Entera Bio Reports Third Quarter 2021 Financial Results

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– Two Presentations at ASBMR, including Late Breaker, on Phase 2 EB613 Clinical Trial Results in Osteoporosis –

– Study Sets Stage for Phase 3 registrational trial in 2022 –

BOSTON and JERUSALEM, Nov. 10, 2021 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, today announced financial and operating results for the third quarter ended September 30, 2021.

Third Quarter 2021 and Recent Highlights

- *Phase 2 EB613 (oral PTH 1-34) clinical data selected for a late breaker oral presentation at the American Society for Bone and Mineral Research Annual Meeting (ASBMR) demonstrated* clinically significant increases in bone mineral density (BMD) at the spine, femoral neck, and total hip in patients with osteoporosis.
    - In the six-month study, EB613 performed comparably to reported results of injectable PTH 1-34 (Forteo®) for increase in lumbar spine BMD and also demonstrated significant increases of BMD at the femoral neck and hip.
    - The trial demonstrated favorable changes in two key biomarkers, an increase in P1NP, the primary study endpoint and a marker of bone formation, and a decrease in serum CTX, a biomarker of bone resorption.
    - EB613's safety profile in the study was consistent with injectable PTH 1-34.
    - Entera has scheduled an End-of-Phase-2 Meeting with the FDA to review the company's proposed single Phase 3 protocol under the 505(b)(2) pathway to demonstrate non-inferiority to Forteo in BMD increase.
- *Key Study Describing Entera's Oral Delivery Platform for Biologic Drugs Published in the Journal of Pharmaceutics X*: Researchers at Entera and at the University of East Anglia in the UK published results from preclinical in vivo studies that demonstrated the efficiency of Entera's platform technology to consistently deliver large molecule biologic drugs into the bloodstream at appropriate levels through oral administration. The study describes the company's innovative dual mechanism of action approach to oral drug delivery of large molecules aimed at protecting biomolecules from breakdown in the gastrointestinal tract and facilitating their absorption into the bloodstream. Entera is utilizing the platform with EB613 and several other molecules now in development by Entera in collaboration with pharmaceutical companies.
- *Robust Balance Sheet*: Entera strengthened its balance sheet, which currently had a cash position of over $27.4 million as of September 30, 2021, providing the Company with an expected cash runway into the fourth quarter of 2022. The funds will support the initial costs of the planned EB613 Phase 3 study which the Company plans to initiate in the second quarter of 2022.

"The strong results of our Phase 2 trial, and their selection as a late breaker oral presentation in a prestigious forum set the stage for our Phase 3 clinical trial, which we expect to begin next year following an end of Phase 2 meeting with the FDA," stated Entera CEO Spiros Jamas. "The publication describing our novel, dual mechanism approach to oral delivery of large molecules, along with our extensive/recent clinical experience with EB613 suggest broad potential application of our technology. We believe our platform technology could significantly improve and enable a wide range of large molecule biological therapies currently available as injections or under development, with some feasibility programs already underway in collaboration with other companies."

Financial Results for the Period Ended September 30, 2021

Revenues for the nine months ended September 30, 2021, were $406,000 compared to $144,000 for the nine months ended September 30, 2020. In this period, the majority of the Company's revenues were attributable to research and development, or R&D services provided to Amgen under our 2018 collaboration agreement. The cost of revenues for the nine months ended September 30, 2021, were $186,000 compared to $104,000 for the nine months ended September 30, 2020, and were primarily attributed to salaries and related expenses in connection with the R&D services provided to Amgen.

Operating expenses for the nine months ended September 30, 2021, were $8.3 million compared to $8.9 million for the nine months ended September 30, 2020. Entera's operating loss was $8.1 million for the nine months ended September 30, 2021, compared to $8.8 million for the nine months ended September 30, 2020.

Research and development expenses for the nine months ended September 30, 2021, were $4.1 million, compared to $5.2 million for the nine months ended September 30, 2020, a decrease of $1.1 million. The decrease was primarily due to a decrease of $0.4 million in materials and production costs and a decrease of $0.6 million in other Phase 2 clinical trial expenses related to EB613 which was completed in June 2021. In addition, there was a decrease of $0.7 million in professional and consulting services expenses due to submission of an Investigational New Drug (IND) application in 2020, offset by an increase of $0.6 million in non-clinical expenses trial in preparation for a Phase 3 clinical trial.

General and administrative expenses for the nine months ended September 30, 2021, were $4.2 million, compared to $3.7 million for the nine months ended September 30, 2020. The increase was primarily an increase of $0.6 million in share-based compensation granted mainly to executive officers and due to the reversal of expenses related to the expiration of the former CEO's unvested options in 2020, an increase of $0.1 million in legal expenses and an increase of $0.1 million in D&O insurance costs. The increase was partially offset by a decrease of $0.3 million in professional fees.

Net comprehensive loss was $17.1 million or $0.68 per ordinary share (basic and diluted) for the nine months ended September 30, 2021, compared to $7.7 million, or $0.42 per ordinary share (basic and diluted) for the nine months ended September 31, 2020.

About Entera Bio

Entera is a leader in the development of orally delivered large molecule therapeutics 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. The Company recently completed the phase 2 study for EB613. 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.

Forward Looking Statements

Various statements in this release are "forward-looking statements" under the securities laws. 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 our interpretation of the 3-month biomarker data from the Phase 2 clinical trial of EB613, the timing of data readouts from the Phase 2 clinical trial of EB613, the full results of the Phase 2 clinical trial of EB613 and our analysis of those full results, the FDA's interpretation and review of our results from and analysis of our Phase 2 trial of EB613, 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, due to travel restrictions, lay-offs or forced closures or repurposing of hospital facilities; 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, if the FDA or other authorities are closed for prolonged periods, choose to allocate resources to review of COVID-19 related drugs or believe that the amount of Phase 2 clinical data collected are insufficient to initiate a Phase 3 trial, or a meaningful deterioration of the current political, legal and regulatory situation in Israel or the United States; the availability, quality and timing of the data from the Phase 2 clinical trial of EB613 in osteoporosis patients; the size and growth of the potential market for EB613 and Entera's other product candidates including any possible expansion of the market if an orally delivered option is available in addition to an injectable formulation; the scope, progress and costs of developing Entera's product candidates including EB612 and GLP-2; 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 expectations regarding its expenses, revenue, cash resources, liquidity and financial condition; Entera's ability to raise additional capital; Entera's interpretation of FDA feedback and guidance and how such guidance may impact its clinical development plans; 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 "Special Note Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Entera's annual and current filings which are on file with the SEC and available free of charge on the SEC's website at http://www.sec.gov. Additional factors may be set forth in those sections of Entera's Annual Report on Form 20-F for the year ended December 31, 2020, filed with the SEC in the first quarter of 2021. In addition to the risks described above and in Entera's annual report on Form 20-F and current reports on Form 6-K and other filings with the SEC, other unknown or unpredictable factors also could affect Entera's results. 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 in such forward-looking statements and estimates will be achieved.

All written and verbal forward-looking statements attributable to Entera or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Entera cautions investors not to rely too heavily on the forward-looking statements Entera makes or that are made on its behalf. The information in this release is provided only as of the date of this release, and Entera undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(US$ in thousands)

	September 30	December 31
	2021	**2020**
	Unaudited	
Cash and cash equivalents	27,395	8,593
Accounts receivable and other current assets	711	516
Property and equipment, net	161	192
Other assets, net	849	961
Total assets	29,116	10,262
Accounts payable and other current liabilities	2,195	1,841
Warrants liabilities	698	1,432
Total non-current liabilities	241	324
Total shareholders' equity	25,982	6,665
Total liabilities and shareholders' equity	29,116	10,262

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Nine months ended	
	September 30	
	2021	**2020**
	U.S. dollars in thousands	
REVENUE	406	144
COST OF REVENUE	186	104
RESEARCH AND DEVELOPMENT EXPENSES, net	4,146	5,222
GENERAL AND ADMINISTRATIVE EXPENSES	4,209	3,656

OTHER INCOME	(33)	-
OPERATING LOSS	8,102	8,838
FINANCIAL EXPENSES (INCOME):		
Loss from change in fair value of financial liabilities at fair value	8,833	(1,123)
Other financial income, net	45	17
FINANCIAL EXPENSES, NET	8,878	(1,106)
LOSS BEFORE TAXES	16,980	7,732
TAXES ON INCOME	123	-
NET COMPREHENSIVE LOSS FOR THE PERIOD	17,103	7,732
	U.S. dollars	
LOSS PER ORDINARY SHARE -		
Basic and Diluted	0.68	0.42
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING -		
Basic and Diluted	25,203,221	18,204,684

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