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 February 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 February 25, 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 and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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: February 25, 2021

Exhibit 99.1

ENTERA BIO ANNOUNCES PUBLICATION OF PHASE 2 HYPOPARATHYROIDISM STUDY IN THE JOURNAL OF BONE AND MINERAL RESEARCH

– EB612 When Added to Standard of Care Led to a Statistically Significant Decrease in Supplemental Calcium Usage –

– Oral Human Parathyroid Hormone (1-34) Has the Potential to Have a Major Impact on Compliance, Adherence, Therapeutic Impact and Quality of Life for Patients –

BOSTON, Massachusetts & JERUSALEM, Israel (February 25, 2021) – Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, announced today the publication of the results of its previously completed Phase 2a study of EB612 in the *Journal of Bone and Mineral Research*. The article, titled "Safety and Efficacy of Oral Human Parathyroid Hormone (1-34) in Hypoparathyroidism: An Open-Label Study," discussed the results of the four-month study in which EB612 was evaluated in 2015 as an adjunct to standard calcium and vitamin D supplement treatment in patients with hypoparathyroidism (HypoPT). EB612, an oral human parathyroid hormone (1-34) (PTH), has received Orphan Drug designation from the U.S. Food and Drug Administration and the European Medicines Agency for the treatment of HypoPT.

The Phase 2a study demonstrated the safety and tolerability of EB612 administered four times daily for 16 weeks to patients with HypoPT. The study achieved its primary and secondary endpoints, including a reduction in calcium supplements, reductions in serum phosphate and 24-hour urine calcium excretion, maintenance of albumin-adjusted serum calcium (ACa) within the reference range, and an improvement in quality of life. Specific results of this trial included:

- A significant reduction of 42% (p=0.001) from baseline in median calcium supplement use;
- Maintenance of median ACa levels above the lower target level for HypoPT patients (>7.5 mg/dL) throughout the study;
- A rapid decline of 23% (p=0.0003) in median serum phosphate levels 2 hours following the first dose that was maintained within the normal range for the duration of the study;
- A notable median decrease of 21% (p=0.07) in 24-hour urine calcium excretion between the first and last treatment days; and
- An increase in quality of life score of 5% (p=0.03) from baseline by the end of the treatment period.

In this study, patients were titrated up to a maximum of 12 EB612 0.75 mg tablets a day (total daily dose of 9 mg) by the investigator, according to each subject's ACa, and supplement treatment regimen. Of the 19 enrolled subjects, 17 completed the trial (of which 15 were per protocol). No drug-related serious adverse events were reported and most of the adverse events were not considered study drug-related.

"The publication of our Phase 2a EB612 study results in this leading peer-reviewed journal support our HypoPT development program and the value of our platform technology. The availability of an oral PTH is expected to improve compliance, as well as therapeutic impact and may offer patients with HypoPT a much-needed alternative to the currently available parathyroid hormone replacement therapy options which are administered via daily injections. We are currently working on improved formulations of EB612 and the design of the next clinical trial which we expect to initiate in 2022," stated Entera CEO Spiros Jamas. "In addition, through the use of our previously announced at-the-market equity program, we have continued to strengthen our balance sheet in the first quarter of 2021, and we are now funded into the fourth quarter of 2021."

The full peer-reviewed publication will be available on Entera's website once the final article is released for publication and can be found here.

About Hypoparathyroidism

Hypoparathyroidism (HypoPT) is a rare condition in which the body produces insufficient amounts of parathyroid hormone. Individuals with HypoPT typically exhibit abnormally low levels of calcium in the blood (hypocalcemia), and high levels of phosphate in the blood (hyperphosphatemia). They also develop increased urine calcium (hypercalciuria). HypoPT is estimated to affect approximately 77,000 individuals in the United States. Historically, the treatments for HypoPT have been calcium supplements and active vitamin D (calcitriol or alfacalcidol). Phosphate binders that inhibit phosphate absorption and thiazide diuretics that reduce urine calcium are occasionally added. It is often difficult to titrate the dose of both calcium supplements and active vitamin D to reduce symptoms of hypocalcemia without producing increased urine calcium or hypercalcemia with tissue calcification during chronic use, which can result in kidney injury and significant healthcare costs. Moreover, the high doses of calcium supplements may produce stomach and gastrointestinal symptoms as well as other symptoms that negatively affect a patient's quality of life. A once-daily injectable form of parathyroid hormone, has been approved by the FDA and EMA for the treatment of hypocalcemia in patients with HypoPT.

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 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 interim data from the ongoing Phase 2 clinical trial of EB613, the timing of data readouts from the ongoing Phase 2 clinical 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 results of formulation development work on EB612 the impact on future clinical trials, the scope, progress and costs of developing Entera's product candidates including EB621 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 Quarterly Report on Form 6-K for the quarter ended September 30, 2020, filed with the SEC in the fourth quarter of 2020. 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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