Entera Bio Reports Financial Results for the Year Ended December 31, 2021

March 8, 2022 11:30 AM EST

— EB613 expected to commence pivotal Phase 3 Osteoporosis trial in 2022 —
— New EB612 formulation for Hypoparathyroidism trial planned in 2022 —
— Oral delivery technology platform advances with more indications, inventions, patents, and collaborations —
— Company to host conference call and webcast today at 8:30 AM EST —

BOSTON and JERUSALEM, March 08, 2022 (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 year ended December 31, 2021, and provided an update on its clinical and pre-clinical programs.

2021 and Recent Highlights

- *Successful End of Phase 2 Meeting with FDA:* Entera met with the U.S. Food and Drug Administration (FDA), presented Phase 2 results, and reviewed the development plan of EB613 including the design of a Phase 3 registration trial expected to commence in 2022. Entera believes that the meeting was positive and confirmed the use of bone mineral density (BMD) as the primary endpoint. The study design is being adjusted to incorporate FDA's input and we intend to maintain close communication with the FDA to support our EB613 Osteoporosis program.
- *Osteoporosis Phase 2 study meets endpoints:* Entera effectively executed the clinical development of EB613 for osteoporosis, as the Company's lead drug candidate met its Phase 2 primary and key secondary endpoints. EB613 significantly increased lumbar spine BMD, in addition to the femoral neck, and total hip BMD when compared to placebo after six months of treatment. EB613 demonstrated a safety profile consistent with Forteo®, a drug that has generated peak worldwide sales of $1.9 billion. Study results were shared with the osteoporosis community in two presentations including being selected for a prestigious Late Breaking Oral Presentation at the American Society for Bone and Mineral Research (ASBMR) Annual Meeting in October 2021.
- Entera engaged Torreya Capital, LLC, a global investment bank, to serve as their exclusive financial advisor for Entera's business development activities to secure non-dilutive funding through strategic alliances for our lead asset, EB613 for Osteoporosis.
- *EB612 Hypoparathyroidism Successful Phase 2a Data Published, Next Trial Expected to Commence in 2022:* Entera's Phase 2a clinical results from its EB612 program, an oral parathyroid hormone (PTH) for the treatment of hypoparathyroidism, were published in February 2021 in the *Journal of Bone and Mineral Research*. The trial achieved its primary and secondary endpoints with published data showing that when added to the standard of care, EB612 led to a statistically significant decrease in supplemental calcium usage. EB612 has the potential to have a major impact on compliance, adherence, therapeutic impact, and quality of life for patients living with Hypoparathyroidism, a rare condition in which a person produces an abnormally low level of PTH. It also causes a heavy disease burden due to its impact on a patient's cardiovascular, neurologic, renal, and skeletal systems. Entera is currently working on an improved formulation of EB612 and is designing its next clinical trial, which it expects to commence in 2022. EB612 has Orphan Drug status with both the FDA and the European Medicines Agency for Hypoparathyroidism.
- *Advanced Platform Technology:* As a leader in the oral delivery of large proteins, Entera further advanced its platform technology in 2021 by identifying potential new treatment indications, filing new patents, and receiving a foundational patent in the European Union, representing new intellectual property with an extended patent life. Entera's platform technology continues to gain recognition for its applications in transforming injectable biologics into oral pills. A study in collaboration with researchers at the University of East Anglia in the UK, describing the platform's dual mechanism of action, was published in the peer-reviewed *International Journal of Pharmaceutics:*

X in October 2021. Additionally, new data were announced[1] suggesting Entera's platform orally delivers human growth hormone, and these data were shared in a poster presentation at the 31st Annual European Pharma Congress in London in 2021.

- *Biopharma Collaborations Continue:* While Entera continues its long-term collaboration with Amgen, the Company entered additional new material transfer agreements in 2021 with other companies in the biopharma industry. Working closely with the new collaborators, Entera has been generating proof of principle data on its platform's applications to large molecules, which may lead to additional new deals.

"We expect multiple milestones in 2022, including commencing patient enrollment in our pivotal Phase 3 EB613 osteoporosis trial, commencing a clinical study to support EB612, and further developing our platform technology for new indications to be advanced in-house and in conjunction with pharma partners," stated Entera CEO, Spiros Jamas, Sc.D. "Heading into our pivotal trial, the prospect of EB613 receiving approval and being available on the market is particularly exciting. We believe our oral bone building product can transform the osteoporosis space by offering a patient-friendly and cost-efficient early treatment to reduce the severity of disease over the long term, potentially leading to improved quality of life. Based on our analysis, EB613 has a multi-billion dollar opportunity to grow the current addressable market by treating patients not on injectables and the 50,000 patients who are on injectables today."

Financial Results for the 12-Months Ended December 31, 2021

Revenues for the twelve months ended December 31, 2021 were $571,000 compared to $365,000 for the twelve months ended December 31, 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 Entera's 2018 collaboration agreement. Cost of revenues for the twelve months ended December 31, 2021 were $373,000 compared to $300,000 for the twelve months ended December 31, 2020, and were primarily attributed to salaries and related expenses in connection with the R&D services provided to Amgen and other material transfer agreements.

Operating expenses for the twelve months ended December 31, 2021 were $12.4 million compared to $11.2 million for the twelve months ended December 31, 2020. Entera's operating loss was $12.2 million for the twelve months ended December 31, 2021, compared to $11.2 million for the twelve months ended December 31, 2020.

Research and development expenses were $6.8 million for the twelve months ended December 31, 2021, compared to $6.4 million for the twelve months ended December 31, 2020, an increase of $0.4 million. The increase was primarily due to an increase in materials and pre-clinical activity as part of the preparation for our Phase 3 clinical trial for EB613.

General and administrative expenses for the twelve months ended December 31, 2021 were $ 5.7 million, compared to $4.9 million for the twelve months ended December 31, 2020. The increase was primarily due to an increase in share-based compensation expenses, D&O insurance costs, and legal expenses.

Net loss was $12.2 million or $0.47 per ordinary share (basic and diluted) for the twelve months ended December 31, 2021, compared to $11.2 million, or $0.67 per ordinary share (basic and diluted) for the twelve months ended December 31, 2020.

At December 31, 2021, Entera had cash and cash equivalents of $24.9 million, compared to $8.6 million at December 31, 2020, and, at March 1, 2022, Entera had $21.7 million in cash and cash equivalents.

Entera expects an operating loss of between $25 and $30 million for the year ending December 31, 2022, and believes its current cash position will be sufficient to fund its operations into the fourth quarter of 2022.

Conference Call and Webcast Information

Entera's management will host a conference call on Tuesday, March 8, 2022 at 8:30 AM EST. A question-and-answer session will follow Entera's remarks. To participate in the live call, please dial (877) 269-7756 (US) or (201) 689-7817 (international) or 1809406247 (Israel) and provide the conference ID "13727633" five to ten minutes before the start of the call.

To access a live audio webcast of the presentation on the "Investor Relations" page of Entera's website, please click here. A replay of the webcast will be archived on Entera's website for approximately 45 days following the presentation.

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.

Cautionary Statement Regarding Forward Looking Statements

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Various statements in this press release are "forward-looking statements" within the meaning of the PSLRA and other U.S. Federal 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 "Cautionary Statement Regarding Forward-Looking Statements," "Risk Factors", "Management's Discussion and Analysis of Financial Condition and Results of Operations" and similarly tilted sections of Entera's annual, quarterly and current report and other documents filed by Entera with the SEC and available free of charge on the SEC's website at http://www.sec.gov. 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. Forward-looking

statements speak only as of the date the statements were made. Entera assumes no obligation to update forward-looking information to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information, except as required by applicable law

ENTERA BIO LTD.
CONSOLIDATED BALANCE SHEETS AUDITED
(U.S. dollars in thousands, except share data)

	December 31	
	2021	**2020**
Cash and cash equivalents	24,892	8,593
Accounts receivable and other current assets	437	516
Property and equipment, net	156	192
Other assets, net	502	421
Total assets	25,987	9,722
Accounts payable and other current liabilities	3,161	1,841
Total non current liabilities	261	371
Total liabilities	3,422	2,212
Total shareholders' equity	22,565	7,510
Total liabilities and shareholders' equity	25,987	9,722

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

	Year ended December 31	
	2021	2020
REVENUES	571	365
COST OF REVENUES	373	300
GROSS PROFIT	198	65
OPERATING EXPENSES:		
Research and development	6,771	6,382
General and administrative	5,690	4,851
Other income	(46)	-
TOTAL OPERATING EXPENSES	12,415	11,233
OPERATING LOSS	12,217	11,168
FINANCIAL EXPENSES, net	29	28
LOSS BEFORE INCOME TAX	12,246	11,196
INCOME TAX (BENEFIT) EXPENSE	(59)	20
NET LOSS	12,187	11,216
LOSS PER SHARE BASIC AND DILUTED	0.47	0.67
WEIGHTED-AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	26,133,770	18,417,093

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