
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 July 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):

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This report on Form 6-K of the registrant consists of a press release issued by the registrant on July 22, 2020, attached hereto as an exhibit and incorporated by reference herein.

Exhibit

[Exhibit 99.1:](#) [Press release dated July 22, 2020.](#)

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/Adam Gridley

Name: Adam Gridley

Title: Chief Executive Officer

Date: July 22, 2020



ENTERA BIO LTD ANNOUNCES HIGHLY ENCOURAGING ORAL PTH MARKET SURVEY RESULTS

- Approximately 85% of Clinicians Surveyed Likely to Prescribe Oral Parathyroid Hormone (PTH) to Treat Moderate to Severe Osteoporosis –*
- Oral PTH Described by Clinicians as Potential Game-Changer that Addresses Substantial Unmet Need with Possibility of Improving Patient Compliance and Comfort –*
- Potential to Significantly Expand the Multi-Billion Dollar Global Market; More than Half of Clinicians Likely to Increase Usage of PTH to Treat Osteoporosis if an Effective Orally Delivered Product is Available –*

BOSTON and JERUSALEM, July 22, 2020 - Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, announced today the results from two primary market research studies of clinicians who treat osteoporosis patients. The studies were conducted by a third-party firm with a goal of gaining a better understanding of the perceived value and potential market penetration of an orally-delivered parathyroid hormone product in the treatment of osteoporosis. The survey populations were comprised of clinicians who frequently prescribe osteoporosis products including endocrinologists, gynecologists, orthopedists, and general practitioners, with over 70% of their osteoporosis patients having moderate to severe osteoporosis. One study surveyed clinicians in the U.S., Canada, and Europe, and the second surveyed clinicians in Japan. In the two studies, physicians were presented with a description of an oral PTH product that provides similar efficacy and safety of injectable PTH without the need for daily subcutaneous injections. The responses to the prospect of prescribing an oral PTH were overwhelmingly positive, driven by expected improvements in patient compliance, ease of administration, and without injection site discomfort. Physicians also considered reduced costs to patients and payers to be important features. Entera's EB613 oral PTH is currently in Phase 2 clinical development for the treatment of osteoporosis, a multi-billion dollar global market.

“We are very pleased with the data from this important global market survey which very clearly validates the value proposition of our lead drug candidate, EB613. Due to the high cost, inconvenience, and pain associated with injectable osteoanabolic products, which are currently the standard of care for treating moderate to severe osteoporosis, it is estimated that only 5% of patients with severe osteoporosis actually receive treatment for their disease,” stated Entera CEO Adam Gridley. “The results of this market analysis confirm Entera’s view that an oral PTH tablet meets an unmet physician and patient need and can potentially grow the number of patients receiving treatment. Remarkably, approximately 45% of the participating physicians indicated the oral PTH would be their first line treatment choice for their patients with severe osteoporosis.”

The study conducted in the U.S./Canada/Europe included 100 clinicians with roughly 80% of the respondents from North America and 20% from Europe. Two-thirds of the clinicians were rheumatologists or endocrinologists with the balance equally split between orthopedists and general practitioners. The study conducted in Japan included 75 clinicians, approximately three-fourths of which were orthopedists. In both studies, patients treated by the physicians were predominantly female, and by progression of disease, the distribution of the patients was approximately 21% with early/mild osteoporosis, approximately 48% with moderate osteoporosis, and approximately 31% with severe osteoporosis. Clinicians in both studies were in general agreement that a safe and effective oral PTH may greatly reduce the use of PTH injectables for the treatment of osteoporosis, drastically changing the market by increasing patient comfort and compliance.

Key findings from the physician surveys included*:

	United States and Europe (n=100)	Japan (n=75)
Oral PTH as preferred method of treatment for severe osteoporosis patients relative to other options	58%	57%
Likely to prescribe oral PTH treatment for osteoporosis	84%	89%
Likely to increase prescribing levels for Osteoporosis patients if an effective oral PTH treatment is available	56%	78%
Oral PTH is compelling	79%	81%

** %s are those clinicians with a positive response to using an oral PTH product that could provide similar efficacy and safety of injectable PTH*

Dr. Arthur Santora, Entera's Chief Medical Officer added, "A majority of clinicians stated the availability of an oral PTH with the attributes presented to them would grow their practice and some of the clinicians surveyed summed things up succinctly when they stated an oral PTH would be a game changer. The data show the potential of an oral PTH to have a transformative impact on the treatment of osteoporosis by serving as a possible first line therapy, enabling doctors to treat patients with moderate to severe osteoporosis who are currently untreated by offering a much needed alternative to needle-phobic and cost-constrained patients. We believe the promising feedback from physicians currently involved in the care of high fracture risk patients with current osteoporosis medications may result in a rapid market adoption of the first oral PTH product. Our goal is for Entera Bio's EB613 oral PTH to be that product. We expect to complete patient enrollment in our Phase 2 study of EB613 in the third quarter of 2020 with a goal of moving into Phase 3 by late 2021 or 2022."

About Entera Bio Ltd.

Entera is a leader in the development of orally delivered macromolecule 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: 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 enrollment in the Phase 2 clinical trial for EB613 in patients with osteoporosis and 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, layoffs 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 so far 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; Entera’s interpretation of the results of the market research studies conducted to date; 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; 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>. 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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