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 June 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 June 23, 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 and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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: June 23, 2021

Exhibit 99.1

ENTERA BIO ANNOUNCES EXCELLENT TOPLINE PHASE 2 BMD DATA FOR EB613, THE STUDY MET ITS PRIMARY AND KEY SECONDARY ENDPOINTS

- **Subjects receiving the 2.5 mg dose of EB613 showed significant dose-related increases in BMD at the lumbar spine, total hip, and femoral neck at 6 months**

- *Subjects receiving the 2.5 mg dose of EB613 for 6 months had a significant placebo adjusted increase of 3.78% in lumbar spine BMD ($p<0.008$)*

- *The study's primary efficacy endpoint, a statistically significant increase in P1NP at 3 months was achieved, as previously reported*

- *EB613 exhibited an excellent safety profile, with no drug related serious adverse events*

- *An End of Phase 2 meeting with FDA to review the EB613 development program is anticipated in the coming months. It is planned to conduct a single 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*

- *EB613 is positioned to be the first oral bone building agent for the treatment of osteoporosis*

BOSTON, Massachusetts & JERUSALEM, Israel (June 23, 2021) – Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule and biologic therapeutics, announced the final 6-month bone mineral density (BMD) results from the completed Phase 2 clinical trial of EB613 for the treatment of osteoporosis. EB613 is 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. Currently, fewer than 5% of osteoporosis patients on any form of therapy are treated with an injectable anabolic agent, widely accepted as the most effective form of treatment[1]. The Phase 2 clinical trial of EB613 was a 6-month double blind, dose-ranging, placebo-controlled study in 161 postmenopausal female subjects with osteoporosis, or with low bone mineral density (BMD). This study was conducted at four leading medical centers in Israel to evaluate the safety and efficacy of varying doses of EB613. All lab tests including biomarkers and safety monitoring were performed at a certified central laboratory, and BMD data from clinical sites was analyzed at an independent certified global imaging center.

The most important BMD endpoint — change in lumbar spine (LS) BMD after 6 months — was met. There were statistically significant dose-related trends in the increases in LS BMD as well as femoral neck and total hip BMD, with the largest increases observed in subjects treated with EB613 2.5 mg. Dose dependent increases in biochemical markers of bone formation were previously reported. A significant increase in lumbar spine (LS) BMD was observed in the 1.5 mg group, the non-titrated 2.5 mg group (those who received 2.5 mg for the full 6 months) and the titrated 2.5 mg group (who received lower doses during titration and 2.5 mg for 4 months). An increase in LS BMD is the primary endpoint for the 505(b)(2) pathway as was described by the FDA in Entera's pre-IND meeting. At present it is believed that the single Phase 3 Pivotal study necessary under the 505b2 pathway would require a 12-month head-to-head study against Forteo® (the "reference drug"), designed to achieve non inferiority for increase in BMD of the lumbar spine.

[1] (D. D. Cosman F, Anabolic Agents for Postmenopausal Osteoporosis: How Do You Choose? 2021)

Increases in LS BMD versus placebo observed at 6 months in previous Forteo® studies conducted with similar patient populations, were in the 3.9% range[1]. In the current study LS BMD increased 3.78% ($p<0.008$) in the group treated with 2.5 mg for the full 6 months. When this group was combined with the titrated 2.5 mg group (who received lower doses during titration and 2.5 mg for just 4 months) LS spine BMD increased, 2.73% ($p<0.002$).

Furthermore, EB613 had a significant impact on both femoral neck and total hip BMD at 6 months. The 2.5 mg EB613 treatment group had a 2.76% ($p<0.002$) increase in femoral neck, and a 1.84% ($p<0.02$) increase in total hip at 6 months, as compared to placebo. In contrast, significant increases in BMD of the femoral neck and total hip are usually not observed with Forteo® treatment at 6 months. Increases in hip BMD have been shown to correlate with decreases in non-vertebral fracture risk[1].

In this dose-ranging study, various doses of EB613 were tested for their effect on markers of bone metabolism after 3 months and BMD of the lumbar spine, femoral neck, and total hip after 6 months. Subjects were initially randomized to receive oral EB613 0.5 mg, 1.0 mg, 1.5 mg, or matching placebo once daily. The study utilized an adaptive design with a limited interim analysis of 3-month biomarker changes in the first 80 subjects treated that demonstrated significant, dose-related increases in P1NP (a bone formation marker) after 1 month of treatment. Based on the analysis of the interim data the 2.5 mg dose was introduced.

As previously reported, the trial's primary endpoint was met - the complete 3-month results from the trial showed a significant increase in the P1NP biomarker in the 2.5 mg dose group after 3 months of treatment ($P <0.04$) as compared to placebo. P1NP is a biomarker that indicates the rate of new bone formation.

Secondary endpoints in the trial included the effect of treatment on several additional serum bone biomarkers at 3 months including, Osteocalcin and CTX. Similar to P1NP, Osteocalcin is a biomarker for bone formation by osteoblasts, the cells that build new bone. CTX is a biomarker that indicates the rate of bone resorption by osteoclasts, the cells that remove old bone. An osteoanabolic, or bone building effect, is based on the difference in bone formation and bone resorption. An increase in P1NP or Osteocalcin, for example, associated with a smaller increase (or decrease) in CTX, usually results in an increase in bone mass.

The decrease in CTX taken together with the increase in P1NP and Osteocalcin would indicate a potential positive impact on BMD and a reduced risk of fractures, which is the goal of an anabolic osteoporosis treatment, as reflected in the 6-month BMD results.

The study medication, EB613, was generally well tolerated throughout the 6 months of treatment. There were no adverse events that were severe in intensity in any treatment group and no serious drug-related adverse events. However, subjects randomized to the 2.5 mg dose of EB613 presented a higher rate of adverse events (AEs), which are in line with AEs known to be associated with daily injections of PTH, such as nausea, headaches, and dizziness (or presyncope). In the clinical study setting, with subjects who are not severely osteoporotic and the COVID pandemic resulting in greater hesitation to remain in a clinical study, some of these expected AEs were resulting in subjects withdrawing their consent. Exploiting one of the advantages of an oral treatment, a novel titration regimen was introduced through a protocol amendment. Subjects randomized to the 2.5 mg dose (or matched placebo) initiated their treatment with a 1.5 mg dose followed by a 2.0 mg dose at their month 1 clinic visit and ultimately starting the 2.5 mg dose at the Month 3 clinic visit. This titration regimen minimized adverse events resulting in subjects' drop-outs, which were within the projected rate of 20% overall, despite the COVID-19 Pandemic.

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[2] (L. N. Cosman F 2010) (Leder BZ 2015)
[3] (Cosman 2020)

“We are very excited and encouraged by these great results which will support advancing discussions with potential strategic partners. These results are in line with our previously reported biomarker results and further validate Entera’s platform technology and its potential to enable oral formulation of various large molecules for a range of indications that could benefit from an oral drug,” said Spiros Jamas, CEO of Entera Bio. “We are looking forward to an end of Phase 2 meeting with the FDA. More detailed results will also be presented in a future scientific conference and publications. The company will evaluate potential additional osteoporosis market opportunities specifically related to increases in hip BMD.”

About EB613

EB613 is an orally delivered human parathyroid hormone (1-34), or PTH, drug candidate positioned as the first potential once daily, oral, bone building (anabolic) treatment for osteoporosis patients. Teriparatide for injection (marketed under the brand name Forteo®) was approved in the U.S. in 2002 for the treatment of osteoporosis in men and postmenopausal women who are at high risk for having a fracture and is taken daily via a subcutaneous injection.

About Osteoporosis

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, which leads to greater fragility and an increase in fracture risk. Osteoporosis is also a silent disease, often displaying no signs or symptoms until a fracture occurs, leaving the majority of patients undiagnosed and untreated, representing a high unmet medical need. The debilitating effects of osteoporosis have substantial costs and osteoporotic fractures create a significant healthcare burden. An estimated two million osteoporotic fractures occur annually in the United States, and this number is projected to grow to three million by 2025. The National Osteoporosis Foundation (NOF) has estimated that eight million women already have osteoporosis, and another approximately 44 million may have low bone mass placing them at increased risk for osteoporosis. In US women 55 years of age and older, the hospitalization burden of osteoporotic fractures and population facility-related hospital cost is greater than that of myocardial infarction, stroke, or breast cancer.

About Entera Bio Ltd.

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 Phase 2 clinical development. 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 complete 3-month biomarker data and the interim BMD 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; a possible suspension of the Phase 2 clinical trial of EB613 for clinical or data-related reasons; the impact of COVID-19 on Entera’s business operations including the ability to collect the necessary data from the Phase 2 trial of EB613; 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 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 find a dose that demonstrates the comparability of EB613 to FORTEO® in the ongoing 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, to be 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.

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Contact:

Spiros Jamas, CEO
Tel: +001 617-362-3579

spiros@enterabio.com