



## Entera Bio Reports First Quarter 2019 Financial Results and Operating Update

June 27, 2019 11:00 AM EDT

- Phase 2b Study for oral PTH in osteoporosis to begin by mid-year 2019
- Completed Part 2 of a Phase 2 PK/PD study in hypoparathyroidism patients. Data processing and statistical analysis are ongoing, with results expected to be presented in 2H 2019.
- Appointed Dana Yaacov-Garbeli, CPA, as interim Chief Financial Officer
- Appointed veteran life sciences investor Sean Ellis to Board of Directors

JERUSALEM, June 27, 2019 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) today provided an operating update and reported financial results for the period of three months ended on March 31, 2019.

"So far in 2019, we have made excellent progress advancing our two lead clinical programs in osteoporosis and hypoparathyroidism," stated Dr. Phillip Schwartz, Chief Executive Officer of Entera Bio. "Having received clarity from the FDA on the development path for oral PTH in osteoporosis, we are now preparing to initiate a Phase 2b dose-ranging study which is expected to provide guidance on the dose to evaluate in a larger, registrational study. Very importantly, the FDA has expressed its willingness to accept Entera's plan to develop oral PTH via the 505 (b)2 regulatory pathway, without the requirement for a large and expensive fracture endpoint study. We have also completed Part 2 of our Phase 2 PK/PD study of Oral PTH in hypoparathyroidism, and once the data have been analyzed, they will be submitted for presentation at a scientific meeting in the second half of 2019."

### Clinical and Corporate Highlights

**Phase 2b Study for Oral PTH in osteoporosis to begin by mid-year 2019:** Entera has received approval from the Israeli Ministry of Health (MOH) to begin this dose-ranging, placebo-controlled Phase 2b study. The study is expected to be initiated in the coming weeks and is designed to enroll 160 postmenopausal women with osteoporosis or low bone mineral density at four internationally recognized clinical sites in Israel. The endpoints include measurements of serum P1NP (a biochemical marker that is correlated with bone formation rate) at 3 months, and bone mineral density (BMD) at 6 months. Results are expected in 2020.

The main purpose of the Phase 2b study is to select the appropriate dose of Oral PTH for the planned Phase 3 study in osteoporosis. Entera received positive feedback on its development plans for Oral PTH in a pre-IND meeting held in 2018 with the U.S. Food and Drug Administration (FDA), that was confirmed in the formal meeting minutes that the Company subsequently received from the FDA. Based on these interactions with the Agency, the Company believes that its planned Phase 3 study may use change in bone mineral density as the primary efficacy endpoint, with efficacy being measured over a 6 to 12 month treatment period, and that a fracture endpoint study will not be required. While a BMD endpoint study comparing Oral PTH and subcutaneous PTH is still a relatively large study, it is expected to be substantially less costly and several years shorter than a fracture endpoint trial.

**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.

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 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, the database for the study has been locked and data processing/statistical analysis are ongoing. The Company plans to submit the complete data set from this PK/PD study for presentation at a scientific meeting later this year, and subsequently for a peer review publication. The results from the complete Phase 2 PK/PD trial will provide input for the design of the Company's anticipated registration clinical trials.

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 the value of the global hypoparathyroidism treatment market will exceed \$600 million in 2019 and grow at a CAGR of approximately 8% through 2026.<sup>1</sup>

### Management and Board Appointments

In April 2019, the Company appointed Dana Yaacov-Garbeli, CPA, as interim Chief Financial Officer. Mrs. Yaacov-Garbeli brings over 11 years of finance and accounting experience, including more than 9 years of experience at a Big-4 accounting firm, PwC. She has expertise in financial planning, operations, management, and strategy with extensive experience in external and internal audit for public multinational clients under US GAAP, IFRS and PCAOB standards. She is currently a Partner at A2Z-Finance, where she served as an outsourced CFO to both private and publicly traded companies and provided additional consulting and accounting services. At PwC she served as the Lead Senior Manager on audits of both public and privately held multi-location companies in Israel, US and Europe, mainly in pharmaceuticals, biotech, holdings, industrial products, retail and high-tech sectors. She received an MBA from The College of Management Academic Studies in Israel, with a concentration in financial management, and is a Certified Public Accountant. Mrs. Yaacov-Garbeli replaces Mira Rosenzweig, who left the Company on amicable terms to pursue other professional opportunities.

Mr. Sean Ellis was appointed to the Board of Directors. Mr. Ellis brings extensive knowledge of both life science industries and the US financial markets, with a longstanding history in asset management. Mr. Ellis is Managing Partner of the Centillion Fund, a venture capital fund dedicated to Israeli investments, with a primary focus on investments in the biotech and healthcare industries. Centillion is one of Entera Bio's earliest investors and largest shareholders. Mr. Ellis is also the Managing Partner and founder of Redstone Capital, a technology venture capital fund operating in Eastern

Europe and funded by SBI Japan and others. He holds a BA from New York University and MBA from Columbia University.

## Financial Results for the Three Months Ended March 31, 2019

*Research and development expenses* for the three months ended March 31, 2019 were \$2.0 million, compared to \$2.9 million for the three months ended March 31, 2018, a decrease of \$0.9 million. The decrease in research and development expenses was primarily attributed to a decrease of \$0.4 million in share-based compensation expenses and a decrease of \$0.5 million for materials, clinical manufacturing and production capabilities for advanced clinical studies. The decrease was partially offset by an increase of \$0.1 million in salaries and related employee expenses due to full time employment of several subcontractors.

*General and administrative expenses* for the three months ended March 31, 2019 were \$1.1 million, compared to \$1.3 million for the three months ended March 31, 2018, a decrease of \$0.2 million. The decrease in general and administrative expenses was primarily due to a decrease of \$0.3 million in share-based compensation expenses, which was partially offset by an increase in legal fees and insurance expenses of \$0.1 million due to regulation and requirement of public company and in facility rent expenses due to extension of Entera's Facility.

*Financial income, net* for the three months ended March 31, 2019, resulted mainly from a decrease in the fair value of warrants to purchase ordinary shares that was recorded as a financial liability at fair value through profit or loss of \$0.1 million.

The Company reported a comprehensive loss of \$3.0 million for the three months ended March 31, 2019 compared to \$4.2 million in the same period in 2018.

Basic and diluted loss per share for the three months ended March 31, 2019 was \$0.26, compared with a basic and diluted loss per share of \$0.93 for the three months ended March 31, 2018.

Cash, cash equivalents and short-term deposits at March 31, 2019 were \$9.6 million, compared to cash, cash equivalents and short-term deposits of \$11.6 million at December 31, 2018.

For further details on the Company's financial results for the three month period ended March 31, 2019, please refer to the exhibits to the report on Form 6-K filed with the SEC.

## 1. Future Market Insights (FMI): Hypoparathyroidism Treatment Market. Global Industry Analysis 2013-2017 & Opportunity Assessment 2018-2026

### 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)

March 31	December 31
2019	2018
U.S. dollars in thousands	

A s s e t s

**CURRENT ASSETS:**

Cash and cash equivalents	5,517	7,506
Short-term bank deposits	4,038	4,015
Accounts receivable	-	725
Other current assets	609	220
<b>TOTAL CURRENT ASSETS</b>	<b>10,164</b>	<b>12,466</b>

**NON-CURRENT ASSETS:**

Property and equipment	244	224
Right to use assets	361	-
Intangible assets	636	651
<b>TOTAL NON-CURRENT ASSETS</b>	<b>1,241</b>	<b>875</b>
<b>TOTAL ASSETS</b>	<b>11,405</b>	<b>13,341</b>

**Liabilities and shareholders' equity****CURRENT LIABILITIES:**

Accounts payable:		
Trade	799	473
Other	1,017	1,090
Lease liabilities	159	-
Contract liabilities	225	225
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,200</b>	<b>1,788</b>

**NON-CURRENT LIABILITIES:**

Warrants to purchase ordinary shares	1,260	1,372
Lease liabilities	216	-
Severance pay obligations, net	67	65
<b>TOTAL NON-CURRENT LIABILITIES</b>	<b>1,543</b>	<b>1,437</b>
<b>TOTAL LIABILITIES</b>	<b>3,743</b>	<b>3,225</b>

**COMMITMENTS AND CONTINGENCIES****SHAREHOLDERS' EQUITY:**

Ordinary Shares, NIS 0.0000769 par value:		
Authorized - as of March 31, 2019 and December 31, 2018, 140,010,000 shares;		
issued and outstanding: as of March 31, 2019, and December 31, 2018 - 11,459,780		
shares,	*	*
Accumulated other comprehensive income	41	41
Other reserves	13,560	13,019
Additional paid in capital	49,173	49,173
Accumulated deficit	(55,112)	(52,117)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>7,662</b>	<b>10,116</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>11,405</b>	<b>13,341</b>

\* Represents an amount less than one thousand US dollars.

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

	<b>Three months ended March 31</b>	
	<b>2019</b>	<b>2018</b>
	<b>U.S. dollars in thousands</b>	
<b>RESEARCH AND DEVELOPMENT EXPENSES, net</b>	2,035	2,893
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b>	1,056	1,263
<b>OPERATING LOSS</b>	3,091	4,156
<b>FINANCIAL EXPENSES (INCOME):</b>		

Income from change in fair value of financial liabilities at fair value	(112)	(20)
Other financial expenses, net	16	20
<b>FINANCIAL INCOME, net</b>	<u>(96)</u>	<u>-</u>
<b>NET COMPREHENSIVE LOSS FOR THE PERIOD</b>	<u><u>2,995</u></u>	<u><u>4,156</u></u>

	<b>U.S. dollars</b>	
<b>LOSS PER ORDINARY SHARE* -</b>		
Basic and diluted	<u>0.26</u>	<u>0.93</u>
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING* -</b>		
Basic and diluted	<u><u>11,459,780</u></u>	<u><u>4,490,720</u></u>

\*Retroactively adjusted due to ordinary shares split.

#### **Entera Bio Ltd.**

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#### **INTERNATIONAL INVESTOR RELATIONS**

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