Entera Bio Announces Upcoming Q1 2026 Corporate Priorities and Pipeline Outlook

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Final EB613 Phase 3 Protocol Submission to FDA Planned for Q1 2026, Following December 19th 2025 FDA Ruling

Next-Generation EB613 Phase 1 Bridging Study Progressing with Results Expected During Q1 2026

Oral Hypoparathyroidism Tablet Program to Accelerate with Lead Long-Acting PTH Variants

Strategic Partnership Discussions Advancing Across Pipeline

JERUSALEM, Jan. 21, 2026 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) ("Entera" or the "Company"), a leader in the development of oral peptide and protein replacement therapies, today announced its expected corporate milestones for the first quarter of 2026.

"We expect to achieve three important goals during Q1 2026 to drive value for patients with osteoporosis and hypoparathyroidism. We would like to thank the investigators from around the world who participated in our Phase 3 feasibility study, and the patients who are reaching out since our FDA alignment for EB613 in July 2025. We hear you and remain steadfast in our commitment to advance this important program back into clinic. As a Company, we continue to invest and innovate in therapeutic spaces that have been ignored, require urgent attention and practical treatments and plan to also accelerate our hypoparathyroidism program this year. This is the second women-centric underserved condition where we believe our oral peptides can make a real difference," said Miranda Toledano, CEO of Entera.

Key Priorities and Expected Milestones for Q1 2026

EB613: First Oral PTH(1-34) Anabolic Tablet Treatment for Post-Menopausal Women with Osteoporosis
Building on Entera's unprecedented July 29th 2025 alignment with FDA and FDA's December 19th 2025 broad qualification of BMD as a regulatory endpoint for anti-osteoporosis drugs, Entera is planning to submit its final Phase 3 protocol to FDA in Q1 2026.

Next-Generation EB613
A Phase 1 bridging study of Next-Gen EB613 that initiated in November 2025 is progressing on schedule, with results expected by the end of Q1 2026. The Next-Gen candidate offers significant administration, commercial and strategic advantages.

EB612: Oral Long Acting PTH(1-34) Peptide Tablet for Patients with Hypoparathyroidism
Entera plans to accelerate its hypoparathyroidism program into clinic in 2026 based on robust preclinical PK/PD data for a proprietary long-acting PTH analog announced in late December 2025.

Entera continues to engage in strategic partnership discussions across its pipeline to optimize the development and commercialization pathway for its first-in-class oral peptide programs.

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), 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). 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.

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Source: Entera Bio