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): March 28, 2025

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 March 28, 2025, 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 year ended December 31, 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 March 28, 2025 announcing the Company's financial results for the year ended December 31, 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: March 28, 2025

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

Exhibit 99.1

Entera Bio Announces Full Year 2024 Financial Results and Provides Business Updates

JERUSALEM, March 28 2025 –Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of oral peptides and proteins replacement therapies, today reported financial results and key business achievements for the year ended December 31, 2024.

"2024 was a truly transformational year for Entera. We delivered key data read-outs and advanced each of our oral peptide PTH(1-34), GLP1/Glucagon and GLP2 tablet programs, significantly increased our stockholder value, and efficiently strengthened our balance sheet. To our core team with whom I started this journey in late 2022 as a board member, and to our rapidly expanding ecosystem of premier global advisors, I thank you for your commitment and dedication. To our existing and new shareholders, we are grateful for your belief and support of our thesis. To our collaborators, especially, the formidable team at OPKO Health, Inc., we are grateful for your partnership and the opportunity to expand our N-Tab™ platform to additional high value peptides," said Miranda Toledano, Chief Executive Officer of Entera.

"To our potential patient base for whom we are developing EB613: the majority of the estimated 200 million women with osteoporosis who wish to preserve their bone health, who remain underserved with current treatments and who have not been able to access a new therapy since 2019, our dedication to you is firm and unwavering. Osteoporosis is one of the foremost underserved health issues globally which disproportionally afflicts women. Most women experience menopause between the ages of 45 and 55 years. One in three women over age 50 will develop osteoporosis, and one in two of those women will develop an osteoporosis-related fracture. The morbidity and mortality risk of osteoporosis fractures to women outpaces that of breast cancer, stroke and heart attack combined. Nevertheless, most patients remain untreated. Furthermore, existing regulatory guidelines requiring fracture outcomes have curtailed innovation in this significant disease due to ethical, time and sizing of studies required to evaluate new treatments. The SABRE (Study to Advance Bone Mineral Density as a Regulatory Endpoint), based on a statistical meta-analysis of over 170,000 patients across 53 randomized clinical studies and 7 osteoporosis drug classes correlating total hip BMD to fracture outcomes, is undergoing review at FDA. This is analogous to prior initiatives that qualified LDL cholesterol as a surrogate marker for CV outcomes and HBA1C as a surrogate for the risk of future diabetes complications, both of which enabled the advancement of many important new therapies for those conditions. We look forward to potential updates from FDA and SABRE on this important ruling and to potentially initiating our pivotal Phase 3 study of EB613 promptly thereafter. Our EB613, the first oral PTH(1-34) peptide treatment candidate is being developed to close the treatment gap in osteoporosis with a validated anabolic mechanism of action in tablet form. We plan to continue our mission to add value to Entera in 2025, with humility and a focus on execution." said Miranda Toledano, Chief Executive Officer of Entera.

2024 Key Achievements:

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

- In March 2024, the ASBMR announced that the FDA had communicated to the SABRE project team that a ruling to qualify the treatment-related change in bone mineral density (BMD) as a surrogate endpoint for fractures in future trials of new anti-osteoporosis drugs would be provided within 10 months

- In April 2024, Entera announced that the Journal of Bone and Mineral Research (JBMR) published EB613 placebo controlled Phase 2 Trial results, highlighting its dual mechanism of action and rapid increases in BMD at trabecular and cortical skeletal sites

- In June 2024, an independent editorial was published by the JBMR "A Novel Oral PTH(1-34) [EB613] Unveils the Promise of Modeling-Based Anabolism with No Increase in Bone Remodeling"

- In September 2024, Entera presented new comparative pharmacological data for EB613 vs. Forteo® at the ASBMR September 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 Tablet Candidate for Obesity

- In September 2024, Entera and OPKO Health 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 combining OPKO's proprietary long-acting oxyntomodulin analog (OPK-88006) and 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

- In March 2025, we entered into a collaboration and license agreement with OPKO relating to the preclinical and clinical development of the Oral OXM program. Under the terms of the agreement, OPKO and Entera will hold 60% and 40% pro-rata ownership interests, respectively, in the program and be responsible for 60% and 40% of the program's development costs, respectively. The companies expect to file an Investigational New Drug application with the U.S. Food and Drug Administration (FDA) later this year

First GLP-2 Peptide Tablets for Short Bowel Syndrome

- During 2024, Entera and OPKO completed a proof of concept (PoC) single dose pharmacokinetic study in rodents. Oral GLP-2 tablets exhibited significant systemic exposure. Furthermore, plasma levels achieved with the oral tablet form of the GLP-2 analogue were about 10-fold higher than therapeutic plasma concentrations reported for subcutaneously administered teduglutide (Gattex®)

- The pharmacokinetic analysis of the data obtained following the IV injections of the GLP-2 peptide showed the plasma half-life in rats to be about six times longer than the half-life reported for teduglutide in the same animal model. This data is consistent with previously reported PK data relating to OPKO's GLP-2 peptide's long-acting profile, which had initially been developed as a weekly subcutaneous injection

- Given the challenging compliance rates attributed to injectable GLP-2 therapy and heterogeneity of short bowel syndrome (SBS) patients, we believe a daily tablet format may address a significant unmet need in treating and titrating SBS patients more effectively than injectable alternatives. OPKO and Entera are determining next steps for this program

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

- In June 2024, Entera presented Phase 1 clinical data for EB612, which is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for patients with hypoparathyroidism, at the Endocrine Society ENDO 2024 Annual Meeting. This Phase 1 data supports potentially moving the BID tablet dose to Phase 2 development in patients with 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 Year Ended December 31, 2024

As of December 31,2024, Entera had cash and cash equivalents of $8.7 million. As of March 28, 2025, Entera had cash and cash equivalents of $21 million, largely attributable to at-market direct investments from existing and new institutional shareholders and our partner, OPKO. The cash is expected to be sufficient to fund our operations into the third quarter of 2026, including ongoing work related to the planned EB613 phase 3 study, regulatory expenses, research and development, patent prosecution, the completion of an additional Phase 1 PK study related to our new generation platform and our share of projected oral GLP1/Glucagon tablet Phase 1 study expenses in collaboration with OPKO.

Research and development expenses for the years ended December 31, 2024 and December 31, 2023 were each $4.5 million. There was a decrease of $0.8 million related to the completion of the first cohorts of a Phase 1 PK study, which occurred in 2023. The decrease was offset by an increase of $0.8 million in 2024 related to optimization related to the preparation of the EB613 phase 3 study

General and administrative expenses for the year ended December 31, 2024 were $5.1 million, compared to $4.4 million for the year ended December 31, 2023. The increase of $0.7 million was mainly attributable to expanding our intellectual property position and advisor compensation. The increase was partially offset by a decrease of $0.2 million in D&O insurance costs and other costs

Operating expenses for the year ended December 31, 2024 were $9.6 million, as compared to $8.9 million for the year ended December 31, 2023

Net loss was $9.5 million, or $0.25 per ordinary share (basic and diluted), for the year ended December 31, 2024, as compared to 8.9 million, or $0.31 per ordinary share (basic and diluted), for the year ended December 31, 2023.

About Entera Bio

Entera is a clinical stage company focused on developing oral peptide and 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 on a disruptive and proprietary technology platform (N-Tab™) and its pipeline includes five differentiated, first-in-class oral peptide programs targeting PTH(1-34), GLP-1 and GLP-2. 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 endpoints (BMD). Entera is preparing to initiate a Phase 3 registrational study for EB613 pursuant to the FDA's qualification of a quantitative BMD endpoint. The EB612 program is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for hypoparathyroidism. Entera is also developing the first oral oxyntomodulin, a dual targeted GLP1/glucagon peptide, in tablet form for the treatment of obesity; and first oral GLP-2 peptide tablet as an injection-free alternative for patients suffering from rare malabsorption conditions such as short bowel syndrome in collaboration with OPKO Health. For more information on Entera Bio, visit www.enterabio.com or follow us on LinkedIn, Twitter, Facebook, Instagram.

Contact:

Entera Bio:
Ms. Miranda Toledano
Chief Executive Officer
Entera Bio
Email: miranda@enterabio.com

Cautionary Statement Regarding Forward Looking Statements

Various statements in this presentation 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 presentation 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 ability to establish and maintain development and commercialization collaborations; Entera's operation as a development stage company with limited operating history; Entera's competitive position with respect to other products on the market or in development for the treatment of osteoporosis, hypoparathyroidism, short bowel syndrome, obesity, metabolic conditions and other disease categories it pursues; 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 Statement 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 Entera'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 presentation. The information in this presentation is provided only as of the date of this presentation, 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)

	December 31, 2024	December 31, 2023
	(Unaudited)	(Audited)
Cash and cash equivalents	8,660	11,019
Accounts receivable and other current assets	312	238
Property and equipment, net	57	100
Other assets, net	361	408
Total assets	9,390	11,765
Accounts payable and other current liabilities	1,176	1,091
Total non-current liabilities	134	288
Total liabilities	1,310	1,379
Total shareholders' equity	8,080	10,386
Total liabilities and shareholders' equity	9,390	11,765

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

(Unaudited)

	Year Ended December 31,	
	2024	**2023**
REVENUES	181	-
COST OF REVENUES	172	-
GROSS PROFIT	9	-
OPERATING EXPENSES:		
Research and development	4,499	4,510
General and administrative	5,095	4,430
Other income	-	(49)
TOTAL OPERATING EXPENSES	9,594	8,891
OPERATING LOSS	9,585	8,891
FINANCIAL INCOME, NET	(58)	(31)
INCOME TAX	14	29
NET LOSS	9,541	8,889
LOSS PER SHARE BASIC AND DILUTED	0.25	0.31
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	37,650,179	29,007,794