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 8, 2026

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 May 8, 2026, 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, 2026 and business updates. 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 8, 2026 announcing the Company's financial results for the three months ended March 31, 2026 and business updates.
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 8, 2026

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

Exhibit 99.1

Entera Announces First Quarter 2026 Financial Results and Updates Across its Oral Peptide Programs

EB613, the first oral anabolic (bone building) peptide tablet for postmenopausal women with osteoporosis – Phase 3 protocol submitted with FDA feedback expected imminently; incremental data submitted to ENDO2026 and ASBMR

EB612, the first oral long-acting PTH peptide replacement tablet for hypoparathyroidism – Expanded 50/50 partnership with OPKO; intention to file IND in late 2026; data submitted to ENDO2026

EB618, the first oral OXM (dual GLP-1/Glucagon) tablet for metabolic and fibrotic conditions – data submitted to ENDO2026

Direct Investment led by BVF Partners L.P. to support EB613 pivotal study acceleration and working capital

TEL AVIV, May 8, 2026 -- Entera Bio Ltd. (NASDAQ: ENTX) ("Entera" or the "Company"), a leader in the development of oral peptides, today reported financial results and key business updates for the quarter ended March 31, 2026.

“The first quarter of 2026 solidified Entera’s position as the leading oral peptide therapeutics company. Our N-Tab® platform is developing arguably the richest pipeline of clinical and near-clinical first in class assets, and we are driven by our mission to develop transformative medicines and invest in therapeutic spaces that have been ignored and require urgent attention,” said Miranda Toledano, CEO of Entera.

“This begins with our EB613 journey to develop the first oral anabolic to potentially help millions of women preserve their bone health while advocating for much needed innovation in a therapeutic space which disproportionately affects the health of women. In March 2026, we submitted documents to FDA related to EB613’s potential registrational package. This quarter, we also completed a critical Phase 1 bridging study for the single, final tablet formulation of EB613. Additionally, we submitted PK and TPTX proof of concept data for EB612 in hypoparathyroidism and NHP PK data for EB618 in metabolic conditions to ENDO2026 and ASBMR. Each of these milestones has been executed with a strong focus on capital efficiency by a core team that has a unifying commitment to succeed in developing therapeutics that matter,” said Miranda Toledano, Chief Executive Officer of Entera.

Key Recent Highlights

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

- **Streamlined Phase 3 Protocol Submitted to FDA:** In March 2026, Entera announced it had submitted a clinical amendment to the FDA providing a streamlined Phase 3 protocol, statistical analysis plan, and extension synopsis under its IND 505(b)(2) for EB613. The planned Phase 3 trial is designed as a multinational, randomized, double-blind, placebo-controlled safety and efficacy study in 750 postmenopausal women with osteoporosis, with percentage change in total hip bone mineral density (BMD) from baseline to month 12 as the primary outcome measure. Entera also submitted a protocol synopsis to conduct an extension study which is designed to evaluate 24 months of EB613 monotherapy treatment or 12 months of EB613 followed by 12 months of treatment with a standard anti-resorptive drug.

- **Next-Gen EB613 Single Tablet Advanced as Phase 3 Candidate**: In January 2026, Entera completed a Phase 1 PK and safety bridging study comparing the single-tablet to the multi-tablet formulation of EB613 and Forteo® (teriparatide SC injection, Eli Lilly). Entera plans to advance the single tablet of EB613 into Phase 3. Data has been submitted as an abstract to ENDO2026.

- **Key Opinion Leader (KOL) Webinar on Osteoporosis Treatment Landscape**: On April 20, 2026, Entera hosted a virtual KOL roundtable with Dr. Felicia Cosman (Professor of Medicine at Columbia University) and Dr. Steven Goldstein (Professor of Obstetrics and Gynecology at NYU Grossman School of Medicine and former President of both the International Menopause Society and the North American Menopause Society) to gain endocrinology and gynecology insights into how the clinician ecosystem treats osteoporosis today. The KOLs highlighted the critical unmet demand for an oral anabolic in this silent, asymptomatic disease and EB613’s potential to transform the paradigm. A replay of the video is available at the following link: https://www.youtube.com/watch?v=2z6oOgwAWmg

EB612: First-in-Class Oral Long-Acting PTH(1-34) Replacement Tablet for Hypoparathyroidism

- **Expanded OPKO 50/50 Partnership Accelerates Path to Clinic, Funded Through Phase 1:** In February 2026, Entera and OPKO amended and restated their 2025 Collaboration Agreement to advance the first oral long-acting PTH (LA-PTH) analog as a once-daily tablet for patients with hypoparathyroidism. The EB612 program has been prioritized, with an expectation to file an IND application in late 2026. TPTX and PK study data completed during the quarter have been submitted as abstracts to ENDO2026.

EB618: First-in-Class Oral Dual GLP-1/Glucagon (OXM) Tablet for Obesity and Metabolic Disease

- In March 2025, Entera and OPKO announced that the potential initiation of EB618 would occur pursuant to analysis of the Phase 1 SAD/MAD studies that OPKO plans to initiate with subcutaneous once weekly injectable OXM. Pharmacokinetic data for the oral OXM tablet developed by Entera in NHP has been submitted to ENDO2026.

Corporate Highlights

- **Geno J. Germano Appointed Chairman of the Board:** In February 2026, Mr. Germano, formerly Group President of Pfizer's Global Innovative Pharmaceutical Business, succeeded Gerald Lieberman as Chairman. Mr. Germano brings more than three decades of leadership experience across development, commercialization, and global operations at Pfizer, Wyeth, and other leading biopharmaceutical companies, and has served on the board of directors of Sage Therapeutics, Bioverativ Inc., and The Medicines Company, among others.

- **Steve Rubin Joined Board of Directors:** In February 2026, Steve Rubin, Executive Vice President of Administration and director at OPKO, joined Entera's Board of Directors. Mr. Rubin brings three decades of experience in corporate governance and strategic oversight of drug development across multiple public biotechnology companies.

Financial Results for the Quarter Ended March 31, 2026

Cash and cash equivalents as of March 31, 2026, were $11.9 million. As of May 8, 2026, cash and cash equivalents were $20.4 million, inclusive of the proceeds from the private placement led by BVF Partners L.P. in April 2026 and the $7.8 million restricted cash which is designated to fund the OPKO collaboration including EB612 and EB618. The Company's available funds are expected to support operations through the first quarter of 2027, including activities related to the preparation of the planned Phase 3 registrational study of EB613.

Research and development expenses for the three months ended March 31, 2026 were $2.3 million, as compared to $1.1 million for the three months ended March 31, 2025.

General and administrative expenses for the three months ended March 31, 2026 were $1.3 million, as compared to $1.4 million for the three months ended March 31, 2025.

Total operating expenses for the three months ended March 31, 2026 were $3.5 million, as compared to $2.6 million for the three months ended March 31, 2025.

Net loss was $3.5 million, or $0.07 per ordinary share (basic and diluted), for the three months ended March 31, 2026, as compared to $2.6 million, or $0.06 per ordinary share (basic and diluted), for the three months ended March 31, 2025.

About Entera

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 a disruptive and proprietary technology platform (N-Tab®) and its pipeline of first-in-class oral peptide programs. 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 for 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 also developing the first oral Long Acting PTH(1-34) tablet as a replacement therapy for patients with hypoparathyroidism (EB612), the first oral oxyntomodulin, a dual targeted GLP1/glucagon peptide tablet for the treatment of obesity and metabolic syndromes; and the first oral GLP-2 tablet as an injection-free alternative for patients suffering from rare malabsorption conditions such as short bowel syndrome in collaboration with OPKO Health, Inc. For more information on Entera, visit www.enterabio.com or follow us on LinkedIn, Twitter, and Facebook.

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, clinical development activities, collaboration arrangements and expected financial and operational results are 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 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.

Company Contact:
IR@enterabio.com

ENTERA BIO LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	March 31, 2026	December 31, 2025
	(Unaudited)	(Audited)
Cash and cash equivalents	4,137	7,108
Restricted cash	7,790	7,775
Accounts receivable and other current assets	566	415
Property and equipment, net	127	134
Other assets	509	561
Total assets	**13,129**	**15,993**
Accounts payable and other current liabilities	1,576	2,203
Total non-current liabilities	866	689
Total liabilities	2,442	2,892
Total shareholders' equity	10,687	13,101
Total liabilities and shareholders' equity	**13,129**	**15,993**

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

	Three Months Ended March 31,	
	2026	**2025**
REVENUES	—	42
COST OF REVENUES	—	42
GROSS PROFIT	**—**	**—**
OPERATING EXPENSES:		
Research and development	2,251	1,123
General and administrative	1,288	1,440
TOTAL OPERATING EXPENSES	**3,539**	**2,563**
OPERATING LOSS	**3,539**	**2,563**
FINANCIAL (INCOME) EXPENSES, NET	(34)	4
NET LOSS	**3,505**	**2,567**
LOSS PER SHARE BASIC AND DILUTED	**0.07**	**0.06**
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	**47,756,409**	**43,377,391**