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

August 20, 2019 11:00 AM EDT

- Phase 2 study for oral PTH in osteoporosis was initiated in June 2019; Data expected in 2020
- Completed Part 2 of a Phase 2 PK/PD study in hypoparathyroidism patients. Results expected to be presented in Q3 2019.
- Appointed Adam Gridley as Chief Executive Officer
- Conference call and live webcast today at 8:30 am Eastern Time

JERUSALEM and BOSTON, Aug. 20, 2019 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) today provided a corporate update and reported financial results for second quarter ended June 30, 2019.

"Entera's evolution into one of the leading oral delivery companies for human parathyroid hormone ("PTH") and other biologics or large molecule drugs continues at a rapid pace. For our internal proprietary Phase 2 therapeutic pipeline, we continue to execute on our two lead PTH programs with a number of near-term milestones over the coming year," stated Adam Gridley, CEO of Entera. "We are pleased to advance our lead program in osteoporosis with the recent initiation of a Phase 2 dose ranging study for EB613, our oral PTH candidate. Given the potential commercial potential for an orally delivered drug for osteoporosis, and the recent FDA guidance on endpoints via the 505(b)2 regulatory pathway, we've accelerated our clinical efforts for this program. This study is designed to build upon the strong safety and efficacy data generated to date, and inform the appropriate dose to evaluate for our global registrational Phase 3 study to support potential FDA review. We have also completed Part 2 of our Phase 2 PK/PD study of Oral PTH in hypoparathyroidism, and we plan to present them at a scientific meeting in the third quarter of 2019."

"In addition to executing on our lead development programs, our strategic priorities over the next 12 months will encompass a concerted investor relations outreach strategy and executing on a holistic business development initiative to drive shareholder value. To that end, we are excited by the opportunity to expand on the work we are doing in our partnership with Amgen, and with other leading biotechnology and pharmaceutical companies to apply our novel technology platform to other efficacious injectable products that may benefit from oral delivery," continued Mr. Gridley. "We currently see three main areas for potential partnerships: (1) companies with leading injectable franchises that are now facing a growing threat from biosimilars, (2) biologics and proteins that may prove to be complementary to our oral delivery platform, as demonstrated by the strategic research collaboration we signed with Amgen in 2018, and (3) opportunities to license EB613 or EB612 globally, or in certain regions of Asia with the goal of rapidly developing and commercializing these products globally."

Clinical and Corporate Highlights

Phase 2 Study for Oral PTH in osteoporosis: The overall design and registration requirements for the planned pivotal Phase 3 study have been largely defined following the input from the U.S. Food and Drug Administration (FDA) in our pre-IND meeting held in 2018. Coupled with the vast clinical experience with the marketed PTH injection (Forteo® by Lilly®), the Company initiated a dose-ranging, placebo-controlled, Phase 2 study in June 2019. 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 first patients were recently enrolled, with recruiting and screening efforts underway at all sites. The Company expects enrollment to be completed in the first quarter of 2020, with results from this Phase 2 expected starting in 2020, the first being the interim 3-month biomarker data, followed by the full 3-month and 6-month biomarker data, per the approved study design. These biomarker data, along with the bone mineral density data expected at 6 months, will inform the design of our registrational Phase 3 study. This registrational study is expected to be substantially smaller and less costly than studies used for previously studied PTH products, where the FDA required a fracture endpoint, which historically require thousands of patients over a number of years.

Osteoporosis is a disease in which the density and quality of bone are reduced. As the loss of bone silently progresses, bones become more porous and fragile, greatly increasing the risk of fracture. Worldwide, osteoporosis causes more than 8.9 million fractures annually, resulting in an osteoporotic fracture every 3 seconds. Worldwide incidence of osteoporosis is estimated to exceed 200 million people[1], with only a small percentage of that population undergoing treatment.

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.

Part 2 of this PK/PD study evaluated a three times per day (TID) treatment regimen with a high and low dose of Oral PTH, as well as additional Natpara® treatments. Results from this study are expected to be reported in September 2019 at an upcoming scientific conference and are subsequently expected to be submitted for peer review publication in 2020. These data will provide input for the design of the Company's anticipated Phase 3 registration clinical trials.

Personnel Appointments & Anticipated Growth of Operations:

Entera announced a number of personnel appointments, with the appointment of Sean Ellis, a Managing Partner of Centillion Fund, to the Board of Directors in June 2019. In August 2019, Adam Gridley joined the Company as CEO, and Phillip Schwartz, Ph.D., former CEO since the Company's

inception in 2010, was appointed as the Company's President of Research & Development and Executive Vice President.

Entera expects to further build out the Company's management teams in the United States and Israel, with several planned executive level hires in the financial and business development functions to support the Company's planned strategic plans. The Company is in the process of establishing a corporate office in the Boston, Massachusetts area.

Investor Relations & Research Coverage:
Frost & Sullivan published an equity research report entitled From Injections to Pills - Entera Bio (ENTX): Initiation of Coverage on July 1, 2019. The Company expects to present at a number of investor conferences over the coming quarters, as well as expanding its investor presence with institutional and retail investors through upcoming non-deal roadshows, and a planned educational event with leading osteoporosis experts, all of which will be webcast and hosted on the Company's investor relations portion of the website.

Financial Results for the Six Months Ended June 30, 2019

Revenues. Revenue for the six months ended June 30, 2019 was $74 thousand from services provided to Amgen.

1 https://www.iofbonehealth.org/facts-statistics

Research and development expenses. Research and development expenses for the six months ended June 30, 2019 were $3.5 million, compared to $4.7 million for the six months ended June 30, 2018, a decrease of $1.2 million, or 25%. The decrease in research and development expenses was primarily attributed to a decrease of $0.8 million in materials, clinical manufacturing and production capabilities and a decrease of $0.5 million in share-based compensation expenses. The decrease was partially offset by an increase of $0.1 million in salaries and related expenses mainly due to hiring of full time employees in the US during the first quarter of 2018.

General and administrative expenses. General and administrative expenses for the six months ended June 30, 2019 were $1.7 million, compared to $0.9 million for the six months ended June 30, 2018, an increase of $0.8 million, or 97%. The increase in general and administrative expenses was primarily attributed to an increase of $0.6 million in share-based compensation expenses due to a reversal of compensation recorded in the previous period as a result of the termination of services of our previous Chairman of the board in the same period in the prior year, an increase of $0.1 million for insurance expenses and $0.1 million of investor relation expenses due to regulation and the requirements of public company.

Financial income. Financial income, net for the six months ended June 30, 2019 was $0.8 million, compared to a financial income, net of $2.9 million for the six months ended June 30, 2018, a decrease of $2.1 million. Financial expenses (income), net for the six months ended June 30, 2019 and for the same period last year, resulted mainly from the change in the fair value of financial liabilities measured at fair value through profit or loss. During the six months ended June 30, 2019 and 2018, we recorded a gain of $0.8 million and $2.9 million, respectively.

Comprehensive loss. Comprehensive loss for the six months ended June 30, 2019 was approximately $4.4 million, compared with approximately $2.6 million in the same period in 2017, an increase of approximately $1.8 million, or 68%.

Basic and Diluted Loss (income) per share. Basic and diluted loss per share for the six months ended June 30, 2019 was $0.38, compared with $0.58 and $0.7 for the six months ended June 30, 2018.

Financial Results for the Three Months Ended on June 30, 2019

Revenues. Revenues for the three months ended June 30, 2019 was $74 thousand from services provided to Amgen.

Research and development, net expenses. Research and development expenses for the three months ended June 30, 2019 were $1.4 million, compared to $1.8 million for the three months ended June 30, 2018, a decrease of $0.4 million, or 20%. The decrease in research and development expenses was primarily attributed to a decrease of approximately $0.3 million in materials, clinical manufacturing and production capabilities and $0.2 million in clinical trials, which was partially offset by an increase of $0.1 million in other research and development expenses primarily for consulting with regard to regulation expenses.

General and administrative expenses (income). General and administrative expenses for the three months ended June 30, 2019 were $0.6 million, compared to general and administrative income of $0.4 million for the three months ended June 30, 2018, an increase in expenses of $1.0 million. The increase in general and administrative expenses was primarily attributed to an increase of $0.9 million in share-based compensation due to a reversal of compensation recorded in the previous period as a result of the termination of services of our previous Chairman of the board. In addition, insurance expenses increased by $0.1 million.

Financial income, net. Financial income, net for the three months ended June 30, 2019 was $0.7 million, compared to a financial income, net of $2.9 million for the three months ended June 30, 2018. Financial income, net for the three months ended June 30, 2019 and for the same period last year, resulted mainly from the change in the fair value of financial liabilities measured at fair value through profit or loss. During the three months ended June 30, 2019 and 2018, we recorded a gain of $0.7 million and $2.9 million, respectively.

Comprehensive loss (income), net. Comprehensive loss for the three months ended June 30, 2019, was approximately $1.4 million, compared with a comprehensive income of approximately $1.6 million in the same period in 2018, an increase in expenses of approximately $2.9 million.

Basic and Diluted Loss (income) per share. Basic and diluted loss per share for the three months ended June 30, 2019 was $0.12 compared with a basic income of $0.35 and diluted loss per share of $0.11, for the three months ended June 30, 2018.

Conference call and webcast, Tuesday, August 20th @ 8:30 am Eastern Time

From the US:	877-407-0784
International:	201-689-8560
From Israel:	1 809 406 247
Conference ID:	13693844
Webcast:	http://public.viavid.com/index.php?id=135865

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)

	June 30 2019	December 31 2018
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	7,386	7,506
Short-term bank deposits	-	4,015
Accounts receivable	-	725
Other current assets	486	220
TOTAL CURRENT ASSETS	7,872	12,466
NON-CURRENT ASSETS:		
Property and equipment	231	224
Right to use assets	327	-
Intangible assets	621	651
TOTAL NON-CURRENT ASSETS	1,179	875
TOTAL ASSETS	9,051	13,341
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable:		
Trade	494	473
Other	939	1,090
Lease liabilities	163	-
Contract liabilities	151	225
TOTAL CURRENT LIABILITIES	1,747	1,788
NON-CURRENT LIABILITIES:		
Warrants to purchase ordinary shares	578	1,372
Lease liabilities	190	-
Severance pay obligations, net	68	65
TOTAL NON-CURRENT LIABILITIES	836	1,437
TOTAL LIABILITIES	2,583	3,225
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.0000769 par value:		

Authorized - as of June 30, 2019 and December 31, 2018, 140,010,000 shares; issued and outstanding: as of June 30, 2019, and December 31, 2018 – 11,899,159 shares and 11,459,780 shares, respectively.	*	*
Accumulated other comprehensive income	41	41
Other reserves	13,563	13,019
Additional paid in capital	49,342	49,173
Accumulated deficit	(56,478)	(52,117)
TOTAL SHAREHOLDERS' EQUITY	6,468	10,116
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	9,051	13,341

* Represents an amount less than one thousand.

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

	Six months ended June 30		Three months ended June 30	
	2019	**2018**	**2019**	**2018**
	U.S. dollars in thousands			
REVENUE	(74)	-	(74)	-
COST OF REVENUE	62	-	62	-
RESEARCH AND DEVELOPMENT EXPENSES, NET	3,448	4,658	1,413	1,765
GENERAL AND ADMINISTRATIVE EXPENSES (INCOME)	1,684	854	628	(409)
OPERATING LOSS	5,120	5,512	2,029	1,356
FINANCIAL EXPENSES (INCOME):				
Income from change in fair value of financial liabilities at fair value	(794)	(2,896)	(682)	(2,876)
Other financial expenses (income), net	35	(23)	19	(43)
FINANCIAL INCOME, net	(759)	(2,919)	(663)	(2,919)
NET COMPREHENSIVE LOSS (INCOME) FOR THE PERIOD	4,361	2,593	1,366	(1,563)

	U.S. dollars		U.S. dollars	
LOSS (INCOME) PER ORDINARY SHARE:				
Basic	0.38	0.58	0.12	(0.35)
Diluted	0.38	0.70	0.12	0.11
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:				
Basic	11,601,289	4,490,720	11,742,797	4,490,720
Diluted	11,601,289	4,735,510	11,742,797	9,640,930

Entera Bio Ltd.

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INTERNATIONAL INVESTOR RELATIONS

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