Entera Bio Reports Q2 2024 Financial Results and Provides Business Updates

JERUSALEM – August 9th, 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 June 30, 2024.

"We continue to deliver strong execution with key milestones achieved during the second quarter of 2024 across each of our N-Tab™ oral peptide programs dedicated to patients with OBGYN/endocrinology, GI and metabolic diseases" said Miranda Toledano, Entera's CEO. "Importantly, we are now just five months away from FDA's potential landmark ruling on the ASBMR-FNIH SABRE regulatory endpoint for osteoporosis drugs, which we view as a major catalyst for EB613. We are especially keen to start our pivotal study of EB613 in a much wider population where injectable anabolic drugs do not play a dominant role. Because of its potential dual mechanism of action, faster onset of action as an anabolic boosting agent and oral minitablet format, we believe EB613 is uniquely positioned to support earlier osteoanabolic intervention in post-menopausal women at high risk of fracture," she added.

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

- In April 2024, the Journal of Bone and Mineral Research (JBMR) published **"Oral daily PTH(1-34) Tablets [EB613] in Postmenopausal Women with Low BMD or Osteoporosis: A Randomized, Placebo-Controlled, 6-Month, Phase 2 Study"**
- In May 2024, Entera welcomed Dr. Rachel Wagman as Key Clinical Advisor to lead EB613 clinical development. Wagman has successfully advanced the development of five molecules, including the osteoporosis products Forteo®, Prolia® and Evenity® through registration
- In June 2024, the JMBR published an independent editorial titled "**A Novel Oral hPTH(1-34) [EB613] Unveils the Promise of Modeling-Based Anabolism with No Increase in Bone Remodeling"**
- In July 2024, Entera announced that **new comparative pharmacological data for its investigational agent EB613 vs. Forteo®** was selected for presentation at the ASBMR September 2024 Annual Meeting in Toronto
- In July 2024, Entera announced that the SABRE (Study to Advance BMD as a Regulatory Endpoint) is expected to provide an update at the ASBMR September 2024 Annual Meeting in Toronto

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

- In June 2024, Entera presented Phase 1 clinical data for its hypoparathyroidism focused investigational program, EB612, at the Endocrine Society ENDO 2024 Annual Meeting. Entera showed that the data supports potentially moving the BID (twice-daily) tablet dose to Phase 2 development in patients with hypoparathyroidism

- Entera continues to collaborate with a third party on the development of another PTH replacement treatment for hypoparathyroidism

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. 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. PK data for the oral OXM tablet are expected early in the second half of 2024

Financial Results for the Quarter Ended June 30, 2024

As of June 30,2024, 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 2025.

Research and development expenses for the three months ended June 30, 2024 were $1.1 million, as compared to $1.2 million for the three months ended June 30, 2023. The decrease of $0.1 million was primarily due to a decrease of $0.3 million in clinical expenses for our Phase 1 PK study related to our new generation platform and new formulations for EB612, which completed its first stage in 2023.

General and administrative expenses for both the three months ended June 30, 2024 and 2023 were $1.1 million.

Operating expenses for the period ended June 30, 2024 were $2.2 million, as compared to $2.3 million for the quarter ended June 30, 2023.

Net loss was $2.1 million, or $0.06 per ordinary share (basic and diluted), for the quarter ended June 30, 2024, as compared to $2.3 million, or $0.08 per ordinary share (basic and diluted), for the quarter ended June 30, 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.

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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, 2024	**December 31, 2023**
	(Unaudited)	(Audited)
Cash and cash equivalents	9,056	11,019
Accounts receivable and other current assets	539	238
Property and equipment, net	76	100
Other assets, net	364	408
Total assets	10,035	11,765
Accounts payable and other current liabilities	1,294	1,091
Total non-current liabilities	219	288
Total liabilities	1,503	1,379
Total shareholders' equity	8,532	10,386
Total liabilities and shareholders' equity	10,035	11,765

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

(Unaudited)

	Three Months Ended June 30,	
	2024	**2023**
REVENUES	57	-
COST OF REVENUES	48	-
GROSS PROFIT	9	-
OPERATING EXPENSES:		
Research and development	1,086	1,209
General and administrative	1,088	1,135
Other income	-	(14)
TOTAL OPERATING EXPENSES	2,174	2,330
OPERATING LOSS	2,165	2,330
FINANCIAL INCOME, NET	(20)	(5)
NET LOSS	2,145	2,325
LOSS PER SHARE BASIC AND DILUTED	0.06	0.08
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	37,090,160	28,812,375