Entera Bio Announces Full Year 2025 Financial Results and Provides Business Updates

March 27, 2026 8:05 PM EDT

EB613, the first oral anabolic (bone building) peptide tablet for postmenopausal women with osteoporosis – FDA Type A endpoint alignment in July 2025, Phase 3 protocol submitted to the FDA with comments expected in early Q2 2026

EB612, the first long-acting oral PTH peptide replacement tablet for patients with hypoparathyroidism - final variants selected, pre-IND initiatives underway with intention to file IND in late 2026 in partnership with OPKO

EB618, the first Oral OXM (GLP-1/Glucagon) peptide tablet for patients with metabolic syndromes – PK/PD validation complete, intention to file IND pursuant to OPKO Phase 1 SAD/MAD SC injection data

TEL AVIV, March 27, 2026 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) ("Entera" or the "Company"), a leader in the development of oral peptides, today reported financial results and key business updates for the year ended December 31, 2025.

"2025 was a landmark year for Entera, our EB613 program and for the osteoporosis community as a whole. We are eager to initiate our important phase 3 study for EB613 and thank the investigator and patient community for their enthusiasm to take part in this mission. While current injectable anabolic or bone forming agents are accepted or accessed by a minority of osteoporosis patients in whom they should be used, our mission with EB613 is to democratize anabolic treatment. EB613 is being developed as the first oral bone building tablet so potentially, every woman and man can have the opportunity to protect their bones whether they are being treated with a primary care practitioner or a specialist," said Miranda Toledano, Chief Executive Officer of Entera. "Throughout 2025, we also met every milestone relating to our pipeline and advanced each program with the utmost capital efficiency. Our N-Tab® oral peptide platform delivered differentiated preclinical data on LA-PTH, GLP-1/Glucagon and GLP-2 targets in partnership with OPKO Health, Inc. ("OPKO"). We believe these assets will further drive value for patients with hypoparathyroidism, metabolic syndromes and rare gastrointestinal chronic conditions."

Key Recent Highlights

EB613: First Oral PTH(1-34) Anabolic Tablet for Osteoporosis

- **Streamlined Phase 3 Protocol Submitted to FDA:** In March 2026, Entera submitted a clinical amendment to the FDA providing a streamlined Phase 3 protocol, statistical analysis plan, and open-label extension synopsis under its IND 505(b)(2) for EB613. The planned Phase 3 trial is a multinational, randomized, double-blind, placebo-controlled safety and efficacy study in 750 postmenopausal women with osteoporosis, with percentage change in total hip bone mineral density (BMD) from baseline to month 12 (rather than month 24) as the primary outcome measure, significantly reducing enrollment requirements and accelerating the potential path to approval. The final single-tablet formulation (Next-Gen EB613) is intended to advance directly into Phase 3, replacing the previous multi-tablet candidate. The Company is still preparing to initiate the study in late 2026, which could translate into topline results in the second half of 2028, approximately one year earlier than previously expected. Entera also submitted a synopsis for a 12-month open-label extension study expected to run in parallel with the NDA review which will provide 12-month, 24-month and sequence data for EB613. FDA feedback is anticipated in late April 2026.

- **FDA Alignment on BMD as Primary Endpoint: In July 2025,** in a written response to a Type

A meeting, the FDA agreed with Entera's proposal that a single multinational, randomized, double-blind, placebo-controlled, 24-month Phase 3 study where change in total hip BMD is evaluated as the primary endpoint, and incidence of new or worsening vertebral fractures as the key secondary endpoint, would support an NDA marketing application for EB613, making Entera the first company to receive such independent alignment. Following this milestone, in December 2025, the FDA issued a broad qualification of BMD with a suggested context of use that the percentage change from baseline at 24 months in total hip BMD could serve as a validated surrogate efficacy endpoint for novel osteoporosis drug development.

- **Next-Gen EB613:** Preclinical PK data presented at ASBMR 2026 showed comparable pharmacokinetic exposure of the single tablet to the multitablet EB613 formulation. In late 2025, Entera conducted a Phase 1 safety and PK bridging study of the single tablet versus the multitablet and versus Forteo®. In early 2026, Entera made the determination to advance the single tablet (the final commercial formulation) to Phase 3 based on its comparability to the multitablet and Forteo®.

- **Strong Phase 2 Data Reinforce Early Onset of EB613 Mechanism of Action to Increase Bone Formation and Decrease Bone Loss**: At both IOF and ASBMR 2025 Annual Meetings, EB613 post-hoc 3D-DXA data were selected for oral presentation. The analysis demonstrated significant increases in both trabecular and cortical bone indices after just six months of EB613 treatment, comparable to those reported for injectable teriparatide and abaloparatide. Mechanistically, the findings suggest that bone strengthening and fracture resistance may occur rapidly with EB613.

- **Expanded Evidence in Early Postmenopausal Women:** At the NAMS 2025 Meeting, new post-hoc Phase 2 analysis showed EB613's ability to drive significant and consistent gains in BMD at the spine, femoral neck and hip in younger women within 10 years of their last menstrual period and after more than 10 years post-last menstrual period. For younger high-risk women without a prior fracture, BMD is the single most important predictor of osteoporotic fractures.

EB612: First-in-Class Oral Long-Acting PTH(1-34) Replacement Tablet for Hypoparathyroidism

- **Positive Preclinical Data Validates Long-Acting PTH Tablet Candidate:** In December 2025, Entera announced positive in vivo pharmacokinetic and pharmacodynamic data for proprietary long-acting PTH (LA-PTH) analogs developed by OPKO and formulated with Entera's N-Tab® platform. In these studies, a single oral tablet achieved a markedly longer plasma half-life compared to unmodified PTH(1-34) controls, with sustained serum calcium elevation for over three days.

- **Expanded OPKO Collaboration Accelerates Path to Clinic, Fully Funded Through Phase 1:** In February 2026, Entera and OPKO expanded their 2025 collaboration agreement to co-develop the oral LA-PTH tablet for hypoparathyroidism as a priority program, with each party holding a 50% pro-rata ownership interest and sharing development costs equally. The companies have jointly decided to accelerate the program and expect to file an IND application in late 2026. Importantly, Entera's expenses related to development of the LA-PTH program into Phase 1 are expected to be funded with existing cash on the balance sheet.

EB618: First-in-Class Oral Dual GLP-1/Glucagon (OXM) Tablet for Obesity and Metabolic Disease

- **Oral OXM PK/PD Validation Completed; Phase 1 Sequencing Established:** Following

successful completion of in vivo PK/PD validation for both the subcutaneous and oral formulations of OPK-88006 in 2025, preclinical data presented at ENDO 2025 demonstrated plasma levels consistent with those reported in humans for the highest approved dose of Wegovy® (semaglutide). Entera and OPKO have jointly determined that Phase 1 data from the injectable formulation, expected by year-end 2026, will catalyse the initiation of the oral OXM tablet to Phase 1.

GLP-2 Program for Short Bowel Syndrome

- **PK data presented at ESPEN 2025:** The joint Entera-OPKO abstract highlighted a plasma half-life of approximately 15 hours, representing an 18-fold improvement over teduglutide (Gattex®), the only approved GLP-2 therapy for the treatment of short bowel syndrome, which requires a daily injection. The daily GLP-2 tablet candidate could fundamentally change how SBS patients are treated, offering a less-invasive administration that can be titrated to enable personalized dosing in this rare and heterogeneous condition.

Financial Results for the Year Ended December 31, 2025

Cash and cash equivalents were $14.9 million as of December 31, 2025, including $7.8 million in restricted cash designated to fund the OPKO collaboration, inclusive of LA-PTH for hypoparathyroidism (EB612). Cash on hand (not including restricted cash) is expected to support operations through the middle of the third quarter of 2026.

Net loss was $11.4 million, or $0.25 per ordinary share, for the year ended December 31, 2025, compared to $9.5 million, or $0.25 per ordinary share, for the year ended December 31, 2024**.**

Research and development expenses were $6.0 million for the year ended December 31, 2025, compared to $4.5 million for the same period in 2024, an increase of $1.5 million, primarily reflecting continued regulatory and Phase 3 preparation activities for EB613 and costs related to our internal programs and collaboration programs.

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

Total operating expenses were $11.5 million for the year ended December 31, 2025, compared to $9.6 million for the year ended December 31, 2024.

Net Cash used in operating activities for the year ended December 31, 2025 was $7.4 million.

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 a disruptive and proprietary technology platform (N-Tab®) and its pipeline of first-in-class oral peptide programs. 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 for 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 also developing the first oral Long Acting PTH(1-34) tablet as a replacement therapy for patients with hypoparathyroidism (EB612), the first oral oxyntomodulin, a dual targeted GLP1/glucagon peptide tablet for the treatment of obesity and metabolic syndromes; and the first oral GLP-2 tablet as an injection-free alternative for patients suffering from rare malabsorption conditions such as short bowel syndrome in collaboration with OPKO Health, Inc. For more information on Entera Bio, visit www.enterabio.com or follow us on LinkedIn, Twitter, and Facebook.

Cautionary Statement Regarding Forward Looking Statements
Various statements in this press release 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 press release regarding our prospects, plans, financial position, business strategy, clinical development activities, collaboration arrangements and expected financial and operational results are 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 press release. The information in this press release is provided only as of the date of this press release, 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.

Company Contact:
IR@enterabio.com

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

	December 31, 2025	December 31, 2024
Cash and cash equivalents	7,108	8,660
Accounts receivable and other current assets	415	312
Restricted cash and deposit	7,775	80
Property and equipment, net	134	57
Other assets	561	281
Total assets	15,993	9,390
Accounts payable and other current liabilities	2,203	1,176
Total non-current liabilities	689	134
Total liabilities	2,892	1,310
Total shareholders' equity	13,101	8,080
Total liabilities and shareholders' equity	15,993	9,390

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

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

Source: Entera Bio