UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16
OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of October 2021

Commission file number: 001-38556

ENTERA BIO LTD.

(Exact Name of Registrant as Specified in Its Charter)

Kiryat Hadassah
Minrav Building – Fifth Floor
Jerusalem, Israel
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

CONTENTS

This report on Form 6-K of the registrant consists of a press release issued by the registrant on October 28, 2021, attached hereto as an exhibit and incorporated by reference herein.

This report on Form 6-K and Exhibit 99.1 hereto shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number: 333-238988) and Form F-3 (Registration Number: 333-239843) of Entera Bio Ltd. and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ENTERA BIO LTD.
(Registrant)

By: /s/ Spiros Jamas, Sc.D
Name: Spiros Jamas, Sc.D
Title: Chief Executive Officer and Director

Date: October 28, 2021

Exhibit 99.1

Entera Bio Publishes Key Study Describing its Oral Delivery Technology Platform for Biologic Drugs

–Study describes a dual mechanism of action approach to oral drug delivery of large molecules, the "Holy Grail" of drug development.

–Technology is utilized in Entera's EB613 oral PTH drug for osteoporosis and several other molecules now in development by Entera and in collaboration with pharmaceutical companies.

BOSTON, Massachusetts & JERUSALEM, Israel – October 28th, 2021 – Entera Bio Ltd. (NASDAQ: ENTX), today announced that researchers at the company and the University of East Anglia in the UK published preclinical in vivo studies which demonstrate the technologies efficiency in the oral delivery of large molecule biologic drugs. The approach described in the research underpins Entera's lead product, EB613, an oral parathyroid hormone (hPTH) entering Phase 3 clinical development for the treatment of osteoporosis. The pivotal Phase 3 study is planned for 2022.

The studies were published on line in the peer-reviewed *International Journal of Pharmaceutics X*.

"Entera's highly innovative technology has the potential to transform the way we treat many diseases," stated William Fraser, MD, Professor of Medicine at The Norfolk and Norwich University Hospitals and Norwich Medical School at the University of East Anglia. "Not only can replacing injections improve patient compliance and reduce patient discomfort, but the administration of oral PTH in both hypoparathyroidism and osteoporosis will allow for the customized titration of dose so critical to each individual patient. At present, most injections are administered via "pen" injectors, which are frequently not amenable to dose titration".

"Entera's innovation is to combine in a single formulation two approaches to enhancing the delivery of large molecule biologics," said Spiros Jamas, the company's CEO. "This research supports our strategy to address the two key challenges in delivering hPTH to the bloodstream at appropriate therapeutic levels consistently: protecting proteins from breaking down in the gastrointestinal tract; and 2) improving absorption of proteins through the gastro-intestinal tract.

"With a burgeoning number of injectable biologics on the market and in development, there is a growing need for effective oral formulations especially in chronic conditions where replacing injections with oral dosage may result in higher patient compliance, adherence, and quality of life," stated Entera CEO Spiros Jamas. "Beyond the near-term opportunity for our EB613 oral PTH in osteoporosis, Entera's platform technology has applications in many other indications currently treated through injectables."

In this paper researchers evaluated three different formulations of oral hPTH (1-34): 1. hPTH with a protease inhibitor which can protect the molecule in the gastrointestinal tract, and 2. hPTH with just a permeation enhancer (SNAC) which allows for the trans-cellular absorption of large molecules in the GI tract, and 3. hPTH combined with both protease inhibitor and permeation enhancer (the formulation technology currently utilized by Entera). In studies utilizing a porcine model, the Entera combined formulation achieved significantly higher PTH blood levels (Cmax and AUC, ~10- and ~20-fold respectively) as compared to each of these approaches on their own. The researchers concluded that an appropriate combination of these different technological approaches considerably contributes to the efficient oral delivery of a number of biological macromolecules.

The study is titled, “The combined effect of permeation enhancement and proteolysis inhibition on the systemic exposure of orally administrated peptides: Salcaprozate sodium, soybean trypsin inhibitor, and teriparatide study in pigs.” The authors on the paper are, Gregory Burshtein, Constantin Itin, Hillel Galitzer and Phillip Schwartz, from Entera Bio, Jonathan C. W. Tang, of the University of East Anglia (Norwich, UK) William D. Fraser, of the University of East Anglia and Norfolk and Norwich University Hospital (Norwich, UK).

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 negligible bioavailability and high absorption variability through the utilization of an approved synthetic absorption enhancer to facilitate the absorption of large molecules, and combined chemical and biological protection from enzymatic degradation in the GI tract. Entera is constantly working on the development and optimization of its delivery platform to enable oral delivery of a wider range of biologic molecules 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. Additionally, Entera 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 complete 3-month biomarker data from the recently completed Phase 2 clinical trial of EB613, the timing of data readouts from the recently completed Phase 2 clinical trial of EB613, the full results of the Phase 2 clinical trial of EB613, 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 impact of COVID-19 on Entera's business operations; 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 ability to find a dose that demonstrates the comparability of EB613 to FORTEO in the recently completed Phase 2 clinical trial of EB613; 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.

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