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 March 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 March 11, 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 and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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: March 11, 2021

Exhibit 99.1

ENTERA BIO LTD ANNOUNCES POSITIVE TOPLINE EB613 PHASE 2 BIOMARKER DATA

– Trial Met Primary Endpoint of Significant Increase in P1NP Based on Final Analysis of 3 Month Data –
– Final Analysis of 6-Month Data, Including Change in Bone Mineral Density, Expected in Q2:21 –

BOSTON, Massachusetts & JERUSALEM, Israel (March 11, 2021) – Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, announced the complete 3-month bone biomarker data analysis from the ongoing Phase 2 clinical trial of EB613. EB613 is an orally delivered human parathyroid hormone (1-34), or PTH, positioned to be the first oral bone building (anabolic) product to treat osteoporosis patients. The Phase 2 clinical trial of EB613 is a 6-month, dose-ranging, placebo-controlled, study in postmenopausal female subjects with osteoporosis, or low bone mineral density (BMD), and is being conducted at four leading medical centers in Israel to evaluate the safety of EB613 and identify the best dose(s) for a potential Phase 3 registration trial.

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 and the change at 3-months is the primary endpoint in this Phase 2 trial.

Secondary endpoints in the trial comprised 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 indicates an increase in bone mass.

Similar to the increase in P1NP, a significant increase in Osteocalcin was also observed in the 2.5 mg group after 3 months ($P < 0.01$). In line with a potential anabolic effect, a significant decrease in CTX was observed after 3 months of treatment ($P < 0.015$). 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.

Biomarker data from the Placebo and EB613 2.5mg dose group are summarized below:

- A significant increase in P1NP from baseline versus placebo at month 3 ($P < 0.04$) as well as significant increases at months 1 ($P < 0.0001$) and 2 ($P < 0.003$);
- A significant increase in Osteocalcin from baseline versus placebo at month 3 ($P < 0.006$) as well as significant increases at months 1 ($P < 0.0001$) and 2 ($P < 0.0001$);
- A significant decrease in CTX from baseline versus placebo at month 3 ($P < 0.015$) as well as a significant decrease at month 1 ($P < 0.001$)

Study Medication, EB613 or placebo, was generally well tolerated through 3 months of treatment. Common adverse events resembled those known to be associated with teriparatide by subcutaneous injection including dizziness, headache, palpitations, and nausea. There were no adverse events that were severe in intensity in any treatment group and no serious drug-related adverse events. Complete safety evaluations of the fully unblinded data will be conducted with the full 6-month data analyses.

The interim analysis of the 3-month data from the first 50% (n=80) of subjects randomized demonstrated a significant increase in P1NP after one month of treatment at the 1.5 mg dose compared to placebo. The complete 3-month biomarker results now show a significant increase in P1NP at months 1 and 2 and significant increases in Osteocalcin from baseline versus placebo at months 1, 2 and 3, with the 1.5 mg dose. The complete 3-month analysis shows a significant ($P<0.0001$) dose response effect of EB613 (0.5, 1.0, 1.5 and 2.5 mg) on P1NP. Entera intends to submit the full dataset for publication and/or presentation at an upcoming medical conference.

“We are very pleased and highly encouraged by the complete 3-month biomarker data from this trial. When taken together with the previously reported interim BMD data, these results support a dose response in BMD. We look forward to reporting the final results, including the 6-month BMD data, from this trial in the second quarter of 2021,” stated Entera CEO Spiros Jamas. “We believe these data support ongoing business development discussions with strategic partners with interests in osteoporosis. We also believe these data and previously reported data illustrate the power of Entera’s drug delivery platform for oral dosing of large biological molecules.”

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. Entera Bio completed enrollment of a 6-month phase 2 study in postmenopausal women with osteoporosis, or low BMD evaluating multiple doses of oral EB613 (and placebo) on BMD of the spine and proximal femur (hip), and anticipates reporting top-line BMD efficacy and safety results for the trial in the second quarter of 2021.

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.

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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