Risk Factors Comparison 2025-03-28 to 2024-03-08 Form: 10-K

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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. ~~Risk~~ **Risks** ~~Factor Summary~~ **Related to** 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~~ **Financial Position** ~~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 ~~; • not derived any significant income from our activities and incurred an accumulated deficit and negative cash flows from operating activities.These factors raise substantial doubt as to the Company' s ability to continue as a going concern.Our expectations are based on management' s~~ current assumptions,clinical development plans and regulatory submission timelines,which may prove to be wrong,and we could spend our available financial resources much faster than we currently expect.Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates,we are unable to accurately predict the timing or amount of the development and clinical expenses or when,or if we will be able to achieve,or maintain,profitability.In addition,our expenses could increase if we are required by the FDA or comparable foreign regulatory authorities to perform preclinical or clinical studies or trials in addition to those currently expected,or if there are any delays in completing our clinical trials or the development and potential commercialization of EB613 or any other product candidates.The amount of our future net losses will depend,in part,on the amount and timing of our expenses,our ability to **generate revenue and** ~~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 working capital.Management has performed an analysis of our ability to continue as a going concern.In addition,our independent registered public accounting firm has raised substantial doubt as to our ability to continue as a going concern.Based on its assessment,management has raised substantial doubt about our** Management has performed an analysis of our ability to continue as a going concern ~~and~~ **. 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** ~~; • All of our product candidates, including EB613 and EB612, are~~ in **research and** ~~preclinical or clinical~~ development **activities,** and ~~we have~~ **it has** not **derived** ~~yet successfully completed the development of any product candidates; • If serious adverse, undesirable or unacceptable side effects are identified during the development of our product candidates, marketing approval may be delayed or we may need to abandon our development of such product candidates, and if such side effects are identified following regulatory approval, any approved product label may be limited or we may be subject to other~~ significant **income** ~~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; • 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 duration and intensity of the ongoing Israel- Hamas War and~~ its **activities** ~~impact on our operations~~ and **has** ~~workforce. Risks Related to Our Financial Position We have~~ incurred ~~significant losses since our inception and anticipate that we will continue to incur substantial losses for the next several years. We have incurred net losses in each year since our inception, including net losses of $ 8. 9 Million in 2023 and $ 13. 1 million in 2022. As of December 31, 2023 we had~~ an accumulated deficit ~~of $ 104. 4 million. We expect to continue to incur substantial losses for the next several years,~~ and **negative** ~~we expect these losses to increase as we continue our development of and potentially seek regulatory approval for, EB613 and EB612 and potentially develop future product candidates, including our GLP- 2 and OXM candidates with OPKO. We anticipate that our net losses and accumulated deficit for the next several years will be significant as we conduct our planned operations. Given our current plans, we anticipate that our existing~~ cash **flows from** ~~and cash equivalents will be sufficient to fund our operations~~ **operating activities since inception** ~~through the second quarter of 2025~~ . ~~This assumes capital required to fund our ongoing operations, including R & D~~

~~and the completion of the Phase 1 study related to the new generation platform and the GLP- 2 / OXM collaborative research we are conducting with OPKO. This does not include the capital required to fund our proposed Phase 3 pivotal study for EB613 in osteoporosis. Delays in securing additional capital or entering into strategic collaborations to capitalize the EB613 Phase 3 program will result in delays in this program. Accordingly, these~~ **These** factors ~~, among others,~~ raise substantial doubt ~~about our ability to continue~~ as **to the Company'** ~~a going concern. Our expectations are based on management'~~ s current assumptions, clinical development plans and..... management has raised substantial doubt about our ability to continue as a going concern. In addition, our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern in their report accompanying our audited consolidated financial statements. As of March ~~1~~ **20** , ~~2024~~ **2025** , we had cash and cash equivalents of approximately $ ~~9.~~ **21 million, of which $** 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 operations ~~through~~ **into** the ~~second~~ **third** quarter of ~~2025~~ **2026 , excluding the initiation of the Phase 3 study for EB613 in osteoporosis** . This assumes capital required to fund our ongoing operations, including ~~R & D~~ **our ongoing operations, including regulatory expenses and optimization related to the preparation for the planned EB613 phase 3 study, research and development** , the completion of ~~the~~ **an additional** Phase 1 **PK** study related to ~~the~~ **our** new generation platform and the GLP- 2 / OXM collaborative research we are conducting with OPKO. **Our ability** ~~This does not include the capital required~~ to **commence the** ~~fund our proposed~~ Phase 3 ~~pivotal~~ study ~~for~~ **of** EB613 in osteoporosis ~~. Our expectations are based on management' s current assumptions, clinical development plans and regulatory submission timelines, which may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Our ability to continue as a going concern~~ will depend on ~~our ability to obtain~~ **finalizing discussions with the FDA in connection with their anticipated qualification of the total hip BMD endpoint and will require** additional ~~financing~~ **funding, which may not be available on reasonable terms, or at all** . ~~The Company~~ **Any delay or our inability to secure such funding will delay or prevent the commencement of these studies. We** constantly ~~evaluates~~ **evaluate** options ~~with respect~~ **in relation** to various financing alternatives including public or private equity offerings, debt financings and strategic collaborations to finance future clinical trials ~~, including the Phase 3 pivotal study for EB613 in osteoporosis~~ , research and development activities and general and administrative expenses. A going concern opinion could impair our ability to finance our operations through public or private equity offerings, or debt financings, or a combination of one or more of these funding sources. Any additional equity or debt financing could be extremely dilutive to our current shareholders. Additional capital may not be available on reasonable terms, or at all, and we may be required to delay, terminate or significantly curtail our operations, or enter into arrangements with collaborative partners or others that may require us to relinquish rights to certain aspects of our product candidates, or potential markets that we would not otherwise relinquish. If we are unable to obtain capital, our business, including our ability to conduct studies and develop our product candidates, would be jeopardized and we may not be able to continue operations. Due to our limited resources and access to capital, we must and have in the past decided to prioritize development of certain product candidates; these decisions may prove to have been wrong and may adversely affect our current and any potential future revenues. Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each product candidate. As such, ~~we~~ **our internal resources** are currently focused on the development of ~~five differentiated, first~~ **EB613 and further development of our N** - **Tab ™ platform. We** ~~in- class oral peptide programs, expected to enter~~ **entered** ~~the~~ into **the** ~~various stages of clinical development by~~ 2025 ~~, including two programs under the collaboration~~ **Collaboration** ~~agreement~~ **Agreement** with OPKO **in relation to our Oral GLP- 1 / Glucagon** . ~~Our most advanced~~ **Under the terms of the agreement, OPKO and Entera will hold 60 % and 40 % pro- rata ownership interests, respectively, in the** ~~programs~~ **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 ongoing development activities and funding of the program. Furthermore, the expenses related to collaborative research with a third party for hypoparathyroidism** are **funded by that collaborator** ~~EB613 and EB612 for the treatment of osteoporosis and hypoparathyroidism, respectively~~ . Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular compounds, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our current or potential decisions to delay, terminate or collaborate with third parties with respect to certain product development programs may also be sub- optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected. We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, reduce or cease our product development activities and operations. We are currently ~~advancing~~ **planning and preparing to initiate a phase 3 study for** our most advanced product candidate, EB613, ~~through clinical development~~ **pending FDA' s qualification of the SABRE BMD endpoint** . Developing therapeutics, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional capital in order to complete research and development, clinical trials, file with the regulatory agencies, including the FDA and EMA, secure commercial manufacturing supply for and commercialize our product candidates. If the FDA or comparable foreign regulatory authorities require that we perform additional preclinical studies or clinical trials at any point, our expenses would further increase beyond what we currently expect, and the anticipated timing of any future clinical development activities and potential regulatory approvals may be delayed depending upon our allocation of resources and available funding. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, or on acceptable terms, we may be required

to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of manufacturing, sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates. We expect that we would need to raise additional funds to support the execution of our long- term growth strategy ~~, including for a potential Phase 3 trial of EB613, additional non- clinical and clinical studies for EB612, and further development of our N- Tab ™ technology platform and pre- clinical product candidates~~ . We can provide no assurance that additional funding will be available on a timely basis, on terms acceptable to us, or at all. Because successful development of our product candidates is uncertain, we are unable to estimate the actual amount of financing we will require to complete research and development and to commercialize our product candidates. The amount and timing of our funding requirements will depend on many factors, including but not limited to: • the scope, progress, timing, cost and results of research, preclinical development, and clinical trials; • the 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** ~~Based upon~~ our ~~currently~~ -- **current plans** ~~expected level of operating expenditures~~ , we believe that we will be able to fund our operations ~~through~~ **into** the ~~second~~ **third** quarter of ~~2025~~ **2026 , excluding the initiation of the Phase 3 study for EB613 in osteoporosis** . This assumes capital required to fund our ongoing operations, including ~~R & D~~ **regulatory expenses and optimization related to the preparation for the planned EB613 phase 3 study, research and development** , the completion of ~~the~~ **an additional** Phase 1 **PK** ~~study related to the new generation platform and the GLP- 2 / OXM collaborative research we are conducting with OPKO. This does not include the capital required to fund our proposed Phase 3 pivotal study for EB613 in osteoporosis. Delays in securing additional capital or entering into strategic collaborations to capitalize the EB613 Phase 3 program will result in delays in this program. Our expectations are based on management' s current assumptions, clinical development plans and regulatory submission timelines, which may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. This period could be shortened if there are any unanticipated increases in spending on development programs or other unanticipated increases in spending related to circumstances outside of our control, including, without limitation, costs associated with litigation or other legal proceedings, hiring of additional consultants and personnel or procurement of additional raw materials.~~ Our existing cash and cash equivalents will not be sufficient to obtain regulatory approval for any of our product candidates. Accordingly, we continue to require substantial additional capital. In order to fund our future capital needs, we may seek additional funding through equity or debt financings, development partnering arrangements, lines of credit or other sources. These conditions raise substantial doubt about our ability to continue as a going concern, and we will be required to raise additional funds, seek alternative means of financial support, including strategic partnerships, or both, in order to continue operations. The accompanying financial statements have been prepared assuming that we will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty. If we are unable to raise the requisite funds, we will need to delay the initiation of core activities, curtail or cease operations. ~~Our fundraising efforts in the future to secure additional financing will divert our management from our day- to- day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, reduce or discontinue the development or commercialization of one or more of our product candidates or curtail our operations, which will have an adverse effect on our business, operating results and prospects.~~ We have a limited operating history and no history of late stage clinical studies and commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability and making an investment in our Ordinary Shares unsuitable for many investors. We began operations in 2010. Our operations to date have been limited to ~~financing and staffing our company,~~ developing our ~~drug delivery technology,~~ N- Tab ™ **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 ~~to~~ complete a large- scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products. Raising additional capital may cause dilution to our shareholders, and these financings, or disputes with shareholders in connection therewith, may restrict our operations or require us to relinquish substantial rights or result in unanticipated legal or other costs. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings and strategic collaborations. We do not have any committed external sources of funds and we will need to raise additional capital. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these new

securities may include liquidation or other preferences that adversely affect the rights of a holder of our Ordinary Shares. Debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends, and may be secured by all or a portion of our assets. Further, we may incur substantial costs in pursuing future capital and / or financing, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs and such efforts may divert our management from their day- to- day activities, which may compromise our ability to develop and market our product candidates. We may also be required to recognize non- cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which could cause our operating results to fluctuate on a quarterly basis. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates, or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. The requirements of being a public company may strain our resources and distract our management, which could make it difficult to manage our business, particularly after we are no longer 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. ~~In addition, changing laws, regulations and standards, in the United States or Israel, relating to corporate governance and public disclosure and other matters, may be implemented in the future, which may increase our legal and financial compliance costs, make some activities more time consuming and divert management' s time and attention from revenue- generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Furthermore, because~~ **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 ~~orally~~ -- **oral** ~~delivered~~ peptide and protein **replacement** ~~therapeutics~~ ---- **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 ™ ~~Technology~~ platform, the clinical and preclinical advancement of our product candidates, the creation, licensing and protection of related intellectual property rights and the provision of general and administrative support for these operations. We have not yet obtained regulatory approval for any product candidates in any jurisdiction or generated any revenues from any product sales. If any of our current or future product candidates fails in clinical trials or preclinical development, or does not gain regulatory approval, or if our product candidates following regulatory approval, if any, do not achieve market acceptance, we may never become profitable or sustain profitability. We commenced our first clinical trials with our oral PTH candidates in osteoporosis and hypoparathyroidism, and we have a limited operating history of developing products upon which our business and prospects can be evaluated. In addition, our Phase 2 clinical trial for EB613 for osteoporosis was the largest clinical trial we have conducted to date, and we have never conducted clinical trials of a size required for regulatory approvals. Furthermore, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by **biotech** companies in rapidly evolving fields ~~, such as the oral delivery of protein therapeutics~~ . To become and remain profitable, we must succeed in developing and commercializing products that generate significant revenues. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages, including developing product candidates, completing pre- clinical and clinical trials for such product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We may never succeed in these activities and, even if we do, we may never generate revenue from product sales **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, EB612 or 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 programs, EB613 ~~and EB612~~ may compete with marketed drugs, such as **Prolia ®, bisphosphonates,** Forteo ®, Tymlos ®, Evenity ®, and osteoanabolic drugs in clinical development for osteoporosis ~~and~~ **; the EB612 program may compete with marketed** drugs **of** ~~in clinical development for~~ hypoparathyroidism such as TransCon ™ PTH ~~or~~ **and those in clinical development such as** Eneboparatide **and MBX2109** . ~~Furthermore~~ **Our Oral GLP- 2 Program will compete with Gattex ™** , ~~EB612~~ **the only approved GLP- 2 treatment for short bowel syndrome and experimental GLP- 2 injectables such** ~~has~~ **as** ~~orphan drug designation in the United States~~ **Zealand' s glepaglutide (FDA CRL 12 / 24)** and ~~in the EU~~ **Vectiv / Ironwood' s apraglutide (Submitted 01 / 025). Our Oral GLP- 1 / Glucagon program may compete with approved GLP- 1 injectables** , ~~which means that the~~ **Rybelsus and experimental incretin targeted injectables and oral small molecules and** potential ~~patient population is limited~~ **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 ~~drug delivery technology,~~ N- Tab ™ **platform** , to other product candidates. An element of our strategy is to combine our N- Tab ™ ~~technology~~ 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. We intend to use N- Tab ™ technology in combination with known APIs, to validate our platform and potentially minimize risk and development timelines. Our initial product candidates combine our oral drug delivery technology, N- Tab ™, with PTH **(1- 34)** , a hormone that has been used in injectable form for ~~many~~ **over 20** years for the treatment of osteoporosis and hypoparathyroidism. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for, and successfully commercialize our oral PTH product candidates in a timely manner. ~~If we are unable to validate N- Tab ™ technology with our PTH product candidates, in particular our lead candidate EB613, we may be unsuccessful in leveraging our N- Tab ™ technology for use with other APIs.~~ In addition, we have modified the formulation of oral PTH to develop new formulations for applications in hypoparathyroidism and other indications. If we are not successful in optimizing the formation of our PTH product candidates for additional indications, or if we are not otherwise able to obtain regulatory approval for them or successfully commercialize them, our business and prospects may be severely limited. In addition, our technology makes use of synthetically bioengineered ingredients. Although our product candidates utilize a synthesized PTH molecule with a known mechanism of action, they may cause patients to exhibit safety or immune responses that do not match the biological effect of a human protein produced by the parathyroid gland. Such responses could result in increased regulatory scrutiny, delays or other impediments to our planned development or the public acceptance and commercialization of our

products. Even if we are successful in expanding our drug delivery technology to other ~~APIs~~ **peptides** for other indications **as we have to GLP- 2 and GLP- 1 / Glucagon** , the potential product candidates that we identify may not be suitable for clinical development, to the extent they are shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. We may never successfully develop or commercialize our technology with other ~~APIs~~ **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. While our oral PTH programs have exhibited no serious drug related adverse events in our clinical trials to date, the results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA, the EMA and other regulatory authorities, or result in marketing approval from the FDA, the EMA and other regulatory authorities with restrictive label warnings or potential product liability claims. 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 ~~product~~ **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 ~~and Gregory Bushtein, our Head of Research and Development~~ . Our success depends upon the continued contributions of these senior executives, employees and advisors, many of whom have substantial scientific and technical experience with, and have been instrumental to our regulatory, clinical development and technology platform. Furthermore, recruiting and retaining new executive talent and qualified scientific personnel to perform future research and clinical development work will be critical to our success. Competition for skilled personnel is intense and turnover rates are high, and our ability to attract and retain qualified personnel may be limited. The loss or unavailability of the services of any of our key employees and consultants for any significant period of time or our inability to attract and retain qualified skilled personnel could have a material adverse effect on our business, technology, prospects, financial condition and results of operations. We do not maintain " key man " life insurance policies for any of our employees. We expect to grow our organization 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 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 Israel- Hamas War** , which ~~has spurred~~ **may contribute to** rising energy costs and ~~exacerbated~~ disruptions to the global supply chain ~~caused by the COVID- 19 pandemic and the government and societal responses to the pandemic~~ . **To the extent we experience any** ~~Supply~~ **supply** chain disruptions **, we** could **experience** ~~continue to result in~~ delays in our R & D and clinical initiatives. As we have substantial international operations, fluctuations in exchange rates between the currencies in which we operate ~~, which~~ could increase our operating costs and adversely affect our results of operations ~~,~~ and cash flows. The duration and extent of such macroeconomic developments are uncertain and we cannot accurately predict whether we will be able to effectively and timely mitigate their impact on our business. Risks Related to Regulatory Approval of Our Product Candidates Clinical drug development is expensive, time consuming and uncertain. Development programs are subject to regulatory requirements, unanticipated delays and we may ultimately not be able to obtain regulatory approvals for the commercialization of our product candidates. Our most advanced product **has** ~~candidates are orally delivered tablet formulations of the synthetic form of the first 34 amino acids of human PTH, teriparatide. We are developing EB613 to treat osteoporosis and EB612 to treat hypoparathyroidism. These product candidates have~~ not yet reached late- stage clinical development and are subject to the risks of failure inherent in regulatory assessments and drug development. The clinical development, manufacturing, quality assurance, labeling, storage, record- keeping, advertising, promotion, pharmacovigilance, import, export, marketing and distribution of our product candidates is subject to extensive regulation by the FDA in the United States and by comparable authorities in foreign markets. We are not permitted to market our product candidates in the United States until we receive approval of 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** ~~PTH product~~ candidates, including EB613 and EB612, are still in clinical development and face a variety of risks and uncertainties, including the following: • future clinical trial results may show that our oral PTH is not effective, including if our **platform** ~~drug delivery technology~~ is not effective, our product candidates are not effective, our clinical trial designs are flawed, or clinical trial investigators or subjects do not comply with trial protocols; • our product candidates may not be well tolerated or may cause negative side effects; • our ability to complete the development and commercialization of our oral PTH for our intended uses may be significantly dependent upon our ability to obtain and maintain experienced and committed collaborators to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of, our oral PTH; • even if our oral PTH is shown to be safe and effective for its intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities at reasonable prices, or at all; • even if our oral PTH is successfully developed, commercially produced and receives all necessary regulatory approvals, there is no guarantee that there will be market acceptance; • even if our oral PTH is successfully developed, commercially produced and receives all necessary regulatory approvals for the treatment of Osteoporosis, there is no guarantee that we will successfully develop and commercialize it for other indications, including hypoparathyroidism and delayed union fractures; and • our competitors may develop therapeutics or other treatments that are superior to or less costly than our own with the result that our products, even if they are successfully developed, manufactured and approved, may not generate significant revenues. If we are unsuccessful in dealing with any of these risks, or if we or a potential partner are unable to successfully commercialize our oral PTH **, GLP- 1 / Glucagon, GLP- 2** or any other product ~~candidates~~ **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 ~~(oral hPTH (1- 34), teriparatide tablets)~~ . The FDA also agreed that Total BMD could serve as the primary endpoint of the registrational study in post- menopausal osteoporosis patients. In February 2023, we announced that a Type D meeting protocol review had been accepted by the FDA. The objective of the Type D meeting review was to confirm that the protocol fully meets FDA' s expectations, including the analysis of the primary endpoint and the population PK evaluations, ahead of potential initiation of the Phase 3 study. On April 3, 2023, we reported that the FDA would not be opposed to Entera initiating the Phase 3 study under the proposed FNIH BQP **SABRE BMD** pathway and that the Company' s proposed PK sampling scheme seemed reasonable. On the same day, we announced that we plan to continue our dialogue with the FDA and await the final qualification of the **SABRE qualification** ~~FNIH- BQP criteria~~ and ~~their~~ **FDA' s** guidance on the statistical evaluation of our BMD endpoint before initiating a Phase 3 study for EB613. In addition, with respect to EB612, we have since developed what we believe could be an improved formulation of EB612 based on new intellectual property, tailored to optimize its PK profile and the potential for reduced daily dosing. We initiated a PK study in May 2023, which is testing various potential drug candidates based on our new platform, including several which could be developed for the treatment of hypoparathyroidism. We are also collaborating on an undisclosed peptide for this indication using our N- Tab ™ Technology. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials for a number of reasons including: • difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial; • delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, contract manufacturing organizations, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly; • 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, ~~the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The MMA expanded Medicare coverage for outpatient drug purchases by those covered by Medicare under a new Part D and introduced a new reimbursement methodology based on average sales prices for Medicare Part B physician- administered drugs. In addition, the MMA authorized Medicare Part D prescription drug plans to limit the number of drugs that will be covered~~ in ~~any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of the MMA could decrease the coverage and price that we receive for any approved products and could seriously harm our future business prospects. While this law applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from this law may result in a similar reduction in payments from private payors. In~~ March 2010, 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 2027 absent additional congressional action. ~~However, pursuant to the CARES Act, and subsequent legislation, these reductions were suspended from May 1, 2020 through March 31, 2022 due to the COVID- 19 pandemic.~~ In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years **. 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, effective January 1, 2019, to close the coverage gap in most Medicare drug plans. In July 2018, CMS, published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation, regarding the method CMS uses to determine this risk adjustment. ~~.~~ Changes and modifications to the ACA are likely to continue, with unpredictable and uncertain results. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products. There have been several recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs.

On September 24, 2020, the FDA released a final rule providing guidance for states to build and submit importation plans for drugs from Canada ~~. Further, on November 20, 2020, the U. S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point- of- sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers~~ . At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. On November 20, 2020, the HHS Office of Inspector General finalized further modifications to the federal Anti- Kickback Statute. Under the final rules, the HHS Office of Inspector General added safe harbor protections under the Anti- Kickback Statute for certain coordinated care and value- based arrangements among clinicians, providers, and others, yet removed safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. ~~The rule also creates a new safe harbor for price reductions reflected at the point- of- sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. This rule (with exceptions) became effective on January 19, 2021. We continue to evaluate what effect, if any, these rules will have on our business.~~ CMS issued a final rule, effective on July 9, 2019, that requires direct- to- consumer advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than $ 35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list. Any adopted health reform measure could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future. 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; • HIPAA imposes criminal and civil liability

for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services; • the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require specified manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other " transfers of value " made to physicians. All such reported information is publicly available; • analogous state and non- U. S. laws and regulations, such as certain state anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and • regulation by the CMS and enforcement by the HHS Office of Inspector General or the U. S. Department of Justice. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from U. S. government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Risks Related to Commercialization of Our Product Candidates We are likely to face significant competition, and if our competitors' products are more effective, safer or less expensive than ours, our commercial opportunities will be negatively affected. Our lead product candidates, if approved, would compete with existing products. Our industry is highly competitive and subject to rapid and significant technological change. While we believe that our technology, drug candidates, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from many different sources, including large pharmaceutical, specialty pharmaceutical, biotechnology and generic drug companies and academic and government institutions. These organizations may have significantly greater resources than we do and conduct similar research, seek and obtain patent protection that may impact our freedom to operate and establish collaborative arrangements for research, development, manufacturing and marketing of products that compete with our product candidates. We believe that the key competitive factors that will affect the development and commercial success of our oral PTH product candidates, and any other product candidates that we develop, are efficacy, safety and tolerability profile, convenience in dosing, product labeling, price and availability of reimbursement from the government and other third- parties. Our commercial opportunity could be reduced or eliminated if our competitors have products that are better in one or more of these categories. Furthermore, our competitors may, among other things, develop and commercialize products that are safer, more effective, less expensive, or more convenient or easier to administer, obtain quicker regulatory approval, establish superior proprietary positions, have access to more manufacturing capacity, implement more effective approaches to sales and marketing, or form more advantageous strategic alliances. Our primary innovation is our development of **our** ~~an oral drug delivery technology,~~ N- Tab ™ ~~, for~~ **platform which enables us to develop** peptides ~~,~~ **and** therapeutic protein replacement therapies in ~~small~~ tablet form. If another company develops an alternative technology for oral delivery of such molecules in small tablet form that is equal to or better than our technology, we may be unable to compete. The osteoporosis market is already served by a variety of competing products. 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** ~~Ascendis Pharma developed a long- acting, oral prodrug formulation of PTH~~ for the treatment of hypoparathyroidism **such** ~~, which was~~ **as** ~~approved in the European Union in November 2023 and has a PDUFA date of May 14, 2024 from the FDA. We believe that our key competitors in hypoparathyroidism treatment include~~ TransCon ™ PTH and **those** ~~eneboparotide, a peptide~~ in **clinical** ~~Phase 3~~ development ~~, both of which require daily subcutaneous injections. If we obtain regulatory approval~~ for ~~EB612, it may~~ **hypoparathyroidism such as Eneboparatide and MBX2109. Our Oral GLP- 2 Program will** compete with ~~TransCon~~ **Gattex** ™ **, the only approved GLP- 2 treatment** ~~PTH and eneboparotide which by that time may have been marketed~~ for ~~several years~~ **short bowel syndrome** and **experimental GLP** ~~may have wide~~ ~~spread market~~

~~acceptance that~~ **2 injectables such as Zealand' s glepaglutide (FDA CRL 12 / 24) and Vectiv / Ironwood' s apraglutide (Submitted 01 / 025). Our Oral GLP- 1 / Glucagon program may compete with approved GLP- 1 injectables, Rybelsus and** ~~may~~ **many experimental incretin targeted injectables** ~~be difficult to overcome. Moreover~~, ~~although we have obtained orphan drug designation~~ **oral peptide candidates and oral small molecules developed** for **metabolic indications** ~~EB612 for the treatment of hypoparathyroidism, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity~~. We are subject to manufacturing risks that could substantially increase our costs and limit supply of our products. The process of manufacturing our products is complex, highly regulated and subject to several risks, including: • We do not have experience in manufacturing our product candidates at commercial scale. We may not succeed in the scaling up of our final manufacturing process. We may need a larger- scale manufacturing process for our oral PTH than what we have planned, depending on the dose and regimen that will be determined in future studies. Any changes in our manufacturing processes as a result of scaling up may result in the need to obtain additional regulatory approvals. Difficulties in achieving commercial- scale production or the need for additional regulatory approvals as a result of scaling up could delay the development and regulatory approval of our product candidates and ultimately affect our success ~~. Contract manufacturers may not have sufficient expertise to manufacture a dry oral formulation with a large molecule API, in which case we may have to establish our own commercial manufacturing capabilities, which could be expensive and delay launch of product candidates~~. • 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 ~~- Hamas War~~, other geopolitical tensions such as the ongoing conflict between Russia and Ukraine, and numerous other factors. • We and our contract manufacturing organizations, or CMOs, must comply with applicable cGMP regulations and guidelines. We and our CMOs may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We and our CMOs are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill- finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of drug product for our clinical trials or the termination or hold on a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and / or may be subject to product recalls, seizures, injunctions, or criminal prosecution. • Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write- offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. • Our product candidates that have been produced and are stored for later use may degrade, become contaminated or suffer other quality defects, which may cause the affected product candidates to no longer be suitable for their intended use in clinical trials or other development activities. If the defective product candidates cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of such product candidates. We currently have no sales, marketing or distribution infrastructure. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely affect the commercialization of our products. If we enter into collaborations to market and sell any approved products, our revenue may be lower and we will be dependent on the efforts of a third party. We ~~have no established sales, marketing or distribution operations. If our product candidates are approved and we were to commercialize these products, such activities would be expensive and time consuming. If we elect to fund and undertake commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. In addition, the costs of establishing sales and marketing operations may be incurred in advance of any approval of our product candidates. Moreover, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely affect the commercialization of our products. Alternatively, we~~ may consider entering into a collaboration to commercialize our oral ~~PTH~~ **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** ~~PTH product~~ candidates, as well as regulatory approvals and registrations. These arrangements are typically complex and time consuming to negotiate. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed and sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third- party collaborators, which may not be

successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses. Even if approved, if any of our product candidates do not achieve broad market acceptance among physicians, patients, the medical community and third- party payors, our revenue generated from their sales will be limited. The commercial success of our product candidates will depend upon their acceptance among physicians, patients and the medical community. The degree of market acceptance of our product candidates will depend on a number of factors, including: • limitations or warnings contained in the approved labeling for a product candidate; • changes in the standard of care for the targeted indications for any of our product candidates; • limitations 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 ~~plan to~~ **are in process of** ~~enter~~ **entering** into long- term supply agreements with several manufacturers for commercial supplies. We may be unable to reach agreement on satisfactory terms with contract manufacturers to manufacture our product candidates. Additionally, the facilities to manufacture our product candidates must be the subject of a satisfactory inspection before the FDA, the EMA or other regulatory authorities approve an NDA or grant a marketing authorization for the product candidate manufactured at that facility. We will depend on these third- party manufacturers for compliance with the FDA' s and EMA' s requirements for the manufacture of our finished products. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with cGMPs. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA, European Commission and other regulatory authorities' cGMP requirements, they will not be able to secure and / or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved, and may subject us to recalls or enforcement action for products already on the market. Our failure or the failure of our third party subcontractors and suppliers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates that we may develop. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including: • the possibility of a breach of the manufacturing agreements by the third parties because of factors beyond our control; • the possibility that the supply is inadequate or delayed; • the risk that the third party may enter the field and seek to compete and may no longer be willing to continue supplying; • the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third- party manufacturer; and • the possibility that we may not be able to secure a manufacturer or manufacturing capacity in a timely manner and on satisfactory terms in order to meet our manufacturing needs. 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 ™** technology and know- how relating to the **development of** oral **peptides and** ~~delivery of large molecules for the treatment of certain conditions with~~ oral ~~PTH and other targeted peptides~~ **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 ~~have been issued a~~ **believe that the granted** ~~patent~~ **patents** ~~with claims generally directed to compositions comprising a protein, an absorption enhancer and a protease inhibitor,~~ as well as **certain** ~~methods for oral administration~~ of ~~a protein with an enzymatic activity in each of~~ the **pending claims contained in our** ~~United States, Australia, Canada, Japan, New Zealand,~~

~~China, Israel and Russia. Related~~ patent applications ~~are pending in the United States~~ , **if issued in substantially** the ~~EU~~ **same form** , ~~Hong Kong, Brazil~~ **would cover our proprietary technology platform (N- Tab ™)** and ~~India. We have also filed~~ **the formulations used in various pipeline programs through 2044 not including** patent **term extensions** ~~applications derived from six patent families in various jurisdictions that currently contain claims directed to oral administration technologies, including compositions and drug delivery devices utilizing an absorption enhancer and methods of treating osteoporosis, hypoparathyroidism and bone fractures and related conditions with orally administered parathyroid hormone~~ . **However** ~~Certain of these patent applications have already matured into patents in the United States~~ , **we** ~~Israel, India, China, Canada, New Zealand, Brazil and Japan. Other applications are in prosecution. We have also recently filed seven additional international patent applications (patent families) with claims pertaining to a novel oral delivery platform, with claims directed at compositions comprising a protein, an absorption enhancer and an alkaline polymer, and methods of oral administration these compositions. We~~ cannot be certain that patents will be issued or granted with respect to any of our pending or future patent applications, or that issued or granted patents will not later be found to be invalid or unenforceable. The patent position of pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the 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 ~~. For example, we are party to the Patent Transfer Agreement with Oramed, pursuant to which we have granted Oramed an exclusive, worldwide, royalty- free, irrevocable and perpetual license, with the right to sublicense, under certain of our patent rights to develop, manufacture and commercialize covered products or otherwise exploit such patent rights in the fields of diabetes and influenza and we have agreed not to, directly or indirectly, engage in any activities within the fields of diabetes and influenza. Even if such agreement were to be terminated, Oramed would retain its exclusive license under such patent rights~~ . In the future, we may enter into additional collaborative agreements or license agreements with third parties which may subject us to obligations that must be fulfilled and require us to manage complex relationships with third parties. If we are unable to meet our obligations or manage our relationships with our collaborators under these agreements, our revenue may decrease. From the standpoint of our future strategic collaborators, the strength of the intellectual property under which we may grant licenses can be a determinant of the value of these relationships. If we are unable to secure, protect and enforce our intellectual property, it may become more difficult for us to attract strategic collaborators. The loss or diminution of our intellectual property rights could also result in a decision by future third- party collaborators to terminate their agreements with us. In addition, these agreements may be complex and may contain provisions that could give rise to legal disputes, including potential disputes concerning financial obligations or ownership of intellectual property and data under such agreements. Such disputes can lead to lengthy, expensive litigation or arbitration, requiring us to divert management time and resources to such dispute. Any such development could have a material adverse effect on our business, prospects, financial condition and results of operations. We may become involved in proceedings to protect or enforce our proprietary rights, which could be expensive and time consuming, and may ultimately be unsuccessful. Competitors or other third parties may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property rights. To counter infringement or other violations, we may be required to file claims, which can be expensive and time consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court may decide

that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Third parties may also raise challenges to the validity of our patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post- grant review and inter partes review proceedings and equivalent proceedings in foreign jurisdictions such as opposition proceedings. If third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO, to determine priority of invention for patent applications filed before March 16, 2013, or in derivation proceedings to determine inventorship for patent applications filed after such date. Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our product candidates or provide us with any competitive advantage. In addition, we may be subject to third- party challenges regarding our exclusive ownership of our intellectual property. If a third party were successful in challenging our exclusive ownership of any of our intellectual property, we may lose our right to use such intellectual property, such third party may be able to license such intellectual property to other third parties, including our competitors, and third parties could market competing products and technology. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our Ordinary Shares could be significantly harmed. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. We may face claims that we are violating the intellectual property rights of others. Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or other proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and future approved products or impair our competitive position. We may face claims, including from direct competitors, asserting that the commercial use of our technology infringes or otherwise violates the intellectual property rights of others. We cannot be certain that our technologies and processes do not violate the intellectual property rights of others. Third parties may assert infringement claims against us based on existing or future intellectual property rights. We expect that we may increasingly be subject to such claims as our product candidates approach commercialization, and as we gain greater visibility as a public company. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses. Thus, we do not know with certainty that our oral PTH (1- 34) tablet or any other product candidate, or our commercialization thereof, does not and will not infringe or otherwise violate any third party' s intellectual property. If we were found to infringe or otherwise violate the intellectual property rights of others, we could face significant costs to implement work- arounds, and we cannot provide any assurance that any such work-around would be available or technically equivalent to our current technology. In such cases, we might need to license a third party' s intellectual property, and such required licenses might not be available on acceptable terms, or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could expose us to similar liabilities and have a similar negative impact on our business. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally, and these lawsuits can be very time consuming and costly. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be successful in doing so. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management' s time and attention in defending these proceedings, which could have a material adverse effect on our business. Also, to the extent that our agreements provide that we will defend and indemnify our suppliers, service providers, future strategic collaborators or any other party for claims against them relating to any alleged infringement of the intellectual property rights of third parties in connection with such suppliers', service providers', strategic collaborators' or other parties' use of our technologies, we may incur substantial costs defending and indemnifying such parties to the extent they are subject to these types of claims. Any claims brought against us, any suppliers, service providers, future strategic collaborators or any other party indemnified by us alleging that we have violated the intellectual property of others could have a material adverse effect on our business, prospects, financial condition and results of operations. We may not be able to protect and enforce our intellectual property rights throughout the world. We currently have limited patent protection for our product candidates and technologies, and filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, we may not pursue or obtain patent protection in all major markets. In addition, the legal systems of some countries, particularly

developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to certain third parties. Furthermore, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Competitors may use our technologies in jurisdictions where we have not obtained or are unable to adequately enforce patent protection to develop or commercialize their own products. These products may compete with our future products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Proceedings to enforce our patent rights in such jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, put our patent applications at risk of not issuing and provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and to enforce our intellectual property. Changes in U. S. patent law could diminish the value of our future patents, if issued, thereby impairing our ability to protect our product candidates. As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time- consuming and inherently uncertain. In addition, the United States has recently enacted wide- ranging patent reform legislation, which includes provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the U. S. patent system from a " first to invent " system to a " first inventor to file " system. It is not clear what, if any, impact such legislation will have on the operation of our business. Additionally, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any U. S. patents that may issue to us in the future, all of which could have a material adverse effect on our business and financial condition. Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our Ordinary Shares to decline. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates or future products, services or intellectual property could be diminished and the market price of our Ordinary Shares may decline as a result. Furthermore, such negative publicity could severely impair our capability to enter into future agreements with key commercial collaborators. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and / or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned patents and / or applications and any patent rights we may own or license in the future. The USPTO and various non- U. S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our business. Under applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. In addition, our Israeli employees may be entitled to seek compensation for their inventions irrespective of their contractual agreements with us. Our agreements with our employees and key consultants generally include non- competition provisions. These provisions prohibit such employees and key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. We may be unable to enforce these provisions under the laws of the jurisdictions in which our employees and consultants work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli courts have required employers seeking to enforce non- compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company' s confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such interests will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our ability to remain competitive may be diminished. In addition, a significant portion of our intellectual property has been developed by our employees and consultants in the course of their employment or consulting relationship with us. Under the Israeli Patent Law, 5727- 1967, inventions conceived by an employee or consultant during the scope of his or her employment or consulting relationship with a company are regarded as " service inventions. " Even when our agreements with our employees and consultants include provisions regarding the assignment and waiver of rights to additional

compensation in respect of inventions created within the course of their employment or consulting relationship with us, including in respect of service inventions, we cannot guarantee that such provisions will be upheld by Israeli courts, as a result of uncertainty under Israeli law with respect to the efficacy of such provisions. If we are required to pay additional compensation or face disputes relating to service inventions, our results of operations could be adversely affected. 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 ~~drug delivery~~ platform technology, globally **. As of March 15, 2025 N- Tab ™ is registered in Israel and pending in the United States, Europe, Japan, Great Britain, Canada, Brazil, Norway, China, Australia, and Switzerland** . 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 oral GLP- 2 and OXM 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 the duration and intensity of the ongoing Israel- Hamas War, and other geopolitical tensions. In addition, ~~the stock market in general has recently experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad~~ **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 expect to take 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** ~~On November 21, 2022~~, the Company **has** received ~~a notice~~ **notices** ~~(the " Notice ")~~ from ~~the~~ Nasdaq ~~Stock Market LLC (" Nasdaq "),~~ stating that the Company' s Ordinary Shares ~~fail~~ **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 ~~the~~ **such** Notice ~~notices~~. **In each case** ~~Pursuant to Nasdaq Listing Rule 5810 (c) (3) (A)~~, the Company was **able** ~~provided an initial compliance period of 180 calendar days, or until May 22, 2023,~~ to regain compliance with the ~~minimum bid price requirement. On March 23, 2023,~~ Nasdaq **continued listing requirements within the** ~~notified us that we had regained~~ compliance **periods provided to** ~~with the minimum bid price requirement given that the closing bid price for our Ordinary Shares had been at or above $ 1. 00 for 14 consecutive trading days, from March 3, 2023~~

~~through March 22, 2023. On June 29, 2023,~~ the Company **by** ~~received an additional notice (the " Additional Notice ") from~~ Nasdaq ~~, stating that the Company' s Ordinary Shares fail to comply with the minimum bid price requirement based upon the closing bid price of the ordinary shares for the 30 consecutive business days prior to the date of the Additional Notice. Pursuant to Nasdaq Listing Rule 5810 (c) (3) (A), the Company was provided an initial compliance period of 180 calendar days to regain compliance with the minimum bid price requirement. On December 27, 2023, we received an extension of 180 calendar days, or until June 24, 2024, from Nasdaq, to regain compliance with the minimum bid price requirement. On March 1, 2024, Nasdaq notified us that we had regained compliance with the minimum bid price requirement given that the closing bid price for our Ordinary Shares had been at or above $ 1. 00 for 10 consecutive trading days, from February 15, 2024 through February 29, 2024~~ . However, there can be no assurance that we will maintain compliance with the $ 1. 00 minimum bid price requirement or comply with Nasdaq' s other continued listing standards in the future. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Ordinary Shares. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud among other objectives. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes- Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also subject us to regulatory scrutiny and sanctions, impair our ability to raise revenue and cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our Ordinary Shares. We are required to disclose changes made in our internal controls and procedures and our management is required to assess the effectiveness of these controls annually. However, for as long as we are 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 ~~, including EB612, EB613 and any other oral PTH product candidates we may develop~~ . The royalty rate may increase to 5 %, with respect to approved applications filed following any year in which we achieve sales of over $ 70 million. Under the Research Law, we are prohibited from manufacturing products **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 ~~those~~ **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. ~~Shareholders that~~ **Notice or undertaking to the IIA may not be required in respect of** ~~purchased~~ **purchase of** Ordinary Shares in **standard acquisition** ~~our~~ **or trading in the stock exchange following to an** IPO **that was approved by the IIA** ~~would not be required to sign such an undertaking~~. These restrictions will continue to apply even after we have repaid the full amount of the grants and the interest. If we fail to satisfy the conditions of the Research Law, we may be required to refund grants previously received together with interest and penalties, to make other payments to the IIA or become subject to criminal charges. 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 ~~and development~~ facilities are located in Israel. In addition, ~~some~~ **most** of our key employees, officers and directors are residents of Israel. Accordingly, political, economic and military conditions in the Middle East may affect our business directly. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries, Hamas (an Islamist militia and political group in the Gaza Strip) ~~and~~ **,** Hezbollah (an Islamist militia and political group in Lebanon) **, and Iran** . ~~In~~ **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** ~~civilian~~ **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** ~~in other areas within~~ the State of Israel. These attacks resulted in thousands of deaths and injuries, and Hamas additionally kidnapped ~~many~~ **over 250** Israeli civilians and soldiers. Following the attack, Israel' s security cabinet ~~declared war against Hamas and~~ 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 are uncertain** . While we have a few employees who are in active military service, the ongoing war ~~with Hamas has~~ **, the escalation of Hezbollah' s attacks on Northern Israel, and the direct offensives from Iran and its proxies have** not, **to date** ~~since its inception~~ , materially impacted our business or operations. Furthermore, we do not expect any delays to any of our programs as a result of **such conflicts. While research and some management are located in Israel,** ~~the~~ **other** ~~situation~~ **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 ~~this war~~ **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 ~~neighbor~~ **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 armed conflict ~~. In addition, Iran has threatened to attack Israel.~~ Iran is also believed to have a strong influence **over various proxy militias across the Middle East, and** among the ~~Syrian government,~~ Hamas and Hezbollah **, in addition to its readiness to engage in conflict with Israel directly** . These situations may potentially escalate in the future into more violent events which may affect Israel and us. ~~These situations, including conflicts which involved missile strikes against civilian targets in various parts of Israel, have, in the past, negatively affected business conditions in Israel.~~ Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could have a material adverse effect on our business. Although such hostilities did not have a material adverse impact on our business in the past, we cannot guarantee that hostilities will not be renewed and have such an effect in the future ~~. The political and security situation in~~

~~Israel may result in parties with whom we have contracts claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions~~ . These or other Israeli political or economic factors could harm our operations and product development. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could adversely affect our operations **. 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. This lowered 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. ~~Furthermore, several countries, as well as certain companies and organizations, continue to restrict business with Israel and Israeli companies, which could have an adverse effect on our business and financial condition in the future. Our business interruption insurance may not adequately compensate us for losses, if at all, that may occur as a result of an event associated with a security situation in the Middle East, and any losses or damages incurred by us could have a material adverse effect on our business.~~ Our operations may be disrupted by the obligations of personnel to perform military service. Our employees in Israel, including executive officers, generally, may be called upon to perform ~~up to 42 days (and in some cases more) of annual~~ military reserve duty until they generally reach the age of 45 (or older in some cases) ~~and, in emergency circumstances, could be called to active duty~~ . In response to ~~increased tension and hostilities, since September 2000 there~~ -- **the** ~~have been occasional call- ups of military reservists, including in connection with the mid- 2006 war in Lebanon and the December 2008, November 2012 and July 2014 conflicts with~~ Hamas ~~. In October 2023, Hamas terrorists invaded southern Israel and launched thousands of rockets in a widespread terrorist~~ attack on ~~Israel. As a result~~ **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, ~~but~~ **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 ~~2023~~ **2024** , the value of the NIS ~~depreciated~~ **increased** against the U. S ~~.~~ dollar by ~~3~~ **0** . ~~1~~ **55** %, which was potentially computed by inflation in Israel of 3 **. 5** %. In ~~2022~~ **2023** , the value of the NIS depreciated against the U. S. dollar by ~~13.~~ 3 **. 1** %, which was potentially computed by inflation in Israel of **3** ~~5. 5~~ %. As a result of these fluctuations, our NIS denominated expenses were affected. Potential future revenue may be derived from abroad, including outside of the United States. As a result, our business and share price may be affected by fluctuations in foreign exchange rates with these other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place. Foreign currency fluctuations could materially adversely affect our results of operations or could positively affect our results of operations in ways that may not necessarily be repeated in future periods. It may be difficult to enforce a U. S. judgment against us or our officers and directors, to assert U. S. securities laws claims in Israel or to serve process on our officers and directors. We are incorporated under the laws of the State of Israel. Service of process upon us, our directors and officers and the Israeli experts, if any, a significant number of whom reside outside the United States, may be difficult to obtain within the United States. Furthermore, because the majority of our assets and investments, and several of our directors, officers and such Israeli experts, if any, are located outside the United States, any judgment obtained in the United States against us or any of them may be difficult to collect within the United States. In addition, such judgment may not be enforced by an Israeli court. In addition, it may also be difficult for an investor to effect service of process on these persons in the U. S. or to assert U. S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U. S. securities laws reasoning that Israel is not the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U. S. law is applicable to the claim. If U. S. law is found to be applicable, the content of applicable U. S. law must be proved as a fact, which can be a time- consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. 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.