Entera Announces Second Quarter 2026 Financial Results and Business Updates

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U.S. Food and Drug Administration (FDA) Alignment on 12-Month Registrational Phase 3 Study to Support NDA for EB613 - the First Oral Anabolic Tablet in Development for Postmenopausal Women with Osteoporosis

Oversubscribed $275 Million Private Placement Led by BVF Partners L.P. ("BVF") with Participation from Leading Institutional Healthcare Investors to Fund EB613 through Anticipated Submission of NDA to the FDA

EB613 Phase 3 Study Initiation Planned for Late 2026 with Topline Data Anticipated in the Second Half of 2028

IND Enabling Studies Ongoing for EB612 - the First Oral Peptide Replacement Tablet in Development for Patients with Hypoparathyroidism – Intention to File IND in First Half of 2027

TEL AVIV, Aug. 07, 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 June 30, 2026.

"The first half of 2026 marked one of the most consequential periods in Entera's history. Since 2022, our core team embarked upon a journey of deconstruction and reconstruction to advance our science and optimize our pipeline. Despite scarce resources and particularly turbulent times, today, our N-Tab® platform is developing one of the richest pipelines of clinical and near-clinical first in class oral peptide assets; and we have garnered the trust of global talent, luminaries, and financiers who support our mission and vision. Thank you. Osteoporosis is one of the foremost underserved health issues globally, and associated fracture rates continue to rise despite existing treatments. Our discussions with patients and their caregivers across primary care, gynecology, orthopedic surgery, rheumatology and endocrinology acknowledge the urgent need for new treatments, especially, an oral anabolic therapy. We are developing EB613 to address this treatment gap. Our plan is to do the same with EB612 for patients with hypoparathyroidism, also a women-centric condition. The capital raising transaction we announced on July 27, 2026, led by BVF is transformational for Entera. To our knowledge, the transaction is the largest biotech PIPE and the 9th largest PIPE, inclusive of the high-tech sector, on record in Israel. So, we shattered a few records and moving forward, we intend to continue to shatter more records across all our programs with a cohesive, global team of colleagues who are obsessed with our vision and steadfast in our execution," said Miranda Toledano, Chief Executive Officer of Entera.

Key Recent Highlights

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

- **Positive FDA Feedback on 12-Month Registrational Phase 3 Study Received:** In June 2026, Entera announced that the FDA accepted Entera's plan to conduct a single, randomized, double-blind, placebo-controlled Phase 3 trial in approximately 750 postmenopausal women with osteoporosis, with a primary endpoint of percent change from baseline in total hip bone mineral density (BMD) at Month 12 to support a potential new drug application ("NDA") submission. The proposed NDA package will also include Entera's scientific bridge analysis with Forteo® (teriparatide SC injection, Eli Lilly) under the 505(b)(2) pathway, and a transiliac crest bone biopsy sub-study in a subset of patients. The FDA also agreed with Entera's proposal to continue following randomized patients for 24 months in an open-label extension study under a separate protocol. Entera plans to submit data through up to 18 months as part of the 120-day safety update to its NDA. Additionally, Entera will submit the complete 2-year data upon completion of the open-label extension study to characterize further the durability of the treatment effect, safety, and sequence data for EB613 followed by a

standard anti-resorptive therapy for 12 months. Entera plans to initiate the registrational Phase 3 study in late 2026, with topline results anticipated in the second half of 2028.

- **Single Tablet EB613 Data Presented as Late-Breaking Oral at ENDO 2026:** In June 2026, at the annual meeting of the Endocrine Society (ENDO 2026), Entera presented comparative Phase 1 data demonstrating that single-tablet EB613 achieved a pharmacokinetic (PK) and pharmacodynamic (PD) profile comparable to both multi-tablet EB613, which was evaluated in the Company's Phase 2 study, and Forteo®. Comparable calcemic effects and consistent suppression of endogenous PTH(1-84) were shown for both oral EB613 treatments and Forteo®. These data support advancing single-tablet EB613 into the planned Phase 3 registrational study.

- **Key Opinion Leader (KOL) Webinar on Osteoporosis Treatment Landscape:** On April 20, 2026, Entera hosted a virtual KOL roundtable with Dr. Felicia Cosman (Professor of Medicine at Columbia University and a globally recognized authority in osteoporosis and anabolic therapies) and Dr. Steven Goldstein (Professor of Obstetrics and Gynecology at New York University Grossman School of Medicine and former President of both the International Menopause Society and the North American Menopause Society) to gain endocrinology and gynecology insights into the current osteoporosis treatment paradigm. The KOLs highlighted the critical unmet demand for an oral anabolic in this silent, asymptomatic disease and EB613's potential to transform the treatment paradigm. The full transcript is available here.

- **EB613 Data Selected for Plenary Poster Presentation at ASBMR 2026:** In August 2026, Entera announced that new Phase 2 analysis of EB613 in postmenopausal women with osteoporosis at high risk of fracture was selected for a plenary poster presentation at the American Society for Bone and Mineral Research (ASBMR) 2026 Annual Meeting, taking place October 9–12, 2026 in Boston, Massachusetts.

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

- **Robust Preclinical Data Presented at ENDO 2026:** In June 2026, Entera reported preclinical data for EB612, a proprietary first-in-class long-acting PTH(1-34) analog formulated with Entera's N-Tab® oral peptide platform, at ENDO 2026. Across three preclinical models - a thyroparathyroidectomized (TPTx) rat model, a minipig model, and a non-human primate model - single oral doses of EB612 produced robust bioavailability and rapid, sustained increases in serum calcium lasting approximately three days. EB612 was well tolerated with no safety concerns identified, and the calcemic effects were consistent with those reported for clinically validated injectable PTH-replacement therapies for hypoparathyroidism. Following the previously announced expansion of the Company's collaboration with OPKO Health ("OPKO") in February 2026, Entera and OPKO intend to file an Investigational New Drug (IND) application for EB612 in the first half of 2027.

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

- **Non-Human Primate PK/PD Data Presented at ENDO 2026:** In June 2026, Entera reported single-dose PK/PD results in non-human primates for EB618, a proprietary long-acting oxyntomodulin analog formulated with Entera's N-Tab® platform, at ENDO 2026. EB618 exhibited robust bioavailability with dose-proportional systemic exposure across three tested tablet strengths and low variability and produced a dose-proportional pharmacologic effect on postprandial blood glucose levels. EB618 was well tolerated at doses exceeding the anticipated clinical dose range by more than tenfold. These data support the continued clinical

development of EB618 as a potential first-in-class oral once-daily GLP-1/glucagon receptor agonist for the treatment of obesity and metabolic disorders. As previously disclosed, Entera expects to evaluate the initiation of EB618 clinical development pursuant to analysis of the Phase 1 SAD/MAD studies of subcutaneous injectable OXM being conducted by OPKO.

Corporate Highlights

- **Oversubscribed $275 Million Private Placement:** Subsequent to quarter end, in July 2026, Entera announced the oversubscribed private placement which provided gross proceeds of approximately $275.0 million before deducting placement agent fees and offering expenses. The Private Placement was led by existing investor 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. Upon closing of the Private Placement, BVF was granted the right to designate two directors to the Company's board of directors. The net proceeds are anticipated to fully support the Phase 3 registrational program of EB613 through the anticipated submission of NDA to the FDA, advance EB612 into the clinic in collaboration with OPKO and extend the Company's cash runway into 2030.

- **Direct Investment Led by BVF:** In April 2026, Entera announced a private placement led by BVF for approximately $10.0 million in gross proceeds, with the potential for up to $24.5 million in total proceeds upon full exercise of accompanying five-year warrants.

Financial Results for the Three Months Ended June 30, 2026

Cash and cash equivalents were $11.3 million as of June 30, 2026, and restricted cash was $7.1 million, primarily designated to fund the OPKO collaboration. On a pro forma basis, following the closing of the July 2026 private placement in which the Company received aggregate gross proceeds of approximately $275.0 million, 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 June 30, 2026 were $3.2 million, as compared to $1.5 million for the three months ended June 30, 2025. The increase of $1.7 million was primarily attributable to increased materials, production and other costs related to the preparation of the EB613 Phase 3 program and to activities under the OPKO collaboration.

General and administrative expenses for the three months ended June 30, 2026 were $1.4 million, as compared to $1.1 million for the three months ended June 30, 2025.

Net loss was $7.3 million, or $0.14 per ordinary share (basic and diluted), for the three months ended June 30, 2026, as compared to $2.7 million, or $0.06 per ordinary share (basic and diluted), for the three months ended June 30, 2025. The increase was primarily driven by a $2.7 million non-cash fair value remeasurement of the pre-funded warrants issued in our April 2026 private placement, which are classified as a financial liability.

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 Long-Acting PTH(1-34) tablet as a replacement therapy for patients with hypoparathyroidism (EB612), the first oral oxyntomodulin, a dual targeted GLP-1/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, 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 IND filings for EB612 and 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)

	June 30, 2026	December 31, 2025
	(Unaudited)	*(Audited)*
Cash and cash equivalents	11,309	7,108
Restricted cash	7,122	7,775
Accounts receivable and other current assets	465	415
Property and equipment, net	121	134
Other assets	463	561
Total assets	**19,480**	**15,993**
Accounts payable and other current liabilities	2,104	2,203
Pre-funded warrants liability	9,563	—
Other non-current liabilities	547	689
Total liabilities	**12,214**	**2,892**
Total shareholders' equity	7,266	13,101
Total liabilities and shareholders' equity	**19,480**	**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 June 30,	
	2026	2025
REVENUES	—	—
COST OF REVENUES	—	—
GROSS PROFIT	**—**	**—**
OPERATING EXPENSES:		
Research and development	3,201	1,520
General and administrative	1,362	1,148
TOTAL OPERATING EXPENSES	**4,563**	**2,668**
OPERATING LOSS	**4,563**	**2,668**
FINANCIAL EXPENSES (INCOME), NET	2,749	(12)
NET LOSS	**7,312**	**2,656**
LOSS PER SHARE BASIC AND DILUTED	**0.14**	**0.06**
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	**50,451,232**	**46,836,700**

Source: Entera Bio Ltd.