Entera Bio Ltd Announces Operating and Financial Results for the Fourth Quarter and Year Ended December 31, 2020

March 18, 2021 12:00 PM EDT

– Achieved Primary Endpoint in EB613 Phase 2 Clinical Trial –
– Final Data, Including Bone Mineral Density, Expected in Q2:21 –
– FDA Approval of EB613 IND for the Treatment of Osteoporosis Enables Initial U.S. Clinical Trial –
– Amgen Collaboration Continues to Progress; Company Evaluating Additional Molecules, Including GLP-2, in Multiple Pre-clinical Studies –
– Company Strengthened Balance Sheet and Now Funded into the Second Quarter of 2022 –
– Company to Host Conference Call and Webcast Today at 8:30 a.m. ET –

BOSTON and JERUSALEM, March 18, 2021 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, announced its financial and operating results for the quarter and year ended December 31, 2020 and provided an update on its clinical programs and pre-clinical programs.

2020 and Recent Highlights

- *FDA Approval of EB613 IND and Completion of Enrollment in EB613 Phase 2 Clinical Trial in Israel:* EB613, an orally delivered human parathyroid hormone (1-34) or PTH, drug candidate, is positioned to be the first oral bone building (osteoanabolic) treatment for osteoporosis. In December 2020, the U.S. Food and Drug Administration, or FDA, approved Entera's Investigational New Drug, or IND, application for the initial US EB613 study in osteoporosis. Enrollment in the Phase 2 clinical trial in Israel was completed in November 2020 with 161 subjects. Assuming positive final results from this trial, Entera intends to meet with the FDA to discuss the design of a pivotal Phase 3 non-inferiority trial examining the increase in spine bone mineral density of EB613 compared to the increase observed with Forteo® (SC PTH 1-34) and confirm the potential for approval under the 505 (b)(2) regulatory pathway.

- *Positive Final 3-Month Biomarker Data from Phase 2 Trial of EB613 in Osteoporosis:* The Phase 2 study's efficacy endpoints include an evaluation of biomarker data after 3- and 6-months of treatment and bone mineral density data, or BMD, after 6 months of treatment. Interim 6-month BMD data reported in August 2020 indicate EB613 has a statistically significant positive impact on lumbar spine BMD in a dose dependent manner. In the recently completed 3-month biomarker data analyses, subjects in the 2.5 mg dose group had a significant increase in bone formation biomarkers P1NP (primary endpoint) and Osteocalcin, from baseline compared to placebo. Patients in the 2.5 mg dose group also had a significant reduction in CTX. Reduction in CTX, a bone resorption marker, is correlated with a reduction in the break down of bone and is an important factor for a potential increase in BMD. Taken together, these results are supportive of the osteoanabolic or bone building effects of EB613, and the potential of EB613 to produce meaningful significant increases in BMD at 6 months. Final data analyses including 6-month BMD data are expected the second quarter of 2021.

- *Publication of Positive Data from EB612 Phase 2a Clinical Trial in Hypoparathyroidism (HypoPT)*: Results from a Phase 2a clinical trial were recently published in The *Journal of Bone and Mineral Research* in an article, titled "Safety and Efficacy of Oral Human Parathyroid Hormone (1-34) in Hypoparathyroidism: An Open-Label Study." The Phase 2a study achieved its primary and secondary endpoints including a statistically significant decrease in supplemental calcium usage, maintenance of serum albumin-adjusted calcium and reduction of serum phosphate with the addition of EB612 to the standard of care. Entera is currently working on optimizing the formulation of EB612 and the design of a Phase 2b clinical trial

which the Company expects to initiate in 2022.

- *Initiation of Oral GLP-2 Program*: Leveraging its large molecule oral delivery platform, Entera initiated a new research program for an oral glucagon-like peptide-2 (GLP-2) analog. The only GLP-2 analog currently on the market is a once-daily injection for the treatment of short bowel syndrome with reported global sales of $574 million in 2019. In preclinical models, Entera's oral GLP-2 analog has shown a comparable pharmacokinetic profile to a subcutaneous injection. GLP-2 analogs, which improve intestinal absorption of nutrients and fluids, have the potential to emerge as a new class of drugs to treat a broad range of gastrointestinal and metabolic diseases. Entera is currently evaluating different strategies to advance the oral GLP-2 program into clinical development.

- *Pipeline and Collaboration Developments:* The Company's collaboration with Amgen reached its third year and Amgen has completed several studies of its drug using Entera's oral delivery technology. In addition, Entera continues to pursue new molecules, targets, and indications for preclinical development with a goal of building its pipeline and creating partnership opportunities.

"We continue to leverage Entera's oral protein delivery platform, with a goal of developing a robust pipeline of orally-delivered large molecules across several therapeutic areas. We believe that the ability to replace a daily injection with an orally delivered alternative, will improve convenience, compliance and outcomes while lowering the total cost of care," stated Entera CEO Spiros Jamas. "We are highly encouraged by the data we have released to date from our EB613 Phase 2 trial in osteoporosis and we are working toward several additional milestones in 2021 including the announcement of the BMD results from this trial in the second quarter of 2021."

Financial Results for the Year Ended December 31, 2020

Revenues for the year ended December 31, 2020 were $365,000 as compared to $236,000 for the year ended December 31, 2019, with revenues in both years attributable to R&D services provided to Amgen. The cost of revenues for year ended December 31, 2020 and 2019 were $209,000 and $210,000 respectively and were comprised of salaries and related expenses in connection with the R&D services provided to Amgen.

Operating expenses were $11.3 million for the year ended December 31, 2020, compared to $11.5 million for the year ended December 31, 2019. Entera's operating loss was $(11.1) million for the year ended December 31, 2020, compared to $(11.5) million for the year ended December 31, of 2019.

Research and development expenses were $6.4 million for the year ended December 31, 2020, compared to $7.2 million for the year ended December 31, 2019. An increase in clinical trial expense in 2020 primarily due to the conduct of the Phase 2 clinical trial of EB613 was offset by decreases in compensation and consulting expenses and manufacturing costs.

General and administrative expenses were $4.9 million for the year ended December 31, 2020, compared to $4.3 million for the year ended December 31, 2019. The increase was primarily due to increases in compensation related expenses, professional and legal fees and insurance costs.

Net comprehensive loss was $(10.0) million or $(0.55) per ordinary share (diluted) for the year ended December 31, 2020 compared to $(10.8) million, or $(0.89) per ordinary share (basic and diluted) for the year ended December 31, 2019. The change in net loss is primarily due to decrease in the operating loss and an increase in financial income related to the change in fair value of outstanding warrants.

At December 31, 2020, Entera had cash and cash equivalents of $8.6 million, compared to $15.2 million at December 31, 2019 and in the 20F the Company intends to file today, it will report $15.4 million in cash and cash equivalents at March 16, 2021. This amount includes total net proceeds of $13.3 million from the sale of ordinary shares under Company's previously filed Equity Distribution Agreement, which has now been fully utilized. Entera currently has approximately 23.7 million primary ordinary shares outstanding.

Entera expects an operating loss of between $11 and $12 million for the year ending December 31, 2021, and believes its current cash position will be sufficient to fund its operations into the second quarter of 2022.

Conference Call and Webcast Information

Entera's management will host a conference call on Thursday, March 18, 2021 at 8:30 a.m. EDT. A question-and-answer session will follow Entera's remarks. To participate on the live call, please dial (855) 547-3865 (US) or (409) 217-8787 (international) and provide the conference ID "5557946" 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 Ltd.

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 Phase 2 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.

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 complete 3-month biomarker data and the interim BMD data from the ongoing Phase 2 clinical trial of EB613, the timing of data readouts from the ongoing Phase 2 clinical trial of EB613, the full results of the Phase 2 clinical trial of EB613, which is still ongoing 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, including with regards to potential discussions regarding the design of a pivotal Phase 3 non-inferiority trial based on such results; 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; a possible suspension of the Phase 2 clinical trial of EB613 for clinical or data-related reasons; the impact of COVID-19 on Entera's business operations including the ability to collect the necessary data from the Phase 2 trial of EB613; 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 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 an otherwise 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 ability find a dose that demonstrates the comparability of EB613 to FORTEO in the ongoing Phase 2 clinical trial of EB613; 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, to be 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.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(US$ in thousands, except share and per share data)

	Year Ended December 31,	
	2020	**2019**
REVENUE	$ 365	$ 236
COST OF REVENUE	209	210
RESEARCH AND DEVELOPMENT EXPENSES, NET	6,398	7,199
GENERAL AND ADMINISTRATIVE EXPENSES	4,891	4,281
OPERATING LOSS	11,133	11,454
FINANCIAL (INCOME):		
Income from change in fair value of financial liabilities at fair value through profit or loss, net	(1,237)	(743)

Other financial expenses (income), net	67	84
FINANCIAL (INCOME), net	(1,170)	(659)
LOSS BEFORE TAXES	9,963	10,795
TAXES ON INCOME	20	–
NET COMPREHENSIVE LOSS FOR THE YEAR	$ 9,983	$ 10,795
LOSS PER ORDINARY SHARE:		
Basic	$ 0.54	$ 0.89
Diluted	$ 0.55	$ 0.89
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:		
Basic	18,417,093	12,146,729
Diluted	18,563,675	12,146,729

ENTERA BIO LTD.
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
(US$ in thousands)

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 8,593	$ 15,185
Accounts receivable and other current assets	516	451
Property and equipment, net	192	202
Other assets, net	961	865
Total assets	$ 10,262	$ 16,703
Accounts payable and other current liabilities	$ 1,841	$ 2,148
Warrant liabilities	1,432	2,444
Total current liabilities	3,273	4,592
Total Non-current liabilities	324	192
Total shareholders' equity	6,665	11,919
Total liabilities and shareholders' equity	$ 10,262	$ 16,703

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