Entera Bio Provides Corporate Updates and Financial Results for the Third Quarter of 2022

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JERUSALEM, Nov. 10, 2022 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), ("Entera" or the "Company") a leader in the development of orally delivered peptides and therapeutic proteins, today announced its financial results for the third quarter of 2022 and provided the following corporate updates.

Corporate Updates:

Achieved FDA Agreement for Pivotal Study of EB613, the World's First Daily Bone Forming Oral PTH Tablet

- On October 6th, 2022, Entera announced that it had successfully completed its Type C meeting and reached a record agreement with the U.S. Food and Drug Administration (FDA) that a single pivotal Phase 3 placebo-controlled study could support a New Drug Application (NDA) submission for its lead clinical candidate, EB613 under the 505(b)(2) regulatory pathway.

- Importantly, the FDA also agreed that total hip bone mineral density (BMD), not fracture, could serve as the primary endpoint for the registrational study of EB613; and that Entera could enroll the same post-menopausal osteoporosis patient population that significantly benefited from EB613 treatment during Entera's Phase 2 clinical study which was reported in 2021.

- EB613 is the first oral, daily tablet formulation of synthetic hPTH (1-34), (teriparatide), consisting of the exact same 34 amino acid sequence as daily subcutaneous teriparatide injection, Forteo® which has been the leading anabolic treatment of osteoporosis since 2002 with peak sales of $1.7 billion in 2018 prior to patent expiration. EB613 tablets are simple, small (~ 6 mm wide) and administered once daily.

- Low BMD osteoporotic patients at high risk of fracture are often reluctant to initiate injectable anabolic (bone forming) therapy and represent an estimated 40% of the 3 million currently treated patients across the United States, while current bone forming injections treat less than 10% of these patients[1]. As the first daily tablet PTH osteoanabolic treatment, EB613 could significantly impact the osteoporosis treatment paradigm. Patient enrollment in the pivotal phase 3 study is expected to commence in 2023.

New Phase 2 Data Presented at the ASBMR Annual Meeting Demonstrate Statistically Significant Correlation of EB613's Dose Proportional Oral Absorption and Clinical Benefit

- New findings on EB613 were presented in a poster titled "A Six-month Phase 2 Study of Oral PTH (EBP05) in Postmenopausal Women with Low Bone Mass – Dose Proportional

Absorption and Effect on Lumbar Spine BMD (SUN-591)" at the American Society for Bone and Mineral Research (ASBMR) 2022 Annual Meeting in September.

- New analyses of hPTH concentration in blood shortly after a dose of EB613 tablets confirmed a strong, statistically significant correlation between mean blood level and the dose of EB613 taken.

- These findings are consistent with the positive correlation between the change in lumbar spine BMD and EB613 dose after six months of treatment.

"Following a full redesign of our proposed Phase 3 study, timely submission, and successful conclusion of our Type C meeting, our third quarter culminated with the FDA's concurrence with our proposed registrational path for EB613. This was an historic moment for Entera. We believe this is the first osteoporosis program that has reached agreement on both a placebo-controlled design and a BMD endpoint, which we believe speaks to the urgent need for highly effective and more patient friendly treatments to help rebuild bone. EB613 leverages the validated and safe mechanism of action of PTH which has been at the forefront of osteoporosis therapy for the last 20 years, and addresses patients' unease with injections via our simple daily tablet form. We continue to strengthen all functional areas at Entera to remain on track for patient enrollment to commence in 2023, while continuing our strategic discussions and preparing our new formulation of EB612 PTH tablets for hypoparathyroidism to re-enter the clinic in 2023," stated Miranda Toledano, Chief Executive Officer of Entera.

Results for Third Quarter Ended September 30, 2022

Revenues for the three months ended September 30, 2022 were $8,000 compared to $140,000 for the three months ended September 30, 2021. For both the three months ended September 30, 2022 and 2021, the majority of our revenues were attributable to pre-clinical R&D services provided to Amgen as part of our ongoing license agreement. The decrease in revenue for the quarter ended September 30, 2022 as compared to the prior year period was primarily due to finalization of third year pre-clinical R&D services to Amgen. The cost of revenues for the three months ended September 30, 2022 was $6,000 compared to $65,000 for the three months ended September 30, 2021 and were primarily attributed to expenses in connection with R&D services provided to Amgen.

Research and development expenses for the three months ended September 30, 2022 were $1.4 million compared to $1.8 million for the three months ended September 30, 2021. The decrease of $0.4 million was primarily due to a decrease of $0.7 million in pre-clinical activities related to our Phase 3 clinical trial for EB613 and a decrease of $0.1 million related to the completion of our Phase 2 trial for EB613 in September 2021. This decrease was partially offset by an increase of $0.1 million in connection with a one-time employee compensation payment as part of a separation agreement and an increase of $0.3 million attributed to ongoing materials and production costs to supply our Phase 3 clinical trial for EB613.

General and administrative expenses for both the three months ended September 30, 2022 and 2021 were $1.5 million. For the quarter ended September 30, 2022, there was an increase of $0.2 million in professional fees and an increase of $0.1 million in D&O insurance costs, as compared to the 2021 period, which was offset by a decrease of $0.3 million in share-based compensation mainly due to a reversal of share-based compensation expense related to the separation agreement of our former Chief Executive Officer.

Operating expenses for the three months ended September 30, 2022 were $2.9 million compared to $3.3 million for the three months ended September 30, 2021. Entera's operating loss was $2.9 million for the three months ended September 30, 2022, compared to $3.2 million for the three months ended September 30, 2021.

The net comprehensive loss was $3.1 million or $0.11 per ordinary share (basic and diluted) for the three months ended September 30, 2022, compared to $3.2 million, or $0.11 per ordinary share (basic and diluted) for the three months ended September 31, 2021.

As of September 30, 2022, Entera had cash and cash equivalents of $14.3 million, compared to $17.3 million as of June 30, 2022. Entera expects that its existing cash resources are sufficient to fund operations through the second quarter of 2023. This assumes ongoing R&D, the Hypo PK study and continued investments in production, analytics, and clinical research operations to enable initiation of EB613 phase 3 during the second half of 2023.

About EB613 (a.k.a. EBP05)

EB613 is the first oral, daily tablet formulation of synthetic hPTH (1-34), (teriparatide), consisting of the exact same 34 amino acid sequence as daily subcutaneous teriparatide injection, Forteo® which has been the leading anabolic treatment of osteoporosis since 2002 with peak sales of $1.7 billion in 2018 prior to patent expiration. Entera's Oral PTH formulations have been administered collectively to a total of 225 subjects in two Phase 1 studies and 3 phase 2 studies (including 35 in 2 phase 2 hypoparathyroidism studies). The most recent study was a dose ranging Phase 2 study in postmenopausal women with low bone mass. This study met primary and key secondary endpoints and was presented in a late-breaker oral presentation at the ASBMR 2021 conference. For the primary efficacy endpoint: a statistically significant increase in P1NP (a bone formation marker) at 3 months was achieved. A significant dose response was observed for 0.5, 1.0, 1.5 and 2.5 mg oral PTH doses on P1NP, Osteocalcin and bone mineral density (BMD). Subjects receiving the 2.5 mg dose of EB613 showed significant increases in dose-related BMD at the Lumbar Spine, Total Hip, and Femoral Neck at 6 months. Subjects receiving the 2.5 mg dose of EB613 daily for 6 months had a significant placebo adjusted increase of 3.78% in Lumbar Spine BMD ($p<0.008$) which is similar to the 3.9% increase in Lumbar Spine BMD seen with Forteo® in clinical studies reported in the literature. Increases in Total Hip and Femoral Neck BMD were greater than those previously reported with Forteo® at 6 months. EB613 exhibited an excellent safety profile, with no drug related serious adverse events. The most common adverse events included mild nausea, moderate back pain, moderate headache, and moderate upper abdominal pain.

About Entera Bio

Entera is a leader in the development of orally delivered macromolecules therapeutics including peptides and other therapeutic proteins, for use in areas with significant unmet medical need where adoption of injectable therapies is limited due to cost, convenience and compliance challenges for patients. The Company's proprietary, oral drug delivery technology is designed to address the technical challenges of poor absorption, high variability, and the inability to deliver large molecules to the targeted location in the body through the use of a synthetic absorption enhancer to facilitate the absorption of large molecules, and protease inhibitors to prevent enzymatic degradation and support delivery to targeted tissues. The Company's most advanced product candidates, EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism are in clinical development. Entera also licenses its technology to biopharmaceutical companies for use with their proprietary compounds and, to date, has established a collaboration with Amgen Inc. For more information on Entera Bio, visit www.enterabio.com.

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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 is contractually obligated to provide, such as those pursuant to Entera's agreement with Amgen; 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, except share data)
(Unaudited)

	September 30 2022	December 31 2021
Cash and cash equivalents	14,323	24,892
Accounts receivable and other current assets	867	437
Property and equipment, net	152	156
Other assets, net	198	502
Total assets	15,540	25,987
Accounts payable and other current liabilities	1,193	3,161
Total non current liabilities	35	261
Total liabilities	1,228	3,422
Total shareholders' equity	14,312	22,565
Total liabilities and shareholders' equity	15,540	25,987

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

	Three Months ended September 30,	
	2022	**2021**
REVENUES	8	140
COST OF REVENUES	6	65
GROSS PROFIT	2	75
OPERATING EXPENSES:		

Research and development	1,413	1,771
General and administrative	1,460	1,535
Other income	(6)	(11)
TOTAL OPERATING EXPENSES	2,867	3,295
OPERATING LOSS	2,865	3,220
FINANCIAL EXPENSES, net	8	7
LOSS BEFORE INCOME TAX	2,873	3,227
INCOME TAX (BENEFIT) EXPENSE	194	(13)
NET LOSS	3,067	3,214
LOSS PER SHARE BASIC AND DILUTED	0.11	0.11
WEIGHTED-AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	28,809,922	28,680,833

[1] Triangle Insights Group June 2022 Analysis, EB613 Osteoporosis Opportunity