Entera Bio Reports Q1 2024 Financial Results and Provides Business Updates

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JERUSALEM, May 10, 2024 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), ("Entera" or the "Company") a leader in the development of orally delivered peptides and small therapeutic proteins, today reported financial results and key business updates for the quarter ended March 31, 2024.

"Entera is off to a strong start in 2024 thanks to the growth strategy we implemented in 2023, expanding our N-Tab™ therapeutic pipeline with potential first in class oral GLP-2, GLP-1/glucagon and PTH(1-34) peptide treatments for patients with GYN/endocrine, metabolic and gastrointestinal disorders. We thank our shareholders for their support. We are continuing on our mission to build Entera into a premier oral peptide therapeutic company and look forward to delivering key updates across all of our programs as this year progresses," said Miranda Toledano, CEO of Entera.

EB613: First Oral PTH(1-34) Daily Osteoanabolic Tablets for Osteoporosis

- In March 2024, Entera echoed the American Society for Bone and Mineral Research (ASBMR) announcement that U.S. Food and Drug Administration (FDA) expects to provide a ruling qualifying bone mineral density (BMD) as a surrogate endpoint for fractures within 10 months. FDA's expected ruling is a key catalyst to the potential initiation of EB613's pivotal phase 3 study. 200 million women globally are estimated to be afflicted with osteoporosis. No new drugs have been approved for osteoporosis since 2019. Fracture rates, morbidity and mortality rates are rising despite effective injectable treatments. EB613 is the first and only PTH(1-34) bone building peptide in tablet format.

- In April 2024, Entera announced that the Journal of Bone and Mineral Research (JBMR) published EB613 placebo controlled Phase 2 Trial results, highlighting its dual mechanism of action, differentiated BMD profile versus injectable PTH(1-34) treatment and its potential to address the treatment chasm in this serious disease.

EB612: First Oral PTH(1-34) Peptide Replacement Therapy Tablets for Hypoparathyroidism

- In April 2024, Entera submitted to the Endocrine Society Annual Meeting (ENDO 2024) pharmacokinetic (PK) and early PD data from a Phase 1 study evaluating an unmodified PTH(1-34) peptide and a new generation of Entera's N-Tab™ platform.

First GLP-2 Peptide Tablets for Short Bowel Syndrome

- In March 2024, Entera announced positive *in vivo* PK results from its program combining OPKO Health, Inc.'s (Nasdaq: "OPK") long acting GLP-2 analogue with N-Tab™ technology. Oral GLP-2 tablets exhibited significant systemic exposure with plasma levels that were approximately 10-fold higher than therapeutic plasma concentrations reported for teduglutide (Gattex®). Pharmacology data is expected early in the second half of 2024

First GLP-1/Glucagon Agonist (Oxyntomodulin) Peptide Tablets for Obesity

- Collaborative work is ongoing combining N-Tab™ with OPKO's long-acting Oxyntomodulin (OXM) analogues for potential treatment for obesity and other metabolic diseases. We expect to report PK data for the oral OXM tablet in mid-2024, pursuant to which a pharmacology study would be initiated.

EB613: First Oral PTH(1-34) Osteoanabolic Tablets to Treat Intense Sport and Military Stress Injuries

- Entera is collaborating with leading researchers in orthopedics and sports medicine to

contribute its proprietary oral PTH(1-34) tablets for an investigator sponsored Phase 2 Study seeking to treat young women athletes who experience stress fractures as a result of intense sports training. Enter expects to provide more details on this study in the second half of 2024.

Financial Results for the Quarter Ended March 31, 2024

As of March 31, 2024, Entera had cash and cash equivalents of $9.2 million. The Company expects that its existing cash resources are sufficient to meet its projected operating requirements into the third quarter of 2025, which includes the capital required to fund our ongoing operations, including the completion of the Phase 1 PK study related to our new generation platform and the GLP-2/OXM collaborative research with OPKO.

Research and development expenses for the three months ended March 31, 2024 were $0.7 million, as compared to $0.9 million for the three months ended March 31, 2023.

General and administrative expenses for both the three months ended March 31, 2024 and 2023 were $1.3 million. For the three months ended March 31, 2024, there was a decrease of $0.1 million in D&O insurance costs and an increase of $0.1 million in compensation, consultant and other fees.

Operating expenses for the period ended March 31, 2024 were $2.1 million, as compared to $2.2 million for the quarter ended March 31, 2024.

Net loss was $2.0 million, or $0.05 per ordinary share (basic and diluted), for the period ended March 31, 2024, as compared to $2.2 million, or $0.08 per ordinary share (basic and diluted), for the period ended March 31, 2023.

About Entera Bio

Entera is a clinical stage company focused on developing oral peptide or protein replacement therapies for significant unmet medical needs where an oral tablet form holds the potential to transform the standard of care. The Company leverages on a disruptive and proprietary technology platform (N-Tab™) and its pipeline includes five differentiated, first-in-class oral peptide programs, expected to enter the clinic (Phase 1 to Phase 3) by 2025. The Company's most advanced product candidate, EB613 (oral PTH (1-34)), is being developed as the first oral, osteoanabolic (bone building) once-daily tablet treatment for post-menopausal women with low BMD and high-risk osteoporosis, with no prior fracture. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (PD/bone turnover biomarker) and secondary endpoints (BMD). Entera is preparing to initiate a Phase 3 registrational study for EB613 pursuant to the FDA's qualification of a quantitative BMD endpoint which is expected to occur by January 2025. The EB612 program is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for hypoparathyroidism. Entera is also developing the first oral oxyntomodulin, a dual targeted GLP1/glucagon peptide, in tablet form for the treatment of obesity; and first oral GLP-2 peptide tablet as an injection-free alternative for patients suffering from rare malabsorption conditions such as short bowel syndrome in collaboration with OPKO Health. For more information on Entera Bio, visit www.enterabio.com or follow us on LinkedIn, Twitter, Facebook, Instagram.

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)

	March 31, 2024	December 31, 2023
	(Unaudited)	(Audited)
Cash and cash equivalents	9,189	11,019
Accounts receivable and other current assets	562	238
Property and equipment, net	87	100

Other assets, net	401	408
Total assets	10,239	11,765
Accounts payable and other current liabilities	1,121	1,091
Total non-current liabilities	255	288
Total liabilities	1,376	1,379
Total shareholders' equity	8,863	10,386
Total liabilities and shareholders' equity	10,239	11,765

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

(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
OPERATING EXPENSES:		
Research and development	735	931
General and administrative	1,327	1,294
Other income	-	(13)
TOTAL OPERATING EXPENSES	2,062	2,212
OPERATING LOSS	2,062	2,212
FINANCIAL EXPENSES (INCOME), NET	(45)	(22)
NET LOSS	2,017	2,190
BASIC AND DILUTED LOSS PER SHARE	0.05	0.08
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	36,735,429	28,809,922

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