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): November 8, 2024

Entera Bio Ltd.

(Exact Name of Registrant as Specified in Its Charter)

Israel	001-38556	Not Applicable
(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

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 November 8, 2024, 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 September 30, 2024. 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 November 8, 2024 announcing the Company's financial results for the three months ended September 30, 2024.
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: November 8, 2024

By: /s/ Miranda Toledano
Name: Miranda Toledano
Title: Chief Executive Officer

Exhibit 99.1

Entera Bio Reports Q3 2024 Financial Results and Provides Business Updates

JERUSALEM – November 8, 2024 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), ("Entera" or the "Company") a leader in the development of oral peptides and small therapeutic proteins, today reported financial results and key business updates for the quarter ended September 30, 2024.

"The third quarter of 2024 drew consistent attention to our pivotal-staged clinical asset, EB613, the first oral PTH(1-34) tablet treatment dedicated to post-menopausal women with high risk osteoporosis. Entera's proprietary N-Tab™ platform consistently delivered across our oral GLP-2 tablet, oral GLP-1/Glucagon tablet and confidential hypoparathyroidism tablet program. Finally, we are humbled by key additions from around the world to our clinical and scientific advisory board which we view as testament to what we are aspiring to build at Entera," said Miranda Toledano, Chief Executive Officer of Entera.

Ms. Toledano continued, "We are headed into a busy year end across all programs and keenly anticipating FDA's potential landmark ruling on the ASBMR-FNIH SABRE regulatory endpoint for osteoporosis drugs, expected in January 2025. Current regulatory guidelines requiring fracture outcomes have curtailed innovation in the treatment of this significant disease due to ethical, time and sizing of studies required to evaluate new treatments. The SABRE work is based on a statistical meta-analysis of over 170,000 patients across 53 randomized clinical studies and 7 osteoporosis drug classes correlating total hip Bone Mineral Density (BMD) to fracture outcomes. We believe that our pivotal program for EB613 is first in line to leverage this pathway. Our recent discussions with patients, regulatory agencies, clinicians and fellow industry colleagues acknowledge the need for new treatments for osteoporosis and, especially, oral anabolic therapy. Osteoporosis is one of the foremost underserved women's health issues globally, where fracture rates continue to rise and where, despite medical guidelines, efficacious injectable anabolics are used in a minority of patients worldwide. We are developing EB613 to help close this treatment gap."

Q3 2024 Updates:

EB613: First Oral PTH(1-34) Anabolic Tablet Treatment for Women with Osteoporosis

- In September 2024, new comparative pharmacological data for EB613 was presented at the American Society for Bone Mineral Research September 2024 (ASBMR 2024) Annual Meeting in Toronto. The abstract was previewed by Dr. Serge Ferrari of Geneva University Hospital in Switzerland in his sneak-peak highlights of cutting-edge clinical abstracts on osteoporosis therapy at ASBMR2024.

First GLP-1/Glucagon Agonist (Oxyntomodulin) Peptide Tablets for Obesity

- In September 2024, Entera and OPKO Health, Inc. ("OPKO"; Nasdaq: OPK), jointly announced topline pharmacokinetic/ pharmacodynamic (PK/PD) results for the oral oxyntomodulin (OXM) tablet program. The program is focused on developing the first oral dual agonist GLP-1/glucagon peptide as a potential once-daily treatment for patients with obesity and metabolic disorders using Entera's proprietary N-Tab™ platform. Oral OXM exhibited significant systemic exposure across two *in vivo* models, a favorable PK profile and bioavailability. The high plasma concentrations with prolonged systemic exposure were consistent with the reported half-life for semaglutide (Rybelsus®), the only approved oral GLP-1 analog. Oral OXM showed a statistically significant reduction in plasma glucose levels compared with placebo. Entera plans to present this data together with OPKO at an upcoming clinical conference.

First GLP-2 Peptide Tablets for Short Bowel Syndrome

- Entera continues pre-IND validation of its oral GLP-2 tablet in partnership with OPKO. Final *in vivo* PK/PD data is expected in the second half of 2024. This program is being developed as the first potential tablet GLP-2 replacement therapy for patients suffering with Short Bowel Syndrome, a rare and devastating intestinal failure condition. The program may also provide value to other critical conditions of GI inflammation, which is being explored with external parties.

EB612: First Oral PTH(1-34) Peptide Replacement Therapy Tablets for Hypoparathyroidism

- Entera continues to collaborate productively with a third party on the oral tablet development of another PTH replacement treatment for hypoparathyroidism.

Financial Results for the Quarter Ended September 30, 2024

As of September 30,2024, Entera had cash and cash equivalents of $6.9 million. The Company expects that its existing cash resources are sufficient to meet its projected operating requirements into the third quarter of 2025.

Research and development expenses for the three months ended September 30, 2024 were $1.5 million, as compared to $1.4 million for the three months ended September 30, 2023. The increase of $0.1 million was primarily due to an increase of $0.5 million in materials required in connection with the optimization processes related to the preparation of the EB613 phase 3 study. The increase was partially offset by a decrease of $0.4 million related to a completed Phase 1 PK, which occurred in 2023.

General and administrative expenses for the three months ended September 30, 2024 were $1.5 million, as compared to $1.0 million for the three months ended September 30, 2023. The increase of $0.5 million was mainly attributable to increases in intellectual property expenses, consultancy fees and share-based compensation.

Operating expenses for the period ended September 30, 2024 were $3.0 million, as compared to $2.4 million for the quarter ended September 30, 2023.

Net loss was $3.0 million, or $0.08 per ordinary share (basic and diluted), for the quarter ended September 30, 2024, as compared to $2.4 million, or $0.08 per ordinary share (basic and diluted), for the quarter ended September 30, 2023.

About Entera Bio

Entera is a clinical-stage company focused on developing oral peptide or protein replacement therapies for significant unmet medical needs where an oral tablet form holds the potential to transform the standard of care. The Company leverages a disruptive and proprietary technology platform (N-Tab™) and its pipeline includes five differentiated, first-in-class oral peptide programs, expected to enter the clinic (Phase 1 to Phase 3) by 2025. The Company's most advanced product candidate, EB613 (oral PTH (1-34)), is being developed as the first oral, osteoanabolic (bone building) once-daily tablet treatment for post-menopausal women with low BMD and high-risk osteoporosis. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n=161) met primary (PD/bone turnover biomarker) and secondary (BMD) endpoints. Entera is preparing to initiate a Phase 3 registrational study for EB613 pursuant to the FDA's qualification of a quantitative BMD endpoint, which is expected to occur by January 2025. The EB612 program is being developed as the first oral PTH (1-34) tablet peptide replacement therapy for hypoparathyroidism. In collaboration with OPKO Health, Entera is also developing the first oral oxyntomodulin, a dual targeted GLP-1/glucagon peptide, in tablet form for the treatment of obesity; and the first oral GLP-2 peptide tablet as an injection-free alternative for patients suffering from rare malabsorption conditions such as short bowel syndrome. For more information, visit www.enterabio.com or follow us on LinkedIn, X (formerly Twitter), Facebook and Instagram.

Contact:

Entera Bio:
Ms. Miranda Toledano
Chief Executive Officer
Entera Bio
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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 may be contractually obligated to provide; 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)

	September 30, 2024	December 31, 2023
	(Unaudited)	(Audited)
Cash and cash equivalents	6,915	11,019
Accounts receivable and other current assets	425	238
Property and equipment, net	65	100
Other assets, net	336	408
Total assets	7,741	11,765
Accounts payable and other current liabilities	1,111	1,091
Total non-current liabilities	178	288
Total liabilities	1,289	1,379
Total shareholders' equity	6,452	10,386
Total liabilities and shareholders' equity	7,741	11,765

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

	Three Months Ended September 30,	
	2024	**2023**
REVENUES	42	-
COST OF REVENUES	42	-
GROSS PROFIT	-	-
OPERATING EXPENSES:		
Research and development	1,477	1,370
General and administrative	1,544	1,028
Other income	-	(12)
TOTAL OPERATING EXPENSES	3,021	2,386
OPERATING LOSS	3,021	2,386
FINANCIAL INCOME, NET	-	(36)
INCOME TAX	-	29
NET LOSS	3,021	2,379
LOSS PER SHARE BASIC AND DILUTED	0.08	0.08
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	37,644,612	28,813,952