Entera Bio Files Patent Applications for Inventions that Optimize its Platform Technology for Oral Delivery of Large Molecule Therapeutics

May 5, 2022 12:00 PM EDT

— Inventions aim to improve bioavailability and reduce drug costs —

— Patent applications include optimized oral delivery of specific molecules for various indications —

BOSTON and JERUSALEM, May 05, 2022 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, today announced that it recently filed multiple U.S. patent applications to further strengthen the Company's patent protection and support future developments.

These patent applications address an optimized platform technology intended to be utilized for future therapeutic applications. The modified platform has the potential for a higher bioavailability and lower cost of goods in comparison to competitive technologies used for the oral delivery of peptides. Additionally, the technology is designed to utilize only well-known and approved pharmaceutical excipients and, therefore, we believe it can simplify regulatory approval. In parallel with the platform technology patent, the Company filed several patent applications related to the oral delivery of specific molecules or families of molecules, including parathyroid hormone (PTH), glucagon-like peptide (GLP)-1, GLP-2, human growth hormone (hGH), and others, utilizing the newly optimized oral delivery platform for indications including osteoporosis, hypoparathyroidism, non-union bone fractures, short bowel syndrome, and GH deficiency, and others.

"We believe Entera is at the forefront of innovating and improving the oral delivery of large molecule proteins. We've filed a substantial number of new patent applications intended to fortify our robust intellectual property position as we evaluate engaging in additional strategic partnerships," stated Entera Chief Executive Officer, Spiros Jamas. "We see opportunities with GLP's, orphan indications, and the extension of major categories of biologic drugs, which have the potential for oral delivery through Entera's platform. Concurrently, we are working on global partnering of our lead asset, EB613, as it moves toward a pivotal Phase 3 for the treatment of osteoporosis."

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" 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 our interpretation of the 3-month biomarker data from the Phase 2 clinical trial of EB613, the timing of data readouts from the Phase 2 clinical trial of EB613, the full results of the Phase 2 clinical trial of EB613 and our analysis of the full results from our Phase 2 clinical trial of EB613, 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 "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 filings 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 10-K for the year ended December 31, 2021 (the "Annual Report"), filed with the SEC in the first quarter of 2022. In addition to the risks described above and in Entera's Annual Report and Current Reports on Form 8-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 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, 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.

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