ENTERA BIO LTD ANNOUNCES FINANCIAL AND OPERATING RESULTS FOR THE FOURTH QUARTER AND YEAR ENDED DECEMBER 31, 2019

March 26, 2020 10:30 AM EDT

– Three Month Biomarker Data from Phase 2 Clinical Trial of EB613 Expected in the Second Quarter of 2020 with Additional Data Readouts Expected in 2020 and Early 2021 –
– Financing Completed in December 2019 Funds Company into the Second Quarter of 2021 –
– Company to Host Conference Call and Webcast Today at 8:30 a.m. EDT –

BOSTON and JERUSALEM, Israel, March 26, 2020 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, announced its financial and operational results for the quarter and year ended December 31, 2019.

"Over the last several weeks we have seen significant changes across the world due to the spread of COVID-19 and the resulting impact on our employees, clinical trials, and the financial markets. We have developed risk mitigation and contingency plans that prioritize the safety of our patients and employees, balanced carefully with a goal of maintaining our operations and clinical trials according to the changing government and hospital regulations. Despite the uncertainty and impact from COVID-19, we have a balance sheet, that with our recently completed $14.3 million financing, provides us with funding into the second quarter of 2021, which we believe positions us well to achieve a number of important milestones in 2020," stated Adam Gridley, CEO of Entera. "With multiple potential data readouts from our Phase 2 dose-ranging study of EB613 in osteoporosis patients and the potential for additional business development collaborations, we are rapidly responding to the emerging COVID-19 challenges to reorient our internal operations and business strategy to ensure Entera can achieve its goal to become a leader in the oral delivery of large molecule therapeutics."

2019 and Recent Milestones

- *Initiated dose-ranging, placebo-controlled, Phase 2 clinical trial of EB613 and have enrolled 98 patients, or more than 60% of the total:* In July 2019, Entera initiated a dose-ranging, placebo-controlled, Phase 2 clinical trial in female patients with osteoporosis, or low bone mineral density (BMD). Based on feedback from the United States Food and Drug Administration (the FDA) in late 2018, Entera expects this trial, if successful, to position the Company for the initiation of a single, global Phase 3 non-inferiority registration trial with a BMD endpoint comparing oral EB613 and subcutaneous FORTEO® (teriparatide, Eli Lilly) in osteoporosis patients in 2021 or 2022.

- *Completed Phase 2 PK/PD trial of EB612 in hypoparathyroidism and presented the results at the 2019 Annual Meeting of the American Society for Bone and Mineral Research*: The trial, which evaluated the Pharmacokinetic (PK) and Pharmacodynamic (PD) profile of EB612, was conducted in 16 patients and followed Entera's prior clinical trials of oral human parathyroid hormone (PTH). The Phase 2 open-label trial employed a rigorous two-period, partial crossover design to evaluate the PK and PD profiles of multiple doses and dosing regimens of orally delivered EB612 against a single, once daily dose of 100 µg of Natpara® (parathyroid hormone) delivered via subcutaneous injection. The results of the trial showed a dose dependent pharmacodynamic response of serum calcium, phosphate and 1,25-dihydroxyvitamin D to EB612, and also indicated that EB612 was generally well tolerated and reduced urinary calcium.

- *Expanded and enhanced executive team and established US headquarters:* To support the advancement of EB613 toward a potential global registration trial, Entera hired Adam Gridley as Chief Executive Officer in August 2019. Entera also bolstered its operations with the addition of new Israeli- and US-based Chief Financial Officers and strengthened the Board of Directors with the addition of experienced life sciences investors and pharmaceutical leaders. These individuals possess many years of biotechnology, pharmaceutical operations and capital markets experience that will be instrumental as Entera advances EB613 and EB612 through development and begins to build a pipeline of high value, orally delivered protein

therapeutics.

- *Completed PIPE financing:* In December 2019, Entera completed a private placement of ordinary shares and warrants that raised gross proceeds of $14.3 million dollars following the final closing in February 2020. The proceeds from the private placement are expected to fund the Company into the second quarter of 2021 and provided an important source of financial flexibility in advance of the data from the Phase 2 clinical trial of EB613 and the Company's ongoing business development discussions.

- *Initiated pre-clinical work in support of Amgen collaboration:* Following the signing of the research collaboration and license agreement with Amgen, Inc. (Amgen) in December 2018, Entera initiated pre-clinical work on the first molecule covered by the collaboration. Under the collaboration, Entera is eligible to receive up to $270 million upon achievement of various clinical and commercial milestones, or Amgen's exercise of options to select additional programs to include in the collaboration. In addition, Entera is entitled to tiered royalty payments ranging from the low- to mid- single digits based on Amgen's net sales of any applicable products developed under the collaboration.

"In 2019 we prioritized our development efforts to therapeutic indications that we believe will create the most value for Entera and our shareholders. We have been executing on our plan to complete enrollment in the Phase 2 clinical trial of EB613 in osteoporosis patients and the related regulatory filings with the FDA to support a potential global Phase 3 program, finalizing formulations for EB612 for Hypoparathyroidism, focusing on business development opportunities and enhancing our investor relations activities," stated Mr. Gridley. "We had been tracking to achieve our previously communicated timelines for our ongoing Phase 2 clinical trial in EB613. However, based on COVID-19 directives implemented in March 2020 by the Israeli Ministry of Health and our medical institutions, we have temporarily suspended enrollment of new patients in the Phase 2 clinical trial. We are continuing to collect patient data from the currently enrolled patients in this trial through various monitoring methods established by the regulatory authorities and continue to plan at this point to report our three-month interim biomarker data in the second quarter of 2020. Completion of enrollment and the associated full biomarker and six-month BMD data may be impacted by approximately one quarter at this juncture."

2020 Corporate Objectives

- *Complete enrollment of ongoing Phase 2 clinical trial of EB613 and report top-line data:* Entera expects the ongoing Phase 2 clinical trial of EB613 in osteoporosis patients to provide several important data readouts over the next 12 months. Entera now expects to complete enrollment in Q3:20, report the interim three-month top-line biomarker data for the first 50% of the patients enrolled in the trial in Q2:20, the full three-month biomarker data in Q4:20 and topline six-month data in Q1:21. Because of the long history of the use of injectable of PTH (1-34) to treat osteoporosis and the well-established correlation of the improvement in biomarkers of bone formation rate and BMD to treatment of the underlying disease, management believes that the biomarker and related BMD data from the trial will be indicative of the potential efficacy of EB613 and important in the finalization of the design of the Phase 3 trial and the ability to use the 505(b)(2) regulatory pathway for potential approval in the United States.

- *Position EB 613 for Phase 3 clinical trial in osteoporosis patients:* Based on FDA guidance received at the Company's pre-IND meeting and subject to the completion of the Phase 2 trial and receipt of positive Phase 2 data, management intends to conduct the additional development work, including filing an Investigation New Drug Application, or IND, with the FDA and preparing a global Phase 3 clinical trial protocol for FDA feedback. Management believes a non-inferiority trial of 600-700 osteoporosis patients comparing EB613 with FORTEO, the currently marketed injectable PTH (1-34) treatment for osteoporosis, over a 12-month treatment period evaluating the improvement in BMD and safety would be sufficient to support the regulatory filings required for marketing approvals in the United States and other territories.

- *Conduct additional development work for EB612 to enable initiation of an additional Phase 2b*

or Phase 3 clinical trial in 2021: Entera intends to conduct additional formulation and development activities to determine the final formulation for EB612 to prepare for an initiation in 2021 of an additional Phase 2b or Phase 3 clinical trial of EB612 for the treatment of hypoparathyroidism.

- *Continue development of technology platform and advance business development initiatives:* In addition to the advancement of EB613 and EB612 and the ongoing support of the Amgen collaboration, Entera intends to build out its oral drug delivery technology platform through the identification of two new targets for future preclinical development. Entera has previously evaluated its technology in multiple large molecules and believes that there are numerous additional product candidates that can benefit from the application of its technology. These product candidates have the potential to generate funds, create value and provide further validation of the technology through additional partnerships, such as the collaboration with Amgen, and the Company is targeting additional alliances in 2020 or 2021.

- *Elevate investor awareness through increased investor outreach:* Following the expansion of the company's management and board of directors in the U.S. in 2019, Entera is focusing its efforts to engage with retail and institutional investors through targeted investor and public relations outreach activities. In anticipation of the various data readouts from the Phase 2 trial of EB613 and the other anticipated corporate milestones, the Company will be establishing a variety of strategies to enhance its investor awareness in 2020.

Our corporate objectives for 2020 may be materially and negatively impacted by the COVID-19 pandemic. The extent to which the COVID-19 pandemic impacts us will depend on the duration and magnitude of such impact as well as on numerous factors that the company may not be able to accurately predict.

Financial Results for the Year Ended December 31, 2019

Revenue for the year ended December 31, 2019 was $0.2 million compared to $0.5 million for the year ended December 31, 2018. The decline was largely due to the recognition in 2018 of a majority of the up-front payment received from Amgen in accordance with current accounting guidance. The cost of revenues for the year ended December 31, 2019 was $0.2 million compared to $0.0 million for the year ended December 31, 2018. In 2019, the cost of revenue was attributable to the R&D services provided to Amgen and there were no such costs in 2018. Operating expenses were $11.5 million for the year ended December 31, 2019, compared to $11.4 million for the year ended December 31, 2018. Entera's operating loss was $(11.5) million for the year ended December 31, 2019, compared to $(10.9) million for the year ended December 31, 2018.

Research and development expenses were $7.2 million for the year ended December 31, 2019, compared to $8.5 million for the year ended December 31, 2018. The decrease was primarily due to reductions in materials and production costs and share-based compensation expenses which were partially offset by increases in consulting expenses and fees related to the preparation of the Company's IND application for EB613 and the initiation and conduct of the Phase 2 clinical trial of EB613. General and administrative expenses were $4.3 million for the year ended December 31, 2019, compared to $2.8 million for the year ended December 31, 2018. The increase was primarily due to increases in compensation related expenses, director's fees and insurance costs related to Entera's public company status for the full year in 2019 relative to only half of the year ended December 31, 2018.

Net comprehensive loss was $(10.8) million for the year ended December 31, 2019, or $(0.89) per ordinary share, compared to $(10.3) million, or $(1.30) per ordinary share – basic and $(1.31) per ordinary share – diluted, for the year ended December 31, 2018. The increase in net loss attributable to common stockholders is attributable to the increased operating loss in 2019 relative to 2018 which was partially offset by changes in the fair value of the warrants and other financial expenses in 2019 as compared to 2018.

At December 31, 2019, Entera had cash and cash equivalents of $15.2 million, compared to $11.5 million at December 31, 2018. Cash at December 31, 2019 excludes approximately $0.8 million, net of expenses, received in February 2020 in connection with the final closing of the private placement that was completed in December 2019.

Entera expects an operating loss of between $10 million and $12 million for the year ending December 31, 2020 subject to the impact of COVID-19 and believes its current cash position will be sufficient to fund its operations into the second quarter of 2021.

Conference Call and Webcast Information

Entera's management will host a conference call on Thursday, March 26, 2020 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 "4939469" 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 macromolecule 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: the impact of COVID-19 on Entera's business operations including enrollment in the Phase 2 clinical trial for EB613 in patients with osteoporosis and the ability to collect the necessary data from the Phase 2 trial of EB613; a possible suspension of the Phase 2 clinical 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 so far 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 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; 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; Entera's ability 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 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, 2019, to be filed with the SEC in the first quarter of 2020. 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,	
	2019	**2018**
REVENUE	$ 236	$ 500
COST OF REVENUE	210	–
RESEARCH AND DEVELOPMENT EXPENSES, NET	7,199	8,518
GENERAL AND ADMINISTRATIVE EXPENSES	4,281	2,843
OPERATING LOSS	11,454	10,861
FINANCIAL EXPENSES (INCOME):		
Loss (income) from change in fair value of financial liabilities at fair value through profit or loss, net	(743)	(523)
Other financial expenses (income), net	84	(34)
FINANCIAL EXPENSES (INCOME), net	(659)	(557)
NET COMPREHENSIVE LOSS FOR THE PERIOD	$ 10,795	$ 10,304

LOSS PER ORDINARY SHARE:

Basic	$ 0.89	$ 1.30
Diluted	$ 0.89	$ 1.31
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:		
Basic	12,146,729	7,955,447
Diluted	12,146,729	7,938,402

ENTERA BIO LTD.
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
(US$ in thousands, except share and per share data)

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 15,185	$ 7,506
Short-term bank deposits	–	4,015
Accounts receivable and other current assets	451	945
Property and equipment, net	202	224
Other assets, net	865	651
Total assets	$ 16,703	$ 13,341
Accounts payable and other current liabilities	$ 2,148	$ 1,788
Warrant liabilities	2,444	1,372
Total current liabilities	4,592	3,160
Non-current liabilities	192	65
Total stockholders' equity	11,919	10,116
Total liabilities and stockholders' equity	$ 16,703	$ 13,341

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