Entera Bio Provides 2022 Corporate Milestones and Financial Results for the Year Ended December 31, 2022

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JERUSALEM, March 31, 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 announced a summary of 2022 corporate achievements and financial results for the year ended December 31, 2022.

"The year 2022 and 2023 year to date, has been a critical time for Entera, during which focus, optimization and execution across our organization has been paramount to adequately prepare our EB613 program to become phase 3 ready, from a clinical, regulatory, and manufacturing standpoint. EB613 (oral PTH(1-34), teriparatide) is positioned as the first potential daily tablet anabolic therapy for the treatment of post-menopausal women with low Bone Mineral Density (BMD) and osteoporosis. In addition, we have continued to harness our scientific capabilities and intellectual property to expand our proprietary platform with novel drug candidates, including a new generation for EB612, potentially the first PTH (1-34) peptide replacement therapy in tablet form for the treatment of hypoparathyroidism," stated Miranda Toledano, Chief Executive Officer of Entera.

A brief review of key EB613 related milestones:

- In June 2021, Entera reported positive results from its double-blind, placebo-controlled Phase 2 study of EB613 in 161 post-menopausal women with low BMD and osteoporosis. The study met all PD/ biomarker, BMD endpoints, and demonstrated a generally well tolerated safety profile. It was also noted that EB613 had a differentiated biomarker and BMD profile versus historical 6-month data reported with daily subcutaneous injections of Forteo® in a similar population.
- In January 2022, Entera received FDA's End of Phase 2 meeting minutes which conveyed concern with the previously proposed Phase 3 study, based on a 12-month non-inferiority head-to-head design versus Forteo® and whether such a trial would be successful.
- In response to the FDA's End of Phase 2 minutes, Entera re-designed the proposed phase 3 to potentially align with FDA's suggestion to explore a placebo-controlled phase 3 design with a Total Hip BMD (TH BMD) endpoint, given emerging seminal publications from the FNIH BQP-ASBMR project.
- On July 18th, 2022, Entera announced that the FDA had granted Entera's request for a Type C Meeting based on the revised phase 3 registrational protocol for EB613.
- On October 6th 2022, Entera announced the conclusion of its Type C meeting and concurrence with the FDA that a single well designed Phase 3 placebo-controlled study with a proposed primary endpoint of TH BMD may support a New Drug Application (NDA) submission of EB613; and that a relative PK study comparing its oral tablet form of teriparatide, EB613 versus the subcutaneous injection of teriparatide, Forteo®, may be utilized as a scientific bridge to support the 505(b)(2) NDA pathway.
- On February 15th, 2023, Entera announced that a Type D meeting had been accepted by the

FDA. As part of its briefing documents for the Type D process, Entera aimed to confirm that the protocol fully met FDA's expectations, including the analysis of the primary TH BMD endpoint and the population PK evaluations.

"We look forward to continuing our dialogue with the FDA and reaching consensus to de-risk our potential pivotal regulatory pathway for EB613. It is our belief that Entera stands as the first osteoporosis drug development company to potentially pursue a placebo-controlled registrational study with a BMD (rather than fracture) endpoint. We are cognizant that to be successful in pioneering a path takes time and the agency's partnership to move forward successfully. From a corporate finance perspective, Entera has sufficient cash on hand into Q3 2024 including the read-out from our planned next generation platform PK study, which may enable us to advance the EB612 program for the treatment of hypoparathyroidism into Phase 2 in 2024. From a strategic standpoint, we will continue to hold both strategic and other discussions to determine the best path forward to finance our pivotal program for EB613. This process is of course dependent on when we conclude our regulatory discussions with FDA. This has been a challenging year for the Company, and I am proud of our resilience and accomplishments," stated Miranda Toledano, Chief Executive Officer of Entera.

Financial Results for the year Ended December 31, 2022

Revenues for the year ended December 31, 2022 and 2021 were $134,000 and $571,000, respectively, mainly attributable to research and development, or R&D services provided to Amgen and other third parties under material transfer agreements. The cost of revenues for the year ended December 31, 2022 was $101,000 as compared to $373,000 for the year ended December 31, 2021 and primarily attributed to expenses in connection with R&D services provided and reimbursed by Amgen.

Research and development expenses for the year ended December 31, 2022, were $5.8 million, as compared to $6.8 million for the year ended December 31, 2021. The decrease was primarily attributed to completion of pre-clinical activities related to our Phase 3 clinical trial for EB613 which was offset by continued materials and production expenses related to clinical supply and a one-time payment to our former President. in 2021.

General and administrative expenses for the year ended December 31, 2022 were $7.3 million, compared to $5.7 million for the year ended December 31, 2021. The increase was mainly attributable to an increase in non-cash share-based compensation granted to directors and executive officers and a one-time payment to our former Chief Executive Officer.

Operating expenses for the year ended December 31, 2022 were $13 million compared to $12.4 million for the year ended December 31, 2021. Entera's operating loss was $13 million for the year ended December 31, 2022, compared to $12.2 million for the year ended December 31, 2021.

Net loss was $13.1 million or $0.45 per ordinary share (basic and diluted) for the year ended December 31, 2022, compared to $12.2 million, or $0.47 per ordinary share (basic and diluted) for the year ended December 31, 2021.

As of December 31, 2022, Entera had cash and cash equivalents of $12.3 million. Entera expects that its existing cash resources are sufficient to meet our 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 EB612. This does not include the capital required to fund our proposed Phase 3 pivotal program for EB613 in osteoporosis.

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 mini daily 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)

	December 31 2022	December 31 2021
Cash and cash equivalents	12,309	24,892
Accounts receivable and other current assets	540	437
Property and equipment, net	139	156
Other assets, net	139	502
Total assets	13,127	25,987
Accounts payable and other current liabilities	1,341	3,161
Total non-current liabilities	32	261
Total liabilities	1,373	3,422
Total shareholders' equity	11,754	22,565
Total liabilities and shareholders' equity	13,127	25,987

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

	Year ended December 31,	
	2022	**2021**
REVENUES	134	571
COST OF REVENUES	101	373
GROSS PROFIT	33	198
OPERATING EXPENSES:		
Research and development	5,848	6,771
General and administrative	7,253	5,690
Other income	(51)	(46)
TOTAL OPERATING EXPENSES	13,050	12,415
OPERATING LOSS	13,017	12,217
FINANCIAL EXPENSES(INCOME), net	(83)	29
LOSS BEFORE INCOME TAX	12,934	12,246
INCOME TAX EXPENSE(BENEFIT)	137	(59)
NET LOSS	13,071	12,187
LOSS PER SHARE BASIC AND DILUTED	0.45	0.47
WEIGHTED-AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	28,808,090	28,133,770

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