Entera Bio Ltd Announces Third Quarter 2020 Financial Results and Provides Clinical Update

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– Completed Enrollment in Phase 2 Clinical Trial of EB613, Positioned as the First Potential Oral Bone Building Product to Treat Osteoporosis –
– Positive Interim 6-Month Bone Mineral Density (BMD) Data Reported in Phase 2 EB613 Clinical Trial –
– Company Expects to Report Biomarker Data that Includes the 2.5 mg Dose in Q1:21 and Final Data from The Phase 2 Trial Including BMD in Q2:21 –
– Company to Host Conference Call and Webcast Today at 8:30 a.m. ET –

BOSTON and JERUSALEM, Nov. 19, 2020 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, announced financial and operating results for the quarter ended September 30, 2020 and provided a clinical update on EB613, its lead, orally delivered product candidate for the treatment of osteoporosis.

Third Quarter 2020 and Recent Highlights

- *Completed Enrollment with 161 Subjects Randomized in the Phase 2 Study of EB613 in Osteoporosis*: EB613 is an orally delivered, human parathyroid hormone (1-34) (PTH) and is positioned as the first potential, oral bone building product to treat osteoporosis. The Phase 2 clinical trial is a dose-ranging, placebo-controlled, study in postmenopausal female subjects with osteoporosis, or low BMD. This trial is being conducted at four leading medical centers in Israel and had an initial target enrollment of 160 subjects. Based on the 3-month interim biochemical marker and safety data from the first 80 subjects randomized, the Phase 2 protocol was amended in third quarter to discontinue the two lower doses of EB613 (0.5 mg and 1.0 mg) and add a 2.5 mg dose.

- *Positive Interim Data in Phase 2 Clinical Trial of EB613 in Osteoporosis:* During the third quarter, Entera announced 6-month interim biomarker and BMD data from the first 50%, or 80 patients, enrolled in its Phase 2 clinical trial of EB613. The data indicate EB613 has a meaningful and positive impact on lumbar spine BMD in a dose dependent manner. EB613 generated a mean placebo adjusted increase in lumbar spine BMD of 2.15% ($p = 0.08$) for the 14 patients in the 1.5 mg treatment arm, as compared to the 16 patients in the placebo arm. The placebo-adjusted increase was comprised of a mean BMD increase of 1.44% in the 1.5 mg treatment arm compared to a mean decrease of 0.71% in the placebo arm. An additional analysis of BMD changes in the three lower EB613 treatment groups (0.5 mg, 1.0 mg and 1.5 mg) showed a significant dose-dependent trend in the percentage change in lumbar spine BMD. The dose response was supportive of Entera's decision to include a higher 2.5 mg dose in the trial to potentially increase efficacy.

- *Continued Pipeline Development:* Entera is identifying new targets for preclinical development based on its oral drug delivery platform, as well as developing optimal formulations for EB612 in preparation for a potential Phase 2b or Phase 3 study in hypoparathyroidism in 2021 or 2022. Entera has previously completed one successful Phase 2a study of EB612 in this indication.

- *Amgen Collaboration Agreement:* Several studies have been completed using Entera's technology to evaluate different formulations of Amgen's drug. In addition to its collaboration with Amgen, Entera is actively evaluating additional business development opportunities with other pharmaceutical companies.

"We are highly encouraged by the interim results from our EB613 program in osteoporosis as well as our ability to complete enrollment given the significant challenges due to the COVID-19 pandemic. EB613's positive impact on lumbar spine BMD in a dose dependent manner is important, as

BMD is a widely accepted measure of the severity of the disease. Having recently completed enrollment, and assuming we achieve positive topline results, we are looking towards a Phase 3 study with a primary endpoint of an increase in lumbar spine BMD under the 505 (b)(2) regulatory pathway based on our previous discussions with the U.S. Food and Drug Administration," stated Roger Garceau, MD, Director and Interim CEO of Entera. "Based on market research data conducted earlier in 2020, it is clear that EB613 has a strong value proposition in the market. If we are able to successfully complete clinical development and gain regulatory approval, EB613 may be well accepted by patients and physicians alike."

Financial Results for the Nine Months Ended September 30, 2020

Revenues for the nine months ended September 30, 2020 were $144,000 as compared to $134,000 in the first nine months of 2019, with revenues in both years attributable to R&D services provided to Amgen. The cost of revenues for the nine months ended September 30, 2020 and 2019 were $104,000 and $102,000, respectively and were comprised of salaries and related expenses in connection with the R&D services provided to Amgen.

Operating expenses were $8.9 million for the nine months ended September 30, 2020, compared to $8.0 million for the first nine months of 2019. Entera's operating loss was $(8.8) million for the nine months ended September 30, 2020, compared to $(8.0) million for the first nine months of 2019.

Research and development expenses were $5.2 million for the nine months ended September 30, 2020, compared to $5.2 million for the nine months ended September 30, 2019. An increase in clinical trial expense in the nine month period in 2020 primarily due to the conduct of the Phase 2 clinical trial of EB613 was offset by decreases in expenses related to preclinical activities, manufacturing costs and compensation-related expenses.

General and administrative expenses were $3.7 million for the nine months ended September 30, 2020, compared to $2.8 million for the nine months ended September 30, 2019. The increase was primarily due to increases in compensation related expenses, professional and legal fees and insurance costs.

Net comprehensive loss was $(7.7) million or $(0.42) per ordinary share for the nine months ended September 30, 2020 compared to $(7.4) million, or $(0.63) per ordinary share for the nine months ended September 30, 2019. The change in net loss is primarily due to the increase in overall operating expenses.

At September 30, 2020, Entera had cash and cash equivalents of $7.1 million, compared to $15.2 million at December 31, 2019.

Entera expects an operating loss of at least $11.4 million for the year ending December 31, 2020, 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, November 19, 2020 at 8:30 a.m. ET. 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 "9495026" 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 interim data from the ongoing Phase 2 clinical trial of EB613, the timing of data readouts from the ongoing Phase 2 clinical 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; 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 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, including the amount of cash and cash equivalents as of September 30, 2020 referenced above, which has not been audited or reviewed by Entera's independent registered public accounting firm and should be viewed in the context of all other available information regarding Entera's results of operations, 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 Quarterly Report on Form 6-K for the quarter ended September 30, 2020, to be filed with the SEC in the fourth 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.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)
(US$ in thousands, except share and per share data)

	Nine months ended September 30		Three months ended September 30	
	2020	**2019**	**2020**	**2019**
REVENUE	$ 144	$ 134	$ 50	$ 60
COST OF REVENUE	104	102	31	40
RESEARCH AND DEVELOPMENT EXPENSES, NET	5,222	5,234	1,606	1,786
GENERAL AND ADMINISTRATIVE EXPENSES	3,656	2,757	829	1,073
OPERATING LOSS	8,838	7,959	2,416	2,839
FINANCIAL INCOME:				
Income from change in fair value of financial liabilities at fair value	(1,123)	(672)	(805)	122
Other financial expenses, net	17	68	13	33
FINANCIAL INCOME, NET	(1,106)	(604)	(792)	155
NET COMPREHENSIVE LOSS FOR THE PERIOD	$ 7,732	$ 7,355	$ 1,624	$ 2,994
	U.S. dollars		**U.S. dollars**	
LOSS PER ORDINARY SHARE:				
Basic and diluted	$ 0.42	$ 0.63	$ 0.09	$ 0.25
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:				
Basic and diluted	18,204,684	11,750,868	18,329,561	12,045,115

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

	September 30, 2020 (Unaudited)	**December 31, 2019** (Audited)
Cash and cash equivalents	$ 7,068	$ 15,185
Accounts receivable and other current assets	722	451
Property and equipment, net	207	202
Other assets, net	783	865
Total assets	$ 8,780	$ 16,703
Accounts payable and other current liabilities	$ 1,371	$ 2,148
Warrant liabilities	1,545	2,444
Total current liabilities	2,916	4,592
Total Non-current liabilities	124	192
Total shareholders' equity	5,740	11,919
Total liabilities and shareholders' equity	$ 8,780	$ 16,703

Contact: Jonathan Lieber, CFO Tel: +001 617-362-3579 jon@enterabio.com