Entera Bio Reports Q3 2023 Financial Results, Highlights Transformational Steps and Unveils Vision as Premier Oral Peptide Company with Five Potential Programs in Development

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JERUSALEM, Nov. 14, 2023 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), ("Entera" or the "Company"), a leader in the development of orally delivered peptides and small therapeutic proteins, today reported corporate updates and financial results for the third quarter ended September 30th, 2023.

"Today, after over a year of steadfast transformation and execution, Entera stands as a premier oral peptide company. It is our goal to potentially move five high value, first-in-class programs, Phase 1 through Phase 3, into the clinic by the end of 2025."

"Our disruptive and proprietary technology simultaneously inhibits gastrointestinal enzymatic degradation and consistently produces bioavailability of peptides, via a simple tablet format (around 6mm in diameter). Each of our oral peptide programs has been carefully selected based on platform alignment and our mission to successfully develop treatments that stand to become the number one choice for patients. Importantly Entera has sufficient cash on hand to enable key read-outs from our significant pipeline expansion efforts over the coming year," said Miranda Toledano, Chief Executive Officer of Entera.

"With our Phase 3 ready EB613 (oral PTH (1-34) peptide), we aim to transform the lives of osteoporosis patients, starting with the estimated 200 million women globally at-risk of fracture. We are also exploring the potential use of EB613 to accelerate stress fracture healing due to high intensity athletic or military training. Our EB612 program aimed at the development of a once-a-day (oral PTH (1- 34) peptide) replacement therapy for patients suffering from hypoparathyroidism, a disease which also disproportionately afflicts women, is being tested using a new generation of our platform. In September 2023, we announced a transformative collaboration with OPKO Health, Inc. ("OPKO") that expands our oral delivery technology across two additional peptides: GLP-2 for the treatment of short bowel syndrome, and oxyntomodulin, a dual targeted GLP-1 / glucagon agonist, for the treatment of obesity," said Ms. Toledano

"On a separate note, we would like to thank our collaborators, partners, and shareholders around the world for reaching out during the last six weeks since the war in Israel erupted to ensure the safety of our team and loved ones. Entera houses R&D, some manufacturing and key personnel across Israel, alongside our clinical, supply chain, regulatory and other functions in the U.S., UK and the EU. While our entire team at Entera is "safe" and continues to meet goals; we are all deeply affected by the current situation. Entera stands with Israel and its right to protect its diverse population of Jewish, Muslim, Druze and Christian citizens and residents. All of us are united in the protection and preservation of our heterogeneous and democratic country," said Ms. Toledano.

Entera Q3 2023 Updates and Goals for 5 Oral Peptide Programs:

EB613: First Oral PTH (1-34) Daily Osteoanabolic Tablets for Osteoporosis
EB613 (oral PTH (1-34), teriparatide), is being developed as the first oral, osteoanabolic (bone building) once-daily tablet treatment for osteoporosis. Entera is prepared to initiate a pivotal phase 3 study in post-menopausal women with high-risk osteoporosis and no prior fracture. Entera successfully completed a phase 2, 6-month, 161-patient, placebo-controlled study. EB613 produced rapid dose-proportional increases in biochemical markers of bone formation, reductions in markers of bone resorption, and increased lumbar spine, total hip, and femoral neck BMD in postmenopausal women with low mass or osteoporosis and no prior fracture. In October 2022, following a Type C meeting and in March 2023 following a Type D meeting, Entera announced the U.S. Food and Drug Administration's (FDA) concurrence that a 2-year, placebo-controlled phase 3 (registrational) study with Total Hip Bone Mineral Density (BMD) as primary endpoint could support an NDA for EB613. On November 9th, 2023, Entera reported that the American Society for Bone and Mineral Research (ASBMR) announced that the SABRE (Strategy to Advance BMD as a Regulatory Endpoint) project team had submitted to its full qualification plan to FDA for the use of BMD as a surrogate endpoint for fractures in future trials of new anti-osteoporosis drugs. EB613 stands as the first program to potentially avail itself of the ASBMR-SABRE BMD endpoint.

EB613: First Oral PTH (1-34) Osteoanabolic Tablets to Treat Intense Sport and Military Stress Injuries
Entera's ability to consistently deliver its oral PTH (1-34) peptide in a simple mini tablet format with reproduceable, dose dependent pharmacokinetics and rapid biological responses across gender, age, and health status was highlighted as part of two poster sessions at the Annual Society of Bone and Mineral Research (ASBMR) 2023 Annual Meeting held on October 13-16, 2023. This work also builds the foundation for Entera's oral PTH (1-34) tablets to potentially treat diverse patient populations including younger men and women athletes at risk of stress fractures. The Company is working towards a potential Phase 2 study for EB613 in this important indication.

EB612: First Oral PTH (1-34) Peptide Replacement Therapy Tablets for Hypoparathyroidism
EB612, is the first oral formulation of PTH (1-34), as a hormone replacement treatment for hypoparathyroidism. An open-label Phase 2a multicenter Phase 2A study, evaluating the safety, tolerability and PK of EB612 in 19 patients with hypoparathyroidism, achieved its primary and secondary endpoints, including a significant reduction in calcium supplementation (42% reduction from baseline, (p=0.001), a decline of 23% (p=0.0003) in median serum phosphate levels two hours following the first dose that was maintained for the duration of the study, improvement in quality of life score and maintenance of median calcium levels above the lower target level for hypoparathyroidism patients (>7.5 mg/dL) throughout the study. There were no treatment emergent adverse events of hypercalcemia reported and no treatment-emergent serious adverse events. Entera is currently evaluating its hypoparathyroidism program with improved formulations of EB612 based on new intellectual property, tailored to optimize its PK profile and the potential for reduced daily dosing as well as by potentially combining Entera's platform with alternative PTH analogues. Updates from the ongoing PK/PD study are expected by the end of 2023.

First GLP-2 Peptide Tablets for Short Bowel Syndrome
Under our collaboration agreement with OPKO, OPKO will supply its proprietary long-acting GLP-2 peptide to combine with Entera's oral peptide platform for the development of the first potential daily oral GLP-2 for the treatment of short bowel syndrome. Treatment with Glucagon-Like Peptide-2 (GLP-2) analogs has been shown to improve the absorption of nutrients in patients with short bowel syndrome (SBS) and reduce parenteral support requirements. Teduglutide, the only approved GLP-2 analog, requires daily subcutaneous injections. In SBS patients, oral drug delivery is particularly challenging because the site of absorption, the intestine, is short and less functional. Entera published pre-clinical data in May 2023 demonstrating

that its oral peptide delivery platform enables gastric absorption of teduglutide, as a convenient potential tablet alternative to daily injections. OPKO and Entera expect to update on the program in the first half of 2024.

First GLP-1/Glucagon Agonist (Oxyntomodulin) Peptide Tablets for Obesity
Oxyntomodulin is a naturally occurring peptide hormone found in the colon, with glucagon-like-peptide 1 (GLP-1) and glucagon dual agonist activity which suppresses appetite and induces weight loss. OPKO has developed several proprietary, modified OXM analogs as potential candidates for treating obesity, including an injectable pegylated peptide which demonstrated significant reductions in weight loss and decreased plasma triglyceride levels with cardioprotective benefits in a 420 patient phase 2 study. Under the collaboration agreement, OPKO will supply certain OXM analogs to combine with Entera's oral peptide platform. OPKO and Entera expect to update on the program in the first half of 2024.

Financial Results for the Three Months Ended September 30, 2023

As of September 30, 2023, Entera had cash and cash equivalents of $7.6 million. The Company expects that its existing cash resources are sufficient to meet its projected operating requirements into the third quarter of 2024, which includes the capital required to fund our ongoing operations, including the completion of the Phase 1 PK study related to our new generation platform and the GLP-2/OXM collaborative research we are conducting with OPKO.

Research and development expenses for the three months ended September 30, 2023 and 2022 were approximately $1.4 million. For the quarter ended September 30, 2023, there was an increase of $0.4 million in clinical expenses for our Phase 1 PK study related to our new generation platform and new formulations for EB612, which was offset by a decrease of $0.3 million materials and production costs and a decrease of $0.1 million in share-based compensation expense.

General and administrative expenses for the three months ended September 30, 2023 were $1.0 million, as compared to $1.5 million for the three months ended September 30, 2022. The decrease of $0.5 million was mainly attributable to a decrease of $0.3 million in professional fees and other consultants and a decrease of $0.2 million in D&O insurance costs.

Operating expenses for the three months ended September 30, 2023 were $2.4 million, as compared to $2.9 million for the three months ended September 30, 2022.

Net loss was $2.4 million, or $0.08 per ordinary share (basic and diluted), for the three months ended September 30, 2023, as compared to $3.1 million, or $0.11 per ordinary share (basic and diluted), for the three months ended September 30, 2022.

About Entera Bio

Entera focuses on significant unmet medical needs where an oral tablet form of a peptide treatment or protein replacement therapy holds the potential to transform the standard of care. The Company's oral PTH (1-34) teriparatide mini tablets have been administered to a total of 240 subjects (153 patients) across Phase 1 and Phase 2 studies, with demonstrated bioavailability and clinical benefit across two distinct diseases. 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, with no prior fracture. 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. EB612 is being developed as the first tablet peptide replacement therapy for the treatment of hypoparathyroidism. The Company is currently conducting a phase 1 PK study of novel PTH formulations using its proprietary, next generation oral delivery platform with data expected in the second half of 2023. Entera is also developing oral GLP-2 peptide as an injection-free alternative for patients suffering from short bowel syndrome and other severe intestinal and malabsorption metabolic conditions and oral Oxyntomodulin (GLP1/glucagon) peptide for obesity in collaboration with OPKO Health. For more information on Entera Bio, visit www.enterabio.com

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 expectations regarding licensing, business transactions and strategic collaborations; Entera's operation as a development stage company with limited operating history; 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 Statements 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 the company'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.

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

	September 30 2023	December 31 2022
	(Unaudited)	(Audited)
Cash and cash equivalents	7,585	12,309
Accounts receivable and other current assets	431	540
Property and equipment, net	108	139
Other assets, net	441	139
Total assets	8,565	13,127
Accounts payable and other current liabilities	2,027	1,341
Total non-current liabilities	302	32
Total liabilities	2,329	1,373
Total shareholders' equity	6,236	11,754
Total liabilities and shareholders' equity	8,565	13,127

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

(Unaudited)

	Three Months Ended September 30,	
	2023	**2022**
REVENUES	-	8
COST OF REVENUES	-	6
GROSS PROFIT	-	2
OPERATING EXPENSES:		
Research and development	1,370	1,413
General and administrative	1,028	1,460
Other income	(12)	(6)
TOTAL OPERATING EXPENSES	2,386	2,867
OPERATING LOSS	2,386	2,865
FINANCIAL EXPENSES (INCOME), NET	(36)	8
LOSS BEFORE INCOME TAX	2,350	2,873
INCOME TAX	29	194
NET LOSS	2,379	3,067
BASIC AND DILUTED LOSS PER SHARE	0.08	0.11
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	28,813,952	28,809,922

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