorded delivery post, or on the second business day after posting with an overnight courier. Without derogating from any relief to which the Company is entitled to pursuant to any law and/or agreement, the Company may set off any amount which the Consultant owes it pursuant to this Agreement and/or any other source from any sum that the Consultant is entitled to receive from the Company, from whatever source. No behaviour by either party hereto shall be deemed to constitute a waiver of any rights according to this Agreement, and/or a waiver of or consent to any breach or default in respect of any of the terms hereof, or a change, invalidation or addition to any term, unless expressly made in writing. The Consultant hereby declares that this Agreement is signed by it upon its request, after it has checked all its rights and obligations deriving from this Agreement, according to any law and after it has investigated all its rights pursuant to this Agreement against the Company.

[Signature Page to Follow]

IN WITNESS WHEREOF, the parties have executed this Consultancy Agreement effective as of the date first written above. This Consultancy Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed an original, and such counterparts shall together constitute one and the same instrument.

Company: **Entera Bio Ltd.** By: /s/ Phillip Schwartz **Phillip Schwartz, CEO**	Address: Hadassah Medical Center, Kiryat Hadassa, PO Box 12117, Jerusalem, Israel Attention: Chief Executive Officer e-mail: phillip@enterabio.com
Consultant: /s/Dana Yaacov-Garbeli **A2Z Finance Ltd.**	Address: Haplech 7, Tel Aviv Israel e-mail: dana@a2z-finance.co.il

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In connection with the above Consultancy Agreement, as may be amended from time to time, the undersigned hereby irrevocably agrees and undertakes to exclusively perform the Services thereunder on behalf of the Consultant (as defined therein), and to comply with and be bound by the provisions of this Consultancy Agreement, as if a party thereto.

Designated Service Provider:

/s/Dana Yaacov-Garbeli
Dana Yaacov-Garbeli

AMENDMENT NO. 1 TO CONSULTING AGREEMENT

This Amendment to the Consulting Agreement (the "Amendment"), is made as of June 25, 2020 , by and between Entera Bio Ltd. (the "Company") and A2Z Finance Ltd. (the "Consultant"). Each of the Company and the Consultant shall be referred to as a "Party" and collectively as the "Parties". Capitalized terms used but not defined herein shall have the meaning assigned to them in the Consulting Agreement (as defined below).

WHEREAS, the Company and the Consultant have entered into that certain Consulting Agreement, dated June 2, 2019, as amended (the "**Consulting Agreement**") pursuant to which the Designated Service Provider is providing the Company with CFO Services;

WHEREAS, the Company has lawfully approved the amendment of the Consulting Agreement according to the terms of this Amendment; and

WHEREAS, the Parties have mutually agreed to amend the Consulting Agreement in accordance with the provisions of this Amendment, effective as of January 1, 2020 (the "**Effective Date**");

NOW THEREFORE, the Parties hereby agree as follows:

1. Fee. As of the Effective Date, the Consultant's Fee as mentioned in **Exhibit A** to the Consulting Agreement shall be amend to $14,000 plus VAT.

2. Unless otherwise specifically provided for herein, all other terms and conditions of the Consulting Agreement remain in full force and effect, and this Amendment shall be deemed an integral part of the Consulting Agreement for all intents and purposes.

3. In case of any conflict or inconsistency between the terms of this Amendment and the terms of the Consulting Agreement, this Amendment shall prevail.

4. This Amendment may not be amended, other than by written instrument executed by both Parties.

[Signature Page to Follow]

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed and delivered by their duly authorized representatives, as of the date hereof.

Company:

/s/ Yonatan Malca
Entera Bio Ltd.
Name: Yonatan Malca
Title: Director

Consultant:

/s/ Dana Yaacov-Garbeli
A2Z Finance Ltd.
Name: Dana Yaacov-Garbeli
Title: Partner

Designated Service Provider:

/s/ Dana Yaacov-Garbeli
Dana Yaacov-Garbeli

AMENDMENT NO. 2 TO CONSULTING AGREEMENT

This Amendment to the Consulting Agreement (the "Amendment"), is made as of October 4, 2021 , by and between Entera Bio Ltd. (the "Company") and A2Z Finance Ltd. (the "Consultant"). Each of the Company and the Consultant shall be referred to as a "Party" and collectively as the "Parties". Capitalized terms used but not defined herein shall have the meaning assigned to them in the Consulting Agreement (as defined below).

WHEREAS, the Company and the Consultant have entered into that certain Consulting Agreement, dated June 2, 2019, as amended (the "**Consulting Agreement**") pursuant to which the Designated Service Provider is providing the Company with CFO Services;

WHEREAS, the Company has lawfully approved the amendment of the Consulting Agreement according to the terms of this Amendment; and

WHEREAS, the Parties have mutually agreed to amend the Consulting Agreement in accordance with the provisions of this Amendment, effective as of January 1, 2021 (the "**Effective Date**");

NOW THEREFORE, the Parties hereby agree as follows:

5. Fee. As of the Effective Date, the Consultant's Fee as mentioned in **Exhibit A** to the Consulting Agreement shall be amend to $16,100 plus VAT.

6. Unless otherwise specifically provided for herein, all other terms and conditions of the Consulting Agreement remain in full force and effect, and this Amendment shall be deemed an integral part of the Consulting Agreement for all intents and purposes.

7. In case of any conflict or inconsistency between the terms of this Amendment and the terms of the Consulting Agreement, this Amendment shall prevail.

8. This Amendment may not be amended, other than by written instrument executed by both Parties.

[Signature Page to Follow]

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed and delivered by their duly authorized representatives, as of the date hereof.

Company:

/s/ Yonatan Malca
Entera Bio Ltd.
Name: Yonatan Malca
Title: Director

Consultant:

/s/ Dana Yaacov-Garbeli
A2Z Finance Ltd.
Name: Dana Yaacov-Garbeli
Title: Partner

Designated Service Provider:

/s/ Dana Yaacov-Garbeli
Dana Yaacov-Garbeli

AMENDMENT NO. 3 TO CONSULTING AGREEMENT

This Amendment to the Consulting Agreement (the "Amendment"), is made as of January 22, 2024 , by and between Entera Bio Ltd. (the "Company") and A2Z Finance Ltd. (the "Consultant"). Each of the Company and the Consultant shall be referred to as a "Party" and collectively as the "Parties". Capitalized terms used but not defined herein shall have the meaning assigned to them in the Consulting Agreement (as defined below).

WHEREAS, the Company and the Consultant have entered into that certain Consulting Agreement, dated June 2, 2019, as amended (the "**Consulting Agreement**") pursuant to which the Designated Service Provider is providing the Company with CFO Services;

WHEREAS, the Company has lawfully approved the amendment of the Consulting Agreement according to the terms of this Amendment; and

WHEREAS, the Parties have mutually agreed to amend the Consulting Agreement in accordance with the provisions of this Amendment, effective as of January 1, 2024 (the "**Effective Date**");

NOW THEREFORE, the Parties hereby agree as follows:

1. Fee. As of the Effective Date, the Consultant's Fee as mentioned in **Exhibit A** to the Consulting Agreement and its amendments shall be amend to $18,750 plus VAT.
2. Unless otherwise specifically provided for herein, all other terms and conditions of the Consulting Agreement remain in full force and effect, and this Amendment shall be deemed an integral part of the Consulting Agreement for all intents and purposes.
3. In case of any conflict or inconsistency between the terms of this Amendment and the terms of the Consulting Agreement, this Amendment shall prevail.
4. This Amendment may not be amended, other than by written instrument executed by both Parties.

[Signature Page to Follow]

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed and delivered by their duly authorized representatives, as of the date hereof.

Company:

/s/ Miranda Toledano

Entera Bio Ltd.

Name: Miranda Toledano

Title: Chief Executive Officer

Consultant:

/s/ Dana Yaacov-Garbeli

A2Z Finance Ltd.

Name: Dana Yaacov-Garbeli

Title: Partner

Designated Service Provider:

/s/ Dana Yaacov-Garbeli

Dana Yaacov-Garbeli

Exhibit 10.15 10.12

Personal Employment Agreement

This Personal Employment Agreement (this "Agreement"), is entered into at Hadassah, J-m on 8 June 2014 this effective as of March, 2014, by and between:

Entera Bio Ltd.
of Kiryat Hadassah, Minrav Building – Fifth Floor,
POB 12117, Jerusalem 91220, Israel
(the "Company");

and

Hillel Galitzer (ID No. 015346109)
of Slav 43, Yad Binyamin
(the "Executive").

WHEREAS, the Company and the Employee have entered into a prior Employment Agreement, dated July 20, 2012, and a new employment agreement on May 1, 2013 (collectively, the **"Prior Employment Agreement"**); and

WHEREAS, the parties hereto wish to amend the Prior Employment Agreement in its entirety and enter into this Agreement to set forth the terms and conditions of Executive's employment by the Company;

NOW, THEREFORE, the parties hereto hereby agree as follows:

1. **Recitals, Headings and Interpretation**

1.1 The recitals to this Agreement constitute an integral part hereof.

1.2 The division of the terms of this Agreement into clauses and the headings is solely for convenience of reference and shall not affect its interpretation.

1.3 For the purposes of this Agreement, the "Effective Date" shall mean February 1, 2014. As of the Effective Date, this Agreement shall replace the Prior Employment Agreement in its entirety.

2. **Exclusivity of the Agreement**

2.1 This Agreement is personal and the terms and conditions of the employment of the Executive shall be solely as set forth in this Agreement.

2.2 Except as provided in this Agreement, no provisions of any collective bargaining agreement ("Heskem Kibbutzi"), collective arrangement ("Hesder Kibutsi") or other industry practice or custom of any kind shall apply.

2.3 This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior understandings, agreements, representations and discussions between them, oral or written.

2.4 Except as expressly provided in this Agreement, the Executive shall not be entitled to any payments or other benefits in respect of his employment and the termination of his employment with the Company. This Agreement may only be modified by an agreement in writing duly signed by both parties hereto.

3. **Absence of Impediment to the Executive's Employment**

3.1 The Executive warrants, confirms and undertakes that he is entitled to enter into this Agreement and to assume all of the obligations pursuant hereto, that there is no contractual or other impediment to his entering into this Agreement, fulfilling his obligations hereunder or to his employment with the Company and that in entering into this Agreement he is not in breach of any other agreement or obligation to which he is or was a party.

3.2 The Executive hereby warrants that he has no medical or other problems, which might prevent him from performing his obligations to work for the Company. The Executive shall notify the Company of any change in his state of health, which has the potential to affect his ability to perform his obligations under this Agreement.

4. **Position and Duties**

4.1 The Executive shall be employed by the Company in the position of Chief Operating Officer. The Executive shall be subject and report to the Company's CEO or any other officer as the Company decides and directs from time to time. For the avoidance of any doubt, it is hereby expressed that the Company may alter the Executive position and subordination, at its discretion.

4.2 During the course of his employment with the Company, the Executive shall honestly, diligently, skillfully and faithfully serve the Company. The Executive undertakes to devote all his working time, efforts and the best of his qualifications and skills to promoting the business and affairs of the Company, and further undertakes to comply with the policies and working arrangements of the Company, to loyally and fully comply with the decisions of the Company, its management and his supervisors in Israel and abroad, to follow the Company procedures as established from time to time, to carry out the duties imposed upon him, whenever established and whatever they shall be.

4.3 The Executive shall at all times act in a manner suitable for his position and status in the Company.

4.4 The Executive shall not, without the prior written authorization of the Company, directly or indirectly undertake any other employment, whether as an Executive of another employer or independently as an agent or consultant or in any other manner (whether for compensation or otherwise), and shall not assume any position or render services in any of the above-stated manners to any other entity.

Notwithstanding the aforesaid, the Company agrees that the Executive is authorized to provide third parties with consulting services of not more than 10 hours per calendar month (the "Additional Engagement"), provided that such Additional Engagement shall not (a) be likely to create a conflict of interest with the Executive position, duties and responsibilities at the Company and (b) derogate from any of his undertaking and obligations according to this Agreement (including as described in Section 18 below with respect to confidentiality, non-competition and protection of intellectual property).

4.5 The Executive undertakes to notify the Company immediately and without delay regarding any matter or subject in respect of which he has a personal interest and/or which might create a conflict of interest with his position in the Company.

4.6 The Executive undertakes to fulfill the responsibilities described in this Agreement and assist the Company, its affiliates, subsidiaries, related corporations and parent company now or hereafter existing (collectively, **"Affiliates"**) and to make himself available to it, even after the termination of his employment relations with the Company, for any reason, in any matter which the Company may reasonably request his assistance, including for the purpose of providing any information relating to his work or actions taken by him and including in the framework of disputes (including legal or quasi-legal proceedings). If the Company requires the Executive's services after the termination of the employment relations with him, for any reason, it shall reimburse the Executive for his expenses in connection with performing the provisions of this Section 4.6.

4.7 The Executive shall be based in the Company's Israeli offices, but he understands that his position involves international and local travel as required to discharge his responsibilities hereunder.

5. **Employment Term and Termination**

5.1 The Executive's employment by the Company commenced on **July 20th 2010.**

5.2 The Executive's employment may be terminated by either party subject to the delivery of thirty (30) days prior written notice by the terminating party (the **"Notice Period"**).

5.3 During the Notice Period the Executive shall continue to perform his duties until the conclusion of the Notice Period. Nevertheless, the Company shall have the right not to take advantage of the full Notice Period. In the event of such termination, the Company shall pay the Executive his Salary for the remainder of the Notice Period (as payment in lieu of prior notice period).

It is hereby expressly stated that the Company reserves the right to terminate the Executive's employment at any time during the Notice Period, regardless of whether notice of termination of employment was delivered by the Company or whether such notice was delivered by the Executive. In the latter case such termination shall not constitute a dismissal of the Executive by the Company.

5.4 Notwithstanding the foregoing, the Company may terminate the Executive's employment without the delivery of prior written notice, in the event of termination under circumstances which deprive the Executive of severance pay under Israeli law, and/or a breach of trust, and/or the Executive's breach of the terms and conditions of Section 18 of this Agreement all at the discretion of the Company.

5.5 In the event that the Executive terminates his employment with the Company, for any reason, without the delivery of a written notice in accordance with Section 5.2 above, or without the completion of the Notice Period or any part thereof, the Company will be entitled to deduct from any debt which it may owe the Executive an amount equal to the salary that would have been paid to the Executive during the Notice Period, had he worked.

5.6 The Executive undertakes that immediately upon the termination of his employment with the Company, for any reason, he shall act as follows:

5.6.1 He shall deliver and/or return to the Company all the documents, diskettes or other magnetic media, letters, notes, reports and other papers in his possession and relating to his employment with the Company and the fulfillment of his duties, as well as any equipment and/or other property belonging to the Company which was placed at his disposal, including any Company car, computer equipment, telephone equipment, Executive ID badge or other equipment;

5.6.2 He shall delete any information relating to the Company or its business from his personal computer, if any; and

5.6.3 He shall coordinate the termination of his employment with his supervisors, and he shall transfer in an orderly fashion and in accordance with Company procedures and in accordance with the timetable determined by his supervisors, all documents and information and all matters with which he dealt, to whomever the Company instructs, all in a manner satisfactory to the Company.

6. **Working Hours**

For the period of February 2014 and March 2014 your working hours shall be as customary for employees of your position, however no less than 25.5 hours per week, reflecting a 60% job basis.

Starting April 1, 2014 your working hours will reflect a full time (100%) basis and shall be as follows: The working hours of the Executive shall be as required by the nature of the Executive's position in the Company, however no less than 9 hours per day, 5 days per week.

The weekly day of rest of the Company shall be Saturday. The Executive may be required, from time to time and according to the work load demanded of him/her, to work beyond the regular working hours and days in order to fulfill his obligations according to this Agreement.

The position the Executive is to hold within the Company is a management position which requires a special measure of personal trust. Therefore, the provisions of the Hours of Work and Rest Law - 1951 ("Hours of Work Law") shall not apply to the Executive. The Executive acknowledges that the consideration set for him hereunder nevertheless includes within it consideration that would otherwise have been due to him pursuant to such law

7. **Salary**

7.1 For the period of February 2014 and March 2014:

As compensation for the Executive's performance, the Company shall pay the Executive a basic gross monthly salary of NIS 14,000 (the "Base Salary"). In light of the aforesaid, in addition to the Base Salary the Executive shall be entitled to a global monthly consideration for working overtime in the gross amount of NIS 6,000 per month ("Global Overtime Consideration").

7.2 Starting April 1, 2014 your gross monthly salary will change as follows: Base salary will increase to NIS 24,500 and Global Overtime Consideration will increase to NIS 10,500.

7.3 In the event that it is claimed or determined that the Hours of Work Law is applicabl to the Executive's employment under this Agreement despite the specific agreement between him and the Company, the Global Overtime Consideration represents any amounts payable under such law. The above-mentioned Salary and Global Overtime Consideration are defined together the **"Salary"**.

The Salary is to be paid to the Executive in accordance with the Company's normal and reasonable payroll practices, no later than the 9th day of each month. For the avoidance of any doubt, it is hereby expressed that the Salary constitutes the overall consideration for the Executive's work and in view of his position and status.

8. **Manager's Insurance/Pension Fund and Severance Pay**

The Executive shall be entitled to a Managers' Insurance Policy (the "Policy") and/or Pension Fund (the "Pension Fund"), and the Company encourages the Executive to tailor a plan or a combination of plans which best suit the Executive's anticipated future needs. For the avoidance of doubt, in the event the Executive chooses to combine plans, the contributions percentages will relate to such portion of Salary which the Executive has allocated towards each benefit plan as follows:

8.1. The Company shall pay into the Policy an aggregate amount representing 13.33% of the Salary as follows: 8.33% for severance compensation (**"Company's Severance Contribution"**) and 5% for pension compensation (which shall be 6% if made to a Pension Fund) ("Tagmulim"). In addition, the Company shall deduct 5% (which shall be 5.5% if made to a Pension Fund) of the Salary and transfer that amount to the Policy. The Company shall also obtain disability insurance, which may be included within the Policy, for the exclusive benefit of the Executive. The Company shall contribute in respect of such disability insurance an amount up to 2.5% of the Salary.

8.2. The instructions of *"The General Approval Regarding Employers' Payments to Pension Fund and Insurance Fund Instead of Severance Pay"* (the "General Approval" a copy of which is attached hereto as **Schedule A**), as amended from time to time, shall apply to the contributions referred to above.

8.3. The Executive hereby agrees and approves that Company's Severance Contribution, as detailed and defined in the General Approval, shall come in lieu of the Executive's severance pay, and shall therefore constitute the full and final severance pay as stated above.

8.4. The Company hereby waives any of its rights to refund of monies from the payments it has transferred according to the General Approval, unless the Executive's right to severance pay is denied by virtue of a court order, under Sections 16 or 17 of the Severance Pay Law 5723-1963, and in the same amount which was denied, or the Executive had withdrawn monies from the Policy and/or the Pension Fund not due to a Granting Event. The term *''Granting Event"* shall mean death, disability or retirement at the age of sixty or more.

9. **Advanced Study Fund *(Keren Hishtalmut)***

The Company shall make monthly contributions on the Executive's behalf to a recognized advanced study fund (the "Study Fund" ("Keren Hishtalmut")) in an amount equal to 7.5% of the Salary. In addition, the Company shall deduct 2.5% from the Salary and transfer those monies to the Study Fund. Said contributions shall not exceed the tax-exempt ceiling set by the applicable law for tax purposes.

10. **Vacation**

10.1 The Executive shall be entitled to 16 business days of paid vacation each year (**"Annual Vacation"**).

10.2 It is hereby expressed that the Executive must make every effort to exercise his Annual Vacation; however, if he/she is unable to utilize all the vacation days, the Executive shall be entitled to accumulate the unused balance of the vacation days standing to his credit up to a ceiling of double the number of the Annual Vacation (the **"Ceiling"**), provided that the Executive takes at least seven consecutive annual working days vacation. If the Executive accumulates vacation days exceeding the Ceiling, the balance shall be deleted.

10.3 The Company may instruct the Executive to use his Annual Vacation, in the event that Company employees are sent by the Company on an organized vacation.

11. **Convalescence**

The Executive shall be entitled to convalescence ("Havra'ah") pay in accordance with Israeli law.

12. **Sick Pay**

The Executive shall be entitled to 18 annual paid sick days according to the Company's policy. Sick leave may be accumulated up to a ceiling of 90 days, but may not be redeemed on a cash basis under any circumstances.

13. **Reserve Duty**

The Company shall pay the Executive his entire Salary for periods that he performs reserve duty, provided that he delivers to the Company all official documents necessary for the Company to obtain reimbursement from the National Insurance Institute.

14. **Expenses**

The Executive will be reimbursed by the Company for pre-approved business expenses incurred by him in connection with his duties and against valid receipts furnished by the Executive to the Company, all in accordance with Company's policy, as may be amended from time to time.

15. **Company Car**

15.1 For February 2014 the Company shall pay the Executive monthly travel expenses of 833 N1S.

15.2 Starting March 1, 2014 Company shall provide Executive with a Car from class 2 (i.e, a price of up to NIS135,000) (the **"Company Car")** to be placed at Executive's disposal, for his business and personal use, and for the use of his spouse and any children over the age of 24 holding valid driver's licenses for at least two years **("Authorized Drivers"), provided** that Company's procedures in respect of said use are followed. Company Car may also be used by Company personnel.

15.3 .153 Executive shall maintain the Company Car in a good state of repair, and take all necessary steps so as to ensure that the Company's rules relating to Company Car, and the provisions of the insurance policy relating to the use of the Company Car, are strictly and carefully observed.

15.4 .154 Executive hereby declares that he is aware that in order to provide him with the Company Car, Company intends to rent or lease the Company Car, pursuant to a car rent/lease agreement. Executive undertakes to strictly comply with all of the provisions of said agreement relating to the use of the Company Car.

15.5 .155 Executive shall bear and pay all expenses relating to any violation of law committed in connection with the use of the Company Car, and shall indemnify and/or reimburse Company, upon its first demand for all expenses incurred by it as a result of such violations as well as with respect to charges made by the leasing Company with respect to road accidents or other damages to the car. Executive shall sign a declaration allowing the Company to endorse any tickets received to his name as described in **Schedule B**.

15.6 .156 Executive shall bear and pay all taxes applicable to Executive in connection with the Company Car.

15.7 .157 Executive hereby irrevocably authorizes Company to set off all amounts, which the Company may have to pay under this Section (including early return fees which the Company may have to pay according the car rent/lease agreement), against any and all amounts due to Executive from Company under this Agreement.

15.8 .158 without derogating the above mentioned, Executive hereby irrevocably authorizes Company to set off all excess amounts, which the Company may have to pay according to the terms set forth in **Schedule C**, against any and all amounts due to Executive from Company under this Agreement.

15.9 .159 Executive shall return the Company Car (together with its keys and any other equipment supplied and/or installed therein by Company, but free of any of Executive's belongings) to Company's principal office at the earliest of (a) immediately upon termination of Executive's employment or (b) within 7 days from the Company's demand, in proper working order and in the condition in which he received it, taking into account normal wear and tear resulting from reasonable use of the Company Car. Executive shall have no rights of lien with respect to the Company Car and/or any of said other equipment.

15.10 .1510 To remove any doubt, it is hereby clarified that the Executive shall be liable under the provisions of this Section for any actions of the Authorized Drivers relating to the Company Car and shall cause said Authorized Drivers to fulfill all of the provisions of this Section.

15.11 For the avoidance of doubt it is hereby clarified that the Car shall come in lieu of any payment in respect of travel expenses in accordance with the Law.

16. **Cellular Phone and Lap Top**

16.1 The Company shall provide Executive with a cellular phone (the "Cellular Phone") and a Lap Top (the "Lap Top") to be placed at Executive's disposal for Executive 's use in the course of performing Executive's obligations under this Agreement, *provided* that the Company's procedures in respect thereof are followed. Executive shall bear all taxes applicable to Executive in connection with the Cellular Phone and the Lap Top.

16.2 Executive shall return the Cellular Phone and the Lap Top (together with any other equipment supplied) to the Company's principal office at the earliest of (a) immediately upon termination of Executive's employment or (b) within 7 days from the Company's demand. Executive shall have no rights of lien with respect to the Cellular Phone, the Lap Top and/or any of said other equipment.

16.3 In Case Executive damages or loses the cellular phone than Executive shall bear the cost of a replacement phone or the deductible that the Cellular Company requires (Hishtatfut Azmit). In case the Cellular Phone is stolen than the Company shall bear half of the cost and the Executive half of the cost of a replacement phone or the deductible that the Cellular Company requires (Hishtatfut Azmit).

17. **Share Options**

In accordance with the Company's policy and subject to prior approval of the Board of Directors of the Company, the Company shall consider making a grant of options to Executive to purchase ordinary shares of the Company, all on such amounts and terms as to be approved by the Board of Directors of the Company. The grant of options shall be subject to Executive's separate execution of the Company's standard option agreement.

18. **Confidentiality, Non-Competition and Intellectual Property**

The Executive warrants and undertakes that for as long as he is employed by the Company, and upon termination of employment thereafter, for any reason, he shall maintain in complete confidence any matters that relate to the Company, its affairs and/or business, including regarding the terms and conditions of his employment pursuant to this Agreement, and that he shall not harm its goodwill or reputation, and he agrees to the provisions of the confidentiality, non-competition and intellectual property clauses as specified below.

The Executive's obligations pursuant to this Section derive from his status and his position in the Company, along with all matters connected therewith, and the terms and conditions of the Executive's employment pursuant to this Agreement, including his Salary, have been determined in part, inter alia, in consideration of this undertaking and constitute sufficient consideration for his obligations hereunder.

18.1 **Confidentiality**

18.1.1 The Executive undertakes to maintain the Confidential Information (as defined below) of the Company, including its Affiliates, during the term of his employment with the Company and after the termination of such employment, for any reason.

18.1.2 Without derogating from the generality of the foregoing, the Executive hereby agrees that he shall not, directly or indirectly, disclose or transfer to any person or entity, at any time, either during or subsequent to his employment period, any trade secrets or other confidential information, whether patentable or not, of the Company and/or its Affiliates, including but not limited to, any (i) processes, formulas, trade secrets, innovations, inventions, discoveries, improvements, research or development and test results, survey, specifications, data and know-how; (ii) marketing plans, business plans, strategies, forecasts, unpublished financial information, budgets, projections, product plans and pricing; (iii) personnel information, including organizational structure, salary, and qualifications of Executives; (iv) customer and supplier information, including identities, product sales and purchase history or forecasts and agreements; and (v) any other information which is not known to the public (collectively, "Confidential Information"), of which the Executive is or becomes informed or aware during the employment period, whether or not developed by the Executive.

18.1.3 The Executive undertakes not to directly or indirectly give and/or transfer, directly or indirectly, to any person or entity, any material and/or raw material and/or product and/or part of a product and/or model and/or document and/or diskette and/or other information storage media and/or photocopied and/or printed and/or duplicated object containing any or all of the Confidential Information.

18.1.4 The Executive undertakes not to make any use, including duplication, production, sale, transfer, imitation and distribution, of all or any of the Confidential Information, without the prior written consent of the Company.

18.1.5 In the event the Executive is in breach of any of his above obligations, he shall be liable to compensate the Company in respect of all damages and/or expenses incurred by the Company as a result of such breach, including trial costs and legal fees and statutory VAT, and such being without derogating from any other relief and/or remedy available to the Company by virtue of any law

18.2 **Non-Competition/ Non-Solicitation**

18.2.1 The Executive undertakes that during the period of his employment with the Company and for a period of (12) months from the termination of his employment therewith, for any reason, he shall not, anywhere in the world, do business, as an Executive, independent contractor, consultant or otherwise, and shall not directly or indirectly participate in or accept any Position, proposal or job offer that may directly or indirectly compete with or harm the Company, or in the field in which the Company engages, is engaged or is about to engaged (the "**Competitive Occupation**").

18.2.2 Without derogating from the generality of the foregoing, the Executive undertakes not to maintain any business relations of any type whatsoever, including a proposal to conduct business relations, directly or indirectly, with any of the Company's customers and/or suppliers and/or agents, including customers and/or suppliers and/or agents with whom the Company conducted negotiations towards an agreement at the time of the termination of his employment with the Company or prior thereto. In addition, the Executive undertakes not to approach and/or solicit and/or recruit any employee of the Company to leave the Company for a period of (12) months from the date of the termination of the employment relationship.

18.2.3 The foregoing shall apply irrespective of whether the Competitive Occupation is carried out by the Executive alone or in cooperation with others and shall apply to the participation of the Executive in a Competitive Occupation, whether as a Controlling shareholder or as an interested party.

18.3 **Intellectual Property. Copyright and Patents**

18.3.1 The Executive hereby acknowledges and agrees that the Company owns and shall own any and all Intellectual Property Rights created, made or discovered by the Executive or employee (whether solely or jointly with others) related to the company's activity (Drug Development and Manufacturing) either: during the term of employment; and/or in connection therewith; and/or in connection with the Company, its business (actual and/ or contemplated), products, technology and/or know how **("Company IPR"). Intellectual Property Rights** means all worldwide (a) patents, patent applications and patent rights; (b) rights associated with works of authorship, including Copyrights, Copyrights applications, Copyrights restrictions, mask work rights, mask work applications and mask work registrations; (c) rights relating to the protection of trade secrets and confidential information; (d) moral rights; (e) rights analogous to those set forth herein and any other proprietary rights relating to intangible property including ideas; and (f) divisions, continuations, renewals, reissues and extensions of the foregoing (as applicable) now existing or hereafter filed, issued, or acquired.

18.3.2 The Executive acknowledges and agrees that all Company IPR belong to, and shall be the sole property of, the Company and shall be Company IPR of the Company upon creation thereof. The Executive hereby irrevocably assigns to the Company and/or its designee, all right, title and interest the Executive may have or may acquire in and to Company IPR upon its creation. The Executive acknowledges and agrees that no rights relating to any Company IPR are reserved to Executive. The Executive will assist the Company to obtain, and from time to time enforce, any Company IPR worldwide, including without limitation, executing, verifying and delivering such documents and performing such other acts as the Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Company IPR. Such Obligation shall remain in effect beyond the termination of the Executive's relationship with the Company, all for no additional consideration provided that Executive shall not be required to bear any expenses as a result of such assignment. In the event the Company is unable for any reason, after reasonable effort, to secure Executive's signature on any document required, Executive hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as its agent and attorney in fact to act for and in its behalf to further the above purposes.

18.3.3 The Executive irrevocably confirms that the consideration explicitly set forth in the employment agreement between the Executive and the Company is inclusive of any and all rights for compensation that may arise in connection with the Company IPR under applicable law and the Executive waives any legal right he may have in connection with the Company IPR including without limitation any moral rights and/or right to claim royalties or any other additional consideration from the Company with regard to the assigned Company IPR, including without limitation, in respect of Section 134 of the Patent Law 5727-1967 and/or other applicable laws.

18.3.4 The Executive represents and warrants that upon execution hereof it has not created and does not have any right, title or interest in and to any Intellectual Property Rights related and/or similar to Company's business, products or Intellectual Property Rights, other than those set forth in **Schedule A1** hereto ("Prior Inventions"). The Executive undertakes not to incorporate any Prior Inventions in any Company IPR.

18.3.5 The Executive undertakes to immediately inform and deliver IN WRITING to the Company, written notice of any Company IPR conceived/ invented by him and/or personal of the Company and/or its successors who are subordinate to him, immediately upon the discovery thereof.

18.3.6 The Executive's obligations pursuant to this Section shall survive the termination of his employment with the Company and/or its successors and assigns with respect to inventions conceived by him during the term of his employment or as a result of his employment with the Company.

18.4 Executive acknowledges that the restricted period of time and geographical area specified hereunder are reasonable, in view of his position and the nature of the business in which the Company is engaged, the Executive's knowledge of the Company's business and the compensation he receives. Notwithstanding anything contained herein to the contrary, if the period of time or the geographical area specified herein should be determined to be unreasonable in any judicial proceeding, then the period of time and area of the restriction shall be reduced so that this Agreement may be enforced in such area and during such period of time as shall be determined to be reasonable by such judicial proceeding. The Executive acknowledges that the compensation and benefits granted to him by the Company under this Agreement were determined, inter alia, in consideration for his obligations under this Section 18.

19. **General**

19.1 The Executive shall bear all the taxes deriving from the rights and benefits received by him pursuant hereto. It is hereby expressed that all the amounts specified in this Agreement are gross, and statutory tax and all the other compulsory payments, including health insurance contributions and national insurance contributions, shall be deducted from them and from all the rights and benefits received by the Executive pursuant hereto.

19.2 This Agreement and all rights and duties of the parties hereunder shall be exclusively governed by and interpreted in accordance with the laws of the State of Israel. The competent courts of the State of Israel, Tel Aviv Jaffa district, shall have the exclusive jurisdiction over the parties with regard to this Agreement, its execution, Interpretation and performance.

19.3 Any modification or amendment to the provisions of this Agreement and the appendices hereto shall only be valid if effected in writing and signed by the parties hereto.

19.4 This Agreement is subject to all the applicable approvals according to applicable law.

19.5 Any notice sent by prepaid registered mail by one party to the other shall be deemed to have been received by the addressee within three business days of its dispatch, and if delivered by hand, at the time of its delivery.

19.6 This Agreement shall be deemed due notification regarding the Employee's employment terms in accordance with the provisions of the Notice of Employment Terms Law (Employment Terms), 2002 and the regulations thereunder.

IN WITNESS WHEREOF THE PARTIES HAVE SET THEIR HANDS HERETO AS OF THE DATE FIRST WRITTEN ABOVE:

Enterabio

By: _____

Name: Phillip Schwartz

Title: CEO

_____

The Executive

SCHEDUALE A
[TRANSLATED FROM HEBREW]
GENERAL APPROVAL REGARDINC PAYMENTS BY EMPLOYERS
TO A PENSION FUND AND INSURANCE FUND IN LIEH OF SEVERANCE PAY

By virtue of my power under section 14 of the Severance Pay Law, 5723-1963 (hereinafter: the "Law"), I certify that payments made by an employer commencing from the date of the publication of this approval for his employee to a comprehensive pension benefit fund that is not an insurance fund within the meaning thereof in the Income Tax (Rules for the Approval and Conduct of Benefit Funds) Regulations, 5724-1964 (hereinafter: the "Pension Fund") or to managers insurance including the possibility to receive annuity payment under an insurance fund as aforesaid (hereinafter: the "Insurance Fund"), including payments made by the employer by a combination of payments to a Pension Fund and an Insurance Fund (hereinafter: the "Employer's Payments"), shall be made in lieu of the severance pay due to the said employee in respect of the salary from which the said payments were made and for the period they were paid (hereinafter: the "Exempt Salary"), provided that all the following conditions are fulfilled:

(1) The Employer's Payments -

(a) to the Pension Fund are not less than 14 1/3% of the Exempt Salary or 12% of the Exempt Salary if the employer pays, his employee's benefit in addition thereto payments to Supplement severance pay to a benefit fund for severance pay or to an Insurance Fund in the employee's name in an amount of 2 1/3% of the Exempt Salary. In the event the employer has not paid the above 2 1/3% in addition to the said 12%, his payments shall be only in lieu of 72% of the employee's severance pay;

(b) to the Insurance Fund are not less than one of the following:

(1) 13 1/3% of the Exempt Salary, if the employer pays for his employee in addition thereto also payments to secure monthly income in the event of disability, in a plan approved by the Commissioner of the Capital Market, Insurance and Savings Department of the Ministry of Finance, in an amount required to secure at least 75% of the Exempt Salary or in an amount of 2 1/2% of the Exempt Salary, the lower of the two (hereinafter: **"Disability Insurance"**);

(2) 11% of the Exempt Salary, if the employer paid, in addition, a payment to the Disability Insurance, and in such case the Employer's Payments shall be only in lieu of 72% of the Employee's severance pay;

In the event the employer has made payments in addition to the foregoing payments to supplement severance pay to a benefit fund for severance pay or to an Insurance Fund in the employee's name in an amount of 2 1/3% of the Exempt Salary, the Employer's Payments shall replace 100% of the employee's severance pay.

(2) No later than three months from the commencement of the Employer's Payments, a written agreement was executed between the employer and the employee which included:

(a) the employee's consent to an arrangement pursuant to this approval in a text specifying the Employer's Payments, the Pension Fund and Insurance Fund, as the case may be; the said agreement shall also include the text of this approval;

(b) an advance waiver by the employer of any right which he may have to a refund of monies from its payments, except in cases in which the employee's right to severance pay was denied by a final judgement pursuant to sections 16 or 17 to the Law and/or in cases in which if such severance pay was denied the employee has withdrawn monies from the Pension Fund or Insurance Fund other than by reason of an entitling event; for these purposes "Entitling Event" means death, disability or retirement at or after the age of 60.

(3) This approval is not such as to derogate from the employee's right to severance pay pursuant to any law, collective agreement, extension order or employment agreement, in respect of salary over and above the Exempt Salary.

15th Sivan 5758 (9th June 1998).

SCHEDUALE A-1 PRIOR INVENTIONS

THERE ARE NO PRIOR INVENTIONS

Entera Bio Ltd.
The Jerusalem Bio Park, Hadassah Ein Kerem,
Minrav Building F. 5,
P.O. box 12117
Jerusalem, Israel 9112002

June 21, 2016

Dr. Hillel Galitzer

Re: Amendment to Agreement

Dear Hillel,

Further to that certain agreement between Entera Bio Ltd. (the "Company") and you dated June 8, 2014 (the "Agreement"), this letter shall confirm our mutual agreement to amend the Agreement as provided herein. Unless otherwise defined herein, capitalized terms used herein shall have the meaning ascribed to them in the Agreement.

Effective as of June 1, 2016 you shall be entitled to a gross monthly salary of NIS 48,460, which includes Global Overtime Consideration in the gross amount of NIS 14,500.

Except as set forth herein, this letter shall not affect any provisions in the Agreement, which shall remain in full force and effect, with the necessary changes. In the event of inconsistency between the provisions of this letter and the Agreement, the provisions of this letter shall prevail.

Please confirm the above agreement by signing and dating this amendment and the enclosed duplicate original copy of this amendment, and returning one such duplicate original to the undersigned.

[Signature page to follow]

Entera Bio Ltd.
The Jerusalem Bio Park, Hadassah Ein Kerem,
Minrav Building F. 5,
P.O. box 12117
Jerusalem, Israel 9112002

Very truly yours,

Entera Bio Ltd.

By: _____
Phillip Schwartz
CEO

Acknowledged and Agreed by:

Date: 30/4/17

Hillel Galitzer

[Signature page – Amendment to Agreement]

Entera Bio Ltd.
The Jerusalem Bio Park, Hadassah Ein Kerem,
Minrav Building F. 5,
P.O. box 12117
Jerusalem, Israel 9112002

March 2, 2017

Dr. Hillel Galitzer

Re: **Amendment to Agreement**

Dear Hillel,

Further to that certain agreement between Entera Bio Ltd. (the **"Company")** and you dated June 8, 2014 (the **"Agreement"),** this letter shall confirm our mutual agreement to amend the Agreement, as provided herein. Unless otherwise defined herein, capitalized terms used herein shall have the meaning ascribed to them in the Agreement.

Effective as of March 2,2017 the Notice Period shall be 90 days.

Except as set forth herein, this letter shall not affect any provisions in the Agreement, which shall remain in full force and effect, with the necessary changes. In the event of inconsistency between the provisions of this letter and the Agreement, the provisions of this letter shall prevail.

Please confirm the above agreement by signing and dating this amendment and the enclosed duplicate original copy of this amendment, and returning one such duplicate original to the undersigned.

[Signature page to follow]

Entera Bio Ltd.
The Jerusalem Bio Park, Hadassah Ein Kerem,
Minrav Building F. 5,
P.O. box 12117
Jerusalem, Israel 9112002

Very truly yours,

Entera Bio Ltd.

By: _____
Phillip Schwartz
CEO

Acknowledged and Agreed by:

Date: 30/4/17

Hillel Galitzer

[Signature page – Amendment to Agreement]

Amendment to the Employment Agreement

This Amendment (the "Amendment") to the Employment Agreement by and between Entera Bio Ltd. (the "Company"), and Hillel Galitzer (the "Employee") is entered into between the Company and the Employee on June 25, 2020.

The Parties have mutually agreed to amend certain terms of the Employment Agreement form June 8 2014, and its amendments, as follows:

1. This Amendment shall enter into effect as of January 1,2020 (the "Effective Date").

2. Section 7.2 of the Employment agreement with the following:

   The Employee shall be entitled to a gross monthly salary of 42,980 NIS (the "Base Salary"). In consideration for overtime hours the Employee shall receive a global payment of 18,420 NIS per month (the "Overtime Payment ", and together with the Base Salary, the "Salary"). A total increase of 8,470 NIS. The Overtime Payment shall be adjusted simultaneously with the adjustment of the Base Salary and the ratio of adjustment as that of the Base Salary, unless specifically stated otherwise.

3. Section 10.1 of the Employment agreement with the following:

   Subject to the provisions of the Annual Vacation Law-1951 (the "Vacation Law"), the Employee shall be entitled to 16 vacation days (the "Vacation Days"), with respect to each twelve (12) months' period of continuous employment with the Company. These Vacation Days include the number of paid vacation days to which the Employee is entitled in accordance with the Vacation Law (the "Vacation Law Days"). Any Vacation Days shall be first credited on account of Vacation Days which are not Vacation Law Days (if any).

4. All other provisions of the Employment Agreement (including any Appendices or Exhibits thereto) shall remain unchanged.

The parties have caused this Amendment to be executed and delivered by their duly authorized representatives, as of the date hereof.

COMPANY
Entera Bio Ltd.
Name: Adam Gridley
Title: CEO

EMPLOYEE

Name: Hillel Galitzer

Title: COO

May 9, 2022

Amendment to the Employment Agreement

Effective as of January 1, 2021 Appendix A to the Employment Agreement from June 8, 2014 and its amendments shall be amended as follows:

1. Item 1 shall be replaced by the following:

   1. **Salary**

   The Employee shall be entitled to a gross monthly salary of 49,420 NIS (the "Base Salary"). In consideration for overtime hours the Employee shall receive a global payment of 21,180 NIS per month (the "Overtime Payment ", and together with the Base Salary, the "Salary"). A total increase of 9,200 NIS. The Overtime Payment shall be adjusted simultaneously with the adjustment of the Base Salary and the ratio of adjustment as that of the Base Salary, unless specifically stated otherwise.

2. All other provisions of the Appendix A and of the Employment Agreement (including any Appendices or Exhibits thereto) shall remain unchanged.

Entera Bio Ltd.
By : Spiros Jamas
Title: CEO

Employee: Galitzer Hillel

January 30, 2024

Amendment to the Employment Agreement

Effective January 1, 2024, Appendix A to the Employment Agreement from October 27, 2010, and its amendments shall be amended as follows:

1. Item 1 shall be replaced by the following:

Salary

The Employee shall be entitled to a gross monthly salary of 52,385.2 NIS (the "Base Salary"). In consideration for overtime hours the Employee shall receive a global payment of 22,450.8 NIS per month (the "Overtime Payment ", and together with the Base Salary, the "Salary"). A total increase of 4,236 NIS. The Overtime Payment shall be adjusted simultaneously with the adjustment of the Base Salary and the ratio of adjustment as that of the Base Salary, unless specifically stated otherwise.

2. All other provisions of the Appendix A and of the Employment Agreement (including any Appendices or Exhibits thereto) shall remain unchanged.

/s/ Miranda Toledano
Entera Bio Ltd.
By : Miranda Toledano
Title: CEO

/s/ Hillel Galitzer
Employee: Hillel Galitzer

Exhibit 21.1

Entera Bio Ltd.

The following is a list of subsidiaries of Entera Bio Ltd. as of December 31, 2022 December 31, 2023:

SUBSIDIARY	STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION	SUBSIDIARY
Delaware	Entera Bio Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. (Nos. 333-272373 and 333-227488) and Form S-3 (Nos. 333-276844, 333-265291 and 333-265286) of Entera Bio Ltd. of our report dated March 31, 2023 March 8, 2024 relating to the financial statements, which appears in this Form 10-K.

/s/ Kesselman & Kesselman
Certified Public Accountants (lsr.)
A member firm of PricewaterhouseCoopers International Limited

Tel-Aviv, Israel
March 31, 2023 8, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Miranda J. Toledano, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2022 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 registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 31, 2023

/s/ Miranda J. Toledano
Miranda J. Toledano
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002
I, Dana Yaacov-Garbeli, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023 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 registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 31, 2023 March 8, 2024

/s/ Miranda Toledano
Miranda Toledano
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002
I, Dana Yaacov-Garbeli, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2023 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 registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c. Evaluated the effectiveness of the registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 8, 2024

/s/ Dana Yaacov Garbeli
Dana Yaacov-Garbeli
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES OXLEY ACT OF 2002

I, Miranda J. Toledano, Chief Executive Officer of Entera Bio Ltd. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350 that, to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the year ended December 31, 2022 December 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); 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 31, 2023 March 8, 2024

/s/ Miranda J. Toledano
Miranda J. Toledano
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES OXLEY ACT OF 2002

I, Dana Yaacov-Garbeli, Chief Financial Officer of Entera Bio Ltd. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350 that, to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the year ended December 31, 2022 December 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); 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 31, 2023 March 8, 2024

/s/ Dana Yaacov-Garbeli Yaacov Garbeli
Dana Yaacov-Garbeli
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 97

Entera Bio Ltd.
Executive Officer Clawback Policy

Approved by the Board of Directors on November 30, 2023 (the "Adoption Date")

I. Purpose

This Executive Officer Clawback Policy describes the circumstances under which Covered Persons of Entera Bio Ltd., a company organized under the laws of the State of Israel, and any of its direct or indirect subsidiaries (collectively, the "Company") will be required to repay or return Erroneously-Awarded Compensation to the Company.

This Policy and any terms used in this Policy shall be construed in accordance with all applicable SEC regulations promulgated to comply with Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "Dodd-Frank Act"), including, without limitation, Rule 10D-1 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the rules adopted by Nasdaq and all applicable provisions of the Israeli Companies Law of 1999 and the applicable regulations (collectively, the "Companies Law"). For the avoidance of doubt, this Policy is adopted in order to accommodate the

requirements and restrictions of the Dodd-Frank Act, and shall not be construed to grant any additional rights to any Covered Person that he or she did not have prior to the date hereof.

Each Covered Person shall sign an Acknowledgement and Agreement to the Clawback Policy in the form attached hereto as Exhibit A as a condition to his or her participation in any of the Company's incentive-based compensation programs; provided, that, this Policy shall apply to each Covered Person, irrespective of whether such Covered Person shall have failed, for any reason, to have executed such acknowledgment and agreement.

II. Definitions

For purposes of this Policy, the following capitalized terms shall have the respective meanings set forth below:

(a) "**Accounting Restatement**" means an accounting restatement (i) due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial restatements that is material to the previously issued financial statements (a "Big R" restatement), or (ii) that corrects an error that is not material to previously issued financial statements, but would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "little r" restatement). Notwithstanding the foregoing, none of the following changes to the Company's financial statements represent error corrections and shall not be deemed an Accounting Restatement: (a) retrospective application of a change in accounting principle; (b) retrospective revision to reportable segment information due to a change in the structure of the Company's internal organization; (c) retrospective reclassification due to a discontinued operation; (d) retrospective application of a change in reporting entity, such as from a reorganization of entities under common control; and (e) retrospective revision for share splits, reverse share splits, share dividends or other changes in capital structure.

(b) "**Administrator**" means the Committee or any other committee designated by the Board, unless the Board determines to administer this Clawback Policy itself.

(c) "**Board**" means the Board of Directors of the Company.

(d) "**Clawback-Eligible Incentive Compensation**" means, in connection with an Accounting Restatement, any Incentive-Based Compensation Received by a Covered Person (regardless of whether such Covered Person was serving at the time that Erroneously-Awarded Compensation is required to be repaid) (i) on or after the Nasdaq Effective Date, (ii) after beginning service as a Covered Person, (iii) while the Company has a class of securities listed on a national securities exchange or national securities association and (iv) during the Clawback Period.

(e) "**Clawback Period**" means, with respect to any Accounting Restatement, the three completed fiscal years immediately preceding the Restatement Date and any transition period (that results from a change in the Company's fiscal year) of less than nine months within or immediately following those three completed fiscal years.

(f) "**Committee**" means the Compensation Committee of the Board.

(g) "**Compensation Policy**" means the Company's compensation policy for officers and directors, as adopted in accordance with the Companies Law.

(h) "**Covered Person**" means any person who is, or was at any time, during the Clawback Period, an Executive Officer. For the elimination of doubt, Covered Person may include a former Executive Officer who left the Company, retired or transitioned to a non-Executive Officer role (including after serving as an Executive Officer in an interim capacity) during the Clawback Period, and this Policy applies regardless of whether the Covered Person was at fault for an accounting error that resulted in, or contributed to, the Accounting Restatement.

(i) "**Erroneously-Awarded Compensation**" means the amount of Clawback-Eligible Incentive Compensation that exceeded the amount of Incentive-Based Compensation that otherwise would have been Received had it been determined based on the restated amounts set forth in the Accounting Restatement. This amount must be computed without regard to any taxes paid.

(j) "**Executive Officer**" means (i) the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person (including an officer of the Company's parent(s) or subsidiaries) who performs similar policy-making functions for the Company, or (ii) an "Officer" within the meaning set forth in the Companies Law. For the sake of clarity, at a minimum, all persons who are executive officers pursuant to Item 401(b) of Regulation S-K shall be deemed "Executive Officers".

(k) "**Financial Reporting Measures**" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and all other measures that are derived wholly or in part from such measures, including, without limitation, measures that are "non-GAAP financial measures" for purposes of Exchange Act Regulation G and Item 10(e) of Regulation S-K, as well as other measures, metrics and ratios that are not non-GAAP measures. For purposes of this Policy, Financial Reporting Measures shall include share price and total shareholder return (and any measures that are derived wholly or in part from share price or total shareholder return). A Financial Reporting Measure need not be presented within the Company's financial statements or included in a Company filing with the SEC.

(l) "**Incentive-Based Compensation**" has the meaning set forth in Section III below.

(m) "**Nasdaq**" means The Nasdaq Stock Market LLC.

(n) "**Nasdaq Effective Date**" means October 2, 2023.

(o) "**Policy**" means this Executive Officer Clawback Policy, as the same may be amended or restated from time to time.

(p) "**Received**" means Incentive-Based Compensation received, or deemed to be received, in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant occurs after such fiscal period.

(q) "**Repayment Agreement**" has the meaning set forth in Section V below.

(r) "**Restatement Date**" means the earlier of (i) the date the Board, a committee of the Board or the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement and (ii) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

(s) "**RSUs**" means restricted share units.

(t) "**SARs**" means share appreciation rights.

(u) "**SEC**" means the U.S. Securities and Exchange Commission.

III. Incentive-Based Compensation

"Incentive-Based Compensation" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

For purposes of this Policy, specific examples of Incentive-Based Compensation include, but are not limited to:

- **Non-equity incentive plan awards that are earned based, wholly or in part, based on satisfaction of a Financial Reporting Measure-based performance goal;**
- **Bonuses paid from a "bonus pool," the size of which is determined, wholly or in part, based on satisfaction of a Financial Reporting Measure-based performance goal;**

- **Other cash awards based on satisfaction of a Financial Reporting Measure-based performance goal;**
- **Restricted shares, RSUs, performance share units, share options and SARs that are granted or become vested, wholly or in part, on satisfaction of a Financial Reporting Measure-based performance goal; and**
- **Proceeds Received upon the sale of shares acquired through an incentive plan that were granted or vested based, wholly or in part, on satisfaction of a Financial Reporting Measure-based performance goal.**

For purposes of this Policy, Incentive-Based Compensation excludes:

- **Base salaries (except with respect to any salary increases earned, wholly or in part, based on satisfaction of a Financial Reporting Measure-based performance goal);**
- **Bonuses paid solely at the discretion of the Committee or Board that are not paid from a "bonus pool" that is determined by satisfying a Financial Reporting Measure-based performance goal;**
- **Bonuses paid solely upon satisfying one or more subjective standards or completion of a specified employment period;**
- **Non-equity incentive plan awards earned solely upon satisfying one or more strategic measures or operational measures; and**
- **Equity awards that vest solely based on the passage of time or satisfaction of one or more non-Financial Reporting Measures.**

IV. Determination and Calculation of Erroneously-Awarded Compensation

In the event of an Accounting Restatement, the Committee shall promptly determine the amount of any Erroneously-Awarded Compensation for each Executive Officer in connection with such Accounting Restatement and shall promptly thereafter provide each Executive Officer with a written notice containing the amount of Erroneously-Awarded Compensation and a demand for repayment, return or forfeiture thereof, as applicable.

(a) **Cash Awards**. With respect to cash awards, the Erroneously-Awarded Compensation is the difference between the amount of the cash award (whether payable as a lump sum or over time) that was Received and the amount that should have been Received applying the restated Financial Reporting Measure.

(b) **Cash Awards Paid From Bonus Pools**. With respect to cash awards paid from bonus pools, the Erroneously-Awarded Compensation is the pro rata portion of any deficiency that results from the aggregate bonus pool that is reduced based on applying the restated Financial Reporting Measure.

(c) **Equity Awards**. With respect to equity awards, if the shares, options, RSUs, SARs or other equity awards are still held at the time of recovery, the Erroneously-Awarded Compensation is the number of such securities Received in excess of the number that should have been Received applying the restated Financial Reporting Measure (or the value in excess of that number). If the restricted shares, options, RSUs, SARs or other equity awards have been exercised, vested, settled, or otherwise been converted into the underlying shares, but the underlying shares have not been sold, the Erroneously-Awarded Compensation is the number of shares underlying the excess shares, options, SARs, RSUs or other equity awards (or the value thereof). If the underlying shares have already been sold, then [the Administrator shall determine the amount that most reasonably estimates the Erroneously-Awarded Compensation and retain documentation reflecting the estimate analysis and provide to Nasdaq if deemed appropriate by the Board or requested by Nasdaq.

(d) **Compensation Based on Share Price or Total Shareholder Return**. For Incentive-Based Compensation based on (or derived from) share price or total shareholder return, where the amount of Erroneously-Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement, the amount shall be determined by the Administrator based on a reasonable estimate of the effect of the Accounting Restatement on the share price or total shareholder return upon which the Incentive-Based Compensation was Received (in which case, the Administrator shall maintain documentation of such determination of that reasonable estimate and provide such documentation to Nasdaq in accordance with applicable listing standards).

V. Recovery of Erroneously-Awarded Compensation

Once the Administrator has determined the amount of Erroneously-Awarded Compensation recoverable from the applicable Covered Person, the Administrator shall take action to recover the Erroneously-Awarded Compensation reasonably promptly. The Company's obligation to recover Erroneously-Awarded Compensation is not dependent on if or when the restated financial statements pursuant to the applicable Accounting Restatement are filed with the SEC. Unless otherwise determined by the Administrator, the Administrator shall pursue the recovery of Erroneously-Awarded Compensation as set forth below:

(a) **Cash Awards**. With respect to cash awards, the Administrator shall either (i) require the Covered Person to repay the Erroneously-Awarded Compensation in a lump sum in cash (or such property as the Administrator agrees to accept with a value equal to such Erroneously-Awarded Compensation) or (ii) if approved by the Administrator, offer to enter into a Repayment Agreement. If the Covered Person accepts such offer and signs the Repayment Agreement within a reasonable time as determined by the Committee, the Company shall countersign such Repayment Agreement.

(b) **Unvested Equity Awards**. With respect to those equity awards that have not yet vested, the Administrator shall take such action as is necessary to cancel, or otherwise cause to be forfeited, the awards in the amount of the Erroneously-Awarded Compensation.

(c) **Vested Equity Awards**. With respect to those equity awards that have vested or exercised and the underlying shares have not been sold, the Administrator shall take such action as is necessary to cause the Covered Person to deliver and surrender the underlying shares in the amount of the Erroneously-Awarded Compensation.

In the event that the Covered Person has sold the underlying shares, the Administrator shall either (i) require the Covered Person to repay the Erroneously-Awarded Compensation in a lump sum in cash (or such property as the Administrator agrees to accept with a value equal to such Erroneously-Awarded Compensation) or (ii) if approved by the Administrator, offer to enter into a Repayment Agreement. If the Covered Person accepts such offer and signs the Repayment Agreement within a reasonable time as determined by the Administrator, the Company shall countersign such Repayment Agreement.

(d) **Repayment Agreement**. "**Repayment Agreement**" means a written agreement (in a form reasonably acceptable to the Committee) with the Covered Person that provides for the Covered Person's repayment of the Erroneously-Awarded Compensation as promptly as possible without unreasonable economic hardship to the Covered Person.

(e) **Effect of Non-Repayment**. To the extent that a Covered Person fails to repay all Erroneously-Awarded Compensation to the Company when due (as determined in accordance with this Policy), the Company shall take all actions reasonable and appropriate to recover such outstanding Erroneously-Awarded Compensation from the applicable Covered Person. Unless otherwise determined by the Committee in its sole discretion, the applicable Covered Person shall be required to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering such Erroneously-Awarded Compensation in accordance with the immediately preceding sentence.

The Administrator shall have broad discretion to determine the appropriate means of recovery of Erroneously-Awarded Compensation based on all applicable facts and circumstances and taking into account the time value of money and the cost to shareholders of delaying recovery. However, in no

event may the Company accept an amount that is less than the amount of Erroneously-Awarded Compensation in satisfaction of a Covered Person's obligations hereunder.

For clarity, the recovery of Erroneously-Awarded Compensation under this Policy will not give rise to any Executive Officer's right to voluntarily terminate employment for "good reason" or due to a "constructive termination" (or any similar term of like effect) under any plan, program or policy of or agreement with the Company or any of its affiliates.

VI. Discretionary Recovery

Notwithstanding anything herein to the contrary, the Company shall not be required to take action to recover Erroneously-Awarded Compensation if any one of the following conditions are met and the Administrator determines that recovery would be impracticable:

(i) The direct expenses paid to a third party to assist in enforcing this Policy against a Covered Person would exceed the amount to be recovered, after the Company has made a reasonable attempt to recover the applicable Erroneously-Awarded Compensation, documented such attempts and provided such documentation to Nasdaq;

(ii) Recovery would violate home country law where that law was adopted prior to November 28, 2022, provided that, before determining that it would be impracticable to recover any amount of Erroneously-Awarded Compensation based on violation of home country law, the Company has obtained an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in such a violation and a copy of the opinion is provided to Nasdaq; or

(iii) Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

VII. Reporting and Disclosure Requirements

The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the U.S. federal securities laws, including the disclosure required by the applicable filings required to be made with the SEC.

VIII. Effective Date

This Policy shall apply to all Incentive-Based Compensation Received on or after the Nasdaq Effective Date.

IX. No Indemnification; No Liability

The Company shall not indemnify any Covered Person against the loss of Erroneously-Awarded Compensation and shall not pay, or reimburse any Covered Persons for premiums, for any insurance policy to fund such Covered Person's potential recovery obligations. None of the Company, an affiliate of the Company, or any member of the Committee or the Board shall have any liability to any person as a result of actions taken under this Policy.

X. Administration

The Administrator has the sole discretion to administer this Policy and ensure compliance with Nasdaq listing rules and any other applicable law, regulation, rule or interpretation of the SEC or Nasdaq promulgated or issued in connection therewith. Actions of the Committee pursuant to this Policy shall be taken by the vote of a majority of its members. The Administrator shall, subject to the provisions of this Policy, make such determinations and interpretations and take such actions as it deems necessary, appropriate or advisable. All determinations and interpretations made by the Administrator shall be final, binding and conclusive. Any action or inaction by the Administrator with respect to a Covered Person under this Policy in no way limits the actions or decisions of the Administrator not to act with respect to any other Covered Person under this Policy or under any similar policy, agreement or arrangement, nor shall any such action or inaction serve as a waiver of any rights the Company may have against any Covered Person other than as set forth in this Policy.

XI. Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary, including as and when it determines that it is legally required by the Companies Law, any U.S. federal securities laws, SEC rule or the rules of any national securities exchange or national securities association on which the Company's securities are then listed. The Board may terminate this Policy at any time. Notwithstanding anything in this Section XI to the contrary, no amendment or termination of this Policy shall be effective if such amendment or termination would (after taking into account any actions taken by the Company contemporaneously with such amendment or termination) cause the Company to violate the Companies Law, any U.S. federal securities laws, SEC rule, or the rules of any national securities exchange or national securities association on which the Company's securities are then listed.

XII. Other Recoupment Rights; No Additional Payments

The Board intends that this Policy will be applied to the fullest extent of the law. The Administrator may require that any employment agreement, equity award agreement or any other agreement entered into on or after the Adoption Date shall, as a condition to the grant of any benefit thereunder, require a Covered Person to agree to abide by the terms of this Policy; provided, that, this Policy shall apply to all Covered Persons irrespective of any such explicit agreement.

Any right of recoupment under this Policy is in addition to, and not in lieu of, any other rights under applicable law, regulation or rule or pursuant to any similar policy in any employment agreement, equity plan, equity award agreement or similar arrangement and any other legal remedies available to the Company. However, unless otherwise prohibited by applicable law, this Policy shall not provide for recovery of Incentive-Based Compensation that the Company has already recovered pursuant to Section 304 of the Sarbanes-Oxley Act or Other Recovery Obligations.

XIII. Severability

The provisions in this Policy are intended to be applied to the fullest extent of the law; provided, however, to the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

XIV. Application; Enforceability

Except as otherwise determined by the Administrator, the adoption of this Policy does not limit, and is intended to apply in addition to any recovery arrangements or clawback provisions contained in any employment agreement, bonus plan, incentive plan, equity-based plan, and, for the avoidance of doubt, the Compensation Policy ("Other Recovery Arrangements"). Without limiting the foregoing, in the event of a conflict between this Policy and the Compensation Policy, the latter shall prevail, except with respect to: (a) the recovery of any portion of Clawback-Eligible Incentive Compensation that is Erroneously-Awarded Compensation that would not be recoverable under the Other Recovery Arrangements, or (b) the recovery of any portion of Clawback-Eligible Incentive Compensation that is Erroneously-Awarded Compensation that is covered under this Policy or that is subject to any of the applicable SEC regulations promulgated to comply with Section 954 of the Dodd-Frank Act, where in each case, this Policy shall prevail.

XV. Successors

This Policy shall be binding and enforceable against all Covered Persons and their beneficiaries, heirs, executors, administrators or other legal representatives.

Exhibit A

ACKNOWLEDGEMENT AND AGREEMENT
TO THE
EXECUTIVE OFFICER CLAWBACK POLICY
OF
ENTERA BIO LTD.

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of Entera Bio Ltd.'s Executive Officer Clawback Policy (the "Policy"). Capitalized terms used but not otherwise defined in this Acknowledgement Form (this "Acknowledgement Form") shall have the meanings ascribed to such terms in the Policy.

By signing this Acknowledgement Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Erroneously-Awarded Compensation (as defined in the Policy) to the Company to the extent required by, and in a manner permitted by, the Policy.

By signing this Acknowledgement Form, the undersigned acknowledges and agrees that any debt he or she shall have toward the Company pursuant to the Policy shall be regarded as an agreed-upon debt, including according to the Israeli Wage Protection Law-1958 (to the extent applicable to the undersigned), and that the Company may deduct the amount of such debt from any amount due to the undersigned from any source whatsoever.

Signature

Name

Date

DISCLAIMER

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