**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, 2025**

**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:**

| 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** |

**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 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 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 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 $84.6 million as of June 30, 2025.

As of March 23, 2026, the registrant had 46,622,239 ordinary shares, par value NIS 0.0000769 per share ("Ordinary Shares") outstanding.

**Documents Incorporated by Reference**

None.

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## 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. Meaningful factors which could cause actual results to differ include, but are not limited 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 for hypoparathyroidism or other oral peptides for the treatment of obesity, metabolic disorders and gastrointestinal rare diseases 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;

- 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 oral peptide platform ("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 and other rare gastrointestinal disorders, 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;
- Our ability to manage growth; and
- The Israel-Hamas conflict, that has been ongoing since October 2023, including involvement from Hezbollah, Iran and its proxies in the Middle East, such as the Houthis in Yemen and militias in Iraq and Syria, and their impact on our operations and workforce, remains unknown.

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.

**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;
- All of our product candidates, including EB613, EB612, EB618 (OXM) and Oral Long Acting GLP-2 are in in preclinical or clinical phases of development, and we have not yet successfully completed the development of any product candidate;
- 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 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;
- 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 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;
- The price of our Ordinary Shares may be volatile, and holders of our Ordinary Shares could lose all or part of their investment;
- The Company regularly evaluates market conditions, its liquidity profile and financing alternatives, including out-licensing arrangements for its products, to enhance its capital structure. The Company may seek to raise capital through debt or equity financings to or through other strategic initiatives. Management has performed an analysis of our ability to continue as a going concern and our current cash resources should be sufficient to fund our operating expenses through the middle of the third quarter of 2026; however, as a result of recurring losses, substantial doubt exists about the Company's ability to continue as a going concern for a period of at least twelve months from the date of this Annual Report;
- 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, including the Iran War, the Israel-Hamas War and its proxies and its impact on our operations and workforce.

## PART I

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

### ITEM 1. BUSINESS

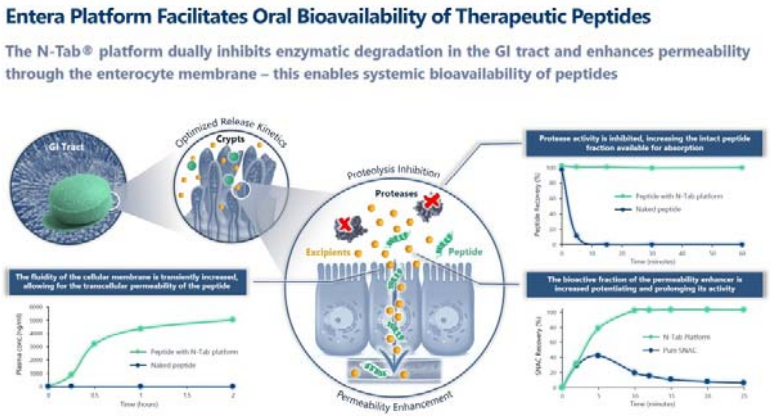
**Overview**

Entera is a clinical stage company focused on developing first-in-class oral tablet formats of peptides or protein replacement therapies. We concentrate on underserved, chronic medical conditions for which oral administration of a protein therapy has the potential to significantly shift a treatment paradigm.

Our pipeline includes differentiated, first-in-class oral peptides targeting PTH(1-34), GLP-1/Glucagon and GLP-2:

| Program | Indication | Target | Preclinical | Phase 1 | Phase 2 | Phase 3 | Partner |
|---|---|---|---|---|---|---|---|
| EB613 | Osteoporosis | PTH 1-34, teriparatide | | | | | |
| EB612 | Hypoparathyroidism | LA-PTH 1-34 | | | | | OPKO |
| EB618 | Obesity / Metabolic | GLP-1 & Glucagon Agonist | | | | | OPKO |
| GLP-2 | Short Bowel Syndrome | Long Acting GLP-2 | | | | | OPKO |
| EB613 | Stress Fractures | PTH 1-34 | | | | | Investigator Sponsored Trial |

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. From a technical standpoint, oral delivery of peptides and therapeutic proteins is challenging due to the enzymatic degradation within the gastrointestinal tract and poor absorption into the blood stream. We leverage our N-Tab® platform, which is designed to simultaneously stabilize large (4kD+) hydrophilic peptides in the gastrointestinal tract and promote their absorption into the bloodstream.




***EB613 Program***

Our most advanced product candidate, EB613 (oral teriparatide, or oral PTH[1-34]), is being developed as the first oral, osteoanabolic (bone building) tablet treatment for osteoporosis. EB613 is being developed under a 505(b)(2) application to the listed drug, Forteo® (teriparatide SC injection, Eli Lilly), which was first approved by the FDA in 2002 for the treatment of postmenopausal women with osteoporosis at high risk of fracture and later indicated for men with osteoporosis and osteoporosis associated with sustained systemic glucocorticoid therapy. Forteo® has been in clinical use for over 20 years with a well-established benefit-risk profile.

Osteoporosis is a chronic, progressive disorder in which bone resorption exceeds formation, resulting in decreased bone strength and increased susceptibility to fracture. Osteoporosis is a major and growing public health issue, responsible for

over two million fractures annually in the United States. After age 50, one in three women and one in five men will suffer an osteoporosis-related fracture in their remaining lifetime. Osteoporotic fractures lead to chronic pain, decreased quality of life, increased disability, and contribute to premature death. Studies show that up to 20-24% of hip fracture patients die within one year of the fracture. The total medical cost of osteoporotic fractures is projected to increase from $57 billion in 2018 to $95 billion by 2040, largely due to the aging population. Postmenopausal women are at higher risk of developing osteoporosis-related fractures, particularly in the hip, spine, and wrist. The mechanism for low bone mineral density ("BMD") in postmenopausal women is primary estrogen deficiency, which leads to accelerated bone loss, especially in the first five to ten years after menopause.

The three approved anabolic drugs, including Forteo®, are indicated for the treatment of very high-risk osteoporosis patients as first line therapy and as second line treatment in osteoporosis patients who cannot tolerate or progress on other osteoporosis drugs. Despite the superior efficacy of anabolic drugs, existing treatments require daily or monthly subcutaneous injections and are estimated to be used in a minority of very high-risk patients. EB613 is intended to provide an oral anabolic treatment earlier in an osteoporosis patient's journey to increase skeletal mass, reduce the risk of fracture, limit the disease progression, and decrease disability and mortality. Our mission with EB613 is to democratize anabolic treatment and enable wider access to both patients and healthcare practitioners.

We have completed a comprehensive nonclinical and clinical package for the EB613 program, including three Phase 1 comparative studies with Forteo® and three Phase 2 clinical studies. EB613 has been safely administered to a total of 270 study participants, including postmenopausal women with low BMD or osteoporosis (n=118 on EB613, n=43 on placebo), healthy volunteers, and male and female patients with hypoparathyroidism.

EB613 completed a Phase 2, 6-month, 161-patient, placebo-controlled study that met all biomarker and BMD endpoints without significant safety concerns in women with postmenopausal osteoporosis or low BMD. In April 2024, Phase 2 data was published in the Journal of Bone and Mineral Research (JBMR). EB613 produced rapid dose-proportional increases in biochemical markers of bone formation, reductions in markers of bone resorption, and increased lumbar spine, total hip, and femoral neck BMD. At 6 months of treatment, EB613 2.5mg produced comparable total hip BMD increases as those that have been reported for Forteo® at 6 months.

In September and April 2025, the effects of EB613 on trabecular and cortical bone indices based on a 3D-Shaper DXA post-hoc analysis of Phase 2 results were presented at the American Society for Bone and Mineral Research ("ASBMR") 2025 Annual Meeting and at the 2025 World Congress on Osteoporosis (WCO-IOF-ESCEO), respectively. The data using 3D-DXA modelling showed evidence of an early effect on both trabecular and cortical bone of the proximal femur. Mechanistically, the findings suggest that bone strengthening and fracture resistance may occur rapidly with EB613.

In October 2025, we reported clinical data from a post-hoc analysis of our Phase 2 trial of EB613 at the 2025 North American Menopause Society (NAMS) Annual Meeting in a poster presentation titled "EB613 (Oral PTH[1-34] Tablets) Increases BMD Over Six Months in Early Postmenopausal Women with Low Bone Mass or Osteoporosis: A Phase 2 Randomized Trial (P-66)". In this analysis of the Phase 2 data, EB613 produced significant and consistent gains in BMD at the spine, femoral neck and hip in women within 10 years of menopause and in women more than 10 years post-menopause.

Since 2023, we have advanced a simplified formulation of EB613 that builds on clinical experience with the multi-tablet formulation which was used in Phase 1 and Phase 2 clinical studies. At the ASBMR Annual Meeting in September 2025, preclinical data for EB613 single tablet formulation from a cross-over pharmacokinetic mini-pig study was presented. This pre-clinical data showed comparable PK to the multiple tablet formulation of EB613. The preliminary results from the ongoing Phase 1b PK study (ENT-11-2023) demonstrate PK comparability between the multiple tablet formulation and the simplified single-tablet formulation of EB613 and Forteo®.

**Regulatory Background**

Initial approvals of drugs for the treatment of osteoporosis have historically required a placebo-controlled trial demonstrating reduction in the risk of fractures as the primary outcome measure in women with postmenopausal osteoporosis. The regulatory requirement for using fracture as the primary efficacy endpoint is challenging due to the patient types who would need to be studied: (1) very high risk patients may be randomized to placebo in a clinical trial, which poses an ethical concern; and (2) evaluation of moderate risk patients would require a very large sample size to evaluate treatment effectiveness. The last drug approval for osteoporosis occurred in 2019.

In the United States, the Foundation for the National Institute of Health-American Society for Bone and Mineral Research-Study to Advance BMD as a Regulatory Endpoint (FNIH-ASBMR-SABRE, previously known as the FNIH-

Bone Quality Project [FNIH-BQP], hereinafter "SABRE") was launched in 2013. This initiative was established as a public-private partnership with the FDA to study whether change in BMD at the lumbar spine, total hip or femoral neck in a placebo-controlled trial of an osteoporosis drug was predictive of vertebral, nonvertebral, hip and all clinical fracture risk reduction. SABRE aims to change the framework for how clinical trials of new anti-osteoporosis drugs are conducted and to promote innovation in the field of osteoporosis.

The FNIH-ASBMR-SABRE working group obtained treatment group-level and patient-level BMD and fracture incidence data from the sponsors of most of the approved osteoporosis drug treatments including individual patient data from 53 clinical trials covering 176,750 individuals across seven osteoporosis drug classes (Black et al., 2020; Eastell et al., 2022; Vilaca & Eastell, 2024). Based on a meta-regression analysis to assess the relationship between change in total hip BMD (active-placebo) and the anti-fracture effect in randomized clinical trials for each fracture type, the SABRE group demonstrated that treatment-related change in total hip BMD is best associated with fracture reduction.

Since the end of our Phase 2 Meeting in December 2021, we have engaged in FDA Type C, D, and A Meetings in 2022, 2023, 2024, and 2025 to obtain clarity and alignment on total hip BMD as a primary endpoint and an appropriate data package to support a new drug application ("NDA") for EB613 under a 505(b)(2) application.

Following Type C and Type D meetings with the FDA in March 2023, 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 an NDA for EB613; however the SABRE BMD endpoint remained unqualified as a surrogate endpoint by FDA at that time. On the same day, we announced that we planned to continue our dialogue with the FDA and await the final qualification of the SABRE qualification and FDA's guidance on the statistical evaluation of our BMD endpoint before initiating a Phase 3 study for EB613.

In March 2024, the ASBMR announced that the FDA had communicated to the SABRE project team that a ruling to qualify the treatment-related change in BMD as a surrogate endpoint for fractures in future trials of new anti-osteoporosis drugs would be provided within 10 months.

In June 2025, as part of our scientific bridging, we received a written concurrence from the FDA that comprehensive nonclinical developmental and reproductive toxicity (DART) studies are not required given the totality of evidence generated from Forteo®, published literature, and EB613 nonclinical studies. In May 2025, we received a written concurrence from the FDA that dedicated oral carcinogenicity studies are not warranted for EB613 given the totality of evidence generated from the literature and nonclinical studies conducted with EB613.

In July 2025, we announced that, in a written response to a Type A meeting request, the FDA agreed that an NDA filing for EB613 could be supported by a phase 3 study in women with postmenopausal osteoporosis, where change in total hip BMD is evaluated as the primary endpoint, and incidence of new or worsening vertebral fractures is evaluated as the key secondary endpoint at 24 months.

In December 2025, the FDA released the Determination for Qualification of BMD qualifying total hip BMD as a surrogate efficacy endpoint for fracture that could be used in future studies of new anti-osteoporosis therapies. FDA's suggested a context of use (COU): "The percentage change from baseline at 24 months in total hip bone mineral density (BMD) assessed by dual-energy X-ray absorptiometry (DXA) can be used as a validated surrogate endpoint for the assessment of investigational therapies for postmenopausal women with osteoporosis at risk for fracture."

In February 2026, we submitted to the FDA a clinical amendment that included the EB613 Phase 3 protocol, statistical analysis plan and open-label extension synopsis. Our planned multinational, randomized, double-blind, placebo-controlled Phase 3 study is expected to enroll approximately 750 postmenopausal women with osteoporosis and will evaluate the percentage change in total hip BMD from baseline to month 12 as the primary endpoint. The double-blind, placebo-controlled 12-month Phase 3 study and the scientific bridge to the listed drug, Forteo®, are planned to be submitted in support of the NDA. We also plan to conduct an open label extension study under separate protocol in which participants on EB613 and placebo would be randomized to either EB613 for an additional 12 months, or transition to a standard anti-resorptive drug. The extension study is expected to provide safety and efficacy data for EB613 at 24 months as a monotherapy and evaluate the sequence of 12 months of EB613 treatment sequenced to a standard anti-resorptive drug for an additional 12 months.

***EB612 (PTH) Hypoparathyroidism Program***

Our product candidate, EB612, is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for patients with hypoparathyroidism. The FDA and the EMA have granted EB612 orphan drug designation for the treatment of hypoparathyroidism. Hypoparathyroidism is a rare, heterogeneous, endocrine disorder that leads to abnormally low

calcium and high phosphorus levels in the blood and requires chronic PTH replacement therapy. Today, the only approved PTH replacement treatment, YORVIPATH® (developed by Ascendis Pharma), requires patients to administer daily injections, while investigational candidates may require weekly injections.

Entera previously demonstrated proof-of-concept clinical data for its EB612 program using an unmodified oral PTH(1-34) analog in a 16-week Phase 2 study in patients with hypoparathyroidism (JBMR, 2021). The study showed significant reduction in calcium supplement use and maintenance of serum calcium levels above the lower limit for hypoparathyroidism (>7.5 mg/dL) throughout the study. However, the trial required a four-times-daily regimen with doses of up to 9mg daily.

In June 2024, Phase 1 clinical data for EB612 was presented at the Endocrine Society ENDO 2024 Annual Meeting. The safety, pharmacokinetic (PK) and pharmacodynamic (PD) data reported from a Phase 1 clinical study supported twice a day dosing of EB612.

In December 2025, we announced new *in vivo* PK/PD data supporting the development of a proprietary long-acting PTH (LA-PTH) analog, which is being developed as part of a material transfer and collaboration agreement with OPKO Biologics, Inc., a subsidiary of OPKO Health, Inc. ("OPKO"), utilizing our N-Tab® platform. Preclinical findings demonstrated a markedly prolonged plasma half-life and sustained elevation of serum calcium levels for more than three days following administration of a single oralThese data support the development of a once-daily oral PTH tablet for patients with hypoparathyroidism. Based on these data, in February 2026, we announced the expansion of our collaboration with OPKO to jointly advance this LA-PTH program. We intend to accelerate pre-IND development of this program and currently expect to submit an IND application to the FDA late 2026.

For additional information regarding our collaboration agreement with OPKO, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments—License and Collaboration Agreement with OPKO, contained in this Annual Report.

***EB618 Program (Oral GLP-1/Glucagon)***

In September 2023, we entered into a research collaboration agreement (the "2023 Collaboration Agreement") with OPKO. Under the terms of this agreement, OPKO agreed to supply its proprietary Oxyntomodulin (OXM) analogs for the development of oral tablet candidates using our proprietary N-Tab® platform. Under this agreement, 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.

OXM is a naturally occurring GLP-1/Glucagon dual agonist peptide hormone found in the small intestine that acts to suppress appetite, induce weight loss and has additional cardioprotective and anti-fibrotic attributes. The program focuses on developing the first oral dual agonist GLP-1/Glucagon peptide as a potential once-daily tablet treatment for patients with obesity, metabolic and fibrotic disorders using the N-Tab® platform. Currently, there are no approved dual GLP-1/Glucagon agonists available. OPKO previously reported that weekly injections of pegylated OXM demonstrated significant weight loss and reduction in HbA1, triglyceride and cholesterol levels in 113 obese and diabetic patients in a Phase 2B study. The OXM agonist peptide (OPK-88006) is a GLP-1/Glucagon dual agonist peptide that has been modified to maintain its long-acting profile while increasing its potential potency.

In September 2024, we and OPKO jointly announced topline PK/PD results for the OXM program. Oral OXM exhibited significant systemic exposure across two *in vivo* models, a favorable PK profile and bioavailability. The high plasma concentrations with prolonged systemic exposure were consistent with the reported half-life for semaglutide (Rybelsus®), the only approved oral GLP-1 analog. Oral OXM showed a statistically significant reduction in plasma glucose levels compared with placebo.

Given the scarcity of oral peptide treatments and potential safety challenges attributed to small molecule approaches, we believe oral OXM may address a significant number of patients suffering from chronic metabolic diseases

In March 2025, we entered into a collaboration and license agreement (the "2025 Collaboration Agreement") with OPKO to collaborate with respect to the preclinical and clinical development and decision making related to the Oral OXM program for the treatment of obesity, metabolic and fibrotic disorders in humans (the "Program"). The Program combines OPKO's OPK-88006 analog and Entera's proprietary N-Tab® platform.

Under the 2025 Collaboration Agreement, we granted to OPKO an exclusive, sublicensable and non-transferable, worldwide license to certain of our intellectual property and technology solely to develop, manufacture, and commercialize any GLP-1/Glucagon dual agonist as an oral treatment form for the treatment of obesity, metabolic,

cardiovascular, and fibrotic disorders in humans, and OPKO has granted to us a non-exclusive, non-sublicensable and non-transferable license to certain of its intellectual property and technology to the extent necessary for us to perform our obligations in relation to the Program, in each case subject to certain exceptions.

Under the terms of the 2025 Collaboration Agreement, we and OPKO will retain 40% and 60%, respectively, of all proceeds deriving from the Program and will be responsible for 40% and 60% of the Program's development costs, respectively. Following the completion of the Phase 1 stage, we may continue to fund our 40% share of the Program to maintain our right to proceeds or to opt-out (the "Opt-Out"). If we Opt-Out, then we and OPKO will retain 15% and 85%, respectively, of all proceeds deriving from the Program, while OPKO will be solely responsible for ongoing development and commercialization funding of the Program.

In June 2025, a poster at ENDO2025 reported PK data from a mini-pig study of oral OPK-88006 (EB618), which showed plasma levels consistent with those reported in humans for the highest subcutaneous dose of Wegovy™ (semaglutide) weekly injection, a standard of care for the treatment of obesity.

As of late 2025, OPKO is planning to initiate a single ascending dose (SAD) and multiple ascending dose (MAD) Phase 1 clinical study with the subcutaneous injection formulation of OXM, with data expected by the end of 2026. We plan to file an IND for the oral OXM tablet formulation thereafter.

***Oral GLP-2***

This program focuses on developing the first glucagon-like-peptide 2 (GLP-2) peptide tablet alternative for patients suffering from short bowel syndrome (SBS) and additional disorders involving mucosal inflammation and nutrient malabsorption. SBS is a rare and potentially life-threatening malabsorptive condition caused by a significant loss of functional bowel mass (secondary to congenital defects or disease-associated loss of absorption) or physical bowel mass (secondary to extensive intestinal resection). Approximately 30,000 patients across the United States and EU are living with SBS. SBS patients have a reduced ability to absorb nutrients and fluids and are at risk of malnutrition, unintended weight loss and additional symptoms due to the loss of essential vitamins and minerals. SBS is the most common cause of chronic intestinal failure, accounting for approximately 75% of chronic intestinal failure cases in adults and 50% of such events in children. Currently, the only approved GLP-2 agonist, which is marketed under the name Gattex® (teduglutide), requires daily sub-cutaneous injections. Zealand Pharma and Ironwood are developing long-acting GLP-2 therapies requiring once and twice weekly injections.

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, Gattex®) - A Novel Approach for Injection-Free Treatment of Short Bowel Syndrome." We believe GLP-2 represents a strong candidate for our N-Tab® platform and warrants further development as an injection-free alternative to patients suffering from SBS and other gastrointestinal disorders where GLP-2 plays a role.

In late 2023, Entera and OPKO completed a proof of concept single dose pharmacokinetic study in rodents. Oral GLP-2 tablets exhibited significant systemic exposure. Furthermore, plasma levels achieved with the oral tablet form of the GLP-2 analogue were approximately 10-fold higher than therapeutic plasma concentrations reported for subcutaneously administered teduglutide (Gattex® label). The pharmacokinetic analysis of the data obtained following the IV injections of the GLP-2 peptide showed the plasma half-life in rats to be approximately six times longer than the half-life reported for teduglutide in the same animal model. This data is consistent with previously reported PK data relating to OPKO's GLP-2 peptide's long-acting profile, which had initially been developed as a weekly subcutaneous injection.

In September 2025, pharmacokinetic data from a mini-pig study of OPK-8801003, our oral GLP-2 analog developed in collaboration with OPKO, were presented at the 47th European Society for Clinical Nutrition & Metabolism (ESPEN) Congress. The data demonstrated a plasma half-life of approximately 15 hours (approximately 18 time longer than teduglutide), which has a half-life of only 0.85 hours in the same species. Oral administration achieved peak plasma levels of ~200 ng/mL and maintained systemic exposure (AUC ≈ 2 h•μg/mL) for over 24 hours with low variability, supporting once-daily oral dosing.

Given the challenging compliance rates attributed to injectable GLP-2 therapy and heterogeneity of SBS patients, we believe a daily tablet format may address a significant unmet need in treating and titrating SBS patients more effectively than injectable alternatives.

**Our Strategy**

Our goal is to develop first-in-class oral peptides and protein replacement therapies for ignored, underserved, chronic medical conditions for which a tablet treatment has the potential to significantly shift a treatment paradigm. We are developing our product candidates to potentially become the first oral, single daily tablet peptide or protein replacement therapies designed to expand access for patients and healthcare practitioners. 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 Oral Anabolic (Bone Building) Tablet, into Phase 3 for the Treatment of Osteoporosis:** Building on our historical alignment with the FDA in July 2025 and the FDA's 2025 broad qualification of BMD as a regulatory endpoint for anti-osteoporosis drugs, we submitted a clinical amendment to the FDA in February 2026, providing a streamlined Phase 3 protocol. We believe that EB613 may be the first osteoporosis program to be permitted by FDA to pursue a placebo controlled, BMD endpoint registrational Phase 3 study in support of an NDA. We view this potential outcome as a testament to the treatment gap and unmet need for a viable alternative for the millions of osteoporosis patients who, despite current guidelines and availability of highly efficacious injectable anabolic agents, remain undertreated. Entera currently retains global rights to EB613.

- **Advancing Potentially the First Oral LA-PTH Analog as a Once-Daily Tablet for Patients with Hypoparathyroidism as part of our Collaboration with OPKO:** 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 in median serum phosphate levels two hours following the first dose, which was maintained for the duration of the study. The FDA and the European Medicines Agency ("EMA") have granted EB612 orphan drug designation for the treatment of hypoparathyroidism. In 2025, we were testing the development of a proprietary LA-PTH analog utilizing our N-Tab® platform and preclinical findings demonstrated a markedly prolonged plasma half-life and sustained elevation of serum calcium levels for more than three days following administration of a single oral. These data support the development of a once-daily oral PTH tablet for patients with hypoparathyroidism. We currently expect to submit an IND application to the FDA in late 2026. We and OPKO each own 50% of the rights related to the LA-PTH hypoparathyroidism EB612 program. Our development expenses through Phase 1 are expected to be funded from the $8 million in proceeds received as part of OPKO's equity investment in Entera in 2025.

- **Identifying and Developing Additional High Value Oral Peptides in Collaboration with Strategic Partners such as our Oxyntomodulin (Oral GLP-1/Glucagon) and Oral GLP-2 Programs:** We intend to leverage our N-Tab® platform by applying it to the development of additional, proprietary peptides and therapeutic proteins. In collaboration with OPKO, we are currently focusing on the development of the first oral OXM, a dual targeted GLP1/glucagon peptide, in tablet form, for the treatment of metabolic disorders and have completed a proof of concept for an oral GLP-2 peptide tablet as an injection-free alternative for patients suffering from rare malabsorption conditions, such as short bowel syndrome. We and OPKO own 40% and 60%, respectively, of the rights related to the OXM EB618 program.

- **Establishing Select Global and Regional Development and Commercial Partnerships**: Our N-Tab® 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.

**PTH**

Parathyroid hormone (PTH) is an 84-amino acid hormone that regulates calcium and phosphate homeostasis and bone metabolism in the body. 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, Forteo® (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: Potentially the First Oral PTH(1-34) Anabolic Tablet Treatment for Post-Menopausal Women with Osteoporosis**

EB613 is the first once daily PTH(1-34, teriparatide) tablet treatment and has the same amino acid sequence as Forteo® (teriparatide daily subcutaneous injection), a leading anabolic agent which has been marketed for 24 years and achieved peak annual sales of $1.7 billion prior to patent expiration in 2018.

Osteoporosis is a chronic, progressive disorder in which bone resorption exceeds formation, resulting in decreased bone strength and increased susceptibility to fracture. Postmenopausal women are at higher risk of developing osteoporosis-related fractures, particularly in the hip, spine, and wrist. The mechanism for low BMD in postmenopausal women is primary estrogen deficiency, which leads to accelerated bone loss, especially in the first five to ten years after menopause. 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 resorptions 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 estimates that approximately 10 million Americans have osteoporosis and that an additional 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. Worldwide, osteoporosis affects an estimated 200 million women, according to the International Osteoporosis Foundation (the "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***

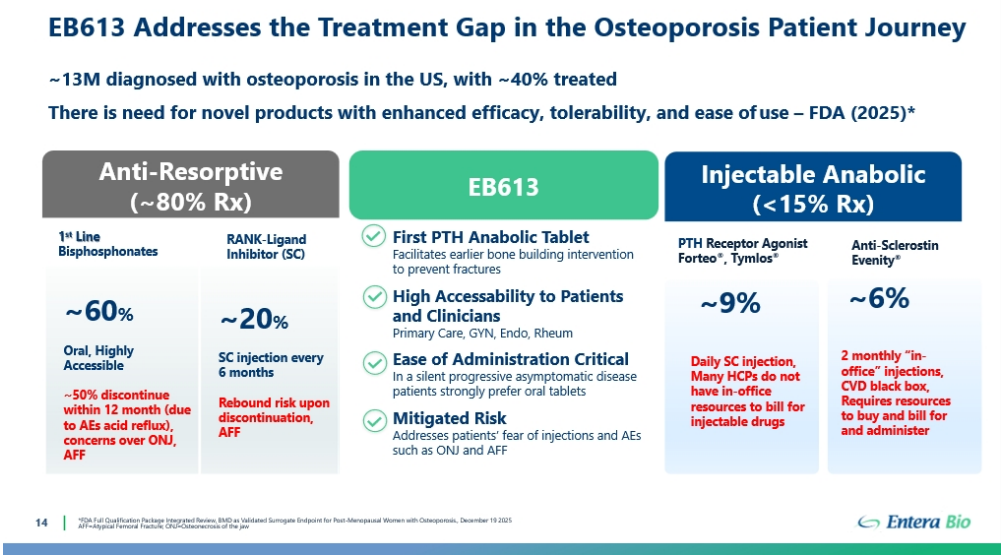
The goal of pharmacological treatment of osteoporosis is to maintain or increase bone mass and strength and to prevent fractures throughout a patient's life. It is critical to identify patients who have significant bone loss. Pharmacologic therapy is strongly recommended for patients with a BMD T-score of -2.5 or lower in the spine, femoral neck, total hip, or 1/3 radius.

Current 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 (PTH(1-34)), Forteo®); abaloparatide (a PTH-related protein analog, Tymlos®)); and romosozumab (an antibody that inhibits sclerostin and also inhibits bone resorption, Evenity®). According to surveys with osteoporosis practitioners including primary care, gynecology, endocrinology and rheumatology, we estimate that less than 15% of currently treated osteoporosis patients agree to or have access to injectable osteoanabolic treatment despite guideline recommendations, their efficacy versus the anti-resorptive drugs and the approval of lower cost injectable generics.

There are currently no FDA-approved oral anabolic treatments for osteoporosis. EB613 is positioned to potentially be the first, once daily osteoanabolic tablet treatment for women with high-risk post-menopausal osteoporosis.

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

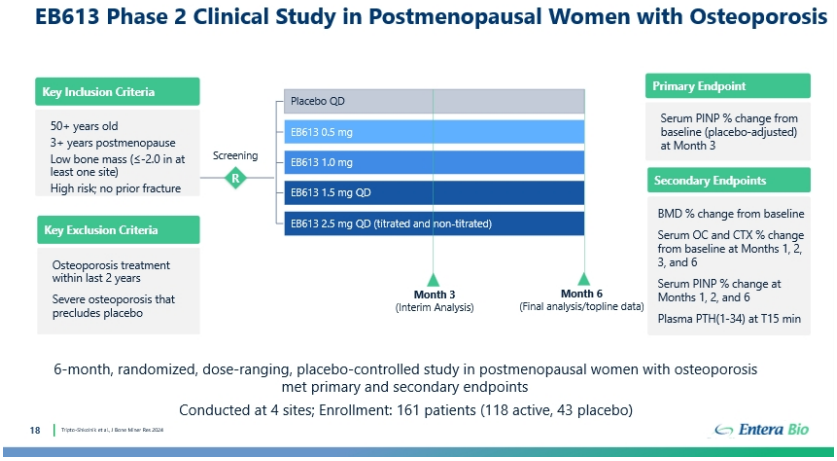
We have completed a comprehensive nonclinical and clinical package for EB613, including three Phase 1 studies and three Phase 2 clinical studies. In the clinical development program, EB613 has been administered collectively to a total of 270 subjects in Phase 1 (n = 117) and Phase 2 (n = 153) studies. EB613 was well-tolerated, and no new drug-related adverse events (AEs) were identified in the Phase 1 and Phase 2 studies, at doses of up to 9 mg daily.




Across Phase 1 studies, the PK profile of EB613 has been characterized by a rapid increase in plasma PTH(1-34) levels, with peak concentrations of the drug observed within 30 minutes after dose and a rapid decline thereafter. The blood half-life of PTH(1-34) in humans is less than five minutes (see Forteo® USPI). Due to this very short elimination time and a short absorption phase, PTH(1-34) levels decrease below the limit of quantitation within two hours after drug administration. As a result, no drug accumulation is expected with once daily tablet dosing.

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

This 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 formation markers, CTX - a bone resorption marker, and various safety endpoints.



***Safety***

The most common drug-related 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 mean calcium or changes in calcium exceeding predefined limits in patients treated with EB613 2.5 mg daily tablets

**EB613 Safety Profile Consistent with PTH Agonists**

| Most Common Treatment Emergent AE (≥5% of participants) | EB613 Treated (N=118) n (%) |
|---|---|
| Headache | 21 (17.8) |
| Nausea | 18 (15.3) |
| Dizziness | 13 (11.0) |
| Nasopharyngitis | 7 (5.9) |
| Back pain | 7 (5.9) |
| Palpitation | 6 (5.1) |
| Dyspepsia | 6 (5.1) |
| Presyncope | 6 (5.1) |

- Similar AE profile to that reported for Forteo® and other PTH agonists
- Mechanistic symptoms of orthostatic hypotension
  - headache, nausea, and dizziness
- EB613 was not associated with serum calcium increases or hypercalcemia adverse events
- 2.5 mg dose with titration (1.5 mg for 1 month, 2.0 mg for the next month and 2.5 mg during months 3 to 6) well tolerated
- No serious AEs related to EB613

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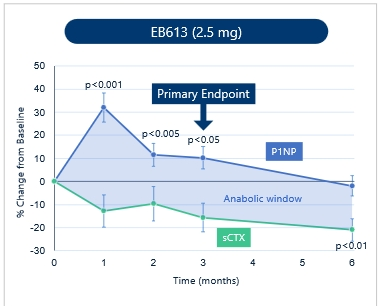
There were no reported drug-related SAEs. All adverse events were mild or moderate in intensity.

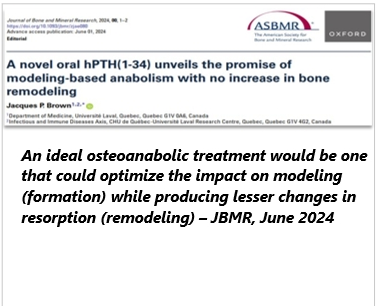
***Bone Biomarkers (PD Effect)***

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 indicates a potential dual mechanism of action for EB613 with preferential stimulation of ostoblastic activity over osteoblastic activity.

**EB613 Induces Bone Formation (P1NP) while Reducing Resorption (CTX)**

EB613's dual mechanism stimulates new bone formation on trabecular and cortical (periosteal and/or endosteal) bone surfaces by preferential stimulation of osteoblastic activity over osteoclastic activity

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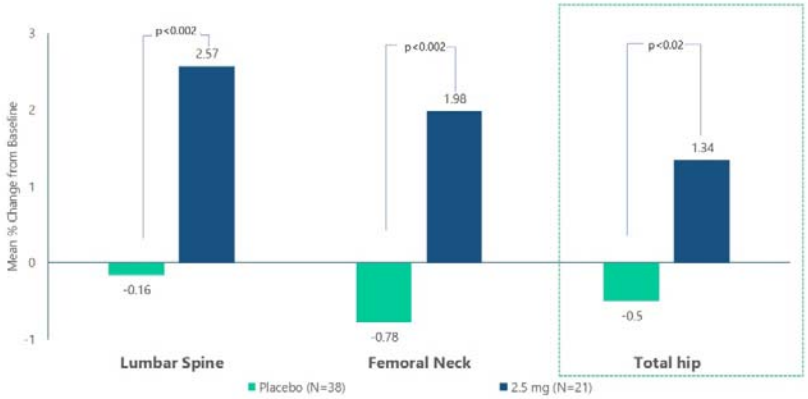
***Bone Mineral Density***

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 ($p<0.0001$).

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).

## 6 Months Treatment with EB613 2.5 mg Produced Significant Increases in BMD at All Skeletal Sites



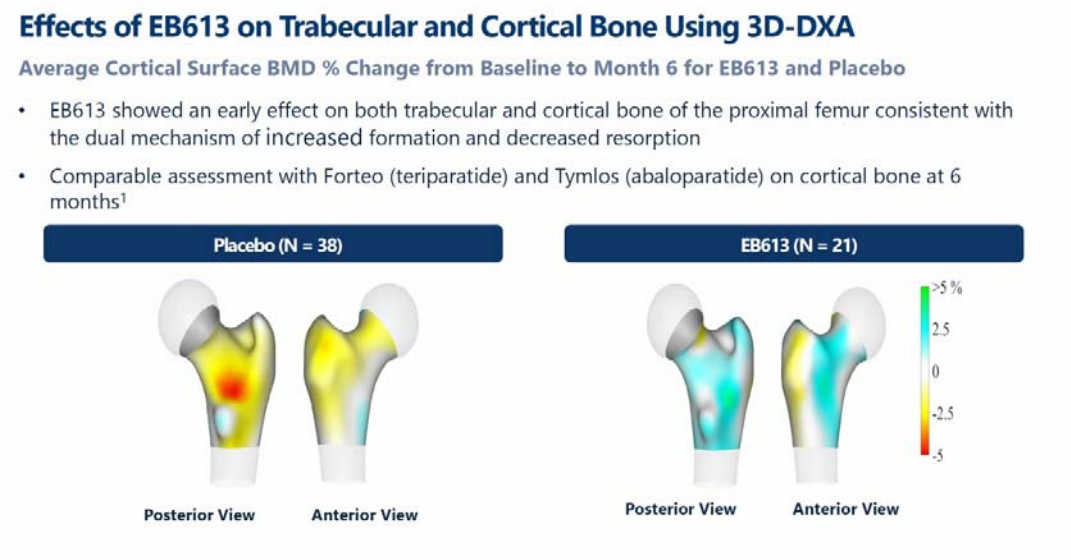

| | Lumbar Spine | Femoral Neck | Total Hip |
|---|---|---|---|
| Placebo Adjusted | 2.73 | 2.76 | 1.84 |

At 6 months of treatment, EB613 2.5mg produced comparable total hip BMD increases as those that have been reported for Forteo® at 6 months.

## EB613 Produced Comparable Total Hip BMD Increases as Forteo® Published 6 Month Data


- Total Hip BMD is an FDA Surrogate Endpoint to fracture as of 12/19/2025
- 6 months of daily Forteo injections resulted in a 0.1 – 1.13% increase in Total Hip BMD[1]
- 6 months of daily Oral EB613 2.5mg resulted in a 1.84 – 2.07% increase in Total Hip BMD[2]

Furthermore, in a post hoc analysis using FDA-approved 3D-DXA, EB613 showed early effects on both trabecular and cortical bone of the proximal femur. The outcomes were comparable with those reported for Forteo and Tymlos on cortical bone indices at 6 months.

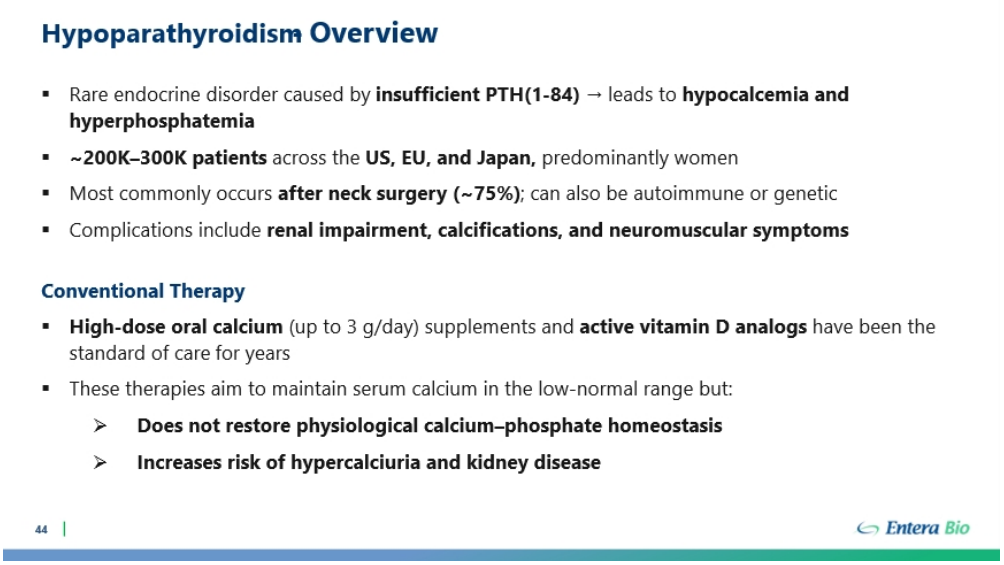



**EB612: First Oral Long-Acting PTH(1-34) Peptide Tablet for the Treatment of Hypoparathyroidism**

Hypoparathyroidism is a rare condition in which the body either fails to produce sufficient 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. 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.

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 was permanently phased out globally at the end of 2024. TransCon PTH, once-daily injectable, long-acting prodrug of parathyroid hormone (PTH(1-34)) developed by Ascendis Pharma A/S was FDA Approved in August 2023 and EU Approved in November 2023. Eneboparatide, once-daily injectable long-acting parathyroid hormone 1 (PTH1) receptor agonist, developed by Amolyt Pharma (acquired by AstraZeneca 2024) reported topline data that the primary endpoint for its Phase 3 study was met in March 2025. A long acting once weekly injectable PTH peptide prodrug (MBX2109) developed by MBX Biosciences, Inc. reported positive Phase 2 topline data in 2025. Finally, oral small molecule PTHR1 5(SEP786) developed by Septerna Inc, discontinued a Phase I trial in February 2025 due to safety and is expected to advance another small molecule into Phase 1 in 2026.

***EB612***

Our current product candidate for hypoparathyroidism, EB612, is the first oral long acting PTH(1-34) hormone replacement treatment developed in a tablet form. We believe that EB612 may have inherent advantages as compared to injectable and small molecule approaches in terms of potential superior safety and flexibility to provide more individualized treatment in this heterogeneous disease.

***Phase 2a Clinical Trial***

In 2015, we successfully completed a multicenter Phase 2a clinical trial of an older, multitablet formulation 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.

***Planned Additional Clinical Development and Regulatory Pathway***

We have since developed a new generation of EB612 based on new intellectual property of our N-Tab® platform, which we have designed to optimize its PK profile and the potential for reduced daily dosing. We initiated a PK study in May 2023, which tested various potential drug candidates based on our new platform, including several which could be developed for the treatment of hypoparathyroidism. In April 2024, we submitted pharmacokinetic (PK) and early PD Data from a Phase 1 study evaluating an unmodified PTH(1-34) peptide and a new generation of Entera's N-Tab® platform to the Endocrine Society Annual Meeting (ENDO 2024). In June 2024, we presented Phase 1 clinical data at the ENDO 2024 Annual Meeting, supporting a BID (twice-daily) tablet dose to Phase 2 development in patients with hypoparathyroidism.

In December 2025, we announced new *in vivo* PK/PD data supporting the development of a proprietary LA-PTH analog utilizing our N-Tab® platform in partnership with OPKO. Preclinical findings demonstrated a markedly prolonged plasma half-life and sustained elevation of serum calcium levels for more than three days following administration of a single oral tablet, in contrast to unmodified PTH(1-34) controls, which showed no calcium response. These data support the development of a once-daily oral PTH tablet for patients with hypoparathyroidism.

**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 23, 2026, our global patent portfolio included issued patents and patent applications. We believe that the granted patents as well as certain of the pending claims contained in our patent applications, if issued in substantially the same form, would cover our proprietary platform (N-Tab®) and the candidates used in various pipeline programs as indicated in the table below.

In addition, during 2025 we further strengthened the patent protection for our EB612 and GLP1/Glucagon product candidates through the in-licensing of composition-of-matter patent applications from OPKO. The composition-of-matter patent applications relating to EB612 and GLP1/Glucagon are expected to expire in 2046 and 2045, respectively, not considering any patent term extensions that may be obtained.

| **Subject Mater** | **# Pending Applications** | **# Issued Patents** | **Geographical Scope** | **Nominal Patent Term** |
|---|---|---|---|---|
| EB613 | 79 | 51 | United States, Europe, Japan, China, Canada, Singapore, United Arab Emirates, Israel, Brazil, Mexico, South Africa, India, Australia, New Zealand, Russia, South Korea and Hong Kong | 2029 - 2044 |
| EB612 | 73 | 44 | United States, Europe, Japan, China, Canada, Singapore, United Arab Emirates, Israel, Brazil, Mexico, South Africa, India, Australia, New Zealand, Russia, South Korea and Hong Kong | 2029 - 2044 |
| GLP-1/Glucagon | 58 | 8 | United States, Europe, Japan, China, Canada, Singapore, United Arab Emirates, Israel, Brazil, Mexico, South Africa, India, Australia, New Zealand, Russia, South Korea and Hong Kong | 2036 - 2044 |
| GLP-2 | 57 | 8 | United States, Europe, Japan, China, Canada, Singapore, United Arab Emirates, Israel, Brazil, Mexico, South Africa, India, Australia, New Zealand, Russia, South Korea and Hong Kong | 2036 - 2044 |
| Platform (N-Tab®) | 131 | 56 | United States, Europe, Japan, China, Canada, Singapore, United Arab Emirates, Israel, Brazil, Mexico, South Africa, India, Australia, New Zealand, Russia, South Korea and Hong Kong | 2029 - 2044 |

Issued patents and any patent that may issue from the pending patent applications are currently expected to expire by the Nominal Patent Term as noted in the above table, assuming national phase filings are timely effected. The nominal patent term does not include potential patent term extension and/or patent term adjustment 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 within 60 days of regulatory approval of the approved drug and 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. In December 2025 an opposition was filed by an anonymous entity against our European patent EP3256113 ('113 patent). The granted claims of the '113 patent are directed to an old-generation product that is not currently under development.

***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 our internally developed product candidate EB613 and intend to maximize the value of EB613 with strong partners that have the requisite commercial infrastructure to successfully launch a candidate that we believe has the potential for significant sales. In relation to EB612, under the terms of the A&R Collaboration Agreement, OPKO and Entera each hold 50% ownership interests in the program and development costs will be shared equally between the parties. Following the completion of the Phase 1 stage, we have the option to continue to fund our 50% share to maintain our pro-rata ownership interest in the program. Should we opt-out, we will retain a 15% ownership interest in the program, while OPKO will retain 85% and be responsible for all ongoing development activities and funding of the program. In relation to EB618 (Oral GLP-1/Glucagon), under the terms of the A&R Collaboration Agreement, OPKO and Entera hold 60% and 40% pro-rata ownership interests, respectively, in the program and be responsible for 60% and 40% of the program's development costs, respectively. Following the completion of the Phase 1 stage, we have the option to continue to fund our 40% share to maintain our pro-rata ownership interest in the program. Should we opt-out, we will retain a 15% ownership interest in the Oral OXM program, while OPKO will retain 85% and be responsible for all ongoing development activities and funding of the program. Our Oral GLP-2 program is governed by a 2023 MTA and Collaboration Agreement which we have shared responsibilities.

**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 product candidates are their 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 and other product candidates that we are developing for metabolic disorders and short bowel syndrome, 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 PTH research and development for Osteoporosis. 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 IIA regulations, which we refer to collectively as 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. 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, 2025, 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. As of December 31, 2025, we had paid royalties to the IIA in the amount of $96 thousand.

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 IIA-related "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. 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. Notice or undertaking to the IIA may not be required with respect to the purchase of Ordinary Shares in standard acquisition or market purchases following an initial public offering (IPO) that was approved by the IIA. 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.

**OPKO Collaboration and License Agreements**

***2023 Collaboration Agreement***

In September 2023, we entered into the 2023 Collaboration Agreement with OPKO Biologics. 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 candidates using our proprietary N-Tab® platform. Under this agreement, 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.

***2025 Collaboration Agreement***

In March 2025, we entered into the 2025 Collaboration Agreement with OPKO and OPKO Biologics to collaborate with respect to the preclinical and clinical development and decision making related to the Oral OXM program for the treatment of obesity, metabolic and fibrotic disorders in humans (the "Program"). The Program combines OPKO's proprietary long-acting oxyntomodulin (OXM, dual targeted GLP-1/Glucagon agonist, OPK-88006) analog and Entera's proprietary N-Tab® technology.

Under the 2025 Collaboration Agreement, we granted to OPKO an exclusive, sublicensable and non-transferable, worldwide license to certain of our intellectual property and technology solely to develop, manufacture, and commercialize any GLP-1/Glucagon dual agonist as an oral treatment form for the treatment of obesity, metabolic,

cardiovascular, and fibrotic disorders in humans, and OPKO has granted to us a non-exclusive, non-sublicensable and non-transferable license to certain of its intellectual property and technology to the extent necessary for us to perform our obligations in relation to the Program, in each case subject to the exceptions contained therein.

Under the terms of the 2025 Collaboration Agreement, we and OPKO will retain 40% and 60%, respectively, of all proceeds deriving from the Program, and will be responsible for 40% and 60% of the Program's development costs, respectively. Following the completion of the Phase 1 stage, we may continue to fund our 40% share of the Program to maintain our right to proceeds or to opt-out (the "Opt-Out"). If we Opt-Out, then we and OPKO will retain 15% and 85%, respectively, of all proceeds deriving from the Program, while OPKO will be solely responsible for ongoing development and commercialization funding of the Program.

In connection with the execution of the 2025 Collaboration Agreement, we issued and sold to OPKO an aggregate of 3,685,226 Ordinary Shares for a purchase price of $8.0 million, the proceeds of which we have agreed to use solely to fund our development cost obligations under the 2025 Collaboration Agreement, subject to the expiration or termination of the agreement.

***A&R Collaboration Agreement***

In February 2026, we entered into an amended and restated collaboration agreement with OPKO (the "A&R Collaboration Agreement) which amends and restates the 2025 Collaboration Agreement to expand the scope of the agreement to include the collaboration with respect to the preclinical and clinical development of a daily LA-PTH for the treatment of hypoparathyroidism and other indications in addition to the original oral dual agonist GLP-1/glucagon peptide program. Development costs incurred by the parties with respect to the development of the LA-PTH program will be shared equally between the Company and OPKO.

**Oramed Patent Transfer Agreement**

In 2011, we entered into a patent transfer agreement with Oramed Ltd. ("Oramed"), which we refer to as the Patent Transfer Agreement, pursuant to which Oramed assigned to us all of its rights, title and interest in the patent rights Oramed licensed to us when we were originally 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 that involve the use of, or utilize, the patents underlying the Patent Transfer Agreement. 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 our 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. On March 27, 2025, we entered into a Novation Agreement with Oramed, and Oramed NewCo Inc. ("Oramed NewCo") pursuant to which Oramed NewCo replaced Oramed as a party to the Patent Transfer Agreement. Under the Novation Agreement, Oramed NewCo assumed all of Oramed's rights and obligations under the Patent Transfer Agreement accruing on or after the effective date, Oramed was released from any obligations and liabilities owed to us under the Patent Transfer Agreement accruing or arising after such date, and we were released from any obligations and liabilities owed to Oramed accruing or arising after such date. All other provisions of the Patent Transfer Agreement remain in full force and effect.

**Manufacturing**

We do not own or operate facilities for large scale product manufacturing, storage and distribution, or testing, nor do we expect to in the future. Our current facility is limited to small-mid scale manufacturing, storage and distribution of materials and oral drug formulations for early stage clinical studies. Our facility has ISO:9001:2015 quality management systems accreditation from The Standards Institution of Israel for the production and development of functional excipients and oral drug formulations to be used in clinical trials. The facility includes a dedicated Class D clean room for tablet production and a dedicated chemical synthesis room designed to meet ISO 8 specifications.

In addition, we have agreements with contract manufacturing organizations, to produce and supply tablets for clinical trials performed worldwide, including formulation and production of the final drug, packaging, storage and distribution. The manufacturers' facilities are FDA/EMA inspected-GMP sites and we expect future clinical studies as well as the potential commercial supply, if approved, will be provided by the same subcontractors. These agreements are not exclusive and we may enter into additional contracts. 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, labelling, 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, 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, or GLP;
- 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, including GLP. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. Some preclinical tests may continue even after submission of the IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research volunteers will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the clinical trials to commence or allowing the clinical trial to commence on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. This order issued by the FDA would delay 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 accordance 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 an NDA or a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate'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 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 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 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 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.

**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;
- 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.

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.

**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 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**

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 current Clinical Trials Regulation (EU) No. 536/2014 to ensure that the rules for clinical trials are identical throughout the EU. 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**

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 centralize 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.

**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, 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 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. Depending upon the timing and duration of the EU marketing authorization process, products may be eligible for up to 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 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) in which the clinical trials are scheduled to be conducted. All clinical trials must first be approved by the Institutional Review Board / Independent Ethics Committee 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 (referred to as "The Israeli Public Health Regulations"). 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 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 ensure 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.

**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 Civil Monetary Penalty Act of 1981 imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health care program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal health care beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier. These penalties include monetary fines ranging from $2,670 and $127,973 per violation and exclusion from participation in a federal health care program such as Medicare and Medicaid, meaning that items and services provided by excluded entities are not directly or separately billable to federal health care programs.

- 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 Patient Protection Affordable Care Act (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.

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 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 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 way 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 August 16, 2022, Congress enacted the Inflation Reduction Act allowing CMS to negotiate directly with drug manufacturers to lower the price of some of the costliest drugs under the Medicare program, as well as requiring drug manufacturers to provide Medicare with a rebate if the price of drugs increases faster than the rate of inflation. In 2025, HHS began implementation of "Most Favored Nation" drug pricing by setting the Medicare price of single-source brand drugs without generic or biosimilar competition to the lowest price available in wealthy countries with aper capita GDP of at least 60% of that in the United States. 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.

On September 9, 2025, the FDA began requiring pharmaceutical advertisements to include full safety warnings during direct-to-consumer advertisements, instead of footnoting such information. Additionally, the FDA expanded its oversight on social medial promotional activities, including influencer partnerships, algorithm-driven targeted advertising, and AI-generated health content, to ensure compliance with the FDA's advertisement requirements. The FDA has indicated it will begin enforcement actions for any advertisement violations.

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, 2025, we had a total of 22 employees, of whom 20 are full-time employees all based in Israel. In addition, we employ a number of specialized clinical, non-clinical, statistical, regulatory and development advisors based in the United States, the United Kingdom and Europe. 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 | 17 |
| General and Administrative | 3 |
| Total | 20 |

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.

**Legal Proceedings**

For more information regarding legal proceedings, see "Item 3—Legal Proceedings" contained in this Annual Report.

**Additional Information**

Our website is at www.enterabio.com. We make available, free of charge, on our "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 Exchange Act, 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. If any of the negative events referred to below occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. In any such case, the trading price of our Ordinary Shares could decline, and you could lose all or part of your investment.*

### Risks Related to Our Financial Position

***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 $11.4 million in 2025 and $9.5 million in 2024. As of December 31, 2025, we had an accumulated deficit of $125.4 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, as well as our collaboration with OPKO related to OXM and GLP-2. 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 ongoing operations through the middle of the third quarter of 2026, excluding the initiation of the Phase 3 study for EB613 in osteoporosis. Our ability to commence the Phase 3 study of EB613 in osteoporosis 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.

The Company regularly evaluates market conditions, its liquidity profile and financing alternatives, including out-licensing arrangements for its products, to enhance its capital structure. The Company may seek to raise capital through debt or equity financings to or through other strategic initiatives. Since inception we have not derived any significant income from our activities and incurred an accumulated deficit and negative cash flows from operating activities. We believe our existing cash resources will be sufficient to meet our projected operating requirements through the middle of the third quarter of 2026 without additional funding; however, as a result of recurring losses, substantial doubt exists about the Company's ability to continue as a going concern for a period of at least twelve months form the date of this Annual Report. 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 enter into strategic partnerships or less dilutive funding agreements or our ability to raise additional capital. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and operating assets and liabilities.

***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.***

The Company is engaged in research and development activities, and it has not derived significant income from its activities and has incurred an accumulated deficit in the amount of $125.4 million as of December 31, 2025 and negative cash flows from operating activities. These factors raise substantial doubt as to the Company's 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 23, 2026, we had cash and cash equivalents of approximately $12.6 million, of which $7.8 million is designated solely to fund our development cost obligations under the collaboration agreement with OPKO. Given our current plans, we anticipate that our existing cash and cash equivalents will be sufficient to fund our ongoing operations through the middle of the third quarter of 2026, excluding the initiation of the Phase 3 study for EB613 in osteoporosis. Our ability to

commence the Phase 3 study of EB613 in osteoporosis 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 constantly evaluate options in relation to various financing alternatives including public or private equity offerings, debt financings and strategic collaborations to finance future clinical trials, 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, our internal resources are currently focused on the development of EB613 and further development of our N-Tab® platform. We entered into the 2025 Collaboration Agreement with OPKO in relation to our Oral GLP-1/Glucagon. Under the terms of the agreement, OPKO and Entera will hold 60% and 40% pro-rata ownership interests, respectively, in the program and be responsible for 60% and 40% of the program's development costs, respectively. Following the completion of the Phase 1 stage, we have the option to continue to fund our 40% share to maintain our pro-rata ownership interest of the program, or we may opt-out. Should we opt-out, we will retain a 15% ownership interest in the Oral OXM program, while OPKO would retain 85% and be responsible for all ongoing development activities and funding of the program. In February 2026, we entered into the A&R Collaboration Agreement, which amends and restates the 2025 Collaboration Agreement to expand the scope of the agreement to include the collaboration with respect to the preclinical and clinical development of a daily long acting PTH tablet ("LA-PTH") for the treatment of hypoparathyroidism and other indications. Development costs incurred by the parties with respect to the development of the LA-PTH program will be shared equally between the Company and OPKO. 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 planning and preparing to initiate a phase 3 study for our most advanced product candidate, EB613, following the FDA's feedback on our phase 3 protocol submission. 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. 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 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 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 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;
- 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.

Many of these factors are outside of our control. Given our current plans, we believe that we will be able to fund our ongoing operations through the middle of the third quarter of 2026, excluding the initiation of the Phase 3 study for EB613 in osteoporosis. 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.

***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 developing our N-Tab® platform, pre-clinical and early clinical development of our product candidates, expanding our intellectual property portfolio, financing and staffing our company. We have not yet demonstrated an ability to successfully 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 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 a non-accelerated filer, we 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 cannot predict or estimate the amount of additional costs we may incur as a result of no longer being a non-accelerated filer or the timing of such costs.

Our Ordinary Shares are listed on Nasdaq. As a public company listed on Nasdaq, we incur significant legal, accounting and other expenses. 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 the Board, particularly to serve on our 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 oral peptide and protein replacement therapies 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 N-Tab® 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 biotech companies in rapidly evolving fields.

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 or strategic alliances that is significant enough to achieve profitability. Our ability to generate future revenue and value from product sales depends heavily on our success in many areas, including but not limited to:

- the completion of future development efforts for EB613 for osteoporosis and EB612 for hypoparathyroidism, other oral peptides for obesity, metabolic disorders and gastrointestinal rare diseases, or any other product candidates;
- 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. 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 program, EB613 may compete with marketed drugs, such as Prolia®, bisphosphonates, Forteo®, Tymlos®, Evenity®, and osteoanabolic drugs in clinical development for osteoporosis such as Angitia's AGA2118; the EB612 program may compete with marketed drugs of hypoparathyroidism such as TransCon™ PTH and those in clinical development such as Eneboparatide and MBX2109. Our Oral GLP-2 program will compete with Gattex™, the only approved GLP-2 treatment for short bowel syndrome and experimental GLP-2 injectables such as Zealand's glepaglutide (FDA CRL 12/24) and Vectiv/ Ironwood's apraglutide (FDA has required another phase 3 trial 04/25)). Our Oral GLP-1/Glucagon program may compete with approved GLP-1 injectables, Wegovy pill, and experimental incretin targeted injectables and oral small molecules and potential oral peptide candidates in the metabolic indications we pursue. 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* N-*Tab® platform, to other product candidates.***

An element of our strategy is to combine our N-Tab® platform with a variety of peptides and therapeutic proteins to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of a variety of different types of diseases.

Our initial product candidates combine our oral platform, N-Tab®, with PTH(1-34), a hormone that has been used in injectable form for over 20 years for the treatment of osteoporosis. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for, and successfully commercialize our oral PTH product candidates in a timely manner. If we are not successful in obtaining regulatory approval for them or successfully commercialize them, our business and prospects may be severely limited.

Even if we are successful in expanding our technology platform to other peptides for other indications as we have to GLP-1/Glucagon and GLP-2, 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 peptides, 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. 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.

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;
- 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 products 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, Gregory Burshtein, our Chief of Research and Development and Hillel Galitzer, our Chief Operating Officer. 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 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 R&D plans evolve, we expect to supplement and expand our employee base, for clinical development, regulatory, operational, 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.

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.

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.

To 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 with many innovations, artificial intelligence (or "AI") presents risks, challenges, and unintended consequences that could affect its adoption, and therefore our business. AI algorithms and training methodologies may be flawed, ineffective or inadequate. The rapid evolution of AI, particularly the anticipated government regulation of AI, could require significant resources for compliance, whether in the development, testing or maintenance of such systems or software. AI development or deployment practices by us or third-party providers could increase vulnerability to cybersecurity risks and require additional resources to implement heightened cybersecurity measures to protect the security of our data. These deficiencies and other failures of any potential AI systems could subject us to competitive harm, regulatory action, legal liability, and brand or reputational harm.

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 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. 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.***

During 2023, record levels of inflation 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 and the regional conflicts throughout the Middle East, which may contribute to rising energy costs and disruptions to the global supply chain. To the extent we experience any supply chain disruptions, we could experience 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 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 most advanced product has 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 an NDA 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;
- 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.

Each of our oral peptide candidates, including EB613 and EB612 for hypoparathyroidism or other oral peptides for obesity, metabolic disorders and gastrointestinal rare diseases, 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 platform is not effective, our product candidates are not effective, our clinical trial designs are flawed, or clinical trial investigators or subjects do not comply with trial protocols;
- our product candidates may not be well tolerated or may cause negative side effects;
- our ability to complete the development and commercialization of our oral PTH for our intended uses may be significantly dependent upon our ability to obtain and maintain experienced and committed collaborators to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of, our oral PTH;
- even if our oral PTH is shown to be safe and effective for its intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities at reasonable prices, or at all;
- even if our oral PTH is successfully developed, commercially produced and receives all necessary regulatory approvals, there is no guarantee that there will be market acceptance;
- even if our oral PTH is successfully developed, commercially produced and receives all necessary regulatory approvals for the treatment of Osteoporosis, there is no guarantee that we will successfully develop and commercialize it for other indications, including hypoparathyroidism and delayed union fractures; and
- our competitors may develop therapeutics or other treatments that are superior to or less costly than our own with the result that our products, even if they are successfully developed, manufactured and approved, may not generate significant revenues.

If we are unsuccessful in dealing with any of these risks, or if we or a potential partner are unable to successfully commercialize our oral PTH, LA-PTH, GLP-1/Glucagon , GLP-2 or any other product candidate 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). 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 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. 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 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 to serve as the Scientific Bridge to Forteo, 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 SABRE BMD pathway and that the Company's proposed PK sampling scheme seemed reasonable. On the same day, we announced that we planned to continue our dialogue with the FDA and await the final qualification of the SABRE qualification and FDA's guidance on the statistical evaluation of our BMD endpoint before initiating a Phase 3 study for EB613 which has since been obtained in December 2025.

On July 28, 2025, we announced that in a written response to a Type A meeting request, the FDA agreed with our proposal that the NDA filing for EB613 would be supported by a single multinational, randomized, double-blind, placebo-controlled, 24-month phase 3 study in women with postmenopausal osteoporosis, where change in total hip BMD is evaluated as the primary endpoint, and incidence of new or worsening vertebral fractures is evaluated as the key secondary endpoint. In December 2025, the FDA broad qualification of total hip bone mineral density (BMD) as a validated efficacy regulatory endpoint for novel drugs in development for post-menopausal women at risk for osteoporotic fracture.

In February 2026, we submitted a clinical amendment to the FDA providing a streamlined Phase 3 protocol, statistical analysis plan (SAP), and open-label extension synopsis to the IND 505(b)(2) submission. We anticipate FDA feedback within 60 days.

In addition, with respect to EB612, in December 2025, we announced new in vivo PK/PD data supporting the development of a proprietary long-acting PTH (LA-PTH) analog utilizing our N-Tab® platform. These data support the development of a once-daily oral PTH tablet for patients with hypoparathyroidism. Following the results, we expanded our collaboration with OPKO to jointly advance this LA-PTH program. We intend to accelerate development and currently expect to submit an IND application to the FDA in late 2026.

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;
- 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.

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.

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, CMS 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;
- 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 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, in March 2010, the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, 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 2031 absent additional congressional action. 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. Further, on August 16, 2022, Congress enacted the Inflation Reduction Act allowing CMS to negotiate directly with drug manufacturers to lower the price of some of the costliest drugs under the Medicare program, as well as requiring drug manufacturers to provide Medicare with a rebate if the price of drugs increases faster than the rate of inflation. 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”. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA 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. 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. In 2025, HHS began implementation of "Most Favored Nation" drug pricing by setting the Medicare price of single-source brand drugs without generic or biosimilar competition to the lowest price available in wealthy countries with aper capita GDP of at least 60% of that in the United States. 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. 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. On September 9, 2025, the FDA began requiring pharmaceutical advertisements to include full safety warnings during direct-to-consumer advertisements, instead of footnoting such information. Additionally, the FDA expanded its oversight on social medial promotional activities, including influencer partnerships, algorithm-driven targeted advertising, and AI-generated health content, to ensure compliance with the FDA's advertisement requirements. The FDA has indicated it will begin enforcement actions for any advertisement violations. 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.

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 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;

- 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 Civil Monetary Penalty Act of 1981 imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health care program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal health care beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier. These penalties include monetary fines ranging from $2,670 and $127,973 per violation and exclusion from participation in a federal health care program such as Medicare and Medicaid, meaning that items and services provided by excluded entities are not directly or separately billable to federal health care programs;

- 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 product candidates, 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 our N-Tab® platform which enables us to develop peptides and therapeutic protein replacement therapies in 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. 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. We anticipate our EB612 program to compete with marketed drugs for the treatment of hypoparathyroidism such as TransCon™ PTH and those in clinical development for hypoparathyroidism such as Eneboparatide and MBX2109. Our Oral GLP-2 Program will compete with Gattex™, the only approved GLP-2 treatment for short bowel syndrome and experimental GLP-2 injectables such as Zealand's glepaglutide (FDA CRL 12/24) and Vectiv/ Ironwood's apraglutide (FDA demanded another phase 3 trial 04/25). Our Oral GLP-1/Glucagon program may compete with approved GLP-1 injectables, Wegovy pill and many experimental incretin targeted injectables, oral peptide candidates and oral small molecules developed for metabolic indications.

***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.

- 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 the duration and intensity of the ongoing war in Israel, 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 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 may consider entering into a collaboration to commercialize our oral peptides candidates globally or in selected regions. Any such collaborator could be responsible for, or substantially support, late stage clinical trials of our oral peptide 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 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 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;
- safe, effective and medically necessary;
- 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;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation, which may be only partially recoverable even in the event of successful defense;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of 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.

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 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.

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 entered into long-term supply agreements with several manufacturers for commercial supplies. 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.

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 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.

**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 N-Tab® platform and know-how relating to the development of oral peptides and oral protein replacement therapies in tablet form. 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. Our global patent portfolio includes issued patents and patent applications. We believe that the granted patents as well as certain of the pending claims contained in our patent applications, if issued in substantially the same form, would cover our proprietary technology platform (N-Tab®) and the formulations used in various pipeline programs through 2046 not including patent term extensions and patent term adjustments. However, 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 USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably, and can change. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in pharmaceutical or biotechnology patents. Even if our pending patent applications issue as patents, such patents may not cover our product candidates in the United States or in other countries. Accordingly, we cannot predict whether additional patents protecting our technology will issue in the United States or in non-U.S. jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide us with a competitive advantage.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing technology and products similar or identical to ours, or limit the duration of the patent protection covering our technology and product candidates. In addition, patents have a limited lifespan. In the

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

Our issued patents may not be sufficient to provide us with a competitive advantage. For example, competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. We may also grant licenses under our intellectual property that may limit our ability to exploit such intellectual property.

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

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

Competitors or other third parties may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property rights. To counter infringement or other violations, we may be required to file claims, which can be expensive and time consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Third parties may also raise challenges to the validity of our patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review and *inter partes* review proceedings and equivalent proceedings in foreign jurisdictions such as opposition proceedings. If third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO, to determine priority of invention for patent applications filed with an effective filing date, or claiming priority to an application with a filing date, before March 16, 2013, or in derivation proceedings to determine inventorship for patent applications claiming priority to an application with a filing date 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 by a patent owner, the patent owner would need to demonstrate that our products or methods infringe the patent claims of the relevant patent. We may need to defend ourselves against such an infringement action, and/or demonstrate 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, in 2013, the United States 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. The United States may enact other patent reforms in the future. It is not clear what, if any, impact such past or potential future 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 legislation by the U.S. government, decisions by the federal courts, and interpretations/implementation by the USPTO, the laws and regulations governing patents could change in unpredictable ways that could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any U.S. patents that may issue to us in the future, all of which could have a material adverse effect on our business and financial condition.

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned patents and/or applications and any patent rights we may own or license in the future. The USPTO

and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our business.

***Under applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. In addition, our Israeli employees may be entitled to seek compensation for their inventions irrespective of their contractual agreements with us.***

Our agreements with our employees and key consultants generally include non-competition provisions. These provisions prohibit such employees and key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. We may be unable to enforce these provisions under the laws of the jurisdictions in which our employees and consultants work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such interests will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our ability to remain competitive may be diminished. In addition, a significant portion of our intellectual property has been developed by our employees and consultants in the course of their employment or consulting relationship with us. Under the Israeli Patent Law, 5727-1967, inventions conceived by an employee or consultant during the scope of his or her employment or consulting relationship with a company are regarded as "service inventions." Even when our agreements with our employees and consultants include provisions regarding the assignment and waiver of rights to additional compensation in respect of inventions created within the course of their employment or consulting relationship with us, including in respect of service inventions, we cannot guarantee that such provisions will be upheld by Israeli courts, as a result of uncertainty under Israeli law with respect to the efficacy of such provisions. If we are required to pay additional compensation or face disputes relating to service inventions, our results of operations could be adversely affected.

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

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

We currently have relationships with different consultants who perform research and development activities for us and who are not employed by us , and we may enter into additional relationships of such nature in the future. We have limited

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

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

Certain of our employees, consultants and contractors were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees, consultants or contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's, consultant's or contractor's former employer. Litigation may be necessary to defend against these claims and, even if we are successful in defending ourselves, could result in substantial costs to us or be distracting to our management. If we do not succeed with respect to any such claims, in addition to paying monetary damages and possible ongoing royalties, we may lose valuable intellectual property rights or personnel. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

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

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

We are currently in the process of registering the trademark N-Tab® for our oral platform, globally. As of March 23, 2026, N-Tab® is registered in Israel and pending in the United States, Europe, Great Britain, Norway, China and Australia. 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**

***The price of our Ordinary Shares may be volatile, and holders of our Ordinary Shares 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 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;
- 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;
- 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 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 oral peptide product candidates we may develop, including the programs we are developing with OPKO;
- 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;
- variances in our financial performance from the expectations of market analysts;
- the limited trading volume of our Ordinary Shares; and
- general economic and market conditions, including factors unrelated to our industry or operating performance, such as political and economic instability in the Middle East.

In addition, broad market and industry factors may materially affect the market price of companies' stocks, including ours, regardless of actual operating performance.

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

Although our Ordinary Shares are listed on Nasdaq, an active trading market for our Ordinary Shares may not be sustained. The lack of an active market may impair the ability of holders of our Ordinary Shares to sell their Ordinary Shares 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 and may cause the trading price of our Ordinary Shares 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 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.

***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 in the public market could lower the market price of our Ordinary 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 are not restricted from resale. In the event of a sale of Ordinary Shares offered by selling shareholders, the price of our Ordinary Shares could decline, and such decline could be material.

***The market price of our Ordinary Shares 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 Ordinary Shares 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 may decline. The perception in the public market that our shareholders might sell our Ordinary Shares could also depress the market price of our Ordinary Shares 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. A decline in the price of our Ordinary Shares may impede our ability to raise capital through the issuance of additional Ordinary Shares or other equity securities, and may cause holders of our Ordinary Shares 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, such U.S. shareholder generally will be subject to certain adverse U.S. federal income tax consequences, including increased tax liability on gains from dispositions of the Ordinary Shares and certain distributions and a requirement to file annual reports with the Internal Revenue Service. 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.

***We are a smaller reporting company and non-accelerated filer, and our compliance with the reduced reporting and disclosure requirements applicable to smaller reporting companies and 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 qualify as a "smaller reporting company," and we are taking advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, we qualify as a "non-accelerated filer," and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not non-accelerated filers, including the auditor attestation requirements of Section 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 less attractive as a result, there may be a less active trading market for our Ordinary Shares and our stock price may be more volatile.

Additionally, because of the exemptions from various reporting requirements provided to us 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. In the past, the Company has received notices from Nasdaq stating that the Company's Ordinary Shares failed 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 such notices. In each case, the Company was able to regain compliance with the Nasdaq continued listing requirements within the compliance periods provided to the Company by Nasdaq. 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, as long as we are 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 PTH research and development efforts in relation to osteoporosis have been financed, in part, through the grants that we have received from the IIA in total amount of $460 thousand. Pursuant to these grants, we must comply with the requirements of 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. 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 for commercial use 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 for such IIA-related products or technologies. 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 IIA-related 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 IIA-related 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 IIA-related know-how or rights outside of the state of Israel without IIA approval is a criminal offense.

These restrictions may impair our ability to sell our technology assets or to perform or outsource manufacturing outside of Israel, engage in change of control transactions or otherwise transfer our IIA-related 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 the Board, are required to sign an undertaking towards the IIA in which they would undertake to comply with the Research Law. Notice or undertaking to the IIA may not be required in respect of purchase of Ordinary Shares in standard acquisition or market purchases following an IPO that was approved by the IIA.

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 the Board.

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

Our principal research facilities are located in Israel. In addition, most of our key employees, officers and two 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), Hezbollah (an Islamist militia and political group in Lebanon), and Iran.

On October 7, 2023, thousands of Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of lethal attacks on Israeli civilians and some military targets. Hamas also launched extensive rocket attacks on the Israeli civilian population and industrial centers located along Israel's border with the Gaza Strip and across the State of Israel. These attacks resulted in thousands of deaths and injuries, and Hamas additionally kidnapped over 250 Israeli civilians and soldiers. Following the attack, Israel's security cabinet commenced a counter-offense military campaign against Hamas in Gaza. Since the onset of these events, hostilities have persisted across Israel, along Israel's northern border with Lebanon, primarily involving the Hezbollah terror organization, as well as other extremist groups in the region, including the Houthis in Yemen and various militia groups in Syria and Iraq. Israel has conducted multiple targeted strikes against these terror organizations.

In addition, since April 2024, Israel has experienced direct attacks from Iran, involving hundreds of drones and ballistic missiles launched towards mostly densely populated civilian towns across Israel and some military bases, threatening continued aggression while also exerting considerable influence over regional militia groups encouraging them to launch attacks against Israel. The Israeli defense systems, aided by international allies, successfully intercepted the majority of the ballistic missile attacks, minimizing physical damage and casualties. Additionally, since October 2023, the Houthis, a military organization based in Yemen, have launched a series of attacks on global shipping routes in the Red Sea, as well as direct attacks on various parts of Israel. Such incidents contribute to regional instability and could potentially escalate into broader conflicts with Iran and its proxies in the Middle East, affecting Israel's political and trade relations, especially with neighboring countries and global allies. The situation remains fluid, and the potential for further escalation exists. In October 2024, Israel initiated both air and ground operations against Hezbollah in Lebanon, culminating in a ceasefire agreement between Israel and Lebanon on November 27, 2024, the results of which remain uncertain. In response to ongoing Iranian aggression and support of proxy attacks against Israel, on June 12, 2025, Israel conducted a series of preemptive defensive air strikes in Iran targeting Iran's nuclear program and military commanders. On June 21, 2025, U.S. President Donald Trump announced that the United States had conducted air strikes against three nuclear sites within Iran. On October 9, 2025, a ceasefire had been reached. Israel, Hamas, the United States and other countries in the region agreed to a framework for a ceasefire in Gaza between Israel and Hamas.

On February 28, 2026, following the breakdown of diplomatic efforts and heightened regional tensions, the United States and Israel conducted a series of preemptive strikes targeting Iranian military infrastructure and strategic assets. Immediately thereafter, Iran launched extensive retaliatory ballistic missile and drone attacks against multiple locations across Israel, including central and southern population centers, critical infrastructure facilities and military installations. On March 2, 2026, Hezbollah resumed hostilities, ending the November 2024 ceasefire, by launching projectiles into northern Israel, prompting Israeli airstrikes in Lebanon targeting Hezbollah operatives and assets. Since the outbreak of these hostilities, Israel has implemented nationwide emergency measures, including restrictions on public gatherings and large-scale reserve duty call-ups affecting the civilian workforce.

How long and how severe the current conflicts in Gaza, Northern Israel, Lebanon, Iran or the broader region become is unknown at this time and any continued clash among Israel, Hamas, Hezbollah, Iran or other countries or militant groups in the region may escalate in the future into a greater regional conflict.

While we have a few employees who are in active military service, the ongoing war, the escalation of Hezbollah's attacks on Northern Israel, and the direct offensives from Iran and its proxies have not, to date, materially impacted our business or operations. Furthermore, we do not expect any delays to any of our programs as a result of such conflicts. While research and some management are located in Israel, other core activities including clinical, regulatory and our supply chain are not. However, we cannot currently predict the intensity or duration of Israel's war against Hamas, Hezbollah and Iran, and its proxies, nor can we predict how such conflicts 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 neighboring countries Syria, Lebanon, Egypt and Jordan, 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 a broader regional armed conflict. Since February 2026, there has been a significant escalation in hostilities involving the U.S., Israel, Iran and several other countries in the middle east, including direct military exchanges. These developments have increased regional instability and may further escalate into more severe and prolonged hostilities, which could affect Israel and us. 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. 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. In light of the intensity of the ongoing Israel-Hamas War, the escalation of Hezbollah's and Iran's attack of Israeli civilian and military sites, in September 2024, the international rating agency Moody's downgraded Israel's credit rating from 'A2' to 'Baa1', reflecting heightened geopolitical risks. In July 2025, this downgrade was affirmed by Moody's. On November 7, 2025, S&P Global Ratings affirmed Israel's credit ratings as 'A' after lowering from 'A+' on October 1, 2025, and updated the outlook from negative to stable. In January 2026, Moody's affirmed Israel's sovereign rating at "Baa1" but changed the outlook from "negative" to "stable". This credit rating, as well as the ongoing war and conflicts described above, could make it more difficult for us to raise capital, if needed, and negatively influence the market price of our Ordinary Shares. We could experience disruptions if acts associated with such conflicts result in any serious damage to our facilities.

***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 military reserve duty until they generally reach the age of 40 or 45 (or older in some cases, depending on rank, the nature of the service, and other factors). In response to the Hamas attack on October 7, 2023, and the following hostilities, 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, and it is possible that there will be further or longer military reserve duty call-ups in the 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 in connection with other military and 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 2025, the value of the NIS increased against the U.S dollar by 14%, which was potentially computed by inflation in Israel of 2.6%. In 2024, the value of the NIS increased against the U.S. dollar by 0.55%, which was potentially computed by inflation in Israel of 3.5%. 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. As a result of the difficulty associated with enforcing a judgment against us in Israel, holders of our Ordinary Shares may not be able to collect any damages awarded by either a U.S. or foreign court.

***Provisions of Israeli law and our 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 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 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. 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 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.

Our Audit Committee of the Board of Directors (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 in Jerusalem, Israel. Most of our clinical development, clinical operations and regulatory functions are located in the United States. Under a lease agreement with Unihead Biopark Ltd., we lease approximately 622 square meters of office and laboratory space. This lease has a term that extends through 2028.The average rent over the 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

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***

Our Ordinary Shares are listed on the Nasdaq Capital Market under the symbol "ENTX".

As of March 23, 2026, there were approximately 44 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.

Individuals who are subject to income tax in Israel (whether any such individual is an Israeli resident or non-Israeli resident, and with respect to a non-Israeli resident, subject to tax treaties not otherwise limiting the applicable tax rate to such non-Israeli resident) are also subject to an additional surtax at a rate of 3% on annual income (including, but not limited to, income derived from dividends, interest and capital gains) exceeding a certain threshold (currently, NIS 721,560 for 2025 through 2027, which amount is linked to the annual change in the Israeli consumer price index (the "Threshold Amount").

According to legislation effective as of January 1, 2025, an additional 2% excess tax will be imposed on "Capital-Sourced Income" (defined as income from any source other than employment income, business income or income from "personal effort"), provided that the Individual's Capital Sourced Income exceeds the Threshold Amount. This additional excess tax applies, among other things, to income from capital gains, dividends, interest, rental income, or the sale of real property.

### ITEM 6. [Reserved]

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

*This Annual Report contains forward-looking statements within the meaning of the PSLRA, Section 27A of the Securities Act, and Section 21E of 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. Our forward-looking statements reflect our views only as of the date they are made. 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.*

**Business Overview**

Entera is a clinical stage company 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 protein therapy has the potential to significantly shift a treatment paradigm. Our pipeline includes differentiated, first-in-class oral peptide programs targeting PTH(1-34), GLP-1/Glucagon and GLP-2.

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. From a technical standpoint, oral delivery of peptides and therapeutic proteins is challenging due to the enzymatic degradation within the gastrointestinal tract and poor absorption into the blood stream. We leverage our N-Tab® platform, which is designed to simultaneously stabilize large (4kD+) hydrophilic peptides in the gastrointestinal tract and promote their absorption into the bloodstream.

***EB613 Program***

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 osteoporosis. EB613 is intended to provide an oral anabolic treatment earlier in an osteoporosis patient's journey to increase skeletal mass, reduce the risk of fracture and limit the disease progression, and decrease disability and mortality. . A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (pharmacodynamic/bone turnover biomarker) and secondary endpoints (BMD). In April 2024, the Phase 2 data was published in the Journal of Bone and Mineral Research (JBMR).

In July 2025, we announced that in a written response to a Type A meeting request, the FDA agreed that the NDA filing for EB613 could be supported by a phase 3 study in women with postmenopausal osteoporosis, where change in total hip BMD is evaluated as the primary endpoint, and incidence of new or worsening vertebral fractures is evaluated as the key secondary endpoint at 24 months.

In December 2025, the FDA released the Determination for Qualification of BMD qualifying total hip BMD as a surrogate efficacy endpoint for fracture that could be used in future studies of new anti-osteoporosis therapies. FDA's suggested a context of use (COU): "The percentage change from baseline at 24 months in total hip bone mineral density (BMD) assessed by dual-energy X-ray absorptiometry (DXA) can be used as a validated surrogate endpoint for the assessment of investigational therapies for postmenopausal women with osteoporosis at risk for fracture."

In February 2026, we submitted to the FDA a clinical amendment which included the EB613 Phase 3 protocol, statistical analysis plan and open-label extension synopsis. Subject to regulatory feedback, we are planning to initiate the Phase 3 study in the second half of 2026.

***EB612 Program***

Our product candidate, EB612, is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for patients with hypoparathyroidism.

In December 2025, we announced new in vivo PK/PD data supporting the development of a proprietary long-acting PTH (LA-PTH) analog utilizing our N-Tab® platform. Preclinical findings demonstrated a markedly prolonged plasma half-life and sustained elevation of serum calcium levels for more than three days following administration of a single oral tablet, in contrast to unmodified PTH(1-34) controls, which showed no calcium response. These data support the development of a once-daily oral PTH tablet for patients with hypoparathyroidism.

In February 2026, we announced the expansion of our collaboration with OPKO Biologics and OPKO to jointly advance this LA-PTH program. Under the expanded collaboration, Entera and OPKO each hold a 50% pro-rata ownership interest in the LA-PTH hypoparathyroidism program, and each is responsible for 50% of development costs. We intend to accelerate development and currently expect to submit an IND application to the FDA in late 2026.

***EB618 Program (Oral GLP-1/Glucagon)***

In September 2023, we entered into the 2023 Collaboration Agreement with OPKO Biologics. Under the terms of this agreement, OPKO has agreed to supply its proprietary long-acting GLP-2 peptide and certain OXM analogs for the development of oral tablet candidates using our proprietary N-Tab® platform.

The program focuses on developing the first oral dual agonist GLP-1/Glucagon peptide as a potential once-daily tablet treatment for patients with obesity and metabolic disorders using the N-Tab® platform. Currently, there are no approved dual GLP-1/Glucagon agonists available.

In September 2024, we jointly announced with OPKO topline PK/PD results for the OXM program.. The high plasma concentrations with prolonged systemic exposure were consistent with the reported half-life for semaglutide (Rybelsus®), the only approved oral GLP-1 analog. Oral OXM showed a statistically significant reduction in plasma glucose levels compared with placebo.

In March 2025, we entered into the 2025 Collaboration Agreement with OPKO and OPKO Biologics to collaborate with respect to the preclinical and clinical development and decision making related to the Oral OXM program for the treatment of obesity, metabolic and fibrotic disorders in humans.

In February 2026, we entered into the A&R Collaboration Agreement which amends and restates the 2025 Collaboration Agreement to expand the scope of the agreement to include the collaboration with respect to the preclinical and clinical development of a daily LA-PTH for the treatment of hypoparathyroidism.

OPKO is planning to initiate a single ascending dose (SAD) and multiple ascending dose (MAD) Phase 1 clinical study with the subcutaneous injection formulation, with data expected by the end of 2026. We plan to file an IND for the oral OXM tablet formulation thereafter.

For additional information regarding our collaboration agreements with OPKO, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Patent Transfer, Licensing Agreements and Grant Funding—OPKO Collaboration and License Agreements, contained in this Annual Report.

***Oral GLP-2***

This program focuses on developing the first GLP-2 peptide tablet alternative for patients suffering from short bowel syndrome and additional disorders involving mucosal inflammation and nutrient malabsorption.

We and OPKO completed a proof of concept single dose pharmacokinetic study in rodents. Oral GLP-2 tablets exhibited significant systemic exposure. Furthermore, plasma levels achieved with the oral tablet form of the GLP-2 analogue were about 10-fold higher than therapeutic plasma concentrations reported for subcutaneously administered teduglutide (Gattex® label). The pharmacokinetic analysis of the data obtained following the IV injections of the GLP-2 peptide showed the plasma half-life in rats to be about six times longer than the half-life reported for teduglutide in the same animal model. This data is consistent with previously reported PK data relating to OPKO's GLP-2 peptide's long-acting profile, which had initially been developed as a weekly subcutaneous injection.

Given the challenging compliance rates attributed to injectable GLP-2 therapy and heterogeneity of SBS patients, we believe a daily tablet format may address a significant unmet need in treating and titrating SBS patients more effectively than injectable alternatives.

**Patent Transfer, Licensing Agreements and Grant Funding**

***OPKO Collaboration and License Agreements***

*2023 Collaboration Agreement*

In September 2023, we entered into the 2023 Collaboration Agreement with OPKO Biologics. 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 candidates using our proprietary N-Tab® platform. Under this agreement, 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.

***2025 Collaboration Agreement***

In March 2025, we entered into the 2025 Collaboration Agreement with OPKO and OPKO Biologics to collaborate with respect to the preclinical and clinical development and decision making related to the Oral OXM program for the treatment of obesity, metabolic and fibrotic disorders in humans (the "Program").

Under the 2025 Collaboration Agreement, we granted to OPKO an exclusive, sublicensable and non-transferable, worldwide license to certain of our intellectual property and technology solely to develop, manufacture, and commercialize any GLP-1/Glucagon dual agonist as an oral treatment form for the treatment of obesity, metabolic, cardiovascular, and fibrotic disorders in humans, and OPKO has granted to us a non-exclusive, non-sublicensable and non-transferable license to certain of its intellectual property and technology to the extent necessary for us to perform our obligations in relation to the Program, in each case subject to the exceptions contained therein.

Under the terms of the 2025 Collaboration Agreement, we and OPKO will retain 40% and 60%, respectively, of all proceeds deriving from the Program, and will be responsible for 40% and 60% of the Program's development costs, respectively. Following the completion of the Phase 1 stage, we may continue to fund our 40% share of the Program to maintain our right to proceeds or to opt-out (the "Opt-Out"). If we Opt-Out, then we and OPKO will retain 15% and 85%, respectively, of all proceeds deriving from the Program, while OPKO will be solely responsible for ongoing development and commercialization funding of the Program.

In connection with the execution of the 2025 Collaboration Agreement, we issued and sold to OPKO an aggregate of 3,685,226 Ordinary Shares for a purchase price of $8.0 million, the proceeds of which we have agreed to use solely to fund our development cost obligations under the 2025 Collaboration Agreement, subject to the expiration or termination of the agreement.

***A&R Collaboration Agreement***

In February 2026, we entered into the A&R Collaboration Agreement with OPKO which amends and restates the 2025 Collaboration Agreement to expand the scope of the agreement to include the collaboration with respect to the preclinical and clinical development of a daily LA-PTH for the treatment of hypoparathyroidism and other indications in addition to the original oral dual agonist GLP-1/glucagon peptide program. Development costs incurred by the parties with respect to the development of the LA-PTH program will be shared equally between the Company and OPKO.

***Oramed Patent Transfer Agreement***

In 2011, we entered into a patent transfer agreement with Oramed Ltd. ("Oramed"), which we refer to as the Patent Transfer Agreement, pursuant to which Oramed assigned to us all of its rights, title and interest in the patent rights Oramed licensed to us when we were originally 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 that involve the use of, or utilize, the patents underlying the Patent Transfer Agreement. 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 our 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. On March 27, 2025, we entered into a Novation Agreement with Oramed, and Oramed NewCo Inc. ("Oramed NewCo") pursuant to which Oramed NewCo replaced Oramed as a party to the Patent Transfer Agreement. Under the Novation Agreement, Oramed NewCo assumed all of Oramed's rights and obligations under the Patent Transfer Agreement accruing on or after the effective date, Oramed was released from any obligations and liabilities owed to us under the Patent Transfer Agreement accruing or arising after such date, and we were released from any obligations and liabilities owed to Oramed accruing or arising after such date. All other provisions of the Patent Transfer Agreement remain in full force and effect.

***Israeli Innovation Authority Grants***

We have received grants of approximately $0.5 million from the IIA to partially fund our PTH research and development for Osteoporosis. The grants are subject to certain requirements and restrictions under 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. 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 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-related 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 (plus interest on the entire increased amount). 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 collaboration agreement. Prior to its termination, we had been required to pay to the IIA 5.38% of each payment made to us under such collaboration agreement with an ultimately liability of up to 600% of the grant received plus interest. As of December 31, 2025, we had paid royalties to the IIA in the amount of $96 thousand.

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.

**Recent Developments Potentially Affecting Our Business**

***Israel-Hamas War and Regional Conflicts***

In October 2023, Israel was attacked by Hamas, a terrorist organization and entered a state of war. Since the commencement of these events, there have been additional active hostilities, including with Hezbollah in Lebanon, the Houthi movement which controls parts of Yemen, and with Iran. In response to ongoing Iranian aggression and support of proxy attacks against Israel, on June 12, 2025, Israel conducted a series of preemptive defensive air strikes in Iran targeting Iran's nuclear program and military commanders. On June 21, 2025, U.S. President Donald Trump announced that the United States had conducted air strikes against three nuclear sites within Iran. On October 9, 2025, a ceasefire had been reached. Israel, Hamas, the United States and other countries in the region agreed to a framework for a ceasefire in Gaza between Israel and Hamas. On February 28, 2026, United States and Israel conducted preemptive strikes targeting Iranian military infrastructure. Iran retaliated with extensive ballistic missile and drone attacks against Israel. On March 2, 2026, Hezbollah resumed hostilities by launching projectiles into northern Israel, ending the November 2024 ceasefire. Israel responded with airstrikes on Lebanon and ground operations in Southern Lebanon, marking a significant escalation in the regional conflict. How long and how severe the current conflicts in Gaza, Northern Israel, Lebanon, Iran or the broader region become is unknown at this time and any continued clash among Israel, Hamas, Hezbollah, Iran or other countries or militant groups in the region may escalate in the future into a greater regional conflict. The Company's research personnel and some management personnel are located in Israel, however other core activities including clinical, regulatory and supply chain are located outside of Israel.

Currently, such activities in Israel remain largely unaffected. During the years ended December 31, 2025 and December 31, 2024, the impact of this war on the Company's results of operations and financial condition was immaterial. See Item 1.A. "Risk Factors—Risks Relating to Our Incorporation and Location in Israel—Security, political and economic instability in the Middle East may harm our business."

**Financial Overview**

We are primarily engaged in research and development activities, and we have not derived significant income from our activities. Since our inception, we have raised a total of $111.6 million from a combination of public and private equity offerings, IIA grants and the exercise of options and warrants. Since inception, we have incurred significant losses. For the years ended December 31, 2025 and 2024, our operating losses were $11.5 million and $9.6 million, respectively, and we expect to continue to incur significant expenses and losses for the foreseeable future. As of December 31, 2025, we had an accumulated deficit of $125.4 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 our collaborations agreements. Our recurring losses from operations, negative cash flows and lack of liquidity raise 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, 2025, expressing the existence of substantial doubt about our ability to continue as a going concern. The audited consolidated financial statements included in this Annual Report 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 programs or otherwise curtail or cease operations. See "Item 1A—Risk Factors-Risks Related to Our Financial Position and Need for Additional Capital."

As of December 31, 2025, we had cash and cash equivalents of $14.9 million, of which $7.8 million has been designated to fund the collaboration activity with OPKO under the A&R Collaboration Agreement. As of March 23, 2026 we had cash and cash equivalents of $12.6 million, of which $7.8 million has been designated to fund the collaboration activity with OPKO under the A&R Collaboration Agreement. Given our current cash position and plans, we believe that our existing cash resources will be sufficient to meet our projected operating requirements through the middle of the third quarter of 2026, excluding the Phase 3 study of EB613 in osteoporosis. Our ability to commence the Phase 3 study of EB613 in osteoporosis 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 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 financing, 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.

***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.

***Research and Development Expenses***

Research and development expenses consist of costs incurred for the development of our N-Tab® platform and our product candidates. We expense both internal and external research and development expenses to operations for the periods in which they are incurred. We mapped the majority of external research and development costs incurred for our product candidates and development programs.

Internal and certain general external research and development expenses that support multiple programs include:

- employee-related expenses, including salaries, bonuses and share-based compensation expenses for employees and service providers in the research and development function;
- costs associated with our research and development platform used across programs, process development, manufacturing, consulting fees and preclinical development for earlier stage programs and new technologies;
- expenses incurred in operating our laboratories including our small-scale manufacturing facility; and
- depreciation of research and development equipment, allocated overhead, rent and facilities-related expenses.

External research and development expenses for our main clinical development programs include:

- expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials;
- other costs associated with pre-clinical and clinical activities;
- supply, development and manufacturing costs relating to clinical trial materials; and
- certain consulting and advisory services related to the program.

Research and development activities are our primary focus. 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 our clinical candidates into later stages of clinical development and invest in additional preclinical candidates.

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 enrolment of patients in clinical trials. For the years ended December 31, 2025 and 2024, our research and development expenses were $6.0 million and $4.5 million, respectively. Research and development expenses for the year ended December 31, 2025 were primarily for the development of EB613 and next-generation of EB613, EB612 and our collaboration with OPKO related to OXM. 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.

A change in the outcome of any of these variables with respect to the development of EB613, EB612, OXM or any other product candidate that we may develop could significantly change the costs and timing associated with the development of any such product candidate. For example, if the FDA or other regulatory authority were to require us to conduct preclinical or clinical studies beyond those that we currently anticipate will be required for the completion of clinical development, if we experience significant delays in enrolment 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.

Our research and development expenses for the years ended December 31, 2025 and 2024 are summarized as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| | (In thousands) | |
| External Expenses related to EB613 | $ 2,095 | $ 1,360 |
| Internal and External expenses related to OXM collaboration with OPKO | 437 | - |
| Internal and External expenses related to other development program: | | |
| Payroll and related expenses | 1,597 | 1,473 |
| Share-based compensation | 1,143 | 840 |
| Rent and related expenses | 398 | 340 |
| Other development expenses | 334 | 486 |
| Research and development expenses, net | 6,004 | 4,499 |

***General and Administrative Expenses***

General and administrative expenses consist principally of salaries and related expenses, 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, accounting and investor relations services, costs associated with maintaining and prosecuting our intellectual property portfolio 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 Income, Net***

Financial income, net is 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.

***Taxes on Income***

We have not generated taxable income since our inception. As of December 31, 2025, we had carry-forward tax losses of $91.8 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 U.S. tax laws. As of December 31, 2025, Entera Bio Inc. had tax loss carry-forwards of $0.2 million.

**Results of Operations**

***Comparison of Years Ended December 31, 2025 and 2024***

| | Year Ended December 31, | | Increase (Decrease) | |
|---|---|---|---|---|
| | 2025 | 2024 | $ | % |
| | (In thousands, except for percentage information) | | | |
| Revenues | $ 42 | $ 181 | $ (139) | (77)% |
| Cost of revenues | $ 42 | $ 172 | $ (130) | (76)% |
| Operating expenses: | | | | |
| Research and development expenses | $ 6,004 | $ 4,499 | $ 1,505 | 33% |
| General and administrative expenses | $ 5,525 | $ 5,095 | $ 430 | 8% |
| Operating loss | $ 11,529 | $ 9,585 | $ 1,944 | 20% |
| Financial income, net | $ (90) | $ (58) | $ (32) | 55% |
| Income tax expenses | $ - | $ 14 | $ (14) | (100)% |
| Net loss | $ 11,439 | $ 9,541 | $ 1,898 | 20% |

***Revenue***

Revenues for the year ended December 31, 2025 and 2024 were $42 thousand and $181 thousand, respectively, which were attributable to research services we provided pursuant to a research services agreement with an external party. The Company completed the first stage of its obligations under the research services agreement in the first quarter of 2025.

***Cost of Revenues***

Cost of revenues for the year ended December 31, 2025 and 2024 was $42 thousand and $172 thousand, respectively, which was attributable to research services we provided pursuant to a research services agreement with an external party.

***Research and Development Expenses***

Research and development expenses for the year ended December 31, 2025 were $6.0 million as compared to $4.5 million for year ended December 31, 2024. The increase of $1.5 million was primarily due to an increase of $0.7 million in other consulting fees, including regulatory fees required in connection with the filing of a type A meeting with the FDA and ongoing optimization processes related to the preparation of the EB613 phase 3 clinical program, an increase of $0.5 million in connection with our internal programs and collaboration programs, an increase of $0.4 million in compensation and an increase of $0.1 million in other expenses. The increase was partially offset by a decrease of $0.2 million in materials and production costs related to the preparation of the EB613 phase 3 program.

***General and Administrative Expenses***

General and administrative expenses for the year December 31, 2025 were $5.5 million as compared to $5.1 million for year ended December 31, 2024. The increase of $0.4 million was primarily due to an increase of $0.1 million of consultants fees and an increase of $0.3 million in compensation.

***Financial Income, Net***

Financial income, net for the year ended December 31, 2025 was $90 thousand compared to $58 thousand for the year ended December 31, 2024. Our financial income is composed mainly of interest income from bank deposits and exchange rate differences of certain currencies against our functional currency, which is the U.S. Dollar. Financial income, net increased predominantly due to increased interest income from our bank deposits.

**Liquidity and Capital Resources**

Since inception, we have incurred significant losses from operations and negative cash flows from operating activities. For the years ended December 31, 2025 and 2024, our operating losses were $11.5 million and $9.6 million, respectively. As of December 31, 2025, we had an accumulated deficit of $125.4 million. 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. These factors raise substantial doubt about our 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, 2025, expressing the existence of substantial doubt about our ability to continue as a going concern.

Since our inception and through December 31, 2025, we have raised a total of $111.6 million from a combination of public and private equity offerings, IIA grants and the exercise of options and warrants, including $36.4 million through at-the-market-offering ("ATM") programs.

As of December 31, 2025, we had cash and cash equivalents and restricted cash of $14.9 million, of which $7.8 million has been designated to fund our obligations under the A&R Collaboration Agreement. 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.

***Equity Offerings***

On September 2, 2022, we entered into a Sales Agreement with Leerink Partners LLC (f/k/a SVB Securities LLC), as sales agent, to implement an ATM program (the "Leerink ATM Program") under which we were originally able to sell up to 5,000,000 Ordinary Shares in an at-the-market offering registered under the Securities Act. 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, 2025, we had sold 4,940,156 Ordinary Shares under the Leerink ATM Program for aggregate proceeds of $9.8 million, net of issuance costs. We currently have the ability, but not the obligation, to sell up to an additional 30,000,000 Ordinary Shares under the Leerink ATM Program under our currently effective Registration Statement on Form S-3.

On 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.

As of December 31, 2025, we have received approximately $0.6 million of net proceeds from the exercise of outstanding Ordinary Share Warrants. If all Ordinary Share Warrants were exercised for cash, then the Company would receive additional proceeds of approximately $7.8 million. There can be no assurance that the holders of the Ordinary Share Warrants exercise their respective warrants for cash, or at all.

In connection with our entering into the 2025 Collaboration Agreement with OPKO, we issued to OPKO an aggregate of 3,685,226 Ordinary Shares for a purchase price of $8.0 million, representing a purchase price per share equal to approximately $2.17, which was the volume weighted average price per share for the 30 trading days immediately preceding the date of such agreement. We have agreed to use the proceeds from the issuance of such Ordinary Shares solely to fund our development cost obligations under the A&R Collaboration Agreement.

***Funding Requirements***

Given our current plans, we believe that our existing cash resources will be sufficient to support the Company's ongoing operations through the middle of the third quarter of 2026, excluding the initial of the Phase 3 program of EB613. Our

ability to commence the Phase 3 program of EB613 in osteoporosis 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. 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.

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 additional 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 our oral peptide programs, including EB613 for osteoporosis and EB612 for hypoparathyroidism or other oral peptides for obesity, metabolic disorders and gastrointestinal rare diseases 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 continuously evaluate various financing alternatives in the public or private equity markets or through license of our N-Tab® platform 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 Leerink 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 financing or collaborations, when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

***Cash Flows***

***Year Ended December 31, 2025 Compared to Year Ended December 31, 2024***

The following table sets forth the primary sources and uses of cash:

| | Year ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| | (in thousands) | |
| Net Cash used in operating activities | $ (7,370) | $ (6,818) |
| Net Cash used in investing activities | (107) | (3) |
| Net Cash provided by financing activities | 13,710 | 4,476 |
| Effect of Exchange Rate changes on cash and cash equivalents | 36 | - |
| Net decrease in cash and cash equivalents | $ 6,197 | $ (2,345) |

***Net Cash Used in Operating Activities***

Net Cash used in operating activities for the year ended December 31, 2025 was $7.4 million, consisting primarily of our operating loss of $11.5 million, which was partially offset by approximately $2.8 million of share-based compensation and depreciation expenses and a decrease of $1.3 million in changes in operating assets and liabilities and other expenses.

Net Cash used in operating activities for the year ended December 31, 2024, was $6.8 million, consisting primarily of our operating loss of $9.6 million, which was partially offset by approximately $2.6 million of share-based compensation and depreciation expenses and a decrease of $0.2 million in changes in operating assets and liabilities and other expenses.

The increase of $0.6 million in cash used in operating activities for the year ended December 31, 2025 compared to 2024 was mainly attributed to an increase of $1.9 million in our operating loss, a decrease of $1.1 million in changes in operating assets and liabilities and other expenses primarily due to payments to suppliers and services providers, which was partially offset by an increase of $0.2 million in share-based compensation and depreciation expenses.

***Net Cash Used in Investing Activities***

Net Cash used in investing activities for the years ended December 31, 2025 and December 31, 2024 consisted of purchase of property and equipment.

***Net Cash Provided by Financing Activities***

Net cash provided by financing activities for year ended December 31, 2025 consisted of the net proceeds of $6.1 million from the issuance of Ordinary Shares under the Leerink ATM Program, $0.5 million from the issuance of Ordinary Shares upon the exercise of warrants and $7.1 million from issuance of Ordinary Shares in connection with the entry into the 2025 Collaboration Agreement.

Net Cash provided by financing activities for the year ended December 31, 2024 consisted of net proceeds of $3.8 million from the issuance of Ordinary Shares under the Leerink ATM Program and $0.8 million from the issuance of Ordinary Shares upon the exercise of outstanding options and warrants.

***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, 2025, 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. 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.

**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, 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.

**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.

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

Not required for smaller reporting companies.

**Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**ENTERA BIO LTD.**

**CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF DECEMBER 31, 2025**

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of Entera Bio Ltd.

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of Entera Bio Ltd. and its subsidiary (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements 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 December 31, 2025 and 2024, and the results of its operations and its cash flows for 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 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 in regard to these matters are also described in Note 1c. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. This matter is also described in the "Critical Audit Matters" section of our report.

***Basis for Opinion***

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

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits 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.

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

***Critical Audit Matters***

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*The Company's ability to continue as a going concern*

As described above and in Note 1c to the consolidated financial statements, the Company has an accumulated deficit and cash outflows from operating activities. The Company's ability to continue its operations relies on securing the necessary funding to support its future research and clinical development activities. These conditions and events raise substantial doubt about the Company's ability to continue as a going concern.

The principal considerations for our determination that performing procedures related to the Company's ability to continue as a going concern is a critical audit matter are the estimation and execution uncertainty regarding the Company's future cash flows and management's judgments and assumptions in estimating these cash flows to conclude the Company would not have sufficient liquidity to fund its operations for at least one year from the date of issuance of the consolidated financial statements. This in turn led to a high degree of auditor subjectivity and judgment to evaluate the audit evidence supporting the liquidity conclusions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with our overall opinion on the consolidated financial statements. Our audit procedures to evaluate the significant judgments and assumptions made by management included, among others, inquiries with management, testing the reasonableness of the forecasted inflows and operating expenses and the underlying management assumptions. We assessed the adequacy of the Company's going concern disclosures included in Note 1c to the consolidated financial statements.

/s/Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

Tel-Aviv, Israel
March 27, 2026

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

**ENTERA BIO LTD.**
**CONSOLIDATED BALANCE SHEETS**
(U.S. dollars in thousands, except share data)

| | December 31 | |
|---|---|---|
| | **2025** | **2024** |
| **Assets** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | 7,108 | 8,660 |
| Accounts receivable | - | 126 |
| Restricted cash | 7,775 | - |
| Other current assets | 415 | 186 |
| **TOTAL CURRENT ASSETS** | 15,298 | 8,972 |
| **NON-CURRENT ASSETS:** | | |
| Property and equipment, net | 134 | 57 |
| Operating lease right-of-use assets | 465 | 275 |
| Restricted deposit | 90 | 80 |
| Funds in respect of employee rights upon retirement | 6 | 6 |
| **TOTAL NON-CURRENT ASSETS** | 695 | 418 |
| **TOTAL ASSETS** | 15,993 | 9,390 |
| **Liabilities and shareholders' equity** | | |
| **CURRENT LIABILITIES:** | | |
| Accounts payable | 448 | 132 |
| Accrued expenses and other payables | 1,525 | 874 |
| Current maturities of operating lease | 230 | 170 |
| **TOTAL CURRENT LIABILITIES** | 2,203 | 1,176 |
| **NON-CURRENT LIABILITIES**: | | |
| Operating lease liabilities | 260 | 102 |
| Other long-term liability | 393 | - |
| Liability for employee rights upon retirement | 36 | 32 |
| **TOTAL NON-CURRENT LIABILITIES** | 689 | 134 |
| **TOTAL LIABILITIES** | 2,892 | 1,310 |
| **COMMITMENTS AND CONTINGENCIES** | | |
| **SHAREHOLDERS' EQUITY:** | | |
| Ordinary Shares, NIS 0.0000769 par value: Authorized - as of December 31, 2025 and December 31, 2024, 140,010,000 shares; issued and outstanding as of December 31, 2025, and December 31, 2024, 46,178,630 and 38,837,220 shares, respectively | 1 | 1 |
| Additional paid-in capital | 138,425 | 121,965 |
| Accumulated other comprehensive income | 41 | 41 |
| Accumulated deficit | (125,366) | (113,927) |
| **TOTAL SHAREHOLDERS' EQUITY** | 13,101 | 8,080 |
| **TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY** | 15,993 | 9,390 |

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

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

| | Year ended December 31 | |
|---|---|---|
| | **2025** | **2024** |
| **REVENUES** | 42 | 181 |
| **COST OF REVENUES** | 42 | 172 |
| **GROSS PROFIT** | - | 9 |
| **OPERATING EXPENSES:** | | |
| Research and development, net | 6,004 | 4,499 |
| General and administrative | 5,525 | 5,095 |
| **TOTAL OPERATING EXPENSES** | 11,529 | 9,594 |
| **OPERATING LOSS** | 11,529 | 9,585 |
| **FINANCIAL INCOME, NET** | (90) | (58) |
| **LOSS BEFORE INCOME TAX** | 11,439 | 9,527 |
| **INCOME TAX EXPENSES** | - | 14 |
| **NET LOSS** | 11,439 | 9,541 |
| **LOSS PER SHARE BASIC AND DILUTED** | 0.25 | 0.25 |
| **WEIGHTED-AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE** | 46,191,067 | 37,650,179 |

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

**ENTERA BIO LTD.**
**CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY**
(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 | Accumulated deficit | Total |
| **BALANCE AT JANUARY 1, 2024** | 35,476,341 | 1 | 114,730 | 41 | (104,386) | 10,386 |
| Net loss | - | - | - | - | (9,541) | (9,541) |
| Exercise of warrants to ordinary shares | 89,820 | * | 90 | - | - | 90 |
| Exercise of options to ordinary shares | 733,704 | * | 749 | - | - | 749 |
| Issuance of ordinary shares under the ATM program, net of issuance costs | 2,236,126 | * | 3,840 | - | - | 3,840 |
| Vested restricted share units | 301,229 | * | (*) | - | - | - |
| Share-based compensation | - | - | 2,556 | - | - | 2,556 |
| **BALANCE AT DECEMBER 31, 2024** | 38,837,220 | 1 | 121,965 | 41 | (113,927) | 8,080 |
| Net loss | - | - | - | - | (11,439) | (11,439) |
| Exercise of warrants to ordinary shares | 546,028 | * | 508 | - | - | 508 |
| Exercise of options to ordinary shares | 26,448 | * | 20 | - | - | 20 |
| Issuance of ordinary shares under the ATM program, net of issuance costs | 2,731,574 | * | 6,067 | - | - | 6,067 |
| Issuance of ordinary shares under collaboration agreement, net | 3,685,226 | * | 7,115 | - | - | 7,115 |
| Vested restricted share units | 352,134 | * | (*) | - | - | - |
| Share-based compensation | - | - | 2,750 | - | - | 2,750 |
| **BALANCE AT DECEMBER 31, 2025** | 46,178,630 | 1 | 138,425 | 41 | (125,366) | 13,101 |

* Represents an amount less than one thousand U.S. dollars.

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

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

| | Year ended December 31 | |
|---|---|---|
| | **2025** | **2024** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net loss | (11,439) | (9,541) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 30 | 46 |
| Deferred income taxes | | 14 |
| Share-based compensation | 2,750 | 2,556 |
| Finance income, net | 32 | (5) |
| Changes in operating assets and liabilities: | | |
| Decrease (increase) in accounts receivable | 126 | (126) |
| Increase in other current assets | (229) | (14) |
| Increase in accounts payable | 316 | 49 |
| Increase in accrued expenses and other payables and other long-term liability | 1,044 | 203 |
| Net cash used in operating activities | (7,370) | (6,818) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Purchase of property and equipment | (107) | (3) |
| Net cash used in investing activities | (107) | (3) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Proceeds from ordinary issuance of shares through ATM programs | 6,254 | 3,960 |
| Issuance of ordinary shares, under collaboration agreement | 7,190 | - |
| Issuance costs | (262) | (323) |
| Exercise of warrants into ordinary shares | 508 | 90 |
| Exercise of options into ordinary shares | 20 | 749 |
| Net cash provided by financing activities | 13,710 | 4,476 |
| **EFFECT OF EXCHANGE RATE CHANGE ON CASH AND CASH EQUIVALENTS** | 36 | - |
| **INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS** | 6,197 | (2,345) |
| **CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS AT BEGINNING OF THE YEAR** | 8,740 | 11,085 |
| **CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS AT END OF THE YEAR** | 14,973 | 8,740 |
| **Reconciliation in amounts on consolidated balance sheets:** | | |
| Cash and cash equivalents | 7,108 | 8,660 |
| Restricted cash | 7,775 | - |
| Restricted deposit | 90 | 80 |
| Total cash and cash equivalents, restricted cash and restricted deposit | 14,973 | 8,740 |
| **SUPPLEMENTAL DISCLOSURE OF CASH FLOW TRANSACTIONS:** | | |
| Interest received | 180 | 68 |
| **SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:** | | |
| Operating lease right of use assets obtained in exchange for operating lease liabilities | 386 | 32 |

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

## NOTE 1 - DESCRIPTION OF BUSINESS

a) Entera Bio Ltd. (collectively with its subsidiary, the "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., 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 protein therapy has the potential to significantly shift a treatment paradigm.

The Company's 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 low bone mineral density ("BMD") and high-risk osteoporosis without prior fracture. The Company is also developing a next-generation formulation of EB613 utilizing its proprietary N-Tab® platform, which is expected to provide significant advantages in administration, commercialization, and strategic partnering. The Company is preparing to submit final protocol to the FDA and initiate a Phase 3 registrational study for EB613 pursuant to the FDA's qualification of a quantitative BMD endpoint.

The Company's product candidate, EB612, is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for hypoparathyroidism. In February 2026, the Company amended and restated the 2025 Collaboration Agreement (as defined in Note 5) with OPKO Biologics, Inc., a subsidiary of OPKO Health, Inc. ("OPKO"), to advance the first oral long-acting PTH analog ("LA-PTH") as a once-daily tablet for patients with hypoparathyroidism.

In addition, EB618 is being developed pursuant to the Company's collaboration with OPKO, pursuant to which the companies are advancing a proprietary novel dual agonist GLP-1/glucagon peptide as a once-daily tablet treatment and as a weekly subcutaneous injection for patients with obesity, metabolic and fibrotic disorders. The oral program combines OPKO's proprietary long-acting oxyntomodulin ("OXM") analog (OPK-88006) and the Company's proprietary N-Tab® platform.

In addition to its internal product development programs, the Company intends to license its proprietary N-Tab® platform 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 listed on the Nasdaq Capital Market under the symbol "ENTX".

c) Because the Company is engaged in research and development activities, it has not derived significant income from its activities and has incurred negative cash flows from operating activities. The Company has incurred an accumulated deficit in the amount of $125.4 million as of December 31, 2025.

The Company's management is of the opinion that its available funds as of December 31, 2025 will be sufficient to support the Company's ongoing operations under its current plans through the middle of the third quarter of 2026.

The Company's current capital resources do not include the capital required to fund the Company's proposed Phase 3 program for EB613 in osteoporosis. These factors raise substantial doubt as to the Company's ability to continue as a going concern. Management continually evaluates various financing alternatives and strategic collaborations, as the Company will need to finance future research and clinical development with additional capital. However, there is no certainty that the Company will be able to obtain such funding. These consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

**NOTE 1 - DESCRIPTION OF BUSINESS (continued)**

d) In October 2023, Israel was attacked by Hamas, a terrorist organization and entered a state of war. Since the commencement of these events, there have been additional active hostilities, including with Hezbollah in Lebanon, the Houthi movement which controls parts of Yemen, and Iran. In response to ongoing Iranian aggression and support of proxy attacks against Israel, on June 12, 2025, Israel conducted a series of preemptive defensive air strikes in Iran targeting Iran's nuclear program and military commanders. On June 21, 2025, U.S. President Donald Trump announced that the United States had conducted air strikes against three nuclear sites within Iran. On October 9, 2025, a ceasefire had been reached. Israel, Hamas, the United States and other countries in the region agreed to a framework for a ceasefire in Gaza between Israel and Hamas. On February 28, 2026, the United States and Israel conducted preemptive strikes targeting Iranian military infrastructure. Iran retaliated with extensive ballistic missile and drone attacks against Israel. On March 2, 2026, Hezbollah resumed hostilities by launching projectiles into northern Israel, ending the November 2024 ceasefire. Israel responded with airstrikes on Lebanon and ground operations in Southern Lebanon, marking a significant escalation in the regional conflict. How long and how severe the current conflicts in Gaza, Northern Israel, Lebanon, Iran or the broader region become is unknown at this time and any continued clash among Israel, Hamas, Hezbollah, Iran or other countries or militant groups in the region may escalate in the future into a greater regional conflict. The Company's research personnel and certain management personnel are located in Israel, however other core activities including clinical, regulatory and supply chain are located outside of Israel.

Currently, the Company's activities in Israel remain largely unaffected by the foregoing events. During the years ended December 31, 2025 and December 31, 2024, the impact of such events on the Company's results of operations and financial condition was immaterial.

**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").

**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 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 Company 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, net, as appropriate.

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

**d. Principles of consolidation**

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.

**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 1-4% for the years ended December 31, 2025 and 2024. Bank deposits with maturity of more than one year are considered long-term.

**g. Restricted cash and deposits**

Restricted deposits are placed in an interest-bearing savings account and serve as security for the Company's office rent and credit card obligations. Restricted cash is designated specifically to fund the development costs under the 2025 Collaboration Agreement.

**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 and restricted cash. 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 with respect to its cash and cash equivalent deposits and restricted cash at its current financial institutions, 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.

**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.

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

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

**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 had been payable at each balance sheet date on an undiscounted basis.

For periods prior to December 2013, the liability 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.

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's 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").

The amounts of severance payment expenses were $181 and $144 for the years ended December 31, 2025 and 2024, respectively.

The Company expects to contribute to insurance companies approximately $181 for the year ending December 31, 2026 in connection with its expected severance liabilities for that year.

**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.

**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:

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

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

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.

**m. Share-based compensation**

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

The Company classifies Share-Based Compensation as equity awards and accounts for such compensation using grant-date fair value. The Company recognizes the value of the Share-Based Compensation awards as an expense over the requisite service period.

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.

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.

**n. 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 development are expensed as incurred.

**o. Revenue recognition**

The Company recognizes revenues according to ASC 606, "Revenues from Contracts with Customers".

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.

Revenues attributed to the research services agreement are recognized over the duration of the research services agreement.

**p. Collaborative Arrangement**

The Company records the elements of a collaboration agreement that represent joint operating activities in accordance with ASC 808, *Collaborative Arrangements* ("ASC 808"). Accordingly, the elements of a collaboration agreement that represent activities in which both parties are active participants, and to which both parties are exposed to the significant risks and rewards that are dependent on the commercial success of the collaborative activities, are recorded as a collaborative arrangement. Generally, the classification of a transaction under a collaborative arrangement is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. See Note 5b.

**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 for the period, divided by the weighted average number of outstanding ordinary shares, vested RSUs and pre-funded warrants during the period.

Diluted loss per share is based upon the weighted average number of ordinary shares and ordinary share equivalents outstanding when dilutive. Ordinary share equivalents include outstanding stock options, warrants and RSUs, which are included under the treasury stock method when dilutive. The calculation of diluted loss per share does not include options, warrants and RSUs exercisable into 17,351,501 ordinary shares and 16,790,842 ordinary shares for the years ended December 31, 2025 and 2024, 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.

**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. To determine whether the freestanding equity instrument qualifies for classification within equity, the Company also considers the equity classification conditions in accordance with ASC 815-40. 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 adopted accounting pronouncements***

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 U.S. and in foreign jurisdictions. ASU 2023-09 became effective for fiscal years beginning after December 15, 2024 and may be applied either retrospectively or prospectively, at the Company's discretion. The Company adopted this standard retrospectively. See Note 9.

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

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

***Recently issued accounting pronouncements, not yet adopted***

In November 2024, the FASB issued ASU 2024-03 "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses", which requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted, and may be applied either prospectively or retrospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

In December 2025, the FASB issued ASU 2025-10 "Government Grants (Topic 832)" to establish authoritative guidance on the accounting for government grants received by business entities. This update is effective beginning with the Company's 2029 fiscal year annual reporting period, with early adoption permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its 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 $196 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 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, 2025, the Company provided bank guarantees of approximately $60, 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 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 $44.

The lease cost was as follows:

| | Year ended December 31, 2025 | Year ended December 31, 2024 |
|---|---|---|
| Operating lease cost ..... | 240 | 198 |

Supplemental cash flow information related to leases was as follows:

| | Year ended December 31, 2025 | Year ended December 31, 2024 |
|---|---|---|
| Operating cash flows from operating leases..... | 240 | 198 |

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

**NOTE 3 - OPERATING LEASES** (continued)

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

| | December 31, 2025 | December 31, 2024 |
|---|---|---|
| **Operating Leases** | | |
| Operating lease right-of-use assets | 465 | 275 |
| Current lease liabilities | 230 | 170 |
| Non-current lease liabilities | 260 | 102 |
| **Total lease liabilities** | 490 | 272 |
| Weighted-average remaining lease term (in years) | 2.43 | 1.54 |
| Weighted-average discount rate | 14% | 14% |

As of December 31, 2025, the maturity of lease liabilities under our non-cancelable operating leases were as follows:

| | |
|---|---|
| 2026 | 238 |
| 2027 | 222 |
| 2028 | 107 |
| Total future minimum lease payments | 567 |
| Less: interest | (77) |
| Present value of operating lease liabilities | 490 |

**NOTE 4 - COMMITMENTS AND CONTINGENCIES**

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

The Company is committed to pay royalties to the Israel Innovation Authority (the "IIA") on proceeds from sales of products for which the government provided grants with respect to the research and development of the PTH for osteoporosis. 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 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 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.

As of December 31, 2025, the total royalty amount that would be payable by the Company to the IIA, before interest and potential increases as described above, was approximately $460. These grants were allocated to research and development in prior periods.

Following the signing of a former collaboration agreement in 2018, the IIA determined that the Company was required to pay 5.38% of each payment received by the Company from the counterparty under such agreement in an amount up to six times the grant received. As of December 31, 2025, the Company had paid a total of $96 to the IIA.

**NOTE 4 - COMMITMENTS AND CONTINGENCIES** (continued)

b. On June 1, 2010, D.N.A. Biomedical Solutions Ltd. ("D.N.A.") and Oramed Ltd., ("Oramed") entered into a joint venture agreement for the establishment of Entera Bio Ltd. According to such 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.

On February 22, 2011, Oramed and the Company entered into a patent transfer agreement, which 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).

**NOTE 5 - COLLABORATION AND RESEARCH AGREEMENTS**

a. In April 2024, the Company entered into a material transfer and research project agreement with a third party. According to the agreement, the third party will pay the Company a monthly payment for certain research services, as well as reimbursement for external expenses based on an agreed budget. During the first quarter of 2025, the Company completed the first stage of the research services under this agreement.

For years ended December 31, 2025 and 2024, the Company recognized revenues of $42 and $181 , respectively, from this agreement.

b. On March 16, 2025, the Company entered into a collaboration and license agreement (the "2025 Collaboration Agreement") with OPKO and its wholly owned subsidiary, OPKO Biologics Ltd., to collaborate with respect to the preclinical and clinical development and decision making related to the oral delivery of a dual agonist GLP-1/glucagon peptide in an oral dosage form using the Company's N-Tab® platform for the treatment of obesity, metabolic and fibrotic disorders in humans (the "Program"). The Program combines OPKO's proprietary long-acting oxyntomodulin (OXM, dual targeted GLP-1/Glucagon agonist, OPK-88006) analog and the Company's proprietary N-Tab® platform.

Under the 2025 Collaboration Agreement, the Company granted to OPKO an exclusive, sublicensable and non-transferable, worldwide license to certain of the Company's intellectual property and technology solely to develop, manufacture, and commercialize any GLP-1/glucagon dual agonist as an oral treatment form for the treatment of obesity, metabolic, cardiovascular, and fibrotic disorders in humans, and OPKO granted to the Company a non-exclusive, non-sublicensable and non-transferable license to certain of OPKO's intellectual property and technology to the extent necessary for the Company to perform its obligations in relation to the Program, in each case subject to the exceptions contained therein.

Under the terms of the 2025 Collaboration Agreement, the Company and OPKO will retain 40% and 60%, respectively, of all proceeds deriving from the Program, and will be responsible for 40% and 60% of the Program's development costs, respectively. Following the completion of the Phase 1 stage, the Company may continue to fund its 40% share of the Program to maintain its right to proceeds or to opt-out (the "Opt-Out"). If the Company exercises the Opt-Out, then the Company and OPKO will retain 15% and 85%, respectively, of all proceeds deriving from the Program, while OPKO will be solely responsible for ongoing development and commercialization funding of the Program.

In connection with the execution of the 2025 Collaboration Agreement, the Company issued and sold to OPKO an aggregate of 3,685,226 ordinary shares for a total purchase price of $8.0 million, representing a purchase price per share equal to approximately $2.17, which was the volume weighted average price per share for the 30 trading days immediately preceding the date of the 2025 Collaboration Agreement.

OPKO has agreed to a customary lockup with respect to such shares, and may not sell or otherwise transfer them for a period of 12 months following the date of the 2025 Collaboration Agreement, and OPKO has additionally agreed to a customary "standstill" provision, pursuant to which, for a 24-month period following the date of the 2025 Collaboration Agreement, OPKO may not acquire additional equity in the Company or otherwise take certain other actions, in each case without the Company's consent.

**NOTE 5 - COLLABORATION AND RESEARCH AGREEMENTS (Cont.)**

The Company has agreed to use the proceeds from the sale of the foregoing ordinary shares solely to fund its development cost obligations under the 2025 Collaboration Agreement, and has entered into an escrow arrangement, together with OPKO and an escrow agent, into which such proceeds in an amount of $8,000 have been deposited. Such proceeds are presented under restricted cash in the consolidated balance sheet, and disbursed to fund such development costs. If the 2025 Collaboration Agreement expires or is terminated for any reason, any funds remaining in such escrow will be disbursed to the Company.

The Company determined that the agreement is a collaboration arrangement under the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. The consideration received was allocated to the collaboration component and the equity component.

The Company recognized as equity the fair value of the ordinary shares issued to OPKO net of issuance costs (issuance costs of $75) based on the fair value of the ordinary shares, which was the Nasdaq closing share price as of the date of the 2025 Collaboration Agreement. The remaining consideration was allocated to the agreement and presented under current other payables (an amount of $295) and Other long-term liabilities (an amount of $515) in the balance sheet and will be recognized as the program is performed.

For the year ended December 31, 2025, the Company recognized net expenses of $437 relating to the 2025 Collaboration Agreement.

See Note 11 for a discussion of the A&R Collaboration Agreement.

**NOTE 6 - SHARE CAPITAL**

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

Each ordinary share is entitled to one vote. The holder of an ordinary share 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. On September 2, 2022, the Company entered into a sales agreement with Leerink Partners LLC (formerly known as SVB Securities LLC), as sales agent, to implement an ATM program under which the Company had originally been able from time to time offer and sell up to 5,000,000 ordinary shares (the "Leerink ATM Program").

On January 10, 2025, the Company filed Supplement No. 1 to the prospectus supplement relating to the Leerink ATM Program, which provides the Company with the ability to sell up to an additional 30,000,000 ordinary shares under the Leerink ATM Program. In June 2025, following the filing a new Registration Statement on Form S-3 to replace the Company's prior expiring Registration Statement on Form S-3, the Company filed a new prospectus supplement that provides the Company with the ability, but not the obligation, to continue to sell up to 30,000,000 ordinary shares under the Leerink ATM Program.

During the year ended December 31, 2025, the Company issued an aggregate of 2,731,574 ordinary shares pursuant to the Leerink ATM Program for net proceeds of $6,067 at a weighted average price of $2.29 per ordinary share.

**NOTE 6 - SHARE CAPITAL** (continued)

As of December 31, 2025, approximately $29.95 million of ordinary shares remained available for sale under the Leerink ATM Program.

b. On January 15, 2025, the Company issued 40,993 ordinary shares to five non-executive members of the board of directors in lieu cash board fees for the fourth quarter of 2024, which was approved by the Company's shareholders at a meeting of the Company's shareholders held on July 31, 2024.

c. In March 2025, in connection with the execution the 2025 Collaboration Agreement with OPKO, the Company issued and sold to OPKO an aggregate of 3,685,226 ordinary shares for a total purchase price of $8.0 million, representing a purchase price per share equal to approximately $2.17, which was the volume weighted average price per share for the 30 trading days immediately preceding the date of the 2025 Collaboration Agreement. For additional information, see Note 5b.

d. During year ended December 31, 2025, 546,028 warrants were exercised for an aggregate of 546,028 ordinary shares for a total consideration of $508.

e. During the year ended December 31, 2025, two employees exercised options for an aggregate of 26,448 ordinary shares for total consideration of $20.

**NOTE 7 - 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"), RSUs, restricted share awards and performance-based awards, that are 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"), RSUs, 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.

The 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, 2025, 2,052,375 ordinary shares remained available for future grants under the 2018 Plan.

On January 1, 2026, the Company's Board of Directors approved an increase of 2,308,931 ordinary shares that may be issued under the Company's 2018 Plan pursuant of the evergreen provision contained in f the 2018 Plan.

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

**NOTE 7 - SHARE-BASED COMPENSATION** (continued)

**2)** Options grants to employees, directors and consultants:

a) The following tables summarizes information concerning outstanding and exercisable options as of December 31, 2025, in terms of ordinary shares for which the options may be exercised:

| | 2025 | |
|---|---|---|
| | **Number of options** | **Weighted average exercise price** |
| Outstanding at beginning of the year | 7,652,654 | $ 2.32 |
| Granted | 1,926,545 | 2.28 |
| Exercised | (26,449) | 0.80 |
| Forfeited | (170,250) | 2.07 |
| Expired | (99,228) | 2.91 |
| Outstanding at end of the year | 9,283,272 | $ 2.32 |
| Exercisable at end of the year | 6,294,226 | $ 2.47 |

1. As of December 31, 2025, the weighted-average remaining contractual life of exercisable options was 6.82 years.

2. The total intrinsic value of options exercised during 2025 and 2024 was approximately $35 thousand and $651 thousand, respectively.

3. As of December 31, 2025, the Company had 2,989,046 unvested options outstanding. The total unrecognized compensation cost of employee options as of December 31, 2025 is $1,735 thousand which is expected to be recognized over a weighted average period of 0.9 years.

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

| | 2025 | 2024 |
|---|---|---|
| Exercise price | $ 2.28 | $ 0.60-$1.99 |
| share price | $ 2.28 | $ 0.60-$1.99 |
| Dividend yield | - | - |
| Expected volatility | 81.2%-82.2% | 74.28%-84.5% |
| Risk-free interest rate | 3.9%-4.45% | 3.93%-4.66% |
| Expected life - in years | 5.3-5.87 | 5.3-5.9 |

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

**NOTE 7 - SHARE-BASED COMPENSATION** (continued)

The total fair value of options granted during the year ended December 31, 2025 and 2024 was $2,943 and $2,059, respectively.

| December 31, 2025 | | | | |
|---|---|---|---|---|
| Options outstanding | | | Options exercisable | |
| Exercise prices per share (USD) | Number of options outstanding at end of Year | Weighted Average Remaining Contractual Life | Number of options exercisable at end of year | Weighted Average Remaining contractual Life |
| 0.6-0.89 | 2,103,342 | 7.45 | 1,669,422 | 7.80 |
| 1.4-1.99 | 1,913,000 | 7.75 | 1,189,000 | 7.58 |
| 2.02-2.86 | 3,719,828 | 7.49 | 1,957,452 | 6.01 |
| 3.15-3.97 | 736,552 | 4.63 | 667,802 | 4.56 |
| 6.31 | 810,550 | 1.95 | 810,550 | 1.95 |
| | 9,283,272 | | 6,294,226 | |

The aggregate intrinsic value of the outstanding and exercisable options as of December 31, 2025 was $3,121 and $3,632, respectively.

a) Restricted shares units grants to employees and consultants:

The following tables summarize information concerning RSUs as of December 31, 2025:

| | Year ended December 31 2025 | |
|---|---|---|
| | Number of RSUs | Weighted Average Grant Date Fair Value |
| Outstanding at beginning of year | 194,472 | 1.75 |
| Changes during the year: | | |
| Granted | 300,643 | 2.09 |
| Vested | (352,134) | 1.92 |
| Outstanding at end of year | 142,981 | 2.06 |

As of December 31, 2025, the Company had 142,981 unvested RSUs. The total unrecognized compensation cost of employee RSUs as of December 31, 2025 was $57, which is expected to be recognized over a weighted average period of 0.33 years.

The total vesting-date value of equity classified RSUs that vested during 2025 was $676.

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

| | Year ended December 31, 2025 | Year ended December 31, 2024 |
|---|---|---|
| Cost of revenues | $ - | $ 7 |
| Research and development expenses | 1,144 | 839 |
| General and administrative | 1,606 | 1,710 |
| | $ 2,750 | $ 2,556 |

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

## NOTE 8 - SEGMENT INFORMATION

a. The Company operates in Israel as a single operating segment. The Company's Chief Executive Officer is the chief operating decision marker (the "CODM"). The CODM makes decisions on resource allocation, assesses performance of the business and monitors budget versus actual results on a consolidated basis.

b. Segment information:

| | Year ended December 31 | |
|---|---|---|
| | 2025 | 2024 |
| Revenues | $ 42 | $ 181 |
| Less: | | |
| *Research and development, net:* | | |
| Sub-contractors and consulting expense (EB613) | $ 2,095 | $ 1,360 |
| Net expenses related to 2025 Collaboration Agreement | 437 | - |
| Payroll and related expenses | 1,597 | 1,473 |
| Share-based compensation | 1,143 | 840 |
| Rent and related expenses | 398 | 340 |
| Other development expenses* | 334 | 486 |
| Other segment expenses** | 5,477 | 5,223 |
| Segment net loss | $ 11,439 | $ 9,541 |

* Other development expenses include materials and productions and others.

** Other segment expenses include payroll and related expenses, share-based compensation, legal and audit and related fees and others.

c. Long lived assets are located in Israel.

## NOTE 9 - INCOME TAX

a) **Corporate tax rate**

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

ii. 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) **Losses for tax purposes carried forward to future years**

The balance of carryforward losses of Entera Bio Ltd. as of December 31, 2025 and 2024 was approximately $91.8 million and $83.5 million, respectively.

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

The balance of carryforward losses of Entera Bio Inc. as of December 31, 2025 and 2024 was each approximately $0.15 million.

c) **Tax assessments**

The Company and its subsidiary have tax assessments that are considered to be final through tax year 2020.

d) **Loss before income taxes is composed of the following:**

| | Year ended December 31 | |
|---|---|---|
| | 2025 | 2024 |
| Entera Bio Ltd.(domestic) | 11,436 | 9,479 |
| Entera Bio Inc.(foreign) | 3 | 48 |
| Total loss before taxes | 11,439 | 9,527 |

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

**NOTE 9 - INCOME TAX** (continued)

e) **Income tax expense:**

| | Year ended December 31 | |
|---|---|---|
| Current: | **2025** | **2024** |
| Subsidiary: (foreign) | - | - |
| Total current income tax | - | - |
| Deferred income taxes – subsidiary (foreign) | - | 14 |
| Total deferred income taxes | - | 14 |
| Total income tax expense | - | 14 |

f) **Deferred income taxes:**

| | December 31, | |
|---|---|---|
| Deferred tax assets: | **2025** | **2024** |
| Net operating loss carry forward | 21,114 | 19,208 |
| Research and development | 1,027 | 854 |
| Share-based compensation | 687 | 639 |
| Other | 133 | 172 |
| Net deferred tax assets before valuation allowance | 22,961 | 20,873 |
| Valuation allowance | (22,961) | (20,873) |
| Net deferred tax assets | - | - |

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 and in the United States, management believes it was more likely than not that the deferred tax assets will not be realized.

g) **Roll-forward of valuation allowance:**

| | |
|---|---|
| Balance at January 1, 2024 | **19,471** |
| Additions | 1,402 |
| Balance at January 1, 2025 | **20,873** |
| Additions | 2,088 |
| Balance at December 31, 2025 | **22,961** |

h) **Reconciliation of theoretical tax expenses to actual expenses:**

Following is a reconciliation of the theoretical provision for income tax, assuming all income is taxed at the statutory corporate tax rate applicable to Israeli corporations, and the actual tax on income:

| | Year Ended December 31, 2025 | | Year Ended December 31, 2024 | |
|---|---|---|---|---|
| | **$** | **%** | **$** | **%** |
| **Statutory corporate tax rate** | (2,630) | (23) | (2,202) | (23) |
| **Foreign tax effects** | | | | |
| United States | (1) | * | (3) | * |
| **Non-taxable or non-deductible items:** | | | | |
| Share-based compensation | 535 | (23) | 815 | (23) |
| Other | 8 | (23) | 2 | (23) |
| **Change in valuation allowance** | 2,088 | (23) | 1,402 | (23) |
| **Effective tax rate** | - | - | 14 | * |

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

## NOTE 10 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

**Balance sheets:**

| | December 31, | |
|---|---|---|
| **Other current assets:** | **2025** | **2024** |
| Prepaid expenses | 37 | 29 |
| Receivable in respect of collaborative arrangement (See Note 5b) | 219 | - |
| Other | 159 | 157 |
| | 415 | 186 |

| | December 31, | |
|---|---|---|
| **Accrued expenses and other payables:** | **2025** | **2024** |
| Employees and employees related | 264 | 161 |
| Provision for vacation | 168 | 178 |
| Accrued expenses | 726 | 535 |
| Other payables (See Note 5b) | 367 | - |
| | 1,525 | 874 |

## NOTE 11 - SUBSEQUENT EVENTS

a) On January 1, 2026, an aggregate of 167,525 options to purchase ordinary shares was granted to five non-executive board members with an exercise price of $1.94 per share. The options will vest over one year in four equal quarterly installments starting on January 1, 2026. This grant was approved by the shareholders of the Company on October 4, 2021.

b) On January 1, 2026, the Company issued 148,872 ordinary shares to five non-executive members of the board of directors in lieu cash board fees for fiscal year 2025, which was approved by the Company's shareholders at a meeting of the Company's shareholders held on July 31, 2024. The fair value of the ordinary shares on the grant date was $289 using the market price of the ordinary shares on the grant date.

c) On February 3, 2026, the Company and OPKO entered into an amended and restated collaboration and license agreement (the "A&R Collaboration Agreement"), which amends and restates the 2025 Collaboration Agreement to expand the scope of the agreement to include the collaboration with respect to the preclinical and clinical development of a daily LA-PTH tablets for the treatment of hypoparathyroidism and other indications in addition to the original oral dual agonist GLP-1/glucagon peptide program. Development costs incurred by the parties with respect to the development of the LA-PTH program will be shared equally between the Company and OPKO. Except for the forgoing, the material terms of the 2025 Collaboration Agreement remain unchanged and in full force and effect.

d) On February, 2026, two former non-executive board members exercised options for an aggregate of 216,666 ordinary shares for a total consideration of $130.

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

None.

## ITEM 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) as of December 31, 2025. Based on such evaluation, those officers concluded that our disclosure controls and procedures were effective as of December 31, 2025.

### 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 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, 2025 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, 2025.

### 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. OTHER INFORMATION

During the quarter ended December 31, 2025, 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. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

None.

## PART III

## 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 Toledano** | 49 | Chief Executive Officer, Director |
| **Gregory Burshtein** | 49 | Chief of Research and Development |
| **Dana Yaacov-Garbeli** | 42 | Chief Financial Officer |
| **Hillel Galitzer** | 47 | Chief Operating Officer |
| ***Non-Employee Directors*** | | |
| **Geno J. Germano**[(1)] | 65 | Director, Chairman of the Board of Directors |
| **Steven D. Rubin**[(1)(2)(3)] | 65 | Director, Chairman of the Audit Committee |
| **Sean Ellis**[(1)(3)(4)] | 51 | Director |
| **Haya Taitel**[(1)(2)(4)] | 63 | Director, Chairperson of the Nominating and Corporate Governance Committee |
| **Yonatan Malca**[(1)(2)(3)] | 59 | Director, Chairman of the Compensation 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 and Corporate Governance Committee.

***Executive Officers***

**Miranda Toledano** has served as the Company's Chief Executive Officer since July 2022 and as member of our Board of Directors since September 2018. Ms. Toledano has over 25 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, a stealth 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 tovecimig) and led strategic execution, including a $117 million China License Transaction and TRIGR's 2021 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). 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.

**Gregory Burshtein, PhD** has led research and development at the Company since he joined Entera in September 2012, as Director of Pharmaceutical R&D, and since May 2024, as our Chief of Research and Development. Dr. Burshtein is a leader in the field of oral delivery of peptides, has published in peer-reviewed journal articles and holds 25 issued patents and has 113 pending patent applications related to development, formulation, and delivery of oral large molecules. Dr. Burshtein holds over 20 years of experience in the field of drug delivery, pharmacology and biopharmaceutics, with a primary focus on the challenging area of oral delivery of therapeutic peptides. in this field. Dr. Burshtein obtained his Ph.D. in Pharmaceutical Sciences, MSc in Clinical Pharmacy, and B. Pharm degree from the Institute for Drug Research, Faculty of Medicine of the Hebrew University of Jerusalem.

**Dana Yaacov-Garbeli** has served as our Chief Financial Officer since June 2019. Ms. Yaacov-Garbeli has over 17 years of 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 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.

**Hillel Galitzer, PhD** has served as our Chief Operating Officer since February 2014, prior to which he served as a Director of Scientific Development from July 2010. Prior to joining Entera, 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. 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.

***Non-Employee Directors***

**Geno J. Germano** is a 35-year veteran of the pharmaceutical and life sciences industry with extensive experience in development and commercialization of a broad range of medicines across most therapeutic categories. Most recently, from August 2018 to June 2024, Mr. Germano served as President and Chief Executive Officer and a board member of Elucida Oncology, Inc., a biotechnology company. He previously served as President of Intrexon Corporation, or Intrexon, a leader in engineering and industrialization of biology, from June 2016 to March 2017. Prior to joining Intrexon, from 2014 to February 2016, Mr. Germano was Group President of the Global Innovative Pharma Business of Pfizer, where he led a growing global $14 billion business with market-leading medicines and an extensive portfolio of late-stage development candidates in several therapeutic areas. Mr. Germano was also Co-Chair of the Portfolio Strategy and Investment Committee at Pfizer from 2013 to February 2016. Previously, from 2009 through 2013, Mr. Germano served as President and General Manager of Pfizer's Specialty Care and Oncology business units where he led commercial, medical, and post proof-of-concept pipeline strategy and development across global markets. Additionally, Mr. Germano has served on the board of directors of Precision Biosciences, Inc., a clinical stage biotechnology company, since March 2020. In the past five years, Mr. Germano served on the boards of directors of Sage Therapeutics (from 2016 until the company was acquired in 2025), Orbital Therapeutics, a private pre-clinical stage biotechnology company (from March 2025 until the company was acquired in December 2025), Bioverativ Inc. (acquired by Sanofi S.A. in March 2018) and The Medicines Company (acquired by Novartis AG in January 2020). Mr. Germano received his B.S. in Pharmacy from Albany College of Pharmacy.

**Steven D. Rubin** has served as OPKO Health's Executive Vice President – Administration since May 2007 and as a director since February 2007. He has extensive experience as a practicing lawyer, and as general counsel and board member to multiple public companies. Mr. Rubin currently serves on the board of directors of the following companies: Niagen Bioscience, Inc. (Nasdaq: NAGE), a bioscience company developing NAD+ products to support cellular health; Cocrystal Pharma, Inc. (NASDAQ:COCP), a biotechnology company developing new treatments for viral diseases; Eloxx Pharmaceuticals (NASDAQ: ELOX), a biotechnology company engaged in ribosomal RNA targeted genetic therapies for rare diseases; and Red Violet, Inc., (NASDAQ: RDVT) a leading analytics and information solutions provider. Mr. Rubin previously served as the Senior Vice President, General Counsel and Secretary of IVAX from August 2001 until September 2006. Mr. Rubin previously served as a director of the following companies: Neovasc, Inc. (NASDAQ:NVCN), a company developing and marketing medical specialty vascular devices; Non-Invasive Monitoring Systems, Inc. (OTCBB:NIMU), a medical device company; Castle Brands, Inc. (NYSE:ROX), a developer and marketer of premium brand spirits; Kidville, Inc. (OTCBB:KVIL), an operator of large, upscale facilities, catering to newborns through five-year-old children and their families and offers a wide range of developmental classes for newborns to five-year-olds; VBI Vaccines Inc. (NASDAQ CM: VBIV), a commercial-stage biopharmaceutical company developing a next generation of vaccines; Dreams, Inc. (NYSE MKT: DRJ), a vertically integrated sports licensing and products company; Safestitch Medical, Inc. prior to its merger with TransEnterix, Inc.; and, PROLOR Biotech, Inc.; and Cognit, Inc. (NASDAQ:COGT), a data and analytics company providing cloud-based mission-critical information and performance marketing solutions. Mr. Rubin holds a B.A. degree from Tulane University and a Juris Doctor from University of Florida.

**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.

**Haya Taitel** has served as a member of our Board since June 2023. 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 Strategic Partnership and Portfolio Planning 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.

**Yonatan Malca** has served as a member of our Board since 2011. Mr. Malca currently serves as Chief Executive Officer and a director of NanoGohst Ltd. From 2009 to 2021, he served as Chief Executive Officer and a director of DNA Biomedical Solutions Ltd. (TASE: DNA). Mr. Malca also serves as a director of Jungo Connectivity Ltd. (TASE: JNGO) and Unicorn Technologies (TASE: UNCT), both Israeli public companies. 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.

**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 CEO is appointed by, and serves at the discretion of, our Board. All other executive officers are also appointed by our Board.

Under our Articles, the Board must consist of at least three and no more than ten persons. Currently, our Board consists of six directors. Our Board is divided into three classes, with staggered three-year terms with one class comes up for election each year. The Class I, Class II and Class III directors have terms expiring at our annual meeting of shareholders in 2027, 2028 and 2026, respectively. The members of the classes as of the date hereof are as follows:

- the Class I directors are Miranda Toledano and Yonatan Malca;
- the Class II director is Haya Taitel;
- the Class III directors are Steven D. Rubin, Geno J. Germano and 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 Chief Executive 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 ($10^{th}$) 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 ($10^{th}$) 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, 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. Each of our 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 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 we require one director with accounting and financial expertise. Our Board has determined that Mr. Sean Ellis, Mr. Steven D. Rubin and Mr. Yonatan Malca each have financial and accounting expertise as defined in the regulations promulgated under the Companies Law.

Other than with respect to our directors 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, 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.

**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: Geno J. Germano, Steven D. Rubin, Sean Ellis, Yonatan Malca, and 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 Relationships and Related Party Transactions, and Director Independence" contained in this Annual 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 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 as required by the rules and regulations of the SEC.

**Insider Trading Policy**

We have adopted an Insider Trading Policy which governs the purchase, sale and/or any other dispositions of our securities by the Company and its directors, officers and employees and is reasonably designed to promote compliance with insider trading laws, rules and regulations and applicable exchange listing standards. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report.

**Board Committees**

Our Board has established the following committees:

***Audit Committee***

*Composition*

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 Steven D. Rubin, 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 and additionally satisfies the heightened standards for audit committee service under 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 Steven D. Rubin is an audit committee financial expert.

*Roles, Responsibilities and Procedures*

Our Audit Committee 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; (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 (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*

We have a Compensation Committee, the members of which are Yonatan Malca, who also serves as chairman of the committee, Steven D. Rubin and Haya Taitel. Each member of our Compensation Committee is independent under Nasdaq rules.

*Roles, Responsibilities and 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, 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 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 then presented to, and approved by, the Company's shareholders for approval.

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

The compensation policy must furthermore consider additional factors, as follows: (a) the knowledge, skills, expertise and accomplishments of the relevant Office Holder; (b) the Office Holder's roles and responsibilities and prior compensation agreements with him or her; (c) the ratio between the terms offered and the average compensation of the other employees of the company, including those employed through manpower companies; (d) the impact of disparities

in salary upon work relationships in the company; (e) the possibility of reducing variable compensation at the discretion of the Board; (f) as to variable compensation, the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and (g) as to severance compensation, the period of service of the Office Holder, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contribution towards the company's achievement of its goals and the maximization of its profits, and the circumstances of termination of 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 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, we must obtain Compensation Committee, Board and shareholder approval every three years for either the continuation of our existing compensation policy or adoption of a new compensation policy.

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 2023 and 2025, in determining the compensation of certain executive officers and in determining our compensation policy, the Compensation Committee retained the services of a compensation consultant, Brightman Almagor Zohar & co., a firm in the Deloitte Touche Tohmatsu Limited network, to conduct a comparative survey of the compensation of such Office Holders. The 2023 and 2025 comparative studies consisted of: (i) executive compensation benchmark analyses which included comparative data of the Company's executive compensation, relative to the peer-group companies in Israel and (ii) executive compensation benchmark analyses which included comparative data of the Company's executive compensation, relative to the peer-group companies in the United States.

On May 27, 2024, the Compensation Committee and the Board voted to approve, and on July 31, 2024, the shareholders of the Company ratified and confirmed, the revised compensation terms of the Company's non-executive directors, retroactively effective as of January 1, 2024, which includes (i) a quarterly grant of fully vested Ordinary shares, in lieu of each non-executive director's respective quarterly cash compensation and (ii) an annual option grant. On July 16, 2025, following the recommendation of the Compensation Committee and the Board's approval and recommendation, the Shareholders of the Company voted to approve an Amended Compensation Policy, which is substantially similar to the Company's prior policy, subject to certain updated thresholds to align with market standards and to attract prospective management members, such that the policy would be effective for the next three years, or such longer period as permitted and in accordance with the Israeli Companies Law.

***Nominating and Corporate Governance Committee***

*Composition*

Our Nominating and Corporate Governance Committee consists of Haya Taitel, who also serves as chairwoman 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. 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.

**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 (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, other than as noted below, we believe that all reporting persons timely filed all reports required by them under Section 16(a) of the Exchange Act with respect to the year ended December 31, 2025.

On May 20, 2025, Leslie Velka Gautam, a former executive officer of the Company, filed an untimely Form 3 due to delays in obtaining such reporting person's EDGAR codes from the SEC.

## ITEM 11. EXECUTIVE COMPENSATION

**Compensation Policy**

Our compensation policy was last approved by our shareholders on July 16, 2025, after having been recommended by our Compensation Committee and approved by our Board, and will therefore, under the Companies Law, will need to be either re-approved, amended, or replaced by a new policy no later than 2028, 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***

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 reward Officers for individual and company performance as well as to align their interests with the interests of shareholders. We have also designed our compensation policy to provide flexibility. It must take into consideration the fact that the appropriate mix of compensation may vary from period to period and from Officer to Officer. To achieve 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; (ii) short to medium-term incentives, such as an annual bonus based on target and above-target performance; and (iii) medium to long-term incentives, such as equity-based compensation and retirement benefits.

***Base Salary***

Base salary compensates our Officers for the performance of their standard duties and reflects each Officer's education, skills, qualifications, expertise, professional experience and accomplishments, as well as the position, areas and scope of responsibilities of such Officer. Adjustments to base salary are periodically reviewed by the Compensation Committee and the Board.

***Bonuses***

Cash bonuses are generally paid annually and are intended to reward Officers based on the performance of the Company and their individual contributions. The target bonus amount and the performance measures and targets for each Officer are determined by the Compensation Committee and the Board at the beginning of each year for which a bonus may be paid. Additionally, the CEO has the power to determine the annual bonus performance measures and targets for all Officers other than for herself.

The performance measures and targets for receiving the annual bonus are intended to be measurable and quantifiable and may include, 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 an Officer's annual bonus, which is based on an evaluation of such Officer in accordance with qualitative measures provided in the annual bonus 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 impact on our business. Under our compensation policy, a special bonus is limited to six times the monthly base salary for a given Officer, other than our CEO, for whom a special bonus is limited to three times the monthly base salary, determined by non-measurable criteria.

***Equity-based Compensation***

Our compensation policy also includes an equity incentive component designed to retain Officers, align Officers and shareholders' interests and incentivize Officers to attain 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 based on, among other elements, each Officer's (a) contribution to the Company's performance, (b) ability to influence the Company's future and 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, as well as the desired competitive levels and dilution or pool limits.

Our compensation policy limits the annual value of equity awards granted to an Officer, measured at the applicable grant date, to 25 times the monthly base salary of such Officer. These equity awards must provide for a vesting period of not less than one year, and options may be granted with terms of not more than 10 years 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 on the date of grant and subject to applicable law.

While the Company does not have a formal policy in place, it is the Company's practice to typically award equity grants to executive officers and non-employee directors at the beginning of each fiscal year, subject to the Company not being in possession of any material non-public information.

***Hedging and Pledging***

Pursuant to the terms of our compensation policy and insider trading policy, Officers and directors are prohibited from hedging or pledging their equity awards and any other Company securities. The no-hedging policy applies to each director and Officer until one year following termination of such director's term of office or such Officer's termination of employment, as applicable. Furthermore, Officers and directors may not pledge or use their equity awards or any other Company securities held by them as collateral for loans unless otherwise approved by the Compensation Committee and Board.

***Benefits and Perquisites***

Under the compensation policy, our Officers are entitled to certain fringe benefits that we believe are commonly provided to similarly situated executives in our industry. These benefits allow us to compete for talent and are therefore 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: (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; or (c) in respect of Officers other than the CEO, if the CEO has recommended granting a retirement bonus.

***Director Compensation***

The compensation policy provides that non-employee directors' compensation packages 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. Our non-employee directors may be eligible to receive an annual Board membership fee, annual Committee membership fee and equity-based compensation. Non-employee directors may also be entitled to receive insurance, indemnification and release arrangements. The chair of the Board and the chairs of the Board committees may also receive additional annual cash payments for their service in such capacities, subject to the provisions of applicable law.

In May 2021, we elected to be exempt from the Companies Law requirement that we appoint external directors or otherwise comply with the Companies Law requirements related to the composition of the Audit Committee and Compensation 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 Nasdaq requirements as to the composition of (a) our Board of Directors, which require that we maintain a majority of independent directors, and (b) the Audit and Compensation Committees, which 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; therefore, the requirements and restrictions relating to external directors (including certain compensation related provisions) do not apply.

***Clawback Policy***

On November 30, 2023, the Board adopted an Executive Officer Clawback Policy (the "Clawback Policy") in compliance with Rule 10D-1 under the Exchange Act and the appliable Nasdaq rules. In the event of an accounting

restatement, under the Clawback Policy, the Board, or another committee designated by the Board, is required to recover certain incentive-based compensation paid to an executive officer of the Company, subject to the terms of the Clawback Policy, to the extent such incentive-based compensation was in excess of the compensation that would have otherwise been payable based upon the restated financials. The Clawback period extends for three years prior to the restatement. The Clawback Policy 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 filing of any financial statement that the issuer is required to restate because of misconduct, and the reimbursement of those funds to the 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, 2025 and December 31, 2024. 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.

The below figures are represented in thousands.

| Name and Principal Position | Year | Salary ($) | Bonus ($) | Option Award(s) ($)(1) | RSUs Award(s) ($)(2) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|
| Miranda Toledano..... | 2025 | 490 | - | 590 | 330 | 72 | 1,482 |
| *Chief Executive Officer and director* ..... | 2024 | 419 | - | 538 | 156 | 36 | 1,149 |
| Hillel Galitzer ..... | 2025 | 282 | - | 176 | 48 | 25 | 531 |
| *Chief Operating Officer*..... | 2024 | 259 | - | 175 | 54 | 43 | 531 |
| Gregory Burshtein .... | 2025 | 217 | - | 202 | 48 | 37 | 504 |
| *Chief of Research and Development* ..... | 2024 | 172 | - | 92 | 45 | 28 | 337 |

(1) Reflects the associated annual expense recorded in our financial statements 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 Note 6 to the Company's audited financial statements for the year ended December 31, 2025 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) Reflects the associate annual expenses for RSUs granted in place of annual bonus in cash recorded in our financial statements based on the fair value of the share-based compensation grant date market computed in accordance with ASC Topic 718. The fair value amount is recognized as an expense over the course of the vesting period of the RSUs in the Company's audited financial statements for the year ended December 31, 2025 included in this Annual Report.

**Outstanding Equity Awards at Fiscal Year End**

The following table sets forth the outstanding equity awards at December 31, 2025 for our Named Executive Officers.

| | Number of Securities Underlying Unexercised Options and Unvested RSUs | | Option Expiration |
|---|---|---|---|
| **Name** | **Exercisable** | **Unexercisable** | **Date** |
| Miranda Toledano | 33,638 | - | 1/17/2029 |
| *Chief Executive Officer and director* | 35,852 | - | 1/1/2032 |
| | 107,557 | - | 1/1/2032 |
| | 437,500 | 62,500(1) | 05/16/2032 |
| | 487,500 | 112,500(2) | 07/15/2032 |
| | 218,750 | 131,250(3) | 04/24/2033 |
| | 250,000 | 250,000(4) | 04/19/2034 |
| | - | 500,000(5) | 28/04/2035 |
| | - | 90,351(6) | N/A |
| Gregory Burshtein | 20,000 | - | 01/17/2029 |
| *Chief of Research and Development* | 18,900 | - | 03/16/2030 |
| | 51,000 | - | 04/07/2031 |
| | 39,375 | 5,625(7) | 04/28/2032 |
| | 40,625 | 24,375(8) | 04/24/2033 |
| | 75,000 | 75,000(9) | 04/19/2034 |
| | | 200,000(10) | 28/04/2035 |
| | - | 13,158(11) | N/A |
| Hillel Galitzer | 175,000 | - | 03/16/2030 |
| *Chief Operating Officer* | 125,000 | - | 04/21/2031 |
| | 56,250 | 3,750(12) | 03/24/2032 |
| | 131,250 | 78,750(13) | 04/24/2033 |
| | 65,000 | 65,000(14) | 04/19/2034 |
| | | 100,000(15) | 28/04/2035 |
| | | 13,158(16) | N/A |

(1) The 62,500 unexercisable options as of December 31, 2025 will vest in two equal quarterly installments beginning on February 16, 2026.

(2) The 112,500 unexercisable options as of December 31, 2025 will vest in three equal quarterly installments beginning on January 15, 2026.

(3) The 131,250 unexercisable options as of December 31, 2025 will vest in six equal quarterly installments beginning on January 24, 2026.

(4) The 250,000 unexercisable options as of December 31, 2025 will vest in six equal quarterly installments beginning on January 19, 2026.

(5) Of the 500,000 unexercisable options as of December 31, 2025, 33.33% vest on April 28, 2026, the first anniversary of the grant date, and the remaining 66.67% vesting in 8 equal quarterly installments over the following two years.

(6) The 90,351 unvested RSUs as of December 31, 2025 will vest in two equal quarterly installments beginning on January 28, 2026.

(7) The 5,625 unexercisable options as of December 31, 2025 will vest in two equal quarterly installments beginning on January 28, 2026.

(8) The 24,375 unexercisable options as of December 31, 2025 will vest in six equal quarterly installments beginning on January 24, 2026.

(9) The 75,000 unexercisable options as of December 31, 2025 will vest in six equal quarterly installments beginning on January 19, 2026.

(10) Of the 200,000 unexercisable options as of December 31, 2025, 33.33% vest on April 28, 2026, the first anniversary of the grant date, and the remaining 66.67% vesting in 8 equal quarterly installments over the following two years.

(11) The 13,158 unvested RSUs as of December 31, 2025 will vest in two equal quarterly installments beginning on January 28, 2026.

(12) The 3,750 unexercisable options as of December 31, 2025 will vest in one installments on March 31, 2026.

(13) The 78,750 unexercisable options as of December 31, 2025 will vest in six equal quarterly installments beginning on March 31, 2026.

(14) The 65,000 unexercisable options as of December 31, 2025 will vest in six equal quarterly installments beginning January 19, 2026.

(15) Of the 100,000 unexercisable options as of December 31, 2024, 33.33% vest on April 28, 2026, the first anniversary of the grant date, and the remaining 66.67% vesting in 8 equal quarterly installments over the following two years.

(16) The 13,158 unvested RSUs as of December 31, 2025 will vest in two equal quarterly installments beginning on January 28, 2026.

**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, 2025, including fees earned in cash and options awarded for services provided as a director. To help the Company maintain sufficient cash for operations, the Company's shareholders approved a revised compensation structure for non-executive directors, which was implemented to enhance the Company's financial flexibility and align directors' interests with those of shareholders. This revised structure involves granting fully vested Ordinary Shares quarterly instead of quarterly cash payments, effective retroactively as of January 1, 2024. Under this arrangement, each non-executive director receives a quarterly grant of fully vested Ordinary Shares. Such quarterly grants for the fiscal year ended December 31, 2025 were granted in a single aggregate grant on January 1, 2026. The value of these shares is equivalent to their respective cash compensation for board and committee services, calculated based on the average daily closing share price of the Ordinary Shares during the applicable fiscal quarter. Directors who serve only part of a quarter receive a pro rata portion of the shares.

| Name | Fees Earned or Paid in Cash ($) | Option Awards ($)(1) | Equity Awards ($)(2) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|
| Gerald Lieberman (3) | - | 45,264 | 74,290 | - | 119,554 |
| Yonatan Malca | - | 45,264 | 58,505 | - | 103,768 |
| Gerald M. Ostrov (3) | - | 45,264 | 55,719 | - | 100,982 |
| Sean Ellis | - | 45,264 | 49,220 | - | 94,483 |
| Haya Taitel | - | 47,580 | 51,078 | - | 98,658 |

(1) Reflects the associated annual expense recorded in our financial statements 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 Note 6 of the Company's audited

financial statements for the year ended December 31, 2025 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) Reflects the associated annual expenses for Ordinary Shares granted in January 2026 in lieu of cash fees earned for services rendered during 2025, based on the grant date market value.

(3) Former board member that resigned as a director of the Company in February 2026.

The table below sets forth the aggregate number of share options of each non-employee director outstanding as of December 31, 2025:

| Name | Share Options |
|---|---|
| Gerald Lieberman | 402,930 |
| Yonatan Malca | 402,930 |
| Gerald M. Ostrov | 402,930 |
| Sean Ellis | 402,930 |
| Haya Taitel | 170,480 |

**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.

***Miranda Toledano***

Ms. Toledano has served on the Board of Directors at Entera since September 2018. Between May and July 2022, Ms. Toledano served as Chief Business Officer, Chief Financial Officer and Head of Corporate Strategy at Entera. In July 2022, Ms. Toledano was appointed Chief Executive Officer at Entera.

In connection with Ms. Toledano's appointment as 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.

In connection with Ms. Toledano's appointment 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.

On April 24, 2023, the Compensation Committee and the Board voted to approve, and on September 13, 2023, the shareholders of the Company ratified and confirmed, (i) a salary increase for Ms. Toledano, according to which her annual employer cost would be increased to $480,000, and (ii) a one-time grant of options to purchase 350,000 Ordinary Shares, at an option exercise price of $0.795 per Ordinary Share, under the Company's 2018 Equity Incentive Plan (the "2018 Plan"), both of which were deemed by the Board to be inside the respective ranges set in the Company's compensation policy. For the sake of good corporate governance, the Company and Ms. Toledano executed an amendment to Ms. Toledano's employment agreement in January 2024, under the terms of which the salary increase became effective on January 1, 2024.

On April 23, 2025 and April 28, 2025, the Compensation Committee and the Board, respectively, voted to approve, and on July 16, 2025, the shareholders of the Company ratified and confirmed for Ms. Toledano: (i) a salary increase for Ms. Toledano, according to which her annual employer cost would be increased to $600,000, as of April 1, 2025 (while with respect to the 12-month period beginning April 1, 2025, in order to preserve Company cash, Ms. Toledano is entitled to receive a one-time grant of 43,860 RSUs in place of $100,000 of her Updated Salary in lieu of cash payment for such one (1) year period (the "2025 Salary RSUs"), under the 2018 Plan and subject to the requirements of applicable laws and regulations. the 2025 Salary RSUs shall vest over a one (1) year period, with 100% of the 2025 Salary RSUs vesting in four substantially equal portions over the 12 month period and (ii) a one-time grant of options to purchase an additional 500,000 Ordinary Shares (the "2025 Options"), at an exercise price of $2.28 per Ordinary Share, under the 2018 Plan, and subject to the requirements of applicable laws and regulations.

***Hillel Galitzer***

In March 2014, we entered into an employment agreement with our Chief Operating Officer, Mr. Hillel Galitzer. Pursuant to the terms of his employment, and within the discretion granted to the Board, Mr. Galitzer was entitled to an annual gross base salary of $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 Mr. Galitzer's annual salary, and he is currently entitled to an annual gross base salary of $246,000. The Board approved an increase to Mr. Galitzer's annual salary, effective April 1, 2025, and he is currently entitled to an annual gross base salary of $254,000. Additionally, pursuant to the terms of his employment agreement, Mr. 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 short-term disability and pension fund benefits. Mr. 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, Mr. Galitzer is also covered by our D&O insurance policy. Pursuant to the terms of his employment agreement, Mr. Galitzer is eligible to receive equity awards under the Company's existing and future incentive plans, on such amount and terms as shall be approved by the Board. Pursuant to the terms of his employment agreement, Mr. Galitzer also agreed to customary non-disclosure and non-competition covenants.

***Gregory Burshtein***

Dr. Burshtein currently serves as the Company's Chief of Research and Development. Pursuant to the terms of his employment, and within the discretion granted to the Board, Dr. Burshtein was entitled to an annual gross base salary of $157,000 for 2024, increasing to $200,000 effective as of April 1, 2025. Additionally, pursuant to the terms of his employment agreement, Mr. Burshtein 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 pension fund benefits. Mr. Burshtein is also generally entitled to reimbursement for travel and other business expenses and other benefits, including, vacation, holidays, travel expenses and sick leave. Subject to applicable law, Mr. Burshtein is also covered by our D&O insurance policy. Pursuant to the terms of his employment agreement, Mr. Burshtein also agreed to customary non-disclosure and non-competition covenants.

On April 28, 2025, the Board voted to approve revised compensation terms and a one-time grant of compensation for Dr. Burshtein, including (i) options to purchase 200,000 Ordinary Shares (the "Gregory's 2025 Options"), at an exercise price of $2.28 per Ordinary Share, under the 2018 Plan, and (ii) a one-time grant of 26,316 RSUs in lieu of a cash bonus for 2024 (the "Gregory's 2025 RSUs") under the 2018 Plan. Gregory's 2025 Options shall vest over a three (3) year period, with a third of the Gregory's 2025 Options vesting at the end of a 12-month period following April 28, 2025, and the remaining two-thirds of Gregory's 2025 Options shall vest in eight substantially equal portions over the next two (2) year period thereafter, on a quarterly basis, rounded down to the nearest whole share, provided, that with respect to the last such quarterly installment, the number of Gregory's 2025 Options that vest in the installment shall be such that Dr.

Burshtein will be fully vested in the total number of Gregory's 2025 Options listed above as of such applicable quarterly anniversary (i.e., such that one hundred percent (100%) of Gregory's 2025 Options shall become fully vested on April 28, 2028). Gregory's 2025 RSUs shall vest over a one (1) year period, with 100% of Gregory's 2025 RSUs vesting in four substantially equal portions over the 12 month period following April 28, 2025, on a quarterly basis, rounded down to the nearest whole share, provided, that with respect to the last such quarterly installment, the number of Gregory's 2025 RSUs that vest in the installment shall be such that Dr. Burshtein will be fully vested in the total number of Gregory's 2025 RSUs listed above as of such applicable quarterly anniversary (i.e., such that one hundred percent (100%) of Gregory's 2025 RSUs shall become fully vested on April 28, 2026)**.**

**Employee Equity Incentive 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, 2025, 810,550 Ordinary Shares were issuable upon the exercise of outstanding awards under the 2013 Plan, at a weighted-average exercise price of $6.31 per share. As of December 31, 2025, all of the foregoing outstanding options had vested under the 2013 Plan. 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. In our shareholders meeting held July 31, 2024, 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 1,788,515 Ordinary Shares. On January 1, 2025, pursuant to the annual evergreen provision and following the approval of our Board, an additional 1,941,859 Ordinary Shares, equal to 5% of the total outstanding shares as of January 1, 2025, became available for issuance under the 2018 Plan. As of December 31, 2025, a total of 2,052,375 Ordinary Shares representing 4.4% of the total outstanding shares remained available for issuance under the 2018 Plan. On January 1, 2026, pursuant to the annual evergreen provision and following the approval of our Board, an additional 2,308,931 Ordinary Shares, equal to 5% of the total outstanding shares as of January 1, 2026, 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, 2025, 8,615,707 Ordinary Shares were issuable upon the exercise of outstanding awards under the 2018 Plan, at a weighted-average exercise price of $1.95 per share. Of the foregoing outstanding awards, as of December 31, 2025, options to purchase 5,483,678 Ordinary Shares, in the aggregate, had vested under the 2018 Plan, with a weighted-average exercise price of $1.90 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. 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 23, 2026 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 23, 2026 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 46,622,239 Ordinary Shares outstanding as of March 23, 2026. 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 person's address is c/o Entera Bio Ltd., Kiryat Hadassah, Minrav Building - Fifth Floor, Jerusalem, Israel. [2]

| Name | Number and Percentage of Ordinary Shares | |
|---|---|---|
| | Number | Percent |
| **5% or Greater Shareholders (other than directors and executive officers)** | | |
| Gakasa Holdings LLC (1) | 5,534,275 | 11.8% |
| Israel Canada Hotels Ltd. (2) | 3,732,540 | 8.01% |
| OPKO Health Inc. (3) | 3,685,226 | 7.90% |
| Centillion Fund (4) | 2,396,953 | 5.14% |
| **Executive Officers and Directors:** | | |
| Miranda Toledano (5) | 2,452,574 | 5.04% |
| Hillel Galitzer (6) | 728,073 | 1.54% |
| Sean Ellis (7) | 599,404 | 1.27% |
| Dana Yaacov-Garbeli (8) | 575,547 | 1.22% |
| Yonatan Malca (9) | 488,722 | 1.04% |
| Gregory Burshtein (10) | 451,759 | * |
| Haya Taitel (11) | 274,532 | * |
| Geno J. Germano (12) | 40,000 | * |
| Steven D. Rubin (13) | 15,000 | * |
| All Directors and Executive Officers as a Group (9 persons) (14) | 5,625,611 | 11.00% |

* Less than 1%

(1) Pursuant to the Schedule 13G/A filed with the SEC on November 20, 2024 regarding Gasaka Holdings LLC's holdings. This consists of: 5,534,275 Ordinary Shares, The holder also owns (i) 347,604 Pre-Funded Warrants and (ii) purchase warrants to acquire 1,197,604 Ordinary Shares. Such warrants include a 9.99% ownership blocker and, as a result, are not included in the ownership amount. Gasaka Holdings LLC's address is at 201 S. Biscayne Blvd suite 800, Miami, FL 33131.

(2) Israel Canada Hotels Ltd. (Formerly: D.N.A Biomedical Solutions Ltd.) holdings consists of 3,732,540 Ordinary Shares. D.N.A's address is at Shimon Hatarsi 43 St., Tel Aviv, Israel.

(3) Pursuant to Schedule 13G filed with the SEC on April 2, 2025 regarding OPKO Health, Inc. holdings which consists of 3,685,226 Ordinary Shares. OPKO Health, Inc.'s address is at 4400 Biscayne Blvd., Miami, FL 33137.

(4) Pursuant to the Schedule 13G/A filed by Centillion Fund Inc. with the SEC on August 20, 2024 regarding its holdings. As of July 19, 2024, Mr. Renat Yliagoyev purchased 100% of Centillion Fund, Inc. In addition, Mr. Yliagoyev maintains warrants to purchase up to 179,640 Ordinary Shares, at $0.71 per Ordinary Share, as disclosed in the Company's Form 8-K filed on December 30, 2023 (the "Warrants"). The Warrants are exercisable for five (5) years from issuance. While the Warrants are not held in the name of Centillion Funds, Inc., and have not been exercised, given that Mr. Yliagoyev may be deemed as a control person, the number of shares he may ultimately be in control of is 2,576,593. Centillion Fund Inc's address is 10 Manoel Street, Castries, Saint Lucia LC04 101.

(5) Consists of (i) 381,399 Ordinary Shares, (ii) 23.952 Ordinary Shares underlying warrants to acquire Ordinary Shares, (iii) 45,176 Ordinary Shares underlying RSUs to acquire Ordinary Shares, and (iv) 2,002,047 Ordinary Shares underlying options to acquire Ordinary Shares.

(6) Consists of (i) 83,994 Ordinary Shares, (ii) 6,579 Ordinary Shares underlying RSUs to acquire Ordinary Shares and (iii) 637,500 Ordinary Shares underlying options to acquire Ordinary Shares.

(7) Consists of (i) 188,098 Ordinary Shares, (ii) 411,306 Ordinary Shares underlying options to acquire Ordinary Shares.

(8) Consists of (i) 106,468 Ordinary Shares, (ii) 6,579 Ordinary Shares underlying RSUs to acquire Ordinary Shares and (iii) 462,500 Ordinary Shares underlying options to acquire Ordinary Shares.

(9) Consists of (i) 77,416 Ordinary Shares and (ii) 411,306 Ordinary Shares underlying options to acquire Ordinary Shares.

(10) Consists of (i) 94,863 Ordinary Shares, (ii) 6,579 Ordinary Shares underlying RSUs to acquire Ordinary Shares and (iii) 350,317 Ordinary Shares underlying options to acquire Ordinary Shares.

(11) Consists of (i) 98,479 Ordinary Shares, (ii) 176,053 Ordinary Shares underlying options to acquire Ordinary Shares.

(12) Consists of 40,000 Ordinary Shares.

(13) Consists of 15,000 Ordinary Shares.

(14) Consists of (i) 1,085,717 Ordinary Shares, (ii) 23,952 Ordinary Shares underlying warrant to acquire Ordinary Shares, (iii) 64,913 RSUs to acquire Ordinary Shares and (iv) 4,451,029 Ordinary Shares underlying options to acquire Ordinary Shares.

**Securities Authorized for Issuance under Equity Compensation Plans**

The following table provides certain information as of December 31, 2025, 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)) (#) |
|---|---|---|---|
| | (a) | (b) | (c) |
| Equity compensation plans approved by security holders | | | |
| *2013 Plan* | 810,550 | $ 6.31 | - |
| *2018 Plan* | 8,615,707 | $ 1.95 | 2,052,375 |
| Equity compensation plans not approved by security holders | - | - | - |
| Total | 9,426,257 | $ 2.32 | 2,052,375 |

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Described below are any transactions occurring since January 1, 2024, 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. 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 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 or in which the Office Holder has a personal interest must be brought before the Audit Committee, in order to determine whether such transaction is an Extraordinary 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 or their employment, if they are not an 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: Geno J. Germano, Steven D. Rubin, Sean Ellis, Yonatan Malca and 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. PRINCIPAL ACCOUNTING FEES AND SERVICES

Kesselman & Kesselman, Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm has served as our independent registered public accounting firm for 2025 and 2024. The following table sets forth fees billed to us by our independent registered public accounting firm during the fiscal years ended December 31, 2025 and 2024 for (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements; and (ii) services rendered during the period in connection with tax compliance, tax advice and tax planning.

| | Year Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Audit fees (1) | $ 224,500 | $ 196,800 |
| Tax fees (2) | 5,150 | 5,150 |
| Total fees | $ 229,650 | $ 201,950 |

(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 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(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 Pre-Funded Warrant (incorporated by reference to Exhibit 10.2 to the Form 8-K filed with the SEC on December 26, 2023) |
| 4.4 | Form of Ordinary Share Warrant (incorporated by reference to Exhibit 10.3 to the Form 8-K filed with the SEC on December 26, 2023) |
| 4.5 | Form of Placement Agent Warrant (and Finder Warrant) (incorporated by reference to Exhibit 10.4 to the Form 8-K filed with the SEC on December 26, 2023) |
| 10.1 | 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) |
| 10.2 | 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) |
| 10.3 | Amendment No. 1 to Sales Agreement, dated June 5, 2025, between Entera Bio Ltd. and Leerink Partners LLC (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed with the SEC on August 8, 2025) |
| 10.4 | Securities Purchase Agreement, dated as of December 20, 2023, by and among Entera Bio Ltd. and the purchasers party thereto (incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on December 26, 2023) |
| 10.5 | 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) |
| 10.6† | 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) |
| 10.7† | 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) |
| 10.8† | 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) |
| 10.9† | 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) |
| 10.10†* | Form of Restricted Stock Award Agreement under the 2018 Equity Incentive Plan |
| 10.11† | 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) |
| 10.12† | Amendment to Employment Agreement, dated January 30, 2024, by and between Entera Bio Ltd. and Miranda Toledano (incorporated by reference to Exhibit 10.10 to the Form 10-K filed with the SEC on |

| | |
|---|---|
| | March 8, 2024) |
| 10.13† | Consulting agreement, dated June 2, 2019, between Entera Bio Ltd. and Dana Yaacov Garbeli (through A2Z Finance Ltd.), as amended (incorporated by reference to Exhibit 10.11 to the Form 10-K filed with the SEC on March 8, 2024) |
| 10.14† | Employment Agreement, dated as of June 8, 2014, between Entera Bio Ltd. and Hillel Galitzer, as amended. (incorporated by reference to Exhibit 10.12 to the Form 10-K filed with the SEC on December March 8, 2024) |
| 10.15†* | Employment Agreement, dated as of July 16, 2025, between Entera Bio Ltd. and Gregory Burshtein |
| 10.16+ | Amended and Restated Collaboration and License Agreement, dated February 3, 2026, by and among Entera Bio Ltd., OPKO Health, Inc. and OPKO Biologics Ltd. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on February 4, 2026) |
| 19.1* | Entera Bio Ltd. Insider Trading Policy |
| 21.1* | List of Subsidiaries |
| 23.1* | Consent of Kesselman & Kesselman firm, Certified Public Accountants (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm. |
| 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 (incorporated by reference to Exhibit 97 to the Form 10-K filed with the SEC on March 8, 2024) |

† Management contract or compensatory plan or arrangement.

+ Pursuant to Item 601(a)(5) of Regulation S-K, schedules and similar attachments to this exhibit have been omitted because they do not contain information material to an investment or voting decision and such information is not otherwise disclosed in such exhibit. The Company will supplementally provide a copy of any omitted schedule or similar attachment to the U.S. Securities and Exchange Commission or its staff upon request.

* Filed herewith.

** Furnished herewith.

**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 27, 2026

ENTERA BIO LTD.

By: /s/ Miranda Toledano
Miranda Toledano
Chief Executive Officer and Director

KNOW ALL MEN BY THESE PRESENTS, that each of the undersigned constitutes and appoints each of Miranda Toledano and Dana Yaacov-Garbeli, 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, 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 Toledano<br>Miranda Toledano | Chief Executive Officer and Director<br>(Principal Executive Officer) | March 27, 2026 |
| /s/ Dana Yaacov-Garbeli<br>Dana Yaacov-Garbeli | Chief Financial Officer<br>(Principal Financial and Accounting Officer) | March 27, 2026 |
| /s/ Geno J. Germano<br>Geno J. Germano | Director | March 27, 2026 |
| /s/ Yonatan Malca<br>Yonatan Malca | Director | March 27, 2026 |
| /s/ Sean Ellis<br>Sean Ellis | Director | March 27, 2026 |
| /s/ Steven D. Rubin<br>Steven D. Rubin | Director | March 27, 2026 |
| /s/ Haya Taitel<br>Haya Taitel | Director | March 27, 2026 |