Entera Bio Announces Third Quarter 2025 Financial Results and Business Updates

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FDA Agreement on BMD as Primary Endpoint for EB613 Registrational, Phase 3 Study

EB613 Phase 2 Data Demonstrating Consistent Efficacy across Younger Post-Menopausal Women with Osteoporosis and its Impact on Trabecular and Cortical Bone Indices, Highlighted at NAMS and ASBMR

Next-Generation EB613 Remains on Track for Phase 1 Initiation in Late 2025

Pre-Clinical Data for Oral OXM in Obesity and Oral GLP-2 in Short Bowel Syndrome in Collaboration with OPKO Presented at ENDO2025 and ESPEN

JERUSALEM, Nov. 14, 2025 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) ("Entera" or the "Company"), a leader in the development of oral peptide and protein replacement therapies, today reported financial results and key business updates for the quarter ended September 30, 2025.

"Our achievements this quarter are testament to Entera's leadership position in oral peptide innovation and our team's unrelenting mission to deliver transformative treatments to patients, starting with post-menopausal women with osteoporosis," said Miranda Toledano, Chief Executive Officer of Entera. "Our FDA agreement for EB613 this July is unprecedented and underscores the strength of our data and the promise for EB613 to close the treatment chasm in osteoporosis, a disease which disproportionately afflicts women and remains grossly undertreated globally. EB613 data continues to be highlighted across major medical conferences focused on advancing novel treatments in bone metabolism, endrocrine and women's health, while our N-Tab™ platform consistently delivered across pipeline programs, including our oral GLP-2 program for short bowel syndrome and our oral OXM program in metabolic diseases in partnership with OPKO Health ("OPKO")."

Key Recent Highlights

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

- **FDA Agreement on BMD as Primary Endpoint:** 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.

- **Strong Phase 2 Data Reinforce Early Onset of EB613 Anabolism:** At the ASBMR 2025 Annual Meeting, Entera presented post-hoc 3D-DXA results showing significant increases in both trabecular and cortical bone indices after just six months of EB613 treatment, comparable to 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 Phase 2 analysis demonstrated EB613 ability to drive significant and consistent gains in BMD at the spine, femoral neck and hip in younger women within 10 years of menopause, with improvements comparable to those observed in women more than 10 years post-menopause. For younger high-risk women without a prior fracture, BMD is the single most important predictor of osteoporotic fractures. Today, it is estimated that less than 15% of women are willing to take or have access to currently approved anabolics, which require daily or monthly injections.

- **Next-Gen EB613:** Preclinical PK data presented at ASBMR showed comparable pharmacokinetic exposure to the current formulation using a single fixed dose regimen, validating the N-Tab™ platform and potential franchise expansion. A Phase 1 trial of Next-Gen EB613 currently remains on track to initiate in late 2025.

GLP-2 Program for Short Bowel Syndrome (in collaboration with OPKO)

- **Positive 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, 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.

Dual GLP-1/Glucagon OXM Tablet Program (in collaboration with OPKO)

- **Encouraging preclinical data presented at the Endocrine Society (ENDO) 2025 annual meeting:** In the abstract titled “First-in-Class Oral Dual GLP-1/Glucagon Agonist for Patients with Obesity and Metabolic Disorders” PK data reported from a minipig study show plasma levels of OPK-88006 consistent with those reported in humans for the highest, 2.4 mg subcutaneous dose of Wegovy (semaglutide) weekly injection, a standard of care for the treatment of obesity. An IND for oral OXM is planned for H1 2026.

EB612: Oral PTH(1-34) Peptide Replacement Therapy for Hypoparathyroidism

- Collaborative studies evaluating a novel, long-acting PTH analog remain on track to deliver first PK/PD pre-clinical data for a single tablet candidate by year-end 2025.

Financial Results for the Quarter Ended September 30, 2025

Cash and cash equivalents were $16.6 million as of September 30, 2025, including $8.0 million in restricted cash designated to fund the OPKO collaboration through Phase 1 studies of oral GLP-1/glucagon candidate OPK-88006. Cash on hand is expected to support operations through the middle of the third quarter of 2026.

Net loss was $3.2 million, or $0.07 per ordinary share, for the three months ended September 30, 2025, compared to $3.0 million, or $0.08 per ordinary share, for the three months ended September 30, 2024.

Research and development expenses were $1.6 million for the three months ended September 30, 2025, compared to $1.5 million for the same period in 2024, an increase of $0.1 million, primarily reflecting continued regulatory and Phase 3 preparation activities for EB613.

General and administrative expenses were $1.6 million for the three months ended September 30, 2025, compared to $1.5 million for the prior-year quarter.

Total operating expenses were $3.3 million for the three months ended September 30, 2025, compared to $3.0 million for the three months ended September 30, 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). 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 metabolic syndromes; and first oral GLP-2 peptide 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, 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 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 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:
Entera Bio:
Ms. Miranda Toledano
Chief Executive Officer, Entera Bio
Email: miranda@enterabio.com

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

	September 30, 2025	December 31, 2024
	(Unaudited)	(Audited)
Cash and cash equivalents	8,574	8,660
Accounts receivable and other current assets	405	312
Restricted cash and deposit	8,114	80
Property and equipment, net	114	57
Other assets	200	281
Total assets	17,407	9,390
Accounts payable and other current liabilities	1,571	1,176
Total non-current liabilities	602	134
Total liabilities	2,173	1,310
Total shareholders' equity	15,234	8,080
Total liabilities and shareholders' equity	17,407	9,390

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

	Three Months Ended September 30,	
	2025	**2024**
REVENUES	-	42
COST OF REVENUES	-	42
GROSS PROFIT	-	-
OPERATING EXPENSES:		
Research and development	1,643	1,477
General and administrative	1,613	1,544
TOTAL OPERATING EXPENSES	3,256	3,021
OPERATING LOSS	3,256	3,021
FINANCIAL INCOME, NET	(56)	-
NET LOSS	3,200	3,021
LOSS PER SHARE BASIC AND DILUTED	0.07	0.08
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	47,085,722	37,644,612

Source: Entera Bio