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): August 11, 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 August 11, 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 and six months ended June 30, 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 August 11, 2022 announcing the Company's financial results for the three and six months ended June 30, 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: August 11, 2022

By: /s/ Miranda J. Toledano

Name: Miranda J. Toledano

Title: Chief Executive Officer

Exhibit 99.1

Entera Bio Provides Business Highlights and Financial Results for the Second Quarter 2022

JERUSALEM – August 11, 2022 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), ("Entera" or the "Company") a leader in the development of orally delivered peptides and therapeutic proteins, today announced its financial and operating results for the quarter ended June 30, 2022.

"We have reset our thesis and executed on several critical milestones in the first half of 2022. On July 18th, we announced the submission of our proposed registrational protocol for EB613 to the U.S. Food and Drug Administration (FDA). We are simultaneously finalizing the validation of an optimized formulation of EB612, while expanding our pre-clinical pipeline with additional anti-inflammatory and metabolic protein candidates. Lastly, we finished the quarter with $17.3 million in cash which, given our revised Phase 3 schedule, is projected to fund our current operations through the first half of 2023." commented Ms. Miranda Toledano, Chief Executive Officer of the Company. "I am incredibly energized by the opportunities ahead. By continuing to carry forward our internal clinical programs and strategic dialogues, we are poised to deliver tremendous value to patients and our shareholders as we reshape the future of Entera. We look forward to providing a comprehensive update to the investment community later this year."

Business Highlights:

Entera expects to hold a Type C Meeting with the FDA to discuss the potential registrational study for its lead clinical asset, EB613 in the second half of 2022. The Phase 3 is designed as an 18 month double blind placebo-controlled study using FNIH-BQP[1] total hip Bone Mineral Density (BMD) thresholds as the primary endpoint to evaluate fracture risk, followed by a 6-month open label transition to alendronate. EB613 is the first oral formulation of PTH (1-34), teriparatide, and the first proposed oral anabolic (bone forming) drug candidate to treat post-menopausal women with osteoporosis. EB613 has the same amino acid sequence as Forteo® which requires daily subcutaneous injections and reported peak sales surpassing $1.7 billion in 2017, prior to patent expiry. According to early commercial assessments and clinician surveys, it is estimated that less than 10% of osteoporosis patients use current anabolic drugs (including PTH receptor activators currently available such as Forteo® and Tymlos®). Despite the validated mechanism of action of these treatments, patients are deterred by their high cost and injectable mode of administration. As the first oral PTH receptor activator EB613 is expected to address this significant unmet clinical need.

Additionally, Entera is finalizing the development of an optimized formulation for EB612 which may enable twice a day administration (versus the previous 4 times a day) to patients with hypoparathyroidism. The Company anticipates conducting a first-in-human PK study of the new formulation in the first half of 2023. Entera previously conducted a pilot 4-month Phase 2 study, results of which were presented (ASBMR 2015) and published in a peer-reviewed journal (JBMR 2021), as well as a Phase 2 PK-PD study versus Natpara,Ò whose findings have also been publicly presented (ASBMR 2019). These studies demonstrated that EB612 induced a rapid decline in median serum phosphate levels and maintenance of target calcium levels throughout the study, even as patients were able to meaningfully reduce their calcium and active vitamin D supplementation which is key to reducing common comorbidities of this disease.

[1] Foundation for the National Institutes of Health Bone Quality Program (FNIH BQP)

Finally, Entera announced the formation of its Clinical and Scientific Advisory Board (CSAB), comprising world class experts in bone diseases, endocrinology, and metabolic disorders and will be presenting incremental data from its 6-month Oral PTH (EB613) Phase 2 Study in postmenopausal women with low bone mass, at the 2022 Annual Meeting of the American Society for Bone and Mineral Research (ASBMR), which will take place in Austin, Texas from September 9-12, 2022.

Financial Results for the Six-Month Period Ended June 30, 2022

Revenues for the six months ended June 30, 2022 were $112,000 compared to $226,000 for the six months ended June 30, 2021. In this period, the majority of our revenues were attributable to research and development, or R&D services provided to Amgen under our 2018 collaboration agreement. The cost of revenues for the six months ended June 30, 2022 were $87,000 compared to $172,000 for the six months ended June 30, 2021 and were primarily attributed to salaries and related expenses in connection with the R&D services provided to Amgen.

Operating expenses for the six months ended June 30, 2022 were $7.1 million compared to $5.0 million for the six months ended June 30, 2021. Entera's operating loss was $7.1 million for the six months ended June 30, 2022, compared to $4.9 million for the six months ended June 30, 2021.

Research and development expenses for the six months ended June 30, 2022 were $3.1 million, compared to $2.4 million for the six months ended June 30, 2021, an increase of $0.7 million. The increase was primarily due to an increase of $0.7 in materials and production costs and pre-clinical activity as part of the preparation for our Phase 3 clinical trial for EB613 and an increase of $0.4 million in employee's compensation. The increase was partially offset by a decrease of $0.4 million in other clinical trial expenses related to our Phase 2 trial for EB613 that was completed in June 2021.

General and administrative expenses for the six months ended June 30, 2022 were $4.1 million, compared to $2.7 million for the six months ended June 30, 2021, an increase of $1.4 million. The increase of $1.4 million was mainly attributable to an increase of $0.8 million in share-based compensation granted to non-executive directors and employees, an increase of $0.4 million in legal, accounting fees and others consultants and an increase of $0.2 million in D&O insurance costs.

The net comprehensive loss was $7.0 million or $0.24 per ordinary share (basic and diluted) for the six months ended June 30, 2022, compared to $4.9 million, or $0.21 per ordinary share (basic and diluted) for the six months ended June 31, 2021.

As of June 30, 2022, Entera had cash and cash equivalents of $17.3 million, compared to $20.1 million as of March 31, 2021.

Entera expects that the current cash is sufficient to fund the operations through the second quarter of 2023.

About EB613 (a.k.a. EBP05)

Parathyroid hormone (PTH) is an 84-amino acid hormone and the primary regulator of calcium and phosphate metabolism in bone and kidney. EB613 is an oral formulation of synthetic hPTH (1-34), (teriparatide), a peptide consisting of the first 34 amino acids of PTH which represent the functional region. Subcutaneous Forteo® (teriparatide injection) has been the leading anabolic treatment of osteoporosis since 2002. EB613 utilizes Entera's oral drug delivery platform which promotes enteric absorption and stabilizes teriparatide in the gastrointestinal tract. Entera's Oral PTH formulations have been administered collectively to a total of 225 subjects in two Phase 1 studies and 3 phase 2 studies (including 35 in 2 phase 2 hypoparathyroidism studies). The most recent study was a dose ranging Phase 2 study in postmenopausal women with low bone mass. This study met primary and key secondary endpoints and was presented in a late-breaker oral presentation at the ASBMR 2021 conference. For the primary efficacy endpoint: a statistically significant increase in P1NP (a bone formation marker) at 3 months was achieved. A significant dose response was observed for 0.5, 1.0, 1.5 and 2.5 mg oral PTH doses on P1NP, Osteocalcin and bone mineral density (BMD). Subjects receiving the 2.5 mg dose of EB613 showed significant increases in dose-related BMD at the lumbar spine, total hip, and femoral neck at 6 months. Subjects receiving the 2.5 mg dose of EB613 daily for 6 months had a significant placebo adjusted increase of 3.78% in lumbar spine BMD ($p<0.008$) which is similar to the 3.9% increase in lumbar spine BMD seen with Forteo® in clinical studies reported in the literature. Increases in total hip and femoral neck BMD were greater than those previously reported with Forteo®. EB613 exhibited an excellent safety profile, with no drug related serious adverse events. The most common adverse events included mild nausea, moderate back pain, moderate headache, and moderate upper abdominal pain.

About Entera Bio

Entera is a leader in the development of orally delivered macromolecules therapeutics including peptides and other therapeutic proteins, 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 and has a Type C meeting scheduled with FDA with respect to its Phase 3 program in H2 2022. 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.

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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. 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 the interpretation of clinical data; results of our clinical trials; the FDA's interpretation and review of our results from and analysis of our clinical trials; 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; 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; the size and growth of the potential markets for our product candidates; 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 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 Statements Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Entera's most recent Annual Report on Form 10-K filed with the SEC, as well as the company's subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. 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 or implied in such forward-looking statements and estimates will be achieved. Entera cautions investors not to rely on the forward-looking statements Entera makes in this press release. The information in this press release is provided only as of the date of this press 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.

ENTERA BIO LTD.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share data)
(Unaudited)

	June 30 2022	December 31 2021
Cash and cash equivalents	17,279	24,892
Accounts receivable and other current assets	1,147	437
Property and equipment, net	166	156
Other assets, net	496	502
Total assets	19,088	25,987
Accounts payable and other current liabilities	1,692	3,161
Total non current liabilities	127	261
Total liabilities	1,819	3,422
Total shareholders' equity	17,269	22,565
Total liabilities and shareholders' equity	19,088	25,987

ENTERA BIO LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except share and per share data)

	SIX Months ended June 30,	
	2022	**2021**
REVENUES	112	266
COST OF REVENUES	87	172
GROSS PROFIT	25	94
OPERATING EXPENSES:		
Research and development	3,084	2,351
General and administrative	4,052	2,674
Other income	(27)	(22)
TOTAL OPERATING EXPENSES	7,109	5,003
OPERATING LOSS	7,084	4,909
FINANCIAL EXPENSES (INCOME), net	(104)	(5)
LOSS BEFORE INCOME TAX	6,980	4,904
INCOME TAX ,(BENEFIT) EXPENSE	(11)	(31)
NET LOSS	6,969	4,873
LOSS PER SHARE BASIC AND DILUTED	0.24	0.21
WEIGHTED-AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	28,806,217	23,377,668