Entera Bio Reports Second Quarter 2021 Financial Results and Provides Clinical Updates

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– Phase 2 EB613 Clinical Trial in Osteoporosis Achieves 6-month Bone Mineral Density Endpoint; Primary and Key Secondary Endpoints Met –

– Preparing for End of Phase 2 Meeting with FDA for Planned Pivotal One-year Phase 3 Study Comparing Changes in Lumbar Spine BMD in Patients Treated with EB613 Versus Treatment with Forteo®, as per a 505(b)(2) Pathway –

– Company to Host Conference Call and Webcast Today at 8:30 a.m. ET –

BOSTON and JERUSALEM, Aug. 16, 2021 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, today announced financial and operating results for the quarter ended June 30, 2021.

Second Quarter 2021 and Recent Highlights

- *6-Month Bone Mineral Density (BMD) Results Show Dose-Related Efficacy*: Final topline results from Entera's Phase 2 clinical trial of EB613, an oral formulation of human parathyroid hormone (1-34) or PTH positioned to be the first oral bone building (anabolic) product to treat osteoporosis patients, achieved its primary and key secondary endpoints. The most important BMD endpoint — change in lumbar spine BMD after 6 months — was met in the double-blinc dose-ranging, placebo-controlled study in 161 postmenopausal female subjects with osteoporosis or with low BMD. Subjects receiving 2.5 mg of EB613 showed significant dose-related increases in BMD at the lumbar spine, total hip, and femoral neck at 6 months with a placebo adjusted increase of 3.78% in lumbar spine BMD ($p<0.008$). EB613 also exhibited an excellent safety profile.
- *Commenced Preparation for End of Phase 2 FDA Meeting*: In the coming months, Entera plans to conduct an End of Phase 2 meeting with the FDA to review data and discuss EB613's advancement into a single pivotal 12-month head-to-head Phase 3 study for approval under a 505(b)(2) pathway. The study is designed to compare changes in lumbar spine BMD in patients treated with oral EB613 versus treatment with Forteo® injections (the "reference drug"). This non-inferiority study will evaluate EB613's effect on spine BMD within 25% that of Forteo's or greater. Increases in lower spine BMD versus placebo observed at 6 months in previous Forteo® studies conducted with similar patient populations, were in the 3.9% range.[1]
- *Foundational Patent Received in Europe for Platform Technology:* The European Patent Office granted a patent titled "Methods and Compositions for Oral Administration of Proteins" to Entera addressing its oral PTH formulations currently in advanced clinical stages for osteoporosis and hypoparathyroidism. This patent, combined with others issued in key markets including the U.S., China, Japan, Australia, New Zealand, and Israel, fortify Entera's

leadership position in the oral delivery of proteins.

- *New Data on Oral Delivery of Human Growth Hormone Presented at European Pharma Congress:* Entera delivered a poster presentation titled “Pharmacokinetics of an Oral Human Growth Hormone (hGH) Formulation in Rats and Mice” at the 31st Annual European Pharma Congress in London. Prescription therapeutic hGH, which is currently only administered via subcutaneous injection, was a $3.7 billion market in 2020 and is expected to grow to $8.5 billion by 2027. In a preclinical study, Entera’s hGH formulation was administered orally to mice and rats. Plasma samples analyzed showed substantial gastrointestinal absorption of the oral hGH formulation and significant systemic exposure to the drug. An oral hGH may offer numerous advantages including greater patient compliance, reduced pain, longer shelf life, no injection site reactions, and lower immunogenicity.
- *Robust Balance Sheet*: Entera strengthened its balance sheet which currently has a cash position of over $26.9 million as of June 30, 2021 giving the Company an expected cash runway into the fourth quarter of 2022, including the initial costs of the EB613 Phase 3 study which the Company hopes to initiate in the second quarter of 2022. As of August 8, 2021, we had cash and cash equivalents of $28.1 million.

“Entera achieved a very significant milestone during the second quarter with the announcement of excellent final 6-month results from our successfully completed Phase 2 study of EB613 in osteoporosis. Our oral PTH candidate has the potential to greatly expand the use of PTH to treat osteoarthritis based on expected higher patient compliance rates, coupled with efficacy and safety that is comparable to the leading the injectable alternative,” stated Entera CEO Spiros Jamas. “We look forward to a productive End of Phase 2 meeting with the FDA in which we intend to confirm our Phase 3 protocol for a single, one-year registration trial. Concurrent with advancing our lead candidate EB613 towards commercialization, we continue to expand our IP portfolio while conducting research on new indications that can be addressed by our platform oral large protein delivery platform.”

Financial Results for the Quarter Ended June 30, 2021

Revenues for the six months ended June 30, 2021 were $266,000 compared to $94,000 for the six months ended June 30, 2020. In this period, the majority of our revenues were attributable to research and development, or R&D services provided to Amgen under our 2018 collaboration agreement. The cost of revenues for the six months ended June 30, 2021 were $121,000 compared to $73,000 for the six months ended June 30, 2020 and were primarily attributed to salaries and related expenses in connection with the R&D services provided to Amgen.

Operating expenses for the six months ended June 30, 2021 were $5.2 million compared to $6.4 million for the six months ended June 30, 2020. Entera’s operating loss 5.0 million for the six months ended June 30, 2021, compared to $6.4 million for the six months ended June 30, 2020.

Research and development expenses for the six months ended June 30, 2021 were $2.4 million, compared to $3.6 million for the six months ended June 30, 2020, a decrease of $1.2 million. The decrease was primarily due to a decrease of $0.6 in professional and consulting services expenses due to submission of the IND in 2020 and a decrease of $0.6 million in EB613 clinical trial related expenses including materials and production costs, which was completed in June 2021.

General and administrative expenses for the six months ended June 30, 2021 and 2020 were $2.8 million. The changes in General and administrative expenses for the six months ended June 30, 2021, compared to the same period previous year, were mainly attributed to a decrease of $0.2 million in professional fees which were offset by an increase of $0.1 million in share-based compensation and an increase of $0.1 million in D&O insurance costs.

Net comprehensive loss was $14.6 million or $0.63 per ordinary share (basic and diluted) for the six months ended June 30, 2021, compared to $6.1 million, or $0.34 per ordinary share (basic and diluted) for the six months ended June 31, 2020.

About Entera Bio

Entera is a leader in the development of orally delivered large molecule therapeutics for use in areas with significant unmet medical need where adoption of injectable therapies is limited due to cost, convenience and compliance challenges for patients. The Company’s proprietary, oral drug delivery technology is designed to address the technical challenges of poor absorption, high variability, and the inability to deliver large molecules to the targeted location in the body through the use of a synthetic absorption enhancer to facilitate the absorption of large molecules, and protease inhibitors to prevent enzymatic degradation and support delivery to targeted tissues. The Company’s most advanced product candidates, EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism are in clinical development. The Company recently completed the phase 2 study for EB613. Entera also licenses its technology to biopharmaceutical companies for use with their proprietary compounds and, to date, has established a collaboration with Amgen Inc. For more information on Entera Bio, visit www.enterabio.com.

Forward Looking Statements

Various statements in this release are “forward-looking statements” under the securities laws. 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 our interpretation of the complete3-month biomarker data from the ongoing Phase 2 clinical trial of EB613, the timing of data readouts from the ongoing Phase 2 clinical trial of EB613, the full results of the Phase 2 clinical trial of EB613, which is still ongoing and our analysis of those full

results, the FDA's interpretation and review of our results from and analysis of our Phase 2 trial of EB613, 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, due to travel restrictions, lay-offs or forced closures or repurposing of hospital facilities; 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, if the FDA or other authorities are closed for prolonged periods, choose to allocate resources to review of COVID-19 related drugs or believe that the amount of Phase 2 clinical data collected are insufficient to initiate a Phase 3 trial, or a meaningful deterioration of the current political, legal and regulatory situation in Israel or the United States; the availability, quality and timing of the data from the Phase 2 clinical trial of EB613 in osteoporosis patients; the size and growth of the potential market for EB613 and Entera's other product candidates including any possible expansion of the market if an orally delivered option is available in addition to an injectable formulation; the scope, progress and costs of developing Entera's product candidates including EB612 and GLP-2; 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 expectations regarding its expenses, revenue, cash resources, liquidity and financial condition; Entera's ability to raise additional capital; Entera's interpretation of FDA feedback and guidance and how such guidance may impact its clinical development plans; 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 "Special Note Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Entera's annual and current filings which are on file with the SEC and available free of charge on the SEC's website at http://www.sec.gov. Additional factors may be set forth in those sections of Entera's Annual Report on Form 20-F for the year ended December 31, 2020, filed with the SEC in the first quarter of 2021. In addition to the risks described above and in Entera's annual report on Form 20-F and current reports on Form 6-K and other filings with the SEC, other unknown or unpredictable factors also could affect Entera's results. 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 in such forward-looking statements and estimates will be achieved.

All written and verbal forward-looking statements attributable to Entera or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Entera cautions investors not to rely too heavily on the forward-looking statements Entera makes or that are made on its behalf. The information in this release is provided only as of the date of this release, and Entera undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

References:

[1] Cosman F, Lane NE, Bolognese MA, et al. 2010. "Effect of transdermal teriparatide administration on bone mineral density in postmenopausal women." J Clin Endocrinol Metab 95: 151-158; and Leder BZ, O'Dea LS, Zanchetta JR, Kumar P, Banks K, McKay K, Lyttle CR, Hattersley G. 2015. "Effects of abaloparatide, a human parathyroid hormone-related peptide analog, on bone mineral density in postmenopausal women with osteoporosis." J Clin Endocrinol Metab. 102 (2): 697-706.

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(US$ in thousands)

	June 30 2021	December 31 2020
	Unaudited	
Cash and cash equivalents	26,926	8,593
Accounts receivable and other current assets	979	516
Property and equipment, net	168	192
Other assets, net	866	961
Total assets	28,939	10,262
Accounts payable and other current liabilities	1,954	1,841
Warrants liabilities	1,395	1,432
Total non-current liabilities	275	324
Total shareholders' equity	25,315	6,665
Total liabilities and shareholders' equity	28,939	10,262

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Six months ended June 30	
	2021	2020
	U.S. dollars in thousands	
REVENUE	266	94

COST OF REVENUE	121	73
RESEARCH AND DEVELOPMENT EXPENSES, net	2,417	3,616
GENERAL AND ADMINISTRATIVE EXPENSES	2,759	2,827
OTHER INCOME	22	-
OPERATING LOSS	5,009	6,422
FINANCIAL EXPENSES (INCOME):		
Loss from change in fair value of financial liabilities at fair value	9,530	(318)
Other financial income, net	25	4
FINANCIAL EXPENSES, NET	9,555	(314)
LOSS BEFORE TAXES	14,654	6,108
TAXES ON INCOME	78	-
NET COMPREHENSIVE LOSS FOR THE PERIOD	14,462	6,108
	U.S. dollars	
LOSS PER ORDINARY SHARE -		
Basic and Diluted	0.63	0.34
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING -		
Basic and Diluted	23,377,668	18,142,016

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