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 December 2020

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 December 10, 2020, 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 and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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/ Dr. Roger Garceau
Name: Roger Garceau
Title: Chief Executive Officer

Date: December 10, 2020

Exhibit 99.1

**ENTERA BIO ANNOUNCES FDA APPROVAL OF IND APPLICATION FOR EB613 –
AN ORAL HUMAN PARATHYROID HORMONE (1-34) FOR THE TREATMENT OF OSTEOPOROSIS**

– EB613 Phase 2 Placebo-Controlled, Dose-Ranging Study Ongoing in Israel with Complete 3 Month Biomarker Data expected in Q1:21 and Final Bone Mineral Density, or BMD, Data Expected in Q2:21 –

BOSTON, Massachusetts & JERUSALEM, Israel (December 10, 2020) – Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, announced today that the U.S. Food and Drug Administration (FDA) has reviewed the company's Investigational New Drug (IND) application for EB613, orally delivered human parathyroid hormone (1-34), or PTH and informed Entera that it may proceed with its initial U.S. clinical trial. EB613 is positioned as the first potential drug candidate that could provide a patient friendly, once daily, oral, bone building (anabolic) treatment for osteoporosis patients.

"There is a clear and compelling need for an oral PTH treatment that builds bone in patients with osteoporosis. With enrollment in the ongoing Phase 2 clinical trial of EB613 complete, we look forward to reporting the final biomarker data in the first quarter of 2021 and the final bone mineral density data from this trial in the second quarter of 2021," stated Arthur Santora, MD, PhD Chief Medical Officer of Entera. "Subject to the successful completion of the EB613 Phase 2 clinical trial, we intend to enter into a dialogue with the FDA to discuss the design of a pivotal Phase 3 clinical trial in order to ensure we meet all of the FDA's requirements for potential approval under the 505 (b)(2) regulatory pathway."

As part of the IND filing, Entera provided to the FDA data from a total of more than 70 subjects from two previously completed Phase 1 trials conducted in Israel during the development of EB613 and from an additional 35 subjects that participated in Entera's EB612 studies in Israel, including a 4 month hypoparathyroidism trial. EB613 is currently in a dose-ranging, placebo-controlled study in postmenopausal female subjects with osteoporosis, or low BMD, that is being conducted at four leading medical centers in Israel.

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

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 scope, progress and costs of developing Entera's product candidates; 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, including the amount of cash and cash equivalents as of September 30, 2020 referenced above, which has not been audited or reviewed by Entera's independent registered public accounting firm and should be viewed in the context of all other available information regarding Entera's results of operations, 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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