Entera Bio Reports Third Quarter 2018 Financial Results and Operating Update

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- *Entered into research collaboration and license agreement with Amgen, potential for up to $270 million in milestone payments, as well as 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*
- *Mr. Gerald Lieberman named as Chairman and three new independent members appointed to the board of directors*
- *Appointed Dr. Arthur Santora, former Merck executive and lead clinical research physician on Fosamax®, as Chief Medical Officer*

JERUSALEM, Jan. 22, 2019 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) today provided an operating update and reported financial results for the quarter ended September 30, 2018.

"We achieved a number of important R&D and corporate milestones in 2018, including the successful execution of an important collaboration and licensing agreement with Amgen, completion of our IPO in July, UK regulatory (MHRA) approval to conduct a clinical trial (CTA, similar to a US FDA IND), the reporting of positive data for the first part of our Phase 2 PK/PD study in hypoparathyroidism patients, completion of our Phase 2 PK/PD study in hypoparathyroidism, and completion of our pre-IND meeting with the FDA to discuss clinical development plans for osteoporosis," stated Dr. Phillip Schwartz, Chief Executive Officer of Entera Bio.

Recent Highlights

Strategic Research Collaboration with Amgen: Entera recently announced a strategic collaboration and licensing 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 agreement, Amgen has agreed to pay all costs associated with development of these three drugs. Entera received a modest initial technology access fee from Amgen and will be eligible to receive up to $270 million in aggregate payments upon achievement of various milestones, as well as tiered royalties 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 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 access 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 relationships, we plan 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 existing pipeline and assets (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."

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®. An initial analysis of the Part 1 data demonstrated that Oral PTH (1-34), administered 4 times daily (Q.I.D.), 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. 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. 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 (T.I.D.) 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 weeks/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, stated, "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."

FDA Meeting: In November 2018, the Company held a productive pre-IND meeting with the U.S. Food and Drug Administration (FDA) to seek guidance and define the clinical pathway for the approval of Oral PTH (1-34) for the treatment of osteoporosis. In addition to discussing various aspect of Entera's development plan, the meeting also focused on the 505 b(2) regulatory pathway and the use of bone mineral density to support an NDA, which would be of considerably shorter duration and less expensive as compared to a bone fracture study. The Company will present the FDA's feedback from this meeting in the near future.

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 later served on numerous FDA advisory committees as well as advising on 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.

Three Months Ended September 30, 2018 Financial Results

Research and development expenses for the three months ended September 30, 2018 were $1.8 million, compared to $0.4 million for the three months ended September 30, 2017. The increase in research and development expenses was primarily due to increases in expenses for materials, clinical manufacturing and production capabilities for advanced clinical studies; increases in salaries and related employee expenses; and increases in payments to subcontractors and CROs; and an increase in other research and development expenses, mainly for regulatory consulting.

General and administrative expenses for the three months ended September 30, 2018 were $1.1 million, compared to $2.4 million for the three months ended September 30, 2017. The decrease in general and administrative expenses was primarily due to a decrease in share-based compensation expenses, offset mainly by an increase in directors' and officers' insurance expenses.

Financial expense, net for the three months ended September 30, 2018, was $2.2 million, compared to $0.9 million for the three months ended September 30, 2017. Financial expense, net for the three months ended September 30, 2018, resulted mainly from the change in the fair value of convertible loans, preferred shares and warrants to purchase preferred shares, compared with the prior period.

Comprehensive loss for the three months ended September 30, 2018, was $5.1 million, compared with $3.7 million in the same period in 2017, an increase in loss of approximately $1.4 million.

Basic and diluted loss per share for the three months ended September 30, 2018 was $0.45, compared with basic and diluted losses per share of $0.81 and $0.85, respectively, for the three months ended September 30, 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.

As of September 30, 2018, the Company had cash and cash equivalents of approximately $13.9 million.

Cash and cash equivalents at December 31, 2018 were approximately $11.5 million, and the Company has no loans. Financial results for the full year ended December 31, 2018, are expected to be reported in March 2019.

Nine Months Ended September 30, 2018 Financial Results

Research and development expenses for the nine months ended September 30, 2018 were $6.5 million, compared to $1.7 million for the nine months ended September 30, 2017. The increase in research and development expenses was primarily due to an increase in expenses for materials, clinical manufacturing and production capabilities for advancement of clinical studies; 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 nine months ended September 30, 2018 were $1.9 million, compared to $5.3 million for the nine months ended September 30, 2017. 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 nine months ended September 30, 2018 was $0.7 million, compared to a financial expense, net of $0.5 million for the nine months ended September 30, 2017. Financial income, net and financial expenses, net resulted mainly from the changes in the fair value of financial liabilities through profit and loss.

Comprehensive loss for the nine months ended September 30, 2018 was $7.6 million, compared with approximately $7.4 million in the same period in 2017, an increase of $0.2 million.

Basic and diluted losses per share for the nine months ended September 30, 2018 was $1.13 and $1.14, respectively, compared with losses of $1.65 and $1.69 for the nine months ended September 30, 2017.

Entera is a Foreign Private Issuer (FPI) and is not required to report quarterly financials. This third quarter financial report was reviewed by Entera's audit committee, approved by the board and is being issued to provide additional financial transparency to Entera's investor community. The Israeli Companies Law requires that the financial statements be reviewed by an audit committee comprised of three independent directors. The minimum three member size of the audit committee (which is not required under NASDAQ rules applicable to Entera) was met with the appointment of Gerald M. Ostrov as an audit committee member in January 2019. As a result, the Company is reporting financial results for the three and nine month periods ended September 30, 2018, later than is typical for US based entities.

For further details on the Company's financials for the three and nine month periods ending September 30, 2018, please refer to the exhibits to the report on Form 6-K filed with the SEC on January 22.

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 statements." 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. 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 Registration Statement on Form F-1 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.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

	September 30 2018	December 31 2017
	U.S. dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	13,858	11,746
Other current assets	398	671
TOTAL CURRENT ASSETS	14,256	12,417
NON-CURRENT ASSETS:		
Property and equipment	238	207
Intangible assets	654	654
TOTAL NON-CURRENT ASSETS	892	861
TOTAL ASSETS	15,148	13,278
Liabilities and shareholders' equity (net of capital deficiency)		
CURRENT LIABILITIES:		
Accounts payable:		
Trade	403	596
Other	1,041	1,424
TOTAL CURRENT LIABILITIES	1,444	2,020
NON-CURRENT LIABILITIES:		
Convertible loan	-	3,893
Preferred shares	-	33,455
Warrants to purchase preferred shares and shares	1,176	5,398
Severance pay obligations, net	67	70
TOTAL NON-CURRENT LIABILITIES	1,243	42,816
TOTAL LIABILITIES	2,687	44,836
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY):		

Ordinary Shares, NIS 0.0000769 par value:		
Authorized - as of September 30, 2018 and December 31, 2017, 140,010,000 shares; issued outstanding:		
as of September 30, 2018, and December 31, 2017 - 11,428,320		
and 4,490,720 shares, respectively	*	*
Accumulated other comprehensive income	41	41
Other reserves	13,128	7,361
Additional paid in capital	48,764	2,853
Accumulated deficit	(49,472)	(41,813)
TOTAL SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)	12,461	(31,558)
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)	15,148	13,278

* Represents an amount less than one thousand US dollars.

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Nine months ended September 30		Three months ended September 30	
	2018	2017	2018	2017
	U.S. dollars in thousands			
RESEARCH AND DEVELOPMENT EXPENSES	6,464	1,686	1,806	406
GENERAL AND ADMINISTRATIVE EXPENSES	1,914	5,267	1,060	2,373
OPERATING LOSS	8,378	6,953	2,866	2,779
FINANCIAL EXPENSES (INCOME):				
Expenses (Income) from change in fair value of financial liabilities at fair value	(719)	403	2,177	882
Other financial expenses (income) , net	-	66	23	(5)
FINANCIAL EXPENSES (INCOME), net	(719)	469	2,200	877
NET COMPREHENSIVE LOSS FOR THE PERIOD	7,659	7,422	5,066	3,656
	U.S. dollars		U.S. dollars	
LOSS PER ORDINARY SHARE* -				
Basic	1.13	1.65	0.45	0.81
Diluted	1.14	1.69	0.45	0.85
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING* -				
Basic	6,777,841	4,490,720	11,277,503	4,490,720
Diluted	6,825,532	4,822,740	11,277,503	5,444,980

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INTERNATIONAL INVESTOR RELATIONS

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Source: Entera Bio