Entera Bio Reports 2018 Annual Financial Results and Operating Update

March 28, 2019 11:00 AM EDT

- *Positive feedback and guidance from the US FDA regarding development plans for Oral PTH in osteoporosis*
- *Entered into research collaboration and license agreement with Amgen, potential for up to $270 million in milestone payments, Amgen's exercise of options to select additional programs and royalties on commercial sales*
- *Met with FDA in late November 2018 to discuss clinical development plan for EB613 in the treatment of osteoporosis*
- *Reported positive results from Part 1 of a Phase 2 PK/PD study in hypoparathyroidism patients and completed the treatment phase of Part 2 of this study*
- *Appointed Dr. Arthur Santora, former Merck executive and lead clinical research physician on Fosamax®, as Chief Medical Officer*
- *Mr. Gerald Lieberman named as Chairman and three new independent members appointed to the board of directors*
- *Conference call and live webcast at 10:00 am ET / 14:00 GMT today*

JERUSALEM, March 28, 2019 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) today provided an operating update and reported financial results for the year and quarter ended December 31, 2018.

"2018 was a productive and successful year for Entera," stated Dr. Phillip Schwartz, Chief Executive Officer of Entera Bio. "Our strategic research collaboration with Amgen serves as an important validation of our oral delivery technology and, on the strength of this, we see an opportunity to create further value through additional license agreements with biotech and pharmaceutical partners. The positive guidance we received from the FDA in the pre-IND meeting regarding our Oral PTH for the treatment of osteoporosis has provided us with clarity on the development path for this program. Our next step will be to conduct a Phase 2a dose-ranging study which we expect to start in the first half of 2019."

Recent Highlights

Strategic Research Collaboration with Amgen: Entera recently announced a strategic collaboration and license agreement with Amgen involving inflammatory diseases and other serious illnesses. Amgen will have the option to advance and develop up to three large molecule / biologic drugs for use in three different indications, using Entera's proprietary oral delivery technology. Entera has been working with Amgen for almost two years on the evaluation and initial development of the first target molecule. As part of the license agreement, Amgen has agreed to pay all costs associated with development of these three drugs. Entera received an initial technology access fee of $725,000 from Amgen and will be eligible to receive up to $270 million in aggregate payments upon achievement of various clinical and commercial milestones, and Amgen's exercise of options to select an additional program to include in the collaboration, as well as tiered royalty payments up to mid-single digits on commercial sales. Entera is responsible for preclinical development at Amgen's expense and Amgen will be responsible for clinical development, manufacturing and commercialization of any of the resulting programs.

Dr. Schwartz continued, "We believe this important collaboration with Amgen, one of the global leaders in the biotechnology industry, further validates our technology for the oral delivery of large molecule drugs. This agreement also allows us to further leverage our technology platform, and potentially provides us with access to significant non-dilutive sources of capital in the future. Building on this first agreement, Entera is currently in discussions with multiple biotech and pharmaceutical partners for additional strategic collaborations, helping other companies enhance their pipelines and potentially develop additional important oral large molecule therapies to help meet the needs of patients. With these potential relationships, we are exploring opportunities to create new sources of future revenue, in the form of milestone payments and royalty streams. At the same time, Entera remains committed to developing its current proprietary pipeline of late-stage compounds (which remain 100% owned by the Company), and these projects and strategic partnerships do not detract from our strategy to create value by advancing our internal programs."

Positive Feedback and Guidance from the US FDA Regarding Development Plans for Oral PTH in Osteoporosis - Entera received positive outcome in a pre-IND meeting held in November 2018 with the U.S. Food and Drug Administration (FDA) to discuss the Company's development plan for Oral PTH for the treatment of osteoporosis. The feedback and guidance were summarized in the formal meeting minutes that Entera subsequently received from the FDA. In addition to discussing various aspects of the nonclinical and clinical development plan, the meeting focused on the 505 (b)(2) regulatory pathway and the use of bone mineral density (BMD) rather than fracture incidence as the primary endpoint to support a New Drug Application (NDA). Based on the FDA's response, Entera believes that the Phase 3 study may use bone mineral density (BMD) as the primary efficacy endpoint and that a fracture endpoint study will not be required.

"We were very pleased with the positive pre-IND meeting with the FDA in late 2018 and greatly appreciate the Agency's detailed guidance in the official minutes of the meeting," stated Dr. Arthur Santora, Chief Medical Officer of Entera Bio. "As we anticipated, the FDA expressed its willingness to accept Entera's plan to bridge nonclinical and clinical study data for our oral PTH (1-34) to data from prior studies of the commercially available PTH (1-34) injection (Forteo®). Moreover, the FDA provided us with an overall direction for the nonclinical and clinical and regulatory path forward; successful bridging between the effects of oral PTH and subcutaneous PTH will allow Entera to conduct a Phase 3 study with a bone mineral density efficacy endpoint rather than a fracture endpoint study. While a BMD endpoint study comparing Oral PTH and subcutaneous PTH is still a relatively large study, it should be substantially less costly and several years shorter than a fracture endpoint trial."

Entera Bio's Oral PTH (1-34) has been shown to produce a blood level profile similar to Forteo ® (teriparatide), which was approved by the FDA in 2002 for the treatment of osteoporosis in men and postmenopausal women who are at high risk for fractures. Forteo® is currently one of two injectable treatments for osteoporosis which are classified by the FDA as "bone building" (anabolic). Dr. Schwartz stated, "The potential osteoporosis drug market is estimated at approximately $19 billion worldwide. If a "blockbuster" drug with comparable efficacy to injectable Forteo ® were available as a once-daily pill, we believe that it would potentially win market share and significantly expand the market for anabolic agents to osteoporotic patients at high risk of fracture who are reluctant to use an injectable medication. At present, it is estimated that fewer than 25% of the osteoporosis population in the US are receiving any pharmaceutical therapy. Existence of a new oral anabolic agent could help significantly expand the market."

Oral PTH (1-34) Phase 2 Study: Entera completed 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 parathyroid hormone (PTH) drug ("Oral PTH (1-34)") and injectable PTH (1-84), Natpara®. Oral PTH in development for hypoparathyroidism is Entera's second major proprietary pipeline program. Hypoparathyroidism is a failure of the parathyroid glands to produce sufficient parathyroid hormone to meet the metabolic demands of the body. Industry sources estimate that there are 60,000 insured hypoparathyroidism patients in the U.S.

An initial analysis of the Part 1 data demonstrated that Oral PTH (1-34), administered 4 times daily (QID), provided a greater effect on all of the parameters measured as compared to the twice a day regime. QID dosing had a positive impact on serum calcium, phosphate and active vitamin D levels, and was associated with a significant decrease in 24-hour urinary calcium levels as compared to baseline. The concentration of PTH (1-34) in blood after administration of Oral PTH (1-34) in the current study was controlled and sufficient to produce the desired physiological and clinical effects. The drug also did not induce hypercalcemia, and no drug related serious adverse events were reported in the study.

The second and final part of this PK/PD study evaluated a three times per day (TID) treatment regimen with a high and low dose of Oral PTH (1-34), as well as Natpara. The treatment phase of Part 2 is complete and the data will be analyzed over the coming months. The results from the complete Phase 2 PK/PD trial will provide input for the design of the Company's anticipated registration clinical trials. Details of the complete data set of this PK/PD study, once available, are expected to be submitted for presentation at scientific meetings and for publication in 2019. Dr. Schwartz added, "The results from our Phase 2 PK/PD study provide valuable insight into the profile of Oral PTH (1-34) as a treatment option for hypoparathyroidism. The available data support our belief that Oral PTH (1-34) can be more effective and convenient for patients than the commercially available injectable PTH (1-84). We look forward to reporting the results from the Phase 2 study in 2019."

Management and Board Appointments
Entera announced the appointment of industry veteran Arthur C. Santora II, MD, PhD to the position of Chief Medical Officer. Dr. Santora has more than 30 years of experience in the biotech industry, including leading the development of new drugs for osteoporosis and other endocrine disorders. Dr. Santora began his career at the FDA and played an important role in developing regulatory guidelines for the approval of osteoporosis drugs. Dr. Santora spent the majority of his career with the clinical research team at Merck, where he was responsible for much of the clinical development of Fosamax® (alendronate sodium), the most widely prescribed osteoporosis medication.

Mr. Gerald Lieberman was appointed as the Chairman of Entera's board of directors. He brings a wealth of operational, finance and public company experience, having held prior positions that include President of AllianceBernstein and CFO of Fidelity Investments. In addition, Mr. Lieberman has been a director at a number of major pharmaceutical companies including Teva Pharmaceuticals and Forest Laboratories.

Commenting on the new developments at Entera, Dr. Schwartz stated, "In order to support the advancement of our programs and our status as a publicly listed company, we have expanded our team with several key executive and Board level appointments, including the appointment of Gerald Lieberman as our Chairman of the Board and Dr. Arthur Santora as our Chief Medical Officer. The extensive experience and additional bandwidth of our larger team will allow us to move our internal osteoporosis and hypoparathyroid programs forward, as well as to continue our business development activities with other companies."

Additionally, the Company expanded its board of directors with the appointments of Faith L. Charles, Miranda J. Toledano and Gerald M. Ostrov, three new external and independent directors. Each director has held senior executive positions in hers/his respective field, and brings a wealth of experience and professional skills that will make them valuable contributors to the Company. In particular, these new independent directors bring extensive knowledge of the capital markets, business development, and the biopharma sector as a whole.

Year Ended December 31, 2018 Financial Results
Revenues for the year ended December 31, 2018 were $0.5 million. Our revenues during 2018 were derived from the license agreement signed with Amgen. We did not have any revenues prior to the signing of the license agreement with Amgen.

Research and development expenses for the year ended December 31, 2018 were $8.5 million, compared to $2.8 million for the year ended December 31, 2017, an increase of $5.7 million. The increase was primarily due to an increase in expenses for materials, clinical manufacturing and production capabilities for advancement of clinical studies and certain pre-clinical activities; an increase in payments to subcontractors and CROs associated with the performance of the Phase 2 PK/PD clinical trial; and increases in salaries and related employee expenses including from share-based compensation expenses. There was also an increase in other research and development expenses, mainly for regulatory matters, including FDA and MHRA/EMA (the British/European drug regulatory authorities) submissions.

General and administrative expenses for the year ended December 31, 2018 were $2.8 million, compared to $8.6 million for the year ended December 31, 2017, a decrease of $5.8 million. The decrease in general and administrative expenses was primarily due to a decrease in share-based compensation expenses, offset by an increase in directors and officers insurance expenses; and an increase in consulting services, legal and accounting fees related to our financing efforts.

Financial income, net for the year ended December 31, 2018 was $0.6 million, compared to $0.1 million for the year ended December 31, 2017. Financial income, net for the year ended December 31, 2018 resulted mainly from financial income through the change in the fair value of convertible loans, preferred shares and warrants to purchase preferred shares that were recorded as a financial liability at fair value through profit or loss up until July 2, 2018 when they were converted to Ordinary Shares and Warrants and were classified as equity, and a change in fair value of the Warrants issued at the Company's initial public offering and are recorded as a financial liability through profit and loss.

Comprehensive loss for the year ended December 31, 2018, was $10.3 million, compared with $11.2 million for the year ended in December 31, 2017, a decrease in loss of approximately $0.9 million.

Basic and diluted losses per share for the year ended December 31, 2018 were $1.30 and $1.31, respectively, compared with basic and diluted losses per share of $2.49, for the year ended December 31, 2017.

On July 2, 2018, the Company completed an IPO in which it offered 1,400,000 Ordinary Shares and Warrants to purchase up to 700,000 ordinary shares for a gross consideration of $11.2 million before issuance costs.

Cash and cash equivalents at December 31, 2018 and as of March 15, 2019 were approximately $11.5 million and $9.6 million, respectively. In addition, the Company has no loans outstanding. For further details on the Company's financials for the year ending December 31, 2018, please refer to our annual report on Form 20-F filed with the SEC on March 28, 2019.

Three Months Ended December 31, 2018 Financial Results
Revenues for the three months ended December 31, 2018 were $0.5 million. Our revenues during 2018 were derived from the license agreement signed with Amgen. We did not have any revenues prior to the signing of the license agreement with Amgen.

Research and development expenses for the three months ended December 31, 2018 were $2.1 million, compared to $1.1 million for the three months ended December 31, 2017. The increase was primarily due to an increase in expenses for materials, clinical manufacturing and production capabilities for advancement of clinical studies and certain pre-clinical activities; and an increase in payments to subcontractors and CROs associated with the performance of the Phase 2 PK/PD clinical trial. There was also an increase in other research and development expenses, mainly for regulatory matters and our pre IND submission.

General and administrative expenses for the three months ended December 31, 2018 were $0.9 million, compared to $3.3 million for the year ended December 31, 2017, a decrease of $2.4 million. The decrease in general and administrative expenses was primarily due to a decrease in share-based compensation expenses, offset by an increase in directors and officers insurance expenses; and an increase in consulting services, legal and accounting fees related to our financing efforts.

Financial expense, net for the three months ended December 31, 2018 was ($0.2) million, compared to financial income of $0.6 million for the year ended December 31, 2017. Financial expense, net for the three months ended December 31, 2018 resulted mainly from the change in fair value of the warrants issued at the Company's initial public offering and are recorded as a financial liability through profit and loss.

Comprehensive loss for the three months ended December 31, 2018, was $2.6 million, compared with $3.8 million for the three months ended December 31, 2017, a decrease in loss of approximately $1.2 million.

Webcast and Conference Call
Entera Bio's management will host a conference call today, Thursday, March 28, 2019 at 10:00 a.m. Eastern Time / 14:00 Greenwich Mean Time to discuss these results and answer questions.

Domestic:	877-407-0784
International:	201-689-8561
Conference ID:	13689008
Webcast:	http://public.viavid.com/index.php?id=133730

The live webcast will also be available on the Investors section of the Entera Bio website at www.enterabio.com. The webcast replay will be available on the website for two weeks following the completion of the call.

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.

Forward Looking Statements
This press release contains "forward-looking statement" 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 or likelihood of regulatory filing 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.

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ENTERA BIO LTD.
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31	
	2018	**2017**

	U.S. dollars in thousands	
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	7,506	11,746
Short-term bank deposits	4,015	-
Accounts receivable	725	-
Other current assets	220	671
TOTAL CURRENT ASSETS	12,466	12,417
NON-CURRENT ASSETS:		
Property and equipment	224	207
Intangible assets	651	654
TOTAL NON-CURRENT ASSETS	875	861
TOTAL ASSETS	13,341	13,278
Liabilities and shareholders' equity (net of capital deficiency)		
CURRENT LIABILITIES:		
Accounts payable:		
Trade	473	596
Other	1,090	1,424
Contract liabilities	225	
TOTAL CURRENT LIABILITIES	1,788	2,020
NON-CURRENT LIABILITIES:		
Convertible loan	-	3,893
Preferred shares	-	33,455
Warrants to purchase ordinary shares and preferred shares	1,372	5,398
Severance pay obligations, net	65	70
TOTAL NON-CURRENT LIABILITIES	1,437	42,816
TOTAL LIABILITIES	3,225	44,836
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY):		
Ordinary Shares, NIS 0.0000769 par value:		
Authorized - as of December 31, 2018 and December 31, 2017, 140,010,000 and 130,000,000 shares, respectively; issued and outstanding: as of December 31, 2018, and December 31, 2017-11,459,780 and 4,490,720 shares, respectively	*	*
Accumulated other comprehensive income	41	41
Other reserves	13,019	7,361
Additional paid in capital	49,173	2,853
Accumulated deficit	(52,117)	(41,813)
TOTAL SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)	10,116	(31,558)
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)	13,341	13,278

* Represents an amount less than one thousand US dollars.

ENTERA BIO LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31		
	2018	2017	2016
	U.S. dollars in thousands		
REVENUE	500	-	-
RESEARCH AND DEVELOPMENT EXPENSES, NET	8,518	2,768	2,648
GENERAL AND ADMINISTRATIVE EXPENSES	2,843	8,575	2,719

OPERATING LOSS	10,861	11,343	5,367
FINANCIALINCOME:			
Income from change in fair value of financial liabilities at fair value through profit or loss	(523)	(251)	(4,311)
Other financial expenses (income), net	(34)	105	143
FINANCIAL INCOME, net	(557)	(146)	(4,168)
NET COMPREHENSIVE LOSS	10,304	11,197	1,199
	U.S. dollars (except for share numbers)		
LOSS PER ORDINARY SHARE* -			
Basic	1.30	2.49	0.27
Diluted	1.31	2.49	0.78
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES* -			
Basic	7,955,447	4,490,720	4,473,170
Diluted	7,983,402	4,490,720	6,756,360

*Retroactively adjusted due to ordinary shares split.

Entera Bio Ltd.

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INTERNATIONAL INVESTOR RELATIONS

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Source: Entera Bio