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 and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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

Exhibit 99.1: Press release dated January 11, 2021.

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
Title: Chief Executive Officer and Director

Date: January 11, 2021

Exhibit 99.1

ENTERA BIO ISSUES LETTER TO SHAREHOLDERS

BOSTON, Massachusetts & JERUSALEM, Israel (January 11, 2021) – Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, today issued a Letter to Shareholders from Spiros Jamas, Sc.D its newly appointed Chief Executive Officer and a member of its Board of Directors.

Dear Shareholders,

We hope you and your family have fared well and been healthy during a difficult 2020. As we begin the new year, we are hopeful the global community, with a little help from the biopharmaceutical industry, will overcome the most significant pandemic in a century. Personally, I am thrilled to start 2021 leading Entera and its highly promising oral protein drug delivery platform through advanced clinical trials with the hope of giving patients a much-needed oral alternative to treatments currently delivered via injection. I believe that Entera's platform can be used to establish multiple partnering opportunities to generate funding and allow the Company to share in the future value of de-risked assets. Working with the talented team here, there is much we will accomplish together from both a clinical and corporate perspective.

Strong balance sheet to drive business objectives

Entera strengthened its balance sheet at December 31, 2020 to approximately $8.6 million in cash and cash equivalents with the addition of $3.2 million in proceeds raised in the fourth quarter through a previously filed at-the-market equity program. This funds the Company's clinical programs and operations into the third quarter of 2021. At December 31, 2020, Entera had 21.1 million primary shares outstanding.

EB613 – Oral PTH to treat patients with osteoporosis

We recently completed enrollment in the Israeli Phase 2 clinical trial and received U.S. Food and Drug Administration approval for our Investigational New Drug (IND) application for our lead program EB613, an orally delivered human parathyroid hormone (1-34) (PTH), for the treatment of osteoporosis. The FDA's approval of our IND clears Entera to proceed with our initial planned U.S. clinical trial of EB613, which is positioned as the first potential drug candidate that could provide a patient friendly, once daily, oral, bone building (anabolic) treatment for osteoporosis patients.

Having announced positive interim bone mineral density (BMD) data in the Phase 2 EB613 study, we anticipate reporting interim biomarker data; and final biomarker, BMD and safety results; in the first and second quarters of 2021, respectively. Assuming positive final results from the current Phase 2 trial, we plan to advance EB613 into a pivotal Phase 3 trial that could commence patient enrollment in 2022. Our current plan is to utilize the 505(b)(2) regulatory pathway for EB613 requiring a single pivotal non-inferiority study compared to Forteo®, the leading daily injectable PTH with an estimated $1.4 billion in annual sales.

Today's osteoporosis market is characterized by high prevalence that is greatly underdiagnosed and undertreated. Only an estimated 5% of osteoporosis patients, those with severe disease, receive treatment today. As a result, the current global market for injectable PTH, the standard of care for severe osteoporosis, is $4 billion. Based on a recent market analysis, we are highly encouraged about EB613's potential to improve the quality of life for many of the estimated 200 million people living with osteoporosis worldwide. If we are able to demonstrate that EB613 is as safe and effective as injectable PTH, we believe we will increase the market size by offering a more patient friendly, pain-free, and lower cost alternative to currently marketed injectable products and potentially grow the total addressable market to $20 billion by treating all osteoporosis patients.

A vast majority of doctors surveyed in the U.S., Europe, and Japan indicated oral PTH would be their preferred method of treatment for severe osteoporosis patients relative to other options. Moreover, they indicated they would likely increase prescribing levels for osteoporosis patients if an effective oral PTH treatment is available. Data from the market analysis show the potential of EB613 to have a transformative impact on the treatment of osteoporosis by serving as a possible first line therapy that enables doctors to treat patients with moderate to severe osteoporosis who are currently untreated due to the constraints associated with injectable PTH.

Beyond the convenience of oral administration and the elimination of pain associated with needles, EB613 also delivers a cost advantage that may be particularly important to insurers and patients alike. Entera has refined its scalable drug production process, reducing the cost per pill to enable a price point considerably lower than currently marketed injectable products.

Oral PTH to treat hypoparathyroidism, an orphan disease

EB612, an oral PTH for the treatment of hypoparathyroidism, successfully met the primary and secondary endpoints in a Phase 2a clinical trial. Hypoparathyroidism, for which EB612 was granted orphan drug designation in the U.S. and Europe, is a rare condition in which a person produces an abnormally low level of PTH, causing a heavy disease burden due to its impact on a patient's cardiovascular, neurologic, renal, and skeletal systems. There is a clear unmet medical need for a safe and effective treatment for the estimated 60,000 insured hypoparathyroidism patients in the U.S., as Natpara®, the one drug currently approved by the FDA for this indication was recalled in 2019 and has only recently been reintroduced to a limited number of those patients due to supply issues. Furthermore, this drug is likely to be used in only the most severe patients due to its potential risk of bone cancer in animal studies.

Platform technology

We believe our platform technology has the potential for use in approximately one third of all large molecule therapeutics. Our platform involves the simulation of the pharmacokinetic profile of target molecules, the development of specific formulations using our proprietary 2-component system and subsequent confirmation of activity in preclinical studies. Our product candidates, EB613 and EB612, serve as the initial validation of the platform and we are evaluating additional research programs that have potential applications in a number of indications that are either currently treated via injectables or untreated. Additionally, our highly productive collaboration with Amgen involving an undisclosed anti-inflammatory target is continuing and Amgen has completed several studies to evaluate different formulations of its drug using Entera's technology.

As a substantial percentage of FDA approved drugs each year are injectable biologics, we see a significant opportunity for Entera's platform technology to deliver these approved products in oral form. While we work to execute on these opportunities, I look forward to a highly productive year with frequent communications with our shareholders. We thank all of you for your ongoing support of Entera as we continue our focused pursuit to improve patients' lives. We wish you a healthy, prosperous, and happy 2021.

Spiros Jamas, Sc.D

Chief Executive Officer and Director

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 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 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 December 31, 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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