Entera Announces Third Quarter 2026 Financial Results and Business Updates

November 6, 2026 9:15 PM EST

Clinical Preparations Advanced for EB613 Phase 3 Osteoporosis Study, with First Site Activation Expected in Late 2026

Clinical and Commercial Leadership Expanded with Appointment of Senior Executives and Directors

EB613 Enhanced Anabolic Effect Highlighted at ASBMR Plenary Poster Presentation

IND-Enabling Activities Ongoing for EB612, in Development with OPKO for Hypoparathyroidism

Tel Aviv, Nov. 06, 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 quarter ended September 30, 2026.

"The third quarter of 2026 transitioned our expanding team into late-stage clinical execution mode. The opportunity to evaluate the safety and efficacy of EB613 as the first oral anabolic treatment for osteoporosis has generated excitement among clinical investigators and patients. Our team is fully focused on ensuring a seamless trial launch, with expected first site activation in late 2026. Additionally, the post-hoc analysis that we presented at ASBMR 2026 demonstrated that our Phase 2 6-month clinical data with EB613 show rapid stimulation of bone formation and robust early bone mineral density (BMD) accrual, especially in patients who start with lower BMD and who need the largest gains. These are the women we plan to enroll in our Phase 3 study. Finally, we continue to invest in expanding our human capital at Entera with early and late-stage clinical leadership and board appointments," said Miranda Toledano, Chief Executive Officer of Entera.

Key Recent Highlights

- **Core Team Expansion:** Entera has expanded its clinical and early development teams, including the following senior appointments:
  - **Riccardo Paolo Camisasca, M.D., Chief Medical Officer**, is a physician with more than 30 years of experience in late-stage clinical development and regulatory approvals, with previous leadership roles at Takeda, Novartis and Sumitomo Pharma Switzerland.
  - **Michele McDermott, M.D., Senior Vice President, Medical Affairs**, formerly Amgen US Bone Health Medical Director, is an endocrinologist with extensive clinical, research and biopharmaceutical experience focused on mid-life and older women. Dr. McDermott directed a Menopause and Osteoporosis center of excellence in Austin, Texas and was an investigator for over 40 women's health trials evaluating new treatments for menopause and osteoporosis.
  - **Ofer Spiegelstein, Ph.D., Vice President and Head of Early Clinical Development**, is an experienced clinical pharmacologist with over 20 years of experience advancing novel drug candidates from early preclinical research through clinical execution and regulatory milestones, including 16 years at Teva Pharmaceuticals, where he most recently served as Head of Clinical Pharmacology & Pharmacometrics.
  - **Graziella Soulban, Ph.D., Vice President, Clinical Development and Study Lead,** is an accomplished clinical development leader with over 30 years of experience leading

clinical research, operations and medical affairs with a particular focus on women's health research, most recently having served at Sumitomo Pharma America and Myovant Sciences.

- **Board of Directors Appointments:** Entera announced the appointments of Laura Hamill and Juan Camilo Arjona Ferreira, M.D., to its Board of Directors, each effective December 1, 2026. Ms. Hamill brings more than 35 years of global commercial, market access and business leadership experience and most recently served as Executive Vice President, Worldwide Commercial Operations at Gilead Sciences, Inc., following nearly two decades in leadership roles at Amgen Inc. Dr. Arjona Ferreira currently serves as Head of Research & Development and Chief Medical Officer at Organon & Co., and brings more than 20 years of global clinical development experience, including roles at Myovant Sciences, Shionogi and Merck & Co.

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

- **New Phase 2 Analysis Presented as Plenary Poster at ASBMR 2026:** On October 9, 2026, Entera presented new Phase 2 post-hoc analysis of EB613 in postmenopausal women with osteoporosis at high risk of fracture in a plenary poster presentation at the American Society for Bone and Mineral Research (ASBMR) 2026 Annual Meeting. Changes in bone turnover markers (increase in bone formation and suppression of bone resorption) were enhanced in women with T-scores of -2.5 or lower. This post-hoc analysis supports the potential benefit of EB613 within the population that is intended to be enrolled in Entera's Phase 3 study.
- **Phase 3 Study Design Presented at ASBMR 2026:** In October 2026, Entera presented the design of its planned Phase 3 study of EB613 at the ASBMR 2026 Annual Meeting. The study is expected to enroll approximately 900 postmenopausal women with osteoporosis, randomized 2:1 to EB613 (N ~ 600) or placebo (N ~ 300). Eligible participants will include postmenopausal women 50-90 years of age and ≥5 years from the last menstrual period with osteoporosis diagnosed by DXA with BMD T-score ≤-2.5 at either lumbar spine, total hip, or femoral neck. Participants completing 12 months of treatment in the registrational study will be eligible to enroll in the planned extension study through Month 24.
- **Phase 3 Initiation Planned for Late 2026:** In June 2026, Entera announced that the FDA accepted its proposed registrational development plan for EB613 and that a randomized, double-blind, placebo-controlled Phase 3 trial with a primary endpoint of percent change from baseline in total hip BMD at Month 12 may support the NDA. In addition, under the 505(b)(2) regulatory pathway, the NDA package will include a scientific bridging analysis with Forteo® (teriparatide SC injection, Eli Lilly) with separate population PK and PK substudies planned. Entera also intends to conduct a transiliac crest bone biopsy substudy in a small subset of patients as part of the registrational plan. Entera is preparing to activate the first clinical site for the Phase 3 study in late 2026, with topline results anticipated in the second half of 2028.

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

- **Phase 1 Initiation Planned for 2027:** Entera is conducting IND-enabling studies for EB612 in collaboration with OPKO Health ("OPKO") and plans to initiate a Phase 1 single ascending dose (SAD) study in 2027.

Financial Results for the Three Months Ended September 30, 2026

Cash and cash equivalents were $265.9 million as of September 30, 2026, and restricted cash was $6.5 million, primarily designated to fund the OPKO collaboration. In July 2026, Entera announced that it had completed an oversubscribed private placement with gross proceeds of approximately $275.0 million before deducting placement agent fees and offering expenses. The Private Placement was led by existing investor BVF Partners L.P. ("BVF"), with participation from new investors, including Longitude Capital, Vivo Capital, TCGX, Spruce Street Capital, Venrock Healthcare Capital Partners, RA Capital Management, Perceptive Advisors, Driehaus Capital Management, Logos Capital, and Catalio Capital Management, among

others. The Company's cash resources are expected to be sufficient to fully fund the planned Phase 3 registrational program of EB613 through topline results and the anticipated submission of an NDA to the FDA and to support the Company's operations into 2030.

Research and development expenses for the three months ended September 30, 2026 were $4.9 million, as compared to $1.6 million for the three months ended September 30, 2025. The increase of $3.3 million was primarily attributable to start-up activities for the EB613 Phase 3 program and to activities under the OPKO collaboration.

General and administrative expenses for the three months ended September 30, 2026 were $2.3 million, as compared to $1.6 million for the three months ended September 30, 2025.

Net loss was $15.6 million, or $0.11 per ordinary share (basic and diluted), for the three months ended September 30, 2026, as compared to $3.2 million, or $0.07 per ordinary share (basic and diluted), for the three months ended September 30, 2025. The increase was primarily driven by a $7.5 million non-cash fair value remeasurement of the pre-funded warrants issued in our April 2026 and July 2026 private placements, which were reclassified to equity in August 2026.

About Entera
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 acylated 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, visit www.enterabio.com or follow us on LinkedIn, X (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: the anticipated use of proceeds from the July 2026 private placement; the timing, design, and results of the planned Phase 3 registrational study of EB613; the FDA's ongoing review of the EB613 program, including the terms and interpretation of the FDA's feedback on our Clinical Amendment; the timing of the anticipated Phase 1 initiation for EB612 and next steps for EB618 in collaboration with OPKO Health; the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates; 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 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.

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

	September 30, 2026 (Unaudited)	December 31, 2025 (Audited)
Cash and cash equivalents	265,883	7,108
Restricted cash	6,536	7,775
Accounts receivable and other current assets	4,046	415
Property and equipment, net	133	134
Other assets	442	561
Total assets	277,040	15,993
Accounts payable and other current liabilities	2,153	2,203
Other non-current liabilities	605	689
Total liabilities	2,758	2,892

Total shareholders' equity	274,282	13,101
Total liabilities and shareholders' equity	277,040	15,993

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

	Three Months Ended September 30,	
	2026	**2025**
REVENUES	—	—
COST OF REVENUES	—	—
GROSS PROFIT	—	—
OPERATING EXPENSES:		
Research and development	4,925	1,643
General and administrative	2,340	1,613
TOTAL OPERATING EXPENSES	7,265	3,256
OPERATING LOSS	7,265	3,256
FINANCIAL EXPENSES (INCOME), NET	8,332	(56)
NET LOSS	15,597	3,200
LOSS PER SHARE BASIC AND DILUTED	0.11	0.07
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	145,075,070	47,089,814

Source: Entera Bio Ltd.