# Entera Bio Announces First Quarter 2025 Financial Results and Business Updates

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JERUSALEM, May 09, 2025 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of oral peptide and protein replacement therapies, today reported financial results and key business updates for the quarter ended March 31, 2025.

“During Q1 2025, Entera continued to generate intrinsic value with progress across our programs while significantly extending our cash runway into late 2026 via direct investment from marquis investors and our strategic partner, OPKO Health Inc. (“OPKO”). EB613 early mechanistic effects on both trabecular and cortical bone compartments data using 3D-Shaper software analysis was selected for oral presentation out of 1,680 abstracts submitted to the 2025 World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases Congress. Subsequent EB613 abstracts have been submitted to both the 2025 American Society for Bone Mineral Research (ASBMR) and the North American Menopause Society (NAMS) conferences. Pre-IND activities for our Next Gen EB613 tablet candidate are in final stages, with plans to initiate a Phase 1 study in H2 2025. Via the execution of our recent license agreement with OPKO, we are fully funded to co-develop Oral OPK-88006 (the first dual acting GLP1/Glucagon single tablet for metabolic diseases) through SAD/MAD Phase 1 studies while retaining a 40% stake in the economics of this important asset. An abstract for Oral OPK-88006 has been submitted to ENDO2025. Finally, we are judiciously strengthening our core team with important appointments including Ms. Leslie Gautam, as Chief Business Officer and Ms. Cherin Smith as Head of Clinical Operations, both of whom have extensive experience in strategic and operational execution in women-centric conditions,” said Miranda Toledano, Chief Executive Officer of Entera.

“We continue to optimize and prepare to initiate our proposed pivotal program for EB613, the first and only oral anabolic “bone building” tablet treatment under clinical investigation in postmenopausal women with osteoporosis. The earlier the age at which menopause occurs the greater the risk of long-term impact on bone and heart health. EB613 is specifically intended to provide an oral anabolic treatment in tablet format earlier in an osteoporosis patient’s journey to increase skeletal mass and reduce the risk of fracture. EB613 comprises the first 34 N-terminal amino acid sequence of the human parathyroid hormone, PTH(1-34) or teriparatide, which is a validated standard of care and only available as a daily subcutaneous injection. The morbidity and mortality risk of osteoporosis fractures to women outpaces that of breast cancer, stroke and heart attack combined. In the U.S., there are over 54 million American women and men with at-risk bone health and osteoporosis. The statistics associated with osteoporosis are staggering: fracture rates are on the rise state by state, severe mortality (20% - 30% die within 12 months of fracture), catastrophic comorbidity (50% of fracture survivors unable to walk independently), a persistent treatment chasm (<25% receive osteoporosis medication) and escalating and preventable pharmacoeconomic burden ($57 billion in Medicare). No new osteoporosis drug has been approved by U.S. Food and Drug Administration (FDA) since 2019 due to the ethical, size and duration challenges imposed by fracture-based studies. At the heart of this significant public health concern is the need for regulatory reform of the fracture endpoint currently required for approval of osteoporosis drugs by the FDA. The single most important predictor of osteoporotic fractures in postmenopausal women without a previous fracture is bone mineral density (BMD). The SABRE (Study to Advance Bone Mineral Density as a Regulatory Endpoint), initiative has amassed the strongest evidence to date substantiating that gains in total-hip BMD reliably predict fracture-risk reduction as a viable surrogate to fracture. This is analogous to prior initiatives that qualified LDL cholesterol as a surrogate to cardiovascular outcomes and HBA1C as a surrogate to diabetes complications. In March 2024 the FDA Biomarker Division indicated to the SABRE group that a decision may be issued within 10 months. Recent presentations by SABRE at medical congresses indicate their continued optimism that a ruling by FDA on the qualification of BMD as a surrogate for fracture is expected in 2025. We strongly endorse the proposed BMD ruling and view it as crucial to reinvigorate much needed innovation and more treatment choices for patients and clinicians in this underserved disease. We will be taking additional steps to ensure the continuity of clinical development for EB613,” said Miranda Toledano, Chief Executive Officer of Entera.

**Key Recent Highlights**

**EB613: First Oral PTH(1-34), teriparatide Anabolic Tablet Treatment Candidate for Women with Osteoporosis**

- On April 15, 2025, our Chief Clinical Advisor Dr. Rachel B Wagman presented at the 2025 WCO-IOF-ESCEO Congress “EFFECTS OF EB613 TABLETS [ORAL PTH(1-34)] ON TRABECULAR AND CORTICAL BONE USING 3D-DXA: POST-HOC RESULTS FROM PHASE 2 STUDY.” After 6 months of treatment, the findings showed increases with EB613 compared with placebo in a variety of indices, including integral volumetric BMD and trabecular volumetric BMD, cortical thickness, and cortical surface BMD. The evaluation

showed a broad distribution of bone loss in the femur with placebo and a similarly broad distribution of bone gain in the femur with EB613. Mechanistically, the findings suggest that bone strengthening, and fracture resistance may occur rapidly with EB613. Furthermore, the data are consistent with those of published subcutaneous teriparatide at the 6-month time point. During the quarter, further abstracts have been submitted to ASBMR and NAMS 2025 conferences

- Next Gen EB613, which is being developed with new generation of our N-TAB™ platform, is finalizing pre-IND activities with a plan to enter the clinic in H2 2025. We plan to submit an abstract on Next Gen EB613 to a major medical conference in 2025

**First GLP-1/Glucagon Agonist (Oxyntomodulin) Peptide Tablet Candidate for Obesity**

- In March 2025, we entered into a collaboration and license agreement with OPKO relating to the preclinical and clinical development of the Oral OXM program. Under the terms of the agreement, OPKO and Entera will hold 60% and 40% pro-rata ownership interests, respectively, in the program and be responsible for 60% and 40% of the program's development costs, respectively. We expect to file an Investigational New Drug application with the FDA later this year or early in 2026

- During the quarter, we submitted an abstract for Oral OPK-88006 to ENDO2025

**First GLP-2 Peptide Tablets for Short Bowel Syndrome**

- Given the challenging compliance rates attributed to injectable GLP-2 therapy and heterogeneity of short bowel syndrome (SBS) patients, we believe a daily tablet format may address a significant unmet need in treating and titrating SBS patients more effectively than injectable alternatives. OPKO and Entera are determining next steps for this program. We plan to submit abstracts to a major clinical conference with PK/PD of the single daily tablet of GLP-2 in late 2025

**Strong Additions to Entera Core Team**

- In March 2025, Cherin Smith joined Entera as EVP, Head of Clinical Operations. Cherin is an accomplished leader with more than 20 years of experience in global clinical operations leadership, project management, and vendor management. With more than a decade of strategic experience in women's health, Cherin has a broad background in various therapeutic areas, including osteoporosis, metabolic and rare diseases, and cardiovascular and CNS disorders. Cherin led the successful execution of 11 Phase 3 trials with BMD endpoints, including registrational Phase 3 programs for Orilissa®, Myfembree®, and Veozah®, and has contributed to NDA submissions. Cherin holds a Bachelor of Science, Psychobiology degree from the University of California, Los Angeles (UCLA) and is a certified Project Management Professional.

- On May 8$^{th}$, 2025, Leslie Gautam joined Entera as Chief Business Officer. Leslie has extensive strategic advisory experience across biopharma, with transaction experience in both clinical and commercial stage companies with a particular focus on women's health and supportive care. Most recently, Leslie was Co-Founder CEO of an early stage women's health company that provided care delivery and innovation for patients with hyperemesis gravidarum.

Prior to this role, Leslie held senior positions in the healthcare investment banking team at Stifel and Houlihan Lokey. Previously, she served as part of the business development teams at Purdue Pharma and Noven Pharmaceuticals and was an Institutional Investor ranked equity research analyst for UBS covering the pharmaceutical sector. Leslie started her career in the healthcare investment banking group of BMO Capital Markets. Leslie holds a B.S. in Psychobiology and Computer Programming from UCLA and an MBA in Finance from Columbia Business School.

"I'm honored to join Entera at such a pivotal moment for women's health. With an outstanding team and a pipeline designed to address long-overlooked conditions, we have an opportunity to turn scientific breakthroughs into meaningful, everyday impact for millions of patients. I'm excited to help accelerate that mission," said Leslie Gautam, Chief Business Officer of Entera.

**Financial Results for the Quarter Ended March 31, 2025**

As of March 31, 2025, Entera had cash and cash equivalents and restricted cash of $20.6 million, of which $8 million has been designated to fund the collaboration activity with OPKO. The cash is expected to be sufficient to support the Company's operations through the middle of the third quarter of 2026.

- Research and development expenses for the three months ended March 31, 2025 were $1.1 million, as compared to $0.7 million for the three months ended March 31, 2024. The increase of $0.4 million was primarily due to an increase of $0.2 million in other consulting fees, including regulatory required in connection with the optimization processes related to the preparation of the EB613 phase 3 program, $0.1 million in connection with our internal programs and collaboration with OPKO and $0.1 million in share-based compensation.

- General and administrative expenses for the three months ended March 31, 2025 were $1.4 million, as compared to $1.3 million for the three months ended March 31, 2024. The increase of $0.1 million was mainly attributable to an increase in IP costs and legal fees related to the execution of our collaboration agreement with OPKO and other potential strategic agreements.

- Operating expenses for the three Months ended March 31, 2025 were $2.6 million, as compared to $2.1 million for the three Months ended March 31, 2024.

Net loss was $2.6 million, or $0.06 per ordinary share (basic and diluted), for the three months ended March 31, 2025, as compared to 2.0 million, or $0.05 per ordinary share (basic and diluted), for the three months ended March 31, 2024.

**About Entera Bio**

Entera is a clinical stage company focused on developing oral peptide and protein replacement therapies for significant unmet medical needs where an oral tablet form holds the potential to transform the standard of care. The Company leverages on a disruptive and proprietary technology platform (N-Tab™) and its pipeline of first-in-class oral peptide programs targeting PTH(1-34), GLP-1 and GLP-2. The Company's most advanced product candidate, EB613 (oral PTH(1-34)), is being developed as the first oral, osteoanabolic (bone building) once-daily tablet treatment for post-menopausal women with low BMD and high-risk osteoporosis. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (PD/bone turnover biomarker) and secondary endpoints (BMD). Entera is preparing to initiate a Phase 3 registrational study for EB613 pursuant to the FDA's qualification of a quantitative BMD endpoint. The EB612 program is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for hypoparathyroidism. Entera is also developing the first oral oxyntomodulin, a dual targeted GLP1/glucagon peptide, in tablet form for the treatment of obesity; and first oral GLP-2 peptide tablet as an injection-free alternative for patients suffering from rare malabsorption conditions such as short bowel syndrome in collaboration with OPKO Health. For more information on Entera Bio, visit www.enterabio.com or follow us on LinkedIn, Twitter, Facebook, Instagram.

**Cautionary Statement Regarding Forward Looking Statements**

Various statements in this presentation are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements (other than statements of historical facts) in this presentation regarding our prospects, plans, financial position, business strategy and expected financial and operational results may constitute forward-looking statements. Words such as, but not limited to, "anticipate," "believe," "can," "could," "expect," "estimate," "design," "goal," "intend," "may," "might," "objective," "plan," "predict," "project," "target," "likely," "should," "will," and "would," or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved.

Important factors that could cause actual results to differ materially from those reflected in Entera's forward-looking statements include, among others: changes in the interpretation of clinical data; results of our clinical trials; the FDA's interpretation and review of our results from and analysis of our clinical trials; unexpected changes in our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make

regulatory filings and obtain and maintain regulatory approvals for our product candidates; the potential disruption and delay of manufacturing supply chains; loss of available workforce resources, either by Entera or its collaboration and laboratory partners; impacts to research and development or clinical activities that Entera may be contractually obligated to provide; overall regulatory timelines; the size and growth of the potential markets for our product candidates; the scope, progress and costs of developing Entera's product candidates; Entera's reliance on third parties to conduct its clinical trials; Entera's ability to establish and maintain development and commercialization collaborations; Entera's operation as a development stage company with limited operating history; Entera's competitive position with respect to other products on the market or in development for the treatment of osteoporosis, hypoparathyroidism, short bowel syndrome, obesity, metabolic conditions and other disease categories it pursues; Entera's ability to continue as a going concern absent access to sources of liquidity; Entera's ability to obtain and maintain regulatory approval for any of its product candidates; Entera's ability to comply with Nasdaq's minimum listing standards and other matters related to compliance with the requirements of being a public company in the United States; Entera's intellectual property position and its ability to protect its intellectual property; and other factors that are described in the "Cautionary Statement Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Entera's most recent Annual Report on Form 10-K filed with the SEC, as well as Entera's subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. There can be no assurance that the actual results or developments anticipated by Entera will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Entera. Therefore, no assurance can be given that the outcomes stated or implied in such forward-looking statements and estimates will be achieved. Entera cautions investors not to rely on the forward-looking statements Entera makes in this presentation. The information in this presentation is provided only as of the date of this presentation, and Entera undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

**ENTERA BIO LTD.**
**CONSOLIDATED BALANCE SHEETS**
(U.S. dollars in thousands)

| | March 31, 2025 | December 31, 2024 |
|---|---|---|
| | (Unaudited) | (Audited) |
| Cash and cash equivalents | 12,573 | 8,660 |
| Accounts receivable and other current assets | 645 | 312 |
| Restricted cash | 8,000 | - |
| Property and equipment, net | 57 | 57 |
| Other assets | 325 | 361 |
| **Total assets** | 21,600 | 9,390 |
| | | |
| Accounts payable and other current liabilities | 1,623 | 1,176 |
| Total non-current liabilities | 598 | 134 |
| Total liabilities | 2,221 | 1,310 |
| Total shareholders' equity | 19,379 | 8,080 |
| **Total liabilities and shareholders' equity** | 21,600 | 9,390 |

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

(Unaudited)

| | Three Months Ended March 31, | |
|---|---|---|
| | **2025** | **2024** |
| **REVENUES** | 42 | - |
| **COST OF REVENUES** | 42 | - |
| **GROSS PROFIT** | - | - |
| **OPERATING EXPENSES:** | | |
| Research and development | 1,123 | 735 |
| General and administrative | 1,440 | 1,327 |
| **TOTAL OPERATING EXPENSES** | 2,563 | 2,062 |
| **OPERATING LOSS** | 2,563 | 2,062 |
| **FINANCIAL INCOME, NET** | 4 | (45) |
| **NET LOSS** | 2,567 | 2,017 |

| | | |
|---|---|---|
| **LOSS PER SHARE BASIC AND DILUTED** | 0.06 | 0.05 |
| **WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE** | 43,377,391 | 36,735,429 |

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