Entera Bio Announces Second Quarter 2025 Financial Results and Business Updates

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- *FDA provides pivotal agreement on EB613 Phase 3 design, confirming Bone Mineral Density (BMD) as primary endpoint and clearing streamlined pathway for first oral anabolic osteoporosis treatment*
- *Significant regulatory and pipeline advancements achieved including FDA waiver of additional safety studies and next-gen EB613 expected to enter Phase 1 in November 2025*
- *Strong momentum across OPKO collaboration with obesity program showing promising preclinical data; and EB612 oral PTH directed hypoparathyroidism program candidate validation*
- *Strong balance sheet provides runway through mid-Q3 2026, including dedicated OPKO collaboration funding*

JERUSALEM, Aug. 08, 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 June 30, 2025.

"Last week's FDA agreement on using BMD as the primary endpoint for EB613's Phase 3 program represents a pivotal milestone in our journey to bring the first oral anabolic osteoporosis tablet treatment to market," said Miranda Toledano, Chief Executive Officer of Entera. "This unprecedented regulatory alignment validates both the strength of our clinical data and our strategic vision that began taking shape in July 2022. The concurrence opens the door to addressing a massive unmet need - with less than 25% of the world's 200 million osteoporotic women having access to safe, effective, and affordable treatment options, and no new therapies approved in this space since 2019. Beyond EB613, throughout Q2, we continued building momentum across our entire pipeline, including presenting promising pharmacokinetic data for our oral GLP-1/glucagon dual agonist program with OPKO. With our strengthened cash position of $18.9 million, including dedicated OPKO collaboration funding, we are well-positioned to execute on multiple value-creating milestones across 2025 and beyond."

Key Recent Highlights

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

- **FDA Agreement that BMD Primary Endpoint Would Support NDA:** In a July Type A meeting, FDA provided written concurrence on our Phase 3 study design - a single multinational, randomized, double-blind, placebo-controlled, 24-month study in women with postmenopausal osteoporosis, where change in total hip BMD is evaluated as the primary endpoint, and incidence of new or worsening vertebral fractures is evaluated as the key secondary endpoint. As a 505(b)(2) application, the submission will rely on FDA's previous findings of effectiveness and safety for the Reference Listed Drug Forteo®, where the correlation between BMD and fracture has been well-established. The study is designed and

powered to demonstrate a statistically significant increase in total hip BMD, coupled with a positive trend on vertebral fracture reduction as key secondary endpoint to provide substantial evidence of effectiveness. This FDA decision is independent of the Agency's qualification of the SABRE BMD Initiative which is still expected within 2025.

- **Regulatory Burden Significantly Reduced:** In May and June, Entera received written agreements from FDA that dedicated oral carcinogenicity studies and comprehensive nonclinical developmental and reproductive toxicity (DART) studies are not warranted given the totality of evidence generated fromForteo® literature and nonclinical studies conducted with EB613.
- **Strong Clinical Data Gains Scientific Recognition:** In April, Dr. Rachel B Wagman presented early effects of EB613 on trabecular and cortical bone using 3D-DXA at the 2025 WCO-IOF-ESCEO Congress. Additionally, 3D Shaper Phase 2 data was selected for oral presentation at ASBMR 2025 in September.
- **Next-Generation EB613 Advancing:** "Advancing Oral Anabolic Treatments for Osteoporosis: Pre-Clinical Data for Next Gen EB613 Tablet Utilizing N-Tab™ Proprietary Technology" was selected for poster presentation at ASBMR 2025. Next Gen EB613 is being developed with a new generation of Entera's N-TAB™ platform and is expected to enter the clinic in a Phase 1 Safety and PK Study in November 2025.
- **Strategic Regulatory Engagement:** In June, CEO Miranda Toledano participated in the Boston "CEO Forums: An FDA Listening Tour to Engage Pharma and Bio CEOs" and presented a one-minute brief on osteoporosis and potential regulatory reform to spur innovation.

First PTH (1-34) Tablet Protein Replacement Therapy for Hypoparathyroidism

- First pre-clinical PK/PD data from undisclosed collaborative research with long-acting PTH agonist as a once-daily tablet format is expected by end of year.

OPKO Health Collaboration Programs

- **First GLP-1/Glucagon Agonist (Oxyntomodulin) Peptide Tablet Candidate for Obesity:** In June, a poster at ENDO2025 reported PK data from a mini-pig study of oral OPK-88006 (dual GLP-1/glucagon receptor agonist in partnership with OPKO Health, Nasdaq: "OPK") which showed plasma levels consistent with those reported in humans for the highest subcutaneous dose of Wegovy™ (semaglutide) weekly injection, a standard of care for the treatment of obesity. The reported pharmacological data supports a once-daily tablet regimen of this first-in-class oral dual agonist. A Phase 1 study is being planned and IND filing is expected in H1 2026.
- **First GLP-2 Peptide Tablets for Short Bowel Syndrome:** In June, Entera in partnership with OPKO's "First-in-Class Oral GLP-2 Analog for Treatment of Short Bowel Syndrome" abstract was selected for poster presentation at the 47th European Society for Clinical Nutrition & Metabolism ("ESPEN") Congress.

Financial Results for the Quarter Ended June 30, 2025

Cash and cash equivalents were $18.9 million as of June 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 mid-third quarter 2026.

Net loss was $2.7 million, or $0.06 per ordinary share, for the three months ended June 30, 2025, compared to $2.1 million, or $0.06 per ordinary share, for the three months ended June 30, 2024.

Research and development expenses were $1.5 million for the three months ended June 30, 2025, compared to $1.1 million for the three months ended June 30, 2024, an increase of $0.4 million. The increase was primarily due to regulatory activities and Phase 3 planning for EB613.

General and administrative expenses were $1.1 million for the three months ended June 30, 2025, compared to $1.1 million for the three months ended June 30, 2024.

Total operating expenses were $2.7 million for the three months ended June 30, 2025, compared to $2.2 million for the three months ended June 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 a 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)teriparatide), 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 with alignment from FDA on the use of BMD as its primary 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)

	June 30, 2025	December 31, 2024
	(Unaudited)	(Audited)
Cash and cash equivalents	10,858	8,660
Accounts receivable and other current assets	438	312
Restricted cash	8,015	-
Property and equipment, net	79	57
Other assets	277	361
Total assets	19,667	9,390
Accounts payable and other current liabilities	1,844	1,176
Total non-current liabilities	567	134
Total liabilities	2,411	1,310

Total shareholders' equity	17,256	8,080
Total liabilities and shareholders' equity	19,667	9,390

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

(Unaudited)

	Three Months Ended June 30,	
	2025	**2024**
REVENUES	-	57
COST OF REVENUES	-	49
GROSS PROFIT	-	9
OPERATING EXPENSES:		
Research and development	1,520	1,086
General and administrative	1,148	1,088
TOTAL OPERATING EXPENSES	2,668	2,174
OPERATING LOSS	2,668	2,165
FINANCIAL INCOME, NET	(12)	(20)
NET LOSS	2,656	2,145
LOSS PER SHARE BASIC AND DILUTED	0.06	0.06
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	46,836,700	37,090,160

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