UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 12, 2022

Entera Bio Ltd.

(Exact Name of Registrant as Specified in Its Charter)

Israel	001-38556	00-0000000
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification)

KIRYAT HADASSAH, MINRAV BUILDING – FIFTH FLOOR, JERUSALEM, Israel 9112002
(Address of principal executive offices) (Zip Code)

+972-2-532-7151
(Registrant's Telephone Number, Including Area Code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a -12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d -2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e -4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, par value of NIS 0.0000769	ENTX	Nasdaq Capital Market
Warrants, each Warrant exercisable for half of an Ordinary Share at an exercise price of $5.85 per Ordinary Share	ENTXW	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 12, 2022, Entera Bio Ltd., a company organized under the laws of the State of Israel ("we," "us,", "our" or the "Company"), issued a press release announcing its financial results for the three months ended March 31, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference in this Item 2.02.

Item 7.01 Regulation FD Disclosure.

The information contained in Item 2.02 of this Current Report on Form 8-K is incorporated by reference in this Item 7.01

The information contained in this Current Report on Form 8-K, including in Exhibit 99.1 attached hereto, is "furnished" and not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. Such information shall not be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, except to the extent such other filing specifically incorporates such information by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	**Description**
99.1	Press Release dated May 12, 2022 announcing the Company's financial results for the three months ended March 31, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: May 12, 2022

By: /s/ Spiros Jamas
Name: Spiros Jamas
Title: Chief Executive Officer

Exhibit 99.1

Entera Bio Reports First Quarter 2022 Financial Results and Business Highlights

- Registrational study design for lead clinical asset, EB613, as the first oral PTH anabolic to treat post-menopausal women at high risk of osteoporosis, is underway

BOSTON and JERUSALEM – May 12, 2022 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, today announced its financial and operating results for the quarter ended March 31, 2022.

First Quarter 2022 and Recent Highlights

EB613 Clinical Update: Entera's lead clinical candidate, EB613, an oral formulation of human parathyroid hormone (1-34), or PTH, for the treatment of osteoporosis, is progressing towards a pivotal Phase 3 clinical trial. The FDA has completed the Chemistry Manufacturing and Control (CMC) review in relation to EB613. Entera and the FDA agreed upon the production and specifications of the drug's components and final product for the Phase 3 study. The Company looks forward to providing further updates related to its productive discussions with the Food and Drug Administration (FDA) in the near term.

EB613 Analytics Study: As part of its pre-pivotal study planning, Entera completed a comprehensive market and analytics study concerning EB613 and its potential as the first oral anabolic and first oral PTH product available to post-menopausal women at high risk of osteoporosis.

The study aimed at understanding treatment paradigms and quantifying the U.S. market potential of EB613 by evaluating prescriber, health plan, and managed care inputs. Key conclusions include:

- Osteoporosis represents a large market of over 15 million patients in the U.S., yet approximately 75% of the target population is not receiving any pharmacological treatment
- Despite endocrinologists recognizing the clinical benefit of initiating anabolic treatments (such as current injectable PTH agents) for higher risk patients prior to first line bisphosphonates, their high cost and patients' unwillingness to opt for a subcutaneous injection is limiting treatment
- Clinicians were receptive to EB613's efficacy (based on phase 2 data) as an anabolic treatment, its improved safety profile, and as an oral route of administration
- Payers surveyed were favorable to EB613 and characterized the value proposition as a safe, oral anabolic treatment option for osteoporosis patients
    - A survey of high prescribing doctors showed that EB613 could become the preferred option in moderate to severe osteoporosis and substantially grow the anabolic market

EB612 Hypoparathyroidism Successful Phase 2a Data Published in the first quarter of 2021: Entera is currently working on an improved formulation of EB612 and is designing its next clinical trial. EB612 has Orphan Drug status with both FDA and the European Medicines Agency for Hypoparathyroidism.

Technology Platform IP Expansion and MTAs: Entera filed multiple U.S. patent applications this quarter to expand its patent protection and support future developments as it continues to optimize its oral delivery platform. Furthermore, Entera continues to evaluate establishing material transfer agreements with potential strategic partners' proprietary molecules.

"We remain excited with our campaign to commence the pivotal Phase 3 trial for EB613 as there is a tremendous opportunity to be the first oral, once-a-day bone building osteoporosis treatment," commented Spiros Jamas, Chief Executive Officer of Entera Bio. "This quarter we made improvements to our oral delivery platform, ultimately strengthening our intellectual property protection as Entera heads into strategic partnership discussions. Furthermore, we are currently seeing promising preclinical results in connection with our partnerships under ongoing material transfer agreements. Entera remains focused on developing and improving its platform technology, and we continue to progress our clinical programs with our goal to address the need for oral delivery of large molecules."

Financial Results for the Quarter Ended March 31, 2022

Revenues for the quarter ended March 31, 2022 were $68,000 compared to $157,000 for the quarter ended March 31, 2021, with revenues in both years attributable to R&D services provided to Amgen. The cost of revenues for quarter ended March 31, 2022 and 2021 were $54,000 and $73,000, respectively, and were comprised of salaries and related expenses in connection with the R&D services provided to Amgen.

Total operating expenses were $3.8 million for the quarter ended March 31, 2022, compared to $2.4 million for the quarter ended March 31, 2021. Entera's operating loss was $3.8 million for the quarter ended March 31, 2022, compared to $2.3 million for the quarter ended March 31, 2021.
Research and development expenses were $1.7 million for the quarter ended March 31, 2022, compared to $1.1 million for the quarter ended March 31, 2021. The increase of $ 0.6 million was primarily due to an increase in materials, production costs and pre-clinical activity as part of the preparation for our Phase 3 clinical trial for EB613, employee's compensation, including share-based compensation and professional and consulting expenses.

General and administrative expenses were $2.2 million for the quarter ended March 31, 2022, compared to $1.3 million for the quarter ended March 31, 2021. The increase of $0.9 million was mainly due to increases in share-based compensation granted to non-executive directors, professional fees and D&O insurance.

Net loss was $3.8 million, or $0.13 per ordinary share (basic and diluted) for the quarter ended March 31, 2022, compared to $2.3 million, or $0.10 per ordinary share (basic and diluted) for the quarter ended March 31, 2021.

As of March 31, 2022, Entera had cash and cash equivalents of $20.1 million, compared to $24.9 million as of December 31, 2021.

Entera expects that the current cash is sufficient to fund the operations into the fourth quarter of 2022.

Conference Call and Webcast Information - Note Rescheduled Date and Time

Entera's management will [host a conference call] on Wednesday, May 18, 2022, at 8:00 AM EDT. A question-and-answer session will follow Entera's remarks. To participate on the live call, please dial (877) 269-7765 (US) or (201) 689-7817 (international) or [1809406247] (Israel) and
provide the conference ID "13730087" five to ten minutes before the start of the call.

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

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 clinical development. The Company recently completed the phase 2 study for EB613. 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.

Cautionary Statement Regarding Forward Looking Statements

Various statements in this press release are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). All statements (other than statements of historical facts) in this press release regarding our prospects, plans, financial position, business strategy and expected financial and operational results may constitute forward-looking statements. 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 3-month biomarker data from the Phase 2 clinical trial of EB613, the timing of data readouts from the Phase 2 clinical trial of EB613, the full results of the Phase 2 clinical trial of EB613 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; 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 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 "Cautionary Statement Regarding Forward-Looking Statements," "Risk Factors", "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Entera's annual, quarterly and current report and other documents filed by Entera 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 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. The information in this release is provided only as of the date of this release, and Entera undertakes no obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

Investors:
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ENTERA BIO LTD.

CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands, except share data)
(Unaudited)

	March 31 2022	December 31 2021
Cash and cash equivalents	20,109	24,892
Accounts receivable and other current assets	1,532	437
Property and equipment, net	163	156
Other assets, net	508	502
Total assets	22,312	25,987
Accounts payable and other current liabilities	2,334	3,161
Total non current liabilities	233	261
Total liabilities	2,567	3,422
Total shareholders' equity	19,745	22,565
Total liabilities and shareholders' equity	22,312	25,987

ENTERA BIO LTD.

CONSOLIDATED STATEMENTS OF OPERATIONS

(U.S. dollars in thousands, except share and per share data)

	Three Months ended March 31,	
	2022	**2021**
REVENUES	68	157
COST OF REVENUES	54	73
GROSS PROFIT	14	84
OPERATING EXPENSES:		
Research and development	1,690	1,124
General and administrative	2,171	1,309
Other income	(12)	(10
TOTAL OPERATING EXPENSES	3,848	2,423
OPERATING LOSS	3,835	2,339
FINANCIAL EXPENSES, net	(44)	(29)
LOSS BEFORE INCOME TAX	3,791	2,310
INCOME TAX ¸(BENEFIT) EXPENSE	(7)	(14)
NET LOSS	3,784	2,296
LOSS PER SHARE BASIC AND DILUTED	0.13	0.10
WEIGHTED-AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	28,804,411	21,890,100