Entera Bio Announces Q1 2023 Financial Results and Corporate Updates

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JERUSALEM, May 05, 2023 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), ("Entera" or the "Company") a leader in the development of orally delivered peptides and therapeutic proteins, today reported corporate updates and financial results for the first quarter ended March 31, 2023.

"Our primary objectives for 2023 are to finalize our discussion with the FDA regarding our registrational phase 3 study for EB613 in post-menopausal women with low bone mineral density (BMD) and osteoporosis, and to update on our PK study which will assess the potential for a novel oral PTH(1-34) candidate for the treatment of hypoparathyroidism," said Miranda Toledano, the Company's Chief Executive Officer. "We also remain focused on our earlier stage R&D initiatives with peptides that best align to our technology, such as GLP-2."

Corporate Updates for First Quarter 2023:

- **Concluded Type D Meeting with the FDA Related to EB613.** Entera previously reported that it will continue discussions with the agency until final guidance is received on the proposed statistical evaluation of its primary endpoint. This is likely to occur pursuant to the FDA's evaluation and qualification of the Foundation for the National Institutes of Health Bone Quality Project (FNIH BQP)[1]. Entera plans to provide an update on its discussions with the FDA as the year progresses. Meanwhile, the Company continues to strengthen its ecosystem of endocrinology and women's health advisory board for EB613 with the addition of Dr. Steve Goldstein, a global leader in menopause health and former President of the North American and International Menopause Society.

- **Institutional Review Board (IRB) Accepted and the Company Plans to Initiate Next Generation Platform PK Study in H1'2023.** Topline results expected in H2'2023 including the potential for a novel candidate to treat hypoparathyroidism with once or twice a day oral PTH(1-34) tablets. This initiative builds on prior PK and Phase 2 results of an earlier generation of EB612 in hypoparathyroidism patients.

- **Entera Oral GLP-2 Pre-Clinical Manuscript Accepted for Publication by the International Journal of Peptide Research and Therapeutics.** Based on this work, Entera believes GLP-2 represents a strong candidate for its oral delivery platform and warrants further development as an injection free alternative to patients suffering from short bowel syndrome and other disorders requiring parenteral nutrition.

- **Amgen Research Collaboration.** After over four years of collaborative pre-clinical work evaluating the use of Entera's delivery technology with one molecule selected by Amgen, both collaborators have agreed to discontinue the Research Collaboration and License Agreement entered into in 2018 out of mutual convenience.

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[1] FNIH BQP is also knows as the ASBMR FNIH-SABRE, American Society for Bone and Mineral Research-Foundation for the National Institutes of Health (FNIH) Strategy to Advance BMD as a Regulatory Endpoint (SABRE)

Financial Results for the Three Months Ended March 31, 2023

As of March 31, 2023, Entera had cash and cash equivalents of $10.7 million. Entera expects that its existing cash resources are sufficient to meet its projected operating requirements into the third quarter of 2024, which includes the capital required to fund our ongoing operations, including R&D and the completion of the Phase 1 PK study related to the new formulation of EB612.

Research and development expenses for the three months ended March 31, 2023 were $0.9 million, as compared to $1.7 million for the three months ended March 31, 2022. The decrease of $0.8 million was primarily due to a decrease of $0.6 million in materials and production costs and a decrease of $0.2 million in employee compensation, including share-based compensation.

General and administrative expenses for the three months ended March 31, 2023 were $1.3 million, as compared to $2.2 million for the three months

ended March 31, 2022. The decrease of $0.9 million was mainly attributable to a decrease of $0.6 million in employee compensation, including share-based compensation, a decrease of $0.2 million in professional fees and a decrease of $0.1 million in D&O insurance costs.

Operating expenses for the quarter ended March 31, 2023 were $2.2 million, as compared to $3.8 million for the quarter ended March 31, 2022. Entera's operating loss was $2.2 million for quarter ended March 31, 2023, as compared to $3.8 million for the quarter ended March 31, 2022.

Net loss was $2.2 million, or $0.08 per ordinary share (basic and diluted), for the quarter ended March 31, 2023, as compared to $3.8 million, or $0.13 per ordinary share (basic and diluted), for the quarter ended March 31, 2022.

About Entera Bio

Entera is a leader in the development of orally delivered macromolecules, including peptides and other therapeutic proteins. The Company focuses on significant unmet medical needs where a daily mini tablet form of a peptide treatment or replacement therapy holds the potential to transform the standard of care. The Company's most advanced product candidates, EB613 for the treatment of high risk, post-menopausal osteoporosis and EB612 for the treatment of hypoparathyroidism, are in clinical development. EB613 is the first oral, once daily mini tablet presentation of synthetic hPTH (1-34), (teriparatide), consisting of the exact same 34 amino acid sequence as daily subcutaneous teriparatide injection, Forteo®, which requires daily SC injections. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (PD/biomarker) and secondary endpoints (BMD) in a dose dependent manner and was presented at the ASBMR 2021 Annual Conference. A phase 1 PK study of novel PTH formulations is planned for H1 2023 to ascertain feasibility of a new hypo candidate (a prior formulation had positive Phase 2a data announced in 2015 and published in JBMR 2019) and for another potential indication. For more information on Entera Bio, visit www.enterabio.com.

Cautionary Statement Regarding Forward Looking Statements

Various statements in this press release are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements (other than statements of historical facts) in this press release regarding our prospects, plans, financial position, business strategy and expected financial and operational results may constitute forward-looking statements. Words such as, but not limited to, "anticipate," "believe," "can," "could," "expect," "estimate," "design," "goal," "intend," "may," "might," "objective," "plan," "predict," "project," "target," "likely," "should," "will," and "would," or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. 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.

Important factors that could cause actual results to differ materially from those reflected in Entera's forward-looking statements include, among others: changes in the interpretation of clinical data; results of our clinical trials; the FDA's interpretation and review of our results from and analysis of our clinical trials; unexpected changes in our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates; the potential disruption and delay of manufacturing supply chains; loss of available workforce resources, either by Entera or its collaboration and laboratory partners; impacts to research and development or clinical activities that Entera is contractually obligated to provide, such as those pursuant to Entera's agreement with Amgen; overall regulatory timelines; the size and growth of the potential markets for our product candidates; the scope, progress and costs of developing Entera's product candidates; Entera's reliance on third parties to conduct its clinical trials; Entera's expectations regarding licensing, business transactions and strategic collaborations; Entera's operation as a development stage company with limited operating history; Entera's ability to continue as a going concern absent access to sources of liquidity; Entera's ability to obtain and maintain regulatory approval for any of its product candidates; Entera's ability to comply with Nasdaq's minimum listing standards and other matters related to compliance with the requirements of being a public company in the United States; Entera's intellectual property position and its ability to protect its intellectual property; and other factors that are described in the "Cautionary Statements Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Entera's most recent Annual Report on Form 10-K filed with the SEC, as well as the company's subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. There can be no assurance that the actual results or developments anticipated by Entera will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Entera. Therefore, no assurance can be given that the outcomes stated or implied in such forward-looking statements and estimates will be achieved. Entera cautions investors not to rely on the forward-looking statements Entera makes in this press release. The information in this press release is provided only as of the date of this press release, and Entera undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

ENTERA BIO LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share data)
(Unaudited)

	March 31 2023	December 31 2022
Cash and cash equivalents	10,691	12,309
Accounts receivable and other current assets	682	540
Property and equipment, net	136	139
Other assets, net	97	139
Total assets	11,606	13,127
Accounts payable and other current liabilities	1,494	1,341
Total non-current liabilities	32	32
Total liabilities	1,526	1,373
Total shareholders' equity	10,080	11,754
Total liabilities and shareholders' equity	11,606	13,127

ENTERA BIO LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	**2022**
REVENUES	-	68
COST OF REVENUES	-	54
GROSS PROFIT	-	14
OPERATING EXPENSES:		
Research and development	931	1,690
General and administrative	1,294	2,171
Other income	(13)	(12)
TOTAL OPERATING EXPENSES	2,212	3,849
OPERATING LOSS	2,212	3,835
FINANCIAL INCOME, NET	(22)	(44)
LOSS BEFORE INCOME TAX	2,190	3,791
INCOME TAX BENEFIT	-	(7)
NET LOSS	2,190	3,784
LOSS PER SHARE BASIC AND DILUTED	0.08	0.13
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	28,809,922	28,804,411

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