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 May 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 May 20, 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 and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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: May 20, 2021

Exhibit 99.1

Entera Bio Reports First Quarter 2021 Financial Results and Provides Clinical Updates

– Phase 2 EB613 Clinical Trial in Osteoporosis Achieves 3-Month Primary Endpoint; Final Data Including BMD Expected Q2:21 –

– Entera's Oral Delivery Platform Shows Potential in Indications Including GLP-2 and Human Growth Hormone –

– Company to Host Conference Call and Webcast Today at 8:30 a.m. ET –

BOSTON, Massachusetts & JERUSALEM, Israel (May 20, 2021) – Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, today announced financial and operating results for the quarter ended March 31, 2021.

First Quarter 2021 and Recent Highlights

• *3-Month Primary Efficacy Endpoint Achieved in Phase 2 Trial of EB613 in Osteoporosis*: EB613, an orally delivered human parathyroid hormone (1-34) or PTH, is positioned to be the first oral bone building (osteoanabolic) treatment for osteoporosis. The Phase 2 study's efficacy endpoints include an evaluation of biomarker data after 3 and 6 months of treatment and bone mineral density data (BMD) after 6 months of treatment. The study met its primary 3-month endpoint. Subjects in the 2.5 mg dose group had a significant ($p<0.04$) increase in bone formation biomarkers P1NP (primary endpoint) and Osteocalcin ($p<0.006$) from baseline compared to placebo. Patients in the 2.5 mg dose group also had a significant ($p<0.015$) reduction in CTX, a bone resorption marker correlated with a reduction in the breakdown of bone and an important factor for a potential increase in BMD. The last patient enrolled in the study has completed the last visit and final data analyses including 6-month BMD data are expected Q2 2021.

Assuming positive final results from this trial, Entera intends to meet with the FDA to discuss the design of a pivotal Phase 3 non-inferiority trial examining the increase in spine bone mineral density of EB613 compared to the increase observed with Forteo® (SC PTH 1-34) and confirm the potential for approval under the 505 (b)(2) regulatory pathway.

• *Positive Data from EB612 Phase 2a Clinical Trial in Hypoparathyroidism (HypoPT) Published*: An article titled "Safety and Efficacy of Oral Human Parathyroid Hormone (1-34) in Hypoparathyroidism: An Open-Label Study" published in *The Journal of Bone and Mineral Research* Results reported results from Entera's Phase 2a clinical study which achieved its primary and secondary endpoints. Treatment with EB612 resulted in a statistically significant decrease in supplemental calcium usage, maintenance of serum albumin-adjusted calcium, and reduction of serum phosphate. The Company expects to initiate a Phase 2b HypoPT trial in 2022.

• *Oral Large Molecule Delivery Platform Shows Potential in GLP-2 and hGH*: Based on positive pre-clinical data, Entera initiated a research program for an oral glucagon-like peptide-2 (GLP-2) analog which may support a new class of drugs to treat a broad range of gastrointestinal and metabolic diseases. Currently, the only GLP-2 analog on the market is a once-daily injection for the treatment of short bowel syndrome with reported global sales of $574 million in 2019. Showing efficacy in yet another indication, Entera delivered a poster presentation titled "Pharmacokinetics of an Oral Human Growth Hormone (hGH) Formulation in Rats and Mice" at the 31st Annual European Pharma Congress in April. Plasma samples analyzed in the preclinical study showed substantial gastrointestinal absorption of Entera's oral hGH formulation and significant systemic exposure to the drug. Prescription hGH, a widely used therapeutic molecule, is currently only administered via subcutaneous injection for the treatment of growth hormone deficiency as well as other indications, a $3.7 billion market in 2020. Entera is currently evaluating different strategies to advance the oral GLP-2 and hGH programs into clinical development including through industry partnerships.

- *Robust Balance Sheet*: Entera strengthened its balance sheet which currently has a cash position of over $16 million as of March 31, 2021 giving the Company an expected cash runway into the second quarter of 2022.

“We were very pleased with the 3-month efficacy data for EB613 in the treatment of osteoporosis and look forward to announcing final 6 month BMD data this quarter. Despite the challenges of COVID, I am grateful to the patients, investigators and team’s focus to successfully executing the study. A safe and effective oral PTH alternative is expected to substantially increase patient compliance and participation, thereby expanding the treatment market and offering a higher quality of life for people living with osteoporosis,” stated Entera CEO Spiros Jamas. “Having identified new indications in which our formulations are showing preclinical efficacy, we are expanding the value of our platform and assets.”

Financial Results for the Quarter Ended March 31, 2021

Revenues for the quarter ended March 31, 2021 were $157,000 compared to $42,000 for the quarter ended March 31, 2020, with revenues in both years attributable to R&D services provided to Amgen. The cost of revenues for quarter ended March 31, 2021 and 2020 were $58,000 and $42,000 respectively and were comprised of salaries and related expenses in connection with the R&D services provided to Amgen.

Operating expenses were $2.5 million for the quarter ended March 31, 2021, compared to $2.9 million for the quarter ended March 31, 2020. Entera’s operating loss was $2.4 million for the quarter ended March 31, 2021, compared to $2.9 million for the quarter ended March 31, 2020.

Research and development expenses were $1.2 million for the quarter ended March 31, 2021, compared to $1.6 million for the quarter ended March 31, 2020. The decrease was primarily due to a decrease of $0.2 million in professional and consulting services expenses due to submission of the IND in 2020 and a decrease of $0.2 million in EB613 clinical trial related expenses, including materials and production costs.

General and administrative expenses were $1.3 million for the quarter ended March 31, 2021, compared to $1.3 million for the quarter ended March 31, 2020. The quarter ended March 31, 2021 saw a decrease of $0.2 million in professional fees which was offset by an increase of $0.1 million in legal fees and $0.1 million in insurance and investor relations expenses.

Net comprehensive loss was $9.5 million or $0.43 per ordinary share (basic and diluted) for the quarter ended March 31, 2021 compared to $2.9 million, or $0.16 per ordinary share (basic and diluted) for the quarter ended March 31, 2020. The change in net loss was primarily due to the increase in the fair value of the warrants classified as financial liability, due to an increase in our market share price.

As of March 31, 2021, Entera had cash and cash equivalents of $16.4 million, compared to $8.6 million as of December 31, 2020. The increase was primarily due to sales under our ATM facility with Canaccord Genuity LLC.

Entera expects an operating loss of approximately $13.0 million for the year ending December 31, 2021 and believes its current cash position will be sufficient to fund its operations into the second quarter of 2022.

The Company's Board of Directors has decided to accelerate the termination date of its outstanding warrants, upon satisfaction of the sale price condition and in accordance with the terms of the warrants.

Conference Call and Webcast Information

Entera's management will host a conference call on Thursday, May 20, 2021 at 8:30 a.m. EDT. A question-and-answer session will follow Entera's remarks. To participate on the live call, please dial (855) 547-3865 (US) or (409) 217-8787 (international) and provide the conference ID "8483793" five to ten minutes before the start of the call.

To access a live audio webcast of the presentation on the "Investor Relations" page of Entera's website, please click here. A replay of the webcast will be archived on Entera's website for approximately 45 days following the presentation.

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 complete3-month biomarker 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 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 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, 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.

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended March 31	
	2021	2020
	U.S. dollars in thousands	
REVENUE	157	42
COST OF REVENUE	58	42
RESEARCH AND DEVELOPMENT EXPENSES, net	1,159	1,605
GENERAL AND ADMINISTRATIVE EXPENSES	1,309	1,290
OTHER INCOME	10	-
OPERATING LOSS	2,359	2,895
FINANCIAL EXPENSES (INCOME):		
Loss from change in fair value of financial liabilities at fair value	7,103	46
Other financial income, net	(12)	(23)
FINANCIAL EXPENSES, NET	7,091	23
LOSS BEFORE TAXES	9,450	2,918
TAXES ON INCOME	38	-
NET COMPREHENSIVE LOSS FOR THE PERIOD	9,488	2,918
	U.S. dollars	
LOSS PER ORDINARY SHARE -		
Basic and Diluted	0.43	0.16
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING -		
Basic and Diluted	21,890,100	18,048,827

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(US$ in thousands)

	March 31 2021	December 31 2020
	Unaudited	
Cash and cash equivalents	16,381	8,593
Accounts receivable and other current assets	1,053	516
Other current assets	1,038	261
Property and equipment, net	182	192
Other assets, net	911	961
Total assets	18,527	10,262
Accounts payable and other current liabilities	2,081	1,841
Warrants liabilities	8,535	1,432
Total current liabilities	10,616	3,273
Total non-current liabilities	298	324
Total shareholders' equity	7,613	6,665
Total liabilities and shareholders' equity	18,527	10,262

Contact:

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