Entera Bio Announces Q2 2023 Financial Results and Corporate Updates

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JERUSALEM, Aug. 11, 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 second quarter ended June 30, 2023.

"In the last year, we have successfully focused our resources to drive value across three main pillars: (1) moving our EB613 program along the right path to a Phase 3 registrational study, (2) developing a potential new generation for EB612 and (3) expanding our technological capabilities and platform. Our 2022 R&D plan resulted in pre-clinical validation of proprietary new generations of our oral peptide delivery platform. These are primarily designed to modify pharmacokinetic (PK)/ pharmacodynamic (PD) parameters, optimize bioavailability and curb oral dosing regimens across more complex peptides and therapeutic proteins. They are also designed to develop novel, proprietary life cycle extension candidates for our own first-in-class PTH(1-34) mini tablet treatments for osteoporosis and hypoparathyroidism. We view this as crucial given current pharmacoeconomic debates across our industry. We are determined to develop a simple, oral mini tablet format of peptides and therapeutic proteins in the most efficient manner to facilitate access to millions of patients globally. We expect to announce data from our Phase 1B study of our new generation platform in the second half of 2023. Likewise, we anticipate critical updates related to the FNIH-BQP qualification process, which has a direct implication to the potential initiation of our pivotal Phase 3 program for EB613," said Miranda Toledano, Entera's Chief Executive Officer.

Corporate Updates:

- **EB613: The First and Only Once Daily PTH(1-34) Mini Tablet Treatment for Post-Menopausal Women with High Risk Osteoporosis.** Alignment continues across our CMC/supply chain, clinical operations, and strategic discussions to potentially initiate the Phase 3 registrational study for EB613. A critical milestone is anticipated with FDA's review and potential qualification of the FNIH-ASBMR SABRE BQP.[1]
- **EB612: Next Generation Oral Peptide Platform Data Read-Outs Expected in H2'2023** . In May 2023, Entera initiated a 45 subject, three cohort, Phase 1B study comparing the safety, PK and early PD outcomes for several novel PTH(1-34) tablet formulations versus our current tablet formulations. The Company is expected to read out data from the first two cohorts of the study in H2'2023. The outcome of this study will serve to (1) validate the new platform using PTH(1-34) as our model molecule, (2) provide a lifecycle management candidate for EB613 once daily tablets for osteoporosis, (3) provide a next generation for EB612 as the first PTH hormone replacement therapy in daily tablet form, and (4) expand the development of additional targeted and potentially more complex oral peptides and therapeutic proteins independently and in collaboration with strategic partners.
- **Expansion of IP Estate.** Over the past quarter we have continued to expand and deepen our global patent portfolio. Prosecution of patent applications pertaining to treatment of osteoporosis or hypoparathyroidism by oral administration of PTH-containing tablets resulted in additional granted patents worldwide. New international patent applications, pertaining to the next generations of our base technology were filed, and additional patent applications covering additional modifications to our technology are expected to be filed later this year.

Financial Results for the Six Months Ended June 30, 2023

As of June 30, 2023, Entera had cash and cash equivalents of $9.1 million. The Company 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 1B PK study related to our new generation platform and potential new formulations for EB612.

Research and development expenses for the six months ended June 30, 2023 were $2.1 million, as compared to $3.1 million for the six months ended June 30, 2022. The decrease of $1.0 million was primarily due to a decrease of $0.4 million in pre-clinical activity and a decrease of $0.6 million in share-based compensation and a one-time payment made to a former employee pursuant to the terms of his separation agreement.

General and administrative expenses for the six months ended June 30, 2023 were $2.4 million, as compared to $4.1 million for the six months ended June 30, 2022. The decrease of $1.7 million was mainly attributable to a decrease of $0.8 million in employee compensation, including share-based compensation, a decrease of $0.6 million in professional fees and other consultants and a decrease of $0.3 million in D&O insurance costs.

Operating expenses for the six months ended June 30, 2023 were $4.5 million, as compared to $7.1 million for the six months ended June 30, 2022.

Net loss was $4.5 million, or $0.16 per ordinary share (basic and diluted), for the six months ended June 30, 2023, as compared to $7.0 million, or $0.24 per ordinary share (basic and diluted), for the six months ended June 30, 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®. 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 was initiated in H1 2023 to ascertain feasibility of a new hypo candidate (a prior formulation had positive Phase 2a data announced in 2015 and published in the JBMR in 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 may be contractually obligated to provide; 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)

	June 30, 2023	December 31, 2022
	(Unaudited)	(Audited)
Cash and cash equivalents	9,135	12,309
Accounts receivable and other current assets	679	540
Property and equipment, net	122	139
Other assets, net	509	139
Total assets	10,445	13,127
Accounts payable and other current liabilities	1,865	1,341
Total non-current liabilities	348	32
Total liabilities	2,213	1,373
Total shareholders' equity	8,232	11,754
Total liabilities and shareholders' equity	10,445	13,127

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

	Six Months Ended June 30,	
	2023	2022
REVENUES	-	112
COST OF REVENUES	-	87
GROSS PROFIT	-	25
OPERATING EXPENSES:		
Research and development	2,140	3,084
General and administrative	2,429	4,052
Other income	(27)	(27)
TOTAL OPERATING EXPENSES	4,542	7,109
OPERATING LOSS	4,542	7,084
FINANCIAL INCOME, NET	(27)	(104)
LOSS BEFORE INCOME TAX	4,515	6,980
INCOME TAX BENEFIT	-	(11)
NET LOSS	4,515	6,969
LOSS PER SHARE BASIC AND DILUTED	0.16	0.24
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	28,811,162	28,806,217

[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)

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