Entera Bio Reports Third Quarter 2019 Financial Results and Provides Operating Update

November 21, 2019 12:00 PM EST

- Enrollment Continues for Phase 2 study for oral PTH in Osteoporosis; Top-line 3-month Biomarker Data expected in mid 2020
- Presented Positive Results of a Phase 2 PK/PD study in Hypoparathyroidism patients.
- Conference call and live webcast today at 8:30 am Eastern Time

BOSTON and JERUSALEM, Nov. 21, 2019 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) today provided a corporate update and reported financial results for the third quarter ended September 30, 2019.

"Since joining the organization in August 2019, we've made significant progress on our strategic priorities in both our lead internal programs and potential future R&D opportunities as we build Entera into one of the leading oral delivery companies of large molecules and biologics," stated Adam Gridley, CEO of Entera. "Enrollment is advancing rapidly in our Phase 2 study of our lead program EB613 for Osteoporosis, and our investigators are pleased to be involved in this landmark study for an oral alternative to injectables. We also presented further positive confirmatory data from our Phase 2 study of EB612 for Hypoparathyroidism in September 2019 and are currently determining our strategies to advance a final formulation into advanced registration studies."

"Our ongoing business development and collaboration discussions are also advancing across all three pillars of our partnering strategy. Our partnership with Amgen is tracking well, and we've developed additional data regarding the utility of our synergistic technology platform in other molecules outside of hormones. This has led to discussions with several large pharmaceutical companies to test our technologies together. There has been considerable interest in Asia for our lead program and new molecules, and we're starting to engage with leaders in the Osteoporosis space regarding our commercial partnering strategies both in U.S. and on a regional basis," continued Mr. Gridley. "As we look forward to 2020, we have a number of important data read-outs for our ongoing Osteoporosis study that we believe will rapidly lead us into FDA discussions to finalize our Phase III study design. Further, we are building our financial, business development and investor focused teams and strategies to elevate Entera's profile with the investment and partnering community."

Clinical and Corporate Highlights:

Phase 2 Study for Oral PTH in osteoporosis: Following input from the U.S. Food and Drug Administration (FDA) in our pre-IND meeting held in 2018, the Company initiated a dose-ranging, placebo-controlled, Phase 2 study in June 2019, and enrollment is well underway. This study will enroll 160 postmenopausal women with osteoporosis or low bone mineral density at four internationally recognized clinical sites in Israel.

The primary endpoint of this study is bone formation biomarkers (serum P1NP, a biochemical marker that is correlated with bone formation rate) at 3 months with an additional evaluation at 6 months, of bone mineral density (BMD).

The Company expects the following milestones to be achieved in 2020:

- Full patient enrollment to be completed by the end of the first quarter of 2020
- Top-line data from the interim (50%) 3-month biomarker endpoint in the second quarter of 2020
- Top-line data from the full 3-month biomarker endpoint in the third quarter of 2020
- Bone mineral density data at 6 months are expected to be completed in fourth quarter 2020

We believe that these data will further inform the design of our registrational Phase 3 study, which the Company has already discussed with FDA. We expect it to be approximately 600-700 patients with similar endpoints as the Phase 2 study being conducted currently. The Company expects to also file an IND to the FDA in 2020 to support the selection of our final dose and formulation for our potential upcoming Phase 3 study.

Phase 2b Study for Oral PTH in hypoparathyroidism: Oral PTH for hypoparathyroidism is Entera's second major proprietary pipeline program. Entera completed in 2018 a two-part Phase 2 trial in patients with hypoparathyroidism that was designed to evaluate the pharmacokinetic (PK) and pharmacodynamic (PD) profiles of its oral PTH drug and injectable PTH (Natpara®).

Results from Part 1 of this study, reported in 2018, demonstrated a positive impact of Oral PTH on three metabolic parameters - serum calcium, phosphate, and 1,25-dihydroxyvitamin D ("active" vitamin D) - in patients with hypoparathyroidism. There was also a decrease in 24-hour urine calcium in the patients treated with Oral PTH.

The recently reported 16 patient Phase 2 PK/PD Study was open-label, and employed a 2-period partial crossover design to evaluate the PK and PD profiles of two doses, 0.75 mg and 2.25 mg, and three regimens (BID, TID and QID) of Oral hPTH (1-34) and included subcutaneous Natpar® [hPTH (1-84)] 100 µg once daily.

The conclusions of the poster presentation indicate that:

- Oral hPTH(1-34) 2.25 mg QID for one day is associated with an increase in serum albumin-

corrected calcium and $1,25(OH)_2D$ (1,25-dihydroxyvitamin D), a decrease in serum phosphate, and a decrease in urinary calcium in patients with hypoparathyroidism. The patients also received calcium supplements and either alfacalcidol or calcitriol.

- Oral PTH produced similar biological effects to Natpara® 100 µg QD, the highest dose of hPTH (1-84) currently indicated for use in patients with hypoparathyroidism, on serum calcium, phosphate and Vit D. Additionally, Oral hPTH (1-34) effected a decrease in urinary calcium. These changes in serum PD parameters were sustained over the 24-hour period of observation from time zero.
- BID, TID and QID regimens showed a dose-dependent increase in $1,25(OH)_2D$ indicating that the long-term treatment, even with the less frequent regimens, may be an effective treatment option for those patients suffering from less severe hypoparathyroidism.
- Treatment with Oral hPTH (1-34) dosed at multiple times during the day has the potential to reduce calciuria generally associated with maintenance of serum calcium within the normal range using calcium supplements and calcitriol analogs alone.
- There were no treatment-emergent adverse events of hypercalcemia, as well as no treatment-emergent Serious Adverse Events reported in the study.

These data will provide input for the design of the Company's anticipated Phase 3 registration clinical trials.

Board Appointment:
Adam Gridley, our CEO was appointed as a member of the Company's Board of Directors.

Financial Results for the Nine Months Ended September 30, 2019

Revenues. Revenues for the nine months ended September 30, 2019 were $134 thousand from services provided to Amgen under the license agreement. The cost of revenues recorded are comprised of related salaries and related expenses.

Research and development, net expenses. Research and development expenses for the nine months ended September 30, 2019 were $5.2 million, compared to $6.5 million for the nine months ended September 30, 2018, a decrease of $1.2 million, or 19%. The decrease in research and development expenses was primarily attributed to a decrease of $1.3 million in materials, clinical manufacturing and production for clinical trials and a decrease of $0.5 million in share-based compensation expenses due to higher fair value of the options granted to the previous CMO in the same period last year. The decrease was partially offset by an increase of $0.5 million in subcontractors and CRO expenses and an increase of $0.1 million in salaries and related expenses mainly due to hiring new employees in the US and in Israel.

General and administrative expenses. General and administrative expenses for the nine months ended September 30, 2019 were $2.8 million, compared to $1.9 million for the nine months ended September 30, 2018, an increase of $0.8 million, or 44%. The increase in general and administrative expenses was primarily attributed to an increase of $0.7 million in salaries and related expenses, as well as share-based compensation expenses mainly due to hiring of our new CEO. In addition, there was an increase of $0.2 million for insurance expenses and investor relation expenses due to the requirements of being a public company.

Financial income, net. Financial income, net for the nine months ended September 30, 2019 was $0.6 million, compared to $0.7 million for the nine months ended September 30, 2018, a decrease of $0.1 million. Financial income, net for the nine months ended September 30, 2019 and 2018 resulted mainly from the change in the fair value of financial liabilities measured at fair value through profit or loss.

Comprehensive loss. Comprehensive loss for the nine months ended September 30, 2019 was approximately $7.4 million, compared with approximately $7.7 million in the same period in 2018, a decrease of approximately $0.3 million.

Basic and diluted Loss per share. Basic and dilutive loss per share for the nine months ended September 30, 2019 was $0.63, compared with $1.13 and $1.14, respectively, for the nine months ended September 30, 2018.

Conference call and webcast, Thursday, November 21st, 2019 @ 8:30 am Eastern Time

From the US:	1 855 547-3865
International:	1 409 217-8787
From Israel:	1 809 315 362
Conference ID:	3677455
Webcast:	https://edge.media-server.com/mmc/p/i5yx6yjw

About Entera Bio Ltd.

Entera Bio is a clinical-stage biopharmaceutical company focused on the development and commercialization of orally delivered large molecule therapeutics for use in orphan indications and other areas with significant unmet medical needs. The Company is initially applying its technology to develop an oral formulation of a human parathyroid hormone analog, Oral PTH (1-34), for treatment of hypoparathyroidism and osteoporosis.

Entera has developed a proprietary platform technology that enables oral delivery of biologicals and large molecule drugs, which are typically delivered via injections and or other non-oral pathways. However, oral drug delivery is the easiest method for self-administering medications, offers patients greater dosing flexibility, and has the highest patient acceptance and compliance rates as compared to all other routes of drug administration. The Company employs this technology for its own pipeline products and may enter into licensing agreements with biopharma companies for application of the technology to their proprietary compounds, such as the Amgen strategic research collaboration. For more information on Entera Bio,

visit www.enterabio.com.

Forward Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, often signify forward-looking statements. 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. Forward-looking statements are based on information that the Company has when those statements are made or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Those risks and uncertainties, include, but are not limited to, the timing and conduct of our clinical trials, the clinical utility of our product candidates, the timing and likelihood of regulatory filings and approvals, our intellectual property position, and our financial position. For a discussion of these and other risks that could cause such differences and that may affect the realization of forward-looking statements, please refer to the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" in the Company's Annual Report on Form 20-F and other filings with the Securities and Exchange Commission (SEC). Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

ENTERA BIO LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

	September 30 2019	December 31 2018
	U.S. dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	5,907	7,506
Short-term bank deposits	-	4,015
Accounts receivable	-	725
Other current assets	297	220
TOTAL CURRENT ASSETS	6,204	12,466
NON-CURRENT ASSETS:		
Property and equipment	217	224
Right to use assets	295	-
Intangible assets	607	651
TOTAL NON-CURRENT ASSETS	1,119	875
TOTAL ASSETS	7,323	13,341
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable:		
Trade	594	473
Other	1,501	1,090
Lease liabilities	156	-
Contract liabilities	91	225
TOTAL CURRENT LIABILITIES	2,342	1,788
NON-CURRENT LIABILITIES:		
Warrants to purchase ordinary shares	700	1,372
Lease liabilities	173	-
Severance pay obligations, net	70	65
TOTAL NON-CURRENT LIABILITIES	943	1,437
TOTAL LIABILITIES	3,285	3,225
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.0000769 par value: Authorized - as of September 30, 2019 and December 31, 2018, 140,010,000 shares; issued and outstanding: as of September 30, 2019, and December 31, 2018 – 12,153,980 shares and 11,459,780 shares, respectively.	*	*
Accumulated other comprehensive income	41	41

Other reserves	11,912	13,019
Additional paid in capital	51,557	49,173
Accumulated deficit	(59,472)	(52,117)
TOTAL SHAREHOLDERS' EQUITY	4,038	10,116
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	7,323	13,341

* Represents an amount less than one thousand US dollars.

The accompanying notes are an integral part of the condensed consolidated financial statements.

ENTERA BIO LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

	Nine months ended September 30		Three months ended September 30	
	2019	**2018**	**2019**	**2018**
	U.S. dollars in thousands			
REVENUE	(134)	-	(60)	-
COST OF REVENUE	102	-	40	-
RESEARCH AND DEVELOPMENT EXPENSES, NET	5,234	6,464	1,786	1,806
GENERAL AND ADMINISTRATIVE EXPENSES	2,757	1,914	1,073	1,060
OPERATING LOSS	7,959	8,378	2,839	2,866
FINANCIAL EXPENSES (INCOME):				
Loss (income) from change in fair value of financial liabilities at fair value	(672)	(719)	122	2,177
Other financial expenses , net	68	-	33	23
FINANCIAL EXPENSES (INCOME), net	(604)	(719)	155	2,200
NET COMPREHENSIVE LOSS FOR THE PERIOD	7,355	7,659	2,994	5,066

	U.S. dollars		**U.S. dollars**	
LOSS PER ORDINARY SHARE:				
Basic	0.63	1.13	0.25	0.45
Diluted	0.63	1.14	0.25	0.45
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:				
Basic	11,750,868	6,777,841	12,045,115	11,277,503
Diluted	11,750,868	6,825,532	12,045,115	11,277,503

The accompanying notes are an integral part of the condensed consolidated financial statements.

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