

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2026

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-38556

ENTERA BIO LTD.

(Exact name of Registrant as specified in its charter)

Israel

(State or other jurisdiction of
incorporation or organization)

Kiryat Hadassah
Minrav Building – Fifth Floor
Jerusalem, Israel

(Address of principal executive offices)

Not applicable

(I.R.S. Employer
Identification No.)

9112002

(Zip Code)

972-2-532-7151

(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Ordinary Shares, par value NIS 0.0000769 per share	ENTX	Nasdaq Capital Market

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-Accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act)

Yes No

As of May 4, 2026, the registrant had 49,225,321 ordinary shares, par value NIS 0.0000769 per share ("Ordinary Shares") outstanding.

Table of Contents

	<u>Page</u>
<u>CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS</u>	1
<u>PART I – FINANCIAL INFORMATION</u>	3
<u>Item 1. Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of March 31, 2026 and December 31, 2025 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2026 and 2025 (unaudited)</u>	5
<u>Condensed Consolidated Statement of Changes in Shareholders' Equity for the three months ended March 31, 2026 and 2025 (unaudited)</u>	6
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2026 and 2025 (unaudited)</u>	7
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	27
<u>Item 4. Controls and Procedures</u>	27
<u>PART II – OTHER INFORMATION</u>	28
<u>Item 1. Legal Proceedings</u>	28
<u>Item 1A. Risk Factors</u>	28
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	29
<u>Item 3. Defaults Upon Senior Securities</u>	29
<u>Item 4. Mine Safety Disclosures</u>	29
<u>Item 5. Other Information</u>	29
<u>Item 6. Exhibits</u>	30
<u>SIGNATURES</u>	31

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this “Quarterly Report”) contains “forward-looking statements,” as that term is defined under the Private Securities Litigation Reform Act of 1995 (“PSLRA”), Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Various statements in this Quarterly Report are “forward-looking statements” within the meaning of the PSLRA and other U.S. Federal securities laws. In addition, historic results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not be different, and historic results referred to in this Quarterly Report may be interpreted differently in light of additional research and clinical and preclinical trial results. Forward-looking statements include all statements that are not historical facts. We have based these forward-looking statements largely on our management’s current expectations and future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Quarterly Report regarding our strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements are subject to risks and uncertainties and are based on information currently available to our management. Words including, but not limited to, “anticipate,” “believe,” “contemplates,” “continue,” “could,” “design,” “estimate,” “expect,” “intend,” “likely,” “may,” “ongoing,” “plan,” “potential,” “predict,” “project,” “will,” “would,” “seek,” “should,” “target,” or the negative of these terms and similar expressions or words, identify forward-looking statements. The events and circumstances reflected in our forward-looking statements may not occur and actual results could differ materially from those projected in our forward-looking statements. These factors include those described in “Part II, Item 1A-Risk Factors” of this Quarterly Report and in “Part I, Item 1A-Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2025 (the “2025 Annual Report”). Meaningful factors that could cause actual results to differ from those expressed in forward-looking statements include, but are not limited to:

- Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates;
- The regulatory approval processes of the U.S. Food and Drug Administration (“FDA”) and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed;
- Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all;
- Positive results from preclinical studies and early-stage clinical trials may not be predictive of future results. Initial positive results in any of our clinical trials may not be indicative of results obtained when the trial is completed or in later stage trials;
- The scope, progress and costs of developing our product candidates such as EB613 for osteoporosis and EB612 for hypoparathyroidism or other oral peptides for the treatment of obesity, metabolic disorders (EB618) and gastrointestinal rare diseases may alter over time based on various factors such as regulatory requirements, collaboration agreements, the competitive environment and new data from pre-clinical and clinical studies;
- The accuracy of our estimates regarding expenses, capital requirements, the sufficiency of our cash resources and the need for additional financing;
- Our ability to continue as a going concern absent access to sources of liquidity;
- Our ability to raise additional funds or consummate strategic partnerships to offset additional required capital to pursue our business objectives, which may not be available on acceptable terms or at all. A failure to obtain this additional capital when needed, or failure to consummate strategic partnerships, could delay, limit or reduce our product development, and other operations;

- Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success;
- The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and third-party payors establish adequate coverage and reimbursement levels and pricing policies;
- Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue;
- If we are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be adversely affected;
- Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain;
- Our reliance on third parties to conduct our clinical trials and on third-party suppliers to supply or produce our product candidates;
- Our interpretation of FDA feedback and guidance and how such guidance may impact our clinical development plan;
- Our ability to use and expand our N-Tab® platform to additional product candidates;
- Our operation as a development stage company with limited operating history and a history of operating losses and our ability to fund our operations going forward;
- Our competitive position with respect to other products on the market or in development for the treatment of osteoporosis, hypoparathyroidism, short bowel syndrome and other rare gastrointestinal disorders, obesity, metabolic conditions and other disease categories we pursue;
- Our ability to establish and maintain development and commercialization collaborations;
- Our ability to manufacture and supply enough material to support our clinical trials and any potential future commercial requirements;
- The size of any market we may target and the adoption of our product candidates, if approved, by physicians and patients;
- Our ability to obtain, maintain and protect our intellectual property and operate our business without infringing, misappropriating, or otherwise violating any intellectual property rights of others;
- Our ability to retain key personnel and recruit additional qualified personnel;
- Our ability to comply with laws and regulations that currently apply or become applicable to our business;
- Our ability to manage growth; and
- The Israel-Hamas conflict, that has been ongoing since October 2023, including involvement from Hezbollah, Iran and its proxies in the Middle East, such as the Houthis in Yemen and militias in Iraq and Syria, as well as the hostilities between the United States, Israel and Iran, and their impact on our operations and workforce, remains unknown.

All forward-looking statements contained in this Quarterly Report are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely heavily on the forward-looking statements we make. Except as required by applicable law, we are under no duty, and expressly disclaim any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult all further disclosures we make in each annual, quarterly or current report that we file with the Securities and Exchange Commission (“SEC”).

We encourage you to read Part II, Item 1A of this Quarterly Report and Part I, Item 1A of our 2025 Annual Report, each entitled “Risk Factors,” and Part I, Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operation—Liquidity and Capital Resources” of this Quarterly Report for additional discussion of the risks and uncertainties associated with our business. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

PART I.

ITEM 1. FINANCIAL STATEMENTS

ENTERA BIO LTD.
UNAUDITED CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS
AS OF MARCH 31, 2026

TABLE OF CONTENTS

	<u>Page</u>
CONDENSED CONSOLIDATED FINANCIAL STATEMENTS:	
<u>Condensed Consolidated Balance Sheets (unaudited)</u>	4
<u>Condensed Consolidated Statements of Operations (unaudited)</u>	5
<u>Condensed Consolidated Statements of Changes in Shareholders' Equity (unaudited)</u>	6
<u>Condensed Consolidated Statements of Cash Flows (unaudited)</u>	7
<u>Notes to the Condensed Consolidated Financial Statements (unaudited)</u>	8

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

Assets	March 31, 2026	December 31, 2025
CURRENT ASSETS:		
Cash and cash equivalents	4,137	7,108
Restricted cash	7,790	7,775
Other current assets	566	415
TOTAL CURRENT ASSETS	<u>12,493</u>	<u>15,298</u>
NON-CURRENT ASSETS:		
Property and equipment, net	127	134
Operating lease right-of-use assets	413	465
Restricted deposit	90	90
Funds in respect of employee rights upon retirement	6	6
TOTAL NON-CURRENT ASSETS	<u>636</u>	<u>695</u>
TOTAL ASSETS	<u>13,129</u>	<u>15,993</u>
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	274	448
Accrued expenses and other payables	1,117	1,525
Current maturities of operating lease	185	230
TOTAL CURRENT LIABILITIES	<u>1,576</u>	<u>2,203</u>
NON-CURRENT LIABILITIES:		
Operating lease liabilities	263	260
Other long-term liabilities	567	393
Liability for employee rights upon retirement	36	36
TOTAL NON-CURRENT LIABILITIES	<u>866</u>	<u>689</u>
TOTAL LIABILITIES	<u>2,442</u>	<u>2,892</u>
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.0000769 par value: Authorized - as of March 31, 2026 and December 31, 2025, 140,010,000 shares; issued and outstanding as of March 31, 2026 and December 31, 2025, 46,622,239 and 46,178,630 shares, respectively	1	1
Additional paid-in capital	139,516	138,425
Accumulated other comprehensive income	41	41
Accumulated deficit	(128,871)	(125,366)
TOTAL SHAREHOLDERS' EQUITY	<u>10,687</u>	<u>13,101</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>13,129</u>	<u>15,993</u>

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

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

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

ENTERA BIO LTD.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(U.S. dollars in thousands, except share and per share data)
(Unaudited)

	<u>Ordinary shares</u>			Additional paid-in capital	Accumulated other Comprehensive income	Accumulated deficit	Total
	Number of shares issued	Amounts	Amounts				
BALANCE AT JANUARY 1, 2026	46,178,630	1	138,425	41	(125,366)	13,101	
Net loss	-	-	-	-	(3,505)	(3,505)	
Exercise of options to ordinary shares	216,666	*	130	-	-	130	
Vested restricted share units	226,943	*	-	-	-	-	
Settlement in share of executive officers compensation (see note 3)	-	-	289	-	-	289	
Share-based compensation	-	-	672	-	-	672	
BALANCE AT MARCH 31, 2026	<u>46,622,239</u>	<u>1</u>	<u>139,516</u>	<u>41</u>	<u>(128,871)</u>	<u>10,687</u>	
BALANCE AT JANUARY 1, 2025	38,837,220	1	121,965	41	(113,927)	8,080	
Net loss	-	-	-	-	(2,567)	(2,567)	
Exercise of warrants to ordinary shares	149,700	*	150	-	-	150	
Issuance of ordinary shares under collaboration agreement, net	3,685,226	*	7,115	-	-	7,115	
Issuance of ordinary shares under the ATM program, net	2,700,000	*	5,997	-	-	5,997	
Vested restricted share units	48,531	*	-	-	-	-	
Share-based compensation	-	-	604	-	-	604	
BALANCE AT MARCH 31, 2025	<u>45,420,677</u>	<u>1</u>	<u>135,831</u>	<u>41</u>	<u>(116,494)</u>	<u>19,379</u>	

* Represents an amount less than one thousand U.S. dollars.

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

ENTERA BIO LTD.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)
(Unaudited)

	Three months ended March 31,	
	2026	2025
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	(3,505)	(2,567)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	7	8
Share-based compensation	672	604
Finance income, net	6	(4)
Changes in operating asset and liabilities:		
Increase in other current assets	(94)	(333)
Increase (decrease) in accounts payable	(174)	2
Increase (decrease) in accrued expenses and other payables and other long-term liabilities	(2)	886
Net cash used in operating activities	<u>(3,090)</u>	<u>(1,404)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	-	(8)
Net cash used in investing activities	<u>-</u>	<u>(8)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares under ATM program	-	6,183
Issuance cost	-	(186)
Issuance of ordinary shares, under collaboration agreement	-	7,190
Exercise of Options to ordinary shares	130	-
Exercise of warrants to ordinary shares	-	150
Net cash provided by financing activities	<u>130</u>	<u>13,337</u>
EFFECT OF EXCHANGE RATE CHANGE ON CASH AND CASH EQUIVALENTS	4	-
INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS	(2,960)	11,925
CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS AT BEGINNING OF THE PERIOD	14,973	8,740
CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS AT END OF THE PERIOD	<u>12,017</u>	<u>20,665</u>
Reconciliation in amounts on consolidated balance sheets:		
Cash and cash equivalents	4,137	12,573
Restricted cash and deposits	7,880	8,092
Total cash and cash equivalents and restricted cash and deposits	<u>12,017</u>	<u>20,665</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOW TRANSACTIONS:		
Interest received	35	-
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Issuance costs	<u>-</u>	<u>75</u>

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 - DESCRIPTION OF BUSINESS

- a. Entera Bio Ltd. (collectively with its subsidiary, the "Company") was incorporated on September 30, 2009 and commenced operation on June 1, 2010. On January 8, 2018, the Company incorporated its wholly owned subsidiary, Entera Bio Inc., in Delaware, United States.

The Company is focused on developing first-in-class oral tablet formats of peptides or protein replacement therapies. The Company focuses on underserved, chronic medical conditions for which oral administration of a protein therapy has the potential to significantly shift a treatment paradigm.

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 osteoporosis. In February 2026, the Company submitted to the FDA a clinical amendment which included the EB613 Phase 3 protocol, statistical analysis plan and open-label extension synopsis.

The Company's second product candidate, EB612, is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for hypoparathyroidism. In February 2026, the Company amended and restated the 2025 Collaboration Agreement (as defined in Note 5) with OPKO Biologics, Inc., a subsidiary of OPKO Health, Inc. ("OPKO"), to advance the first oral long-acting PTH analog ("LA-PTH") as a once-daily tablet for patients with hypoparathyroidism.

In addition, EB618 is being developed pursuant to the Company's collaboration with OPKO, pursuant to which the companies are advancing a proprietary novel dual agonist GLP-1/glucagon peptide as a once-daily tablet treatment for patients with obesity, metabolic and fibrotic disorders.

In addition to its internal product development programs, the Company intends to license its proprietary N-Tab[®] platform to biopharmaceutical companies for use with their proprietary compounds.

- b. The Company's ordinary shares, NIS 0.0000769 par value per share ("ordinary shares"), are listed on the Nasdaq Capital Market under the symbol "ENTX".
- c. Because the Company is engaged in research and development activities, it has not derived significant income from its activities and has incurred negative cash flows from operating activities. The Company has incurred an accumulated deficit in the amount of \$128.9 million as of March 31, 2026.

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 - DESCRIPTION OF BUSINESS (Cont.)

As disclosed in Note 7, in April 2026, the Company completed a private placement financing resulting in gross proceeds of approximately \$10.0 million. The Company expects to use the net proceeds, in part, to support activities related to the preparation and initiation of its Phase 3 registrational study of EB613, as well as for general working capital and corporate purposes. The Company's management is of the opinion that its available funds as of March 31, 2026, including the proceed from the private placement disclosed in note 7, will be sufficient to support the Company's ongoing operations under its current plans through the first quarter of 2027, including activities related to the preparation for its planned Phase 3 registrational study of EB613. The Company's current capital resources do not include the capital required to fully fund the Company's proposed Phase 3 program for EB613 in osteoporosis. These factors raise substantial doubt as to the Company's ability to continue as a going concern. Management continually evaluates various financing alternatives and strategic collaborations, as the Company will need to finance future research and clinical development with additional capital. However, there is no certainty that the Company will be able to obtain such funding. These condensed consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

- d. In October 2023, Israel was attacked by Hamas, a terrorist organization and entered a state of war. Since the commencement of these events, there have been additional active hostilities, including with Hezbollah in Lebanon, the Houthi movement which controls parts of Yemen, and Iran. In response to ongoing Iranian aggression and support of proxy attacks against Israel, on June 12, 2025, Israel conducted a series of preemptive defensive air strikes in Iran targeting Iran's nuclear program and military commanders. On June 21, 2025, U.S. President Donald Trump announced that the United States had conducted air strikes against three nuclear sites within Iran. On October 9, 2025, a ceasefire had been reached. Israel, Hamas, the United States and other countries in the region agreed to a framework for a ceasefire in Gaza between Israel and Hamas. On February 28, 2026, the United States and Israel conducted preemptive strikes targeting Iranian military infrastructure. Iran retaliated with extensive ballistic missile and drone attacks against Israel. On March 2, 2026, Hezbollah resumed hostilities by launching projectiles into northern Israel, ending the November 2024 ceasefire. Israel responded with airstrikes on Lebanon and ground operations in Southern Lebanon, marking a significant escalation in the regional conflict. In early April 2026, a two-week ceasefire between the United States and Iran was agreed and on April 21, 2026, U.S. President Donald Trump announced that the United States would extend the ceasefire with Iran, to allow Iran's leadership to present a unified proposal for negotiations. However, the ceasefire's durability remains uncertain. The United States has maintained a naval blockade of Iranian ports, and Iran has responded by intermittently restricting commercial vessel passage through the Strait of Hormuz, declaring that the waterway would remain effectively closed until the blockade is lifted. There can be no assurance that this ceasefire will hold or be extended, and hostilities between the United States, Israel and Iran could resume at any time. On April 16, 2026, following direct talks between Israeli and Lebanese officials in Washington, D.C., a 10-day cessation of hostilities between Israel and Lebanon was announced, brokered by the United States. The parties have requested that the United States facilitate further direct negotiations with the objective of achieving a comprehensive agreement for lasting security and peace. Israeli forces remain stationed in southern Lebanon and Hezbollah has not accepted the terms as binding, stating that its fighters will remain deployed and will respond to any violations. The ceasefire remains fragile, with reports of continued military operations by both sides in southern Lebanon. How long and how severe the current conflicts in Gaza, Northern Israel, Lebanon, Iran or the broader region become is unknown at this time and any continued clash among Israel, Hamas, Hezbollah, Iran or other countries or militant groups in the region may escalate in the future into a greater regional conflict. The Company's research personnel and certain management personnel are located in Israel, however other core activities including clinical, regulatory and supply chain are located outside of Israel.

Currently, the Company's activities in Israel remain largely unaffected by the foregoing events. For the three months ended March 31, 2026 and 2025 and the year ended December 31, 2025, the impact of such events on the Company's results of operations and financial condition was immaterial.

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation of the financial statements

These unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") for interim financial statements. Accordingly, they do not include all of the information and notes required by U.S. GAAP for annual financial statements. In the opinion of management, these unaudited condensed consolidated financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of the Company's consolidated financial position as of March 31, 2026, the consolidated results of operations and statements of changes in shareholders' equity for the three months ended March 31, 2026 and 2025, and cash flows for the three months ended March 31, 2026 and 2025.

The consolidated results of operations for the three months ended March 31, 2026 are not necessarily indicative of the results to be expected for the year ending December 31, 2026.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company as of and for the year ended December 31, 2025, as filed with the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 27, 2026.

b. Loss per share

Basic loss per share is computed on the basis of net loss for the period divided by the weighted average number of outstanding ordinary shares, pre-funded warrants and vested restricted share units ("RSUs") during the period. Each outstanding pre-funded warrant has no expiration and is exercisable at a price of NIS 0.0000769 per ordinary share.

Diluted loss per share is based upon the weighted average number of ordinary shares and ordinary share equivalents outstanding when dilutive. Ordinary share equivalents include outstanding stock options, warrants and "RSUs", which are included under the treasury stock method when dilutive. The calculation of diluted loss per share does not include options, RSUs and warrants exercisable into 17,323,164 ordinary shares and 16,186,270 ordinary shares for the three months ended March 31, 2026 and 2025, respectively, because the effect would have been anti-dilutive.

c. Newly issued and recently adopted accounting pronouncements:

Recently issued accounting pronouncements, not yet adopted

In November 2024, the FASB issued ASU 2024-03 "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses", which requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted, and may be applied either prospectively or retrospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

In December 2025, the FASB issued ASU 2025-10 “Government Grants (Topic 832)” to establish authoritative guidance on the accounting for government grants received by business entities. This update is effective beginning with the Company’s 2029 fiscal year annual reporting period, with early adoption permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

In December 2025, the FASB issued ASU 2025-11, “Interim Reporting (Topic 270) Narrow-Scope Improvements.” The amendments in this Update clarify interim disclosure requirements and the applicability of Topic 270. The objective of the update is to provide clarity about current interim requirements. The amendments in this update also include a disclosure principle that requires entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. The amendments in this ASU are required to be adopted for interim periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company does not expect ASU 2025-11 to have a material impact on its consolidated financial statements disclosures.

NOTE 3 - EQUITY AND SHARE-BASED COMPENSATION

Changes in Share Capital:

- a. On January 1, 2026, the Company issued 148,872 ordinary shares to five non-executive members of the board of directors in lieu of cash board fees for fiscal year 2025, which was approved by the Company’s shareholders at a meeting of the Company’s shareholders held on July 31, 2024. The fair value of the ordinary shares on the grant date was \$289 thousand.
- b. In February 2026, two former non-executive board members exercised options for an aggregate of 216,666 ordinary shares for total consideration of \$130 thousand.

Share-based Compensation:

- a. On January 1, 2026, an aggregate of 167,525 options to purchase ordinary shares was granted to five non-executive board members with an exercise price of \$1.94 per share. The options vest over one year in four equal quarterly installments, starting on January 1, 2026. This grant was approved by the shareholders of the Company on October 4, 2021. The fair value of the options at the date of grant was \$227 thousand.

The fair value of each option granted was estimated as of the date of grant using the Black-Scholes option-pricing model, using the following assumptions:

	Three months ended March 31, 2026
Exercise price	\$ 1.94
Dividend yield	-
Expected volatility	84.2%
Risk-free interest rate	5.74%
Expected life - in years	5.3

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 4 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

Balance sheets:

	<u>March 31,</u> <u>2026</u>	<u>December 31,</u> <u>2025</u>
Other current assets:		
Prepaid expenses	310	37
Receivable in respect of collaborative arrangement	-	219
Other	256	159
	<u>566</u>	<u>415</u>
	<u>March 31,</u> <u>2026</u>	<u>December 31,</u> <u>2025</u>
Accrued expenses and other payables:		
Employees and employees related	242	264
Provision for vacation	211	168
Payable in respect of collaborative arrangement	46	-
Accrued expenses	455	726
Other payables	163	367
	<u>1,117</u>	<u>1,525</u>

NOTE 5 - COLLABORATION AND RESEARCH AGREEMENTS

On March 16, 2025, the Company entered into a collaboration agreement with OPKO (the “2025 Collaboration Agreement”), which is accounted for as a collaboration arrangement within the scope of ASC 808.

Under the terms of the 2025 Collaboration Agreement, the Company and OPKO have agreed to collaborate with respect to the preclinical and clinical development and decision making related to the oral delivery of a dual agonist GLP-1/glucagon peptide in an oral dosage form using Entera’s N-Tab™ technology platform for the treatment of obesity, metabolic and fibrotic disorders in humans. The Company and OPKO share in the economics and development costs of such program at 40% and 60%, respectively, subject to certain opt-out provisions. In connection with the agreement, the Company issued 3,685,226 ordinary shares to OPKO for aggregate gross proceeds of \$8.0 million, which were allocated between equity and the collaboration components of the arrangement. Amounts allocated to the collaboration component are recognized over the period of performance and presented within other liabilities in the consolidated balance sheet.

On February 3, 2026, the Company and OPKO amended and restated the 2025 Collaboration Agreement (the “A&R Collaboration Agreement”) to expand the scope of the collaboration to include the preclinical and clinical development of a daily LA-PTH tablet for the treatment of hypoparathyroidism (EB612) and additional indications. Development costs related to the LA-PTH program are shared equally between the parties. Except for the foregoing expansion, the material terms of the 2025 Collaboration Agreement remain unchanged.

For the three months ended March 31, 2026, the Company recognized net expenses of \$523 thousand relating to the A&R Collaboration Agreement.

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 6 - SEGMENT INFORMATION

- a. The Company operates in Israel as a single operating segment. The Company's Chief Executive Officer is the chief operating decision maker (the "CODM"). The CODM makes decisions on resource allocation, assesses performance of the business and monitors budget versus actual results on a consolidated basis based on net losses.
- b. Segment information:

	<u>March 31,</u> <u>2026</u>	<u>March 31,</u> <u>2025</u>
Revenues	-	42
Less:		
<i>Research and development, net:</i>		
Sub-contractors and consulting expense (EB613)	780	373
Net expenses related to OPKO Collaboration Agreement	523	-
Payroll and related expenses	435	395
Share-based compensation	313	176
Rent and related expenses	128	123
Other development expenses*	72	56
Other segment expenses**	1,254	1,486
Segment net loss	<u>3,505</u>	<u>2,567</u>

* Other development expenses include materials and productions and others.

** Other segment expenses mainly related to general and administrative expenses, including payroll and related expenses, share-based compensation, legal and audit fees and others.

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 7 - SUBSEQUENT EVENTS

- a. On April 1, 2026, the Company entered into a securities purchase agreement with certain funds affiliated with BVF Partners LP (collectively, the "Purchaser"), providing for the private placement to the Purchaser of an aggregate of 7,916,879 units (the "2026 Units"), each 2026 Unit consisting of (i) one ordinary share (or, in lieu thereof, one pre-funded warrant to purchase one ordinary share (the "2026 Pre-Funded Warrants")) and (ii) one warrant to purchase one and one-half ordinary shares (the "2026 Ordinary Share Warrants"), for aggregate proceeds of approximately \$10.0 million (or \$1.2775 per 2026 Unit), the issuance costs was \$57. On April 2, 2026 (the "Closing Date"), the Company issued 2,425,000 ordinary shares, 5,402,789 2026 Pre-Funded Warrants, and 11,741,683 2026 Ordinary Share Warrants in connection with this offering.

Each 2026 Ordinary Share Warrant has an exercise price of \$1.24 per share, becomes exercisable six months following the Closing Date, expires five years from the date of issuance, and is subject to customary adjustments. The 2026 Ordinary Share Warrants are exercisable only for cash so long as the Company has an effective registration statement registering the shares underlying the 2026 Ordinary Share Warrants. The 2026 Pre-Funded Warrants have an exercise price of NIS 0.0000769 per share, are immediately exercisable and may be exercised at any time and have no expiration date.

- b. In April 2026, two former non-executive board members exercised options for an aggregate of 178,082 ordinary shares for a total consideration of \$130 thousand.
- c. On May 7, 2026, the board of directors approved the following options grants:

- 1) options to purchase an aggregate of 1,772,000 ordinary shares were granted to employees, executive officers and a key consultant with an exercise price of \$1.37 per share, which was the closing share price on the grant date. 1,120,000 of the options grants are subject to the filing of an S-8 registration statement registering the shares underlying such option grants.
- 2) options to purchase an aggregate of 500,000 ordinary shares were granted to the Company's Chief Executive Officer with an exercise price of \$1.37 per share, which was the closing share price on the grant date. This grant is subject to shareholder approval and the filing of an S-8 registration statement registering the shares underlying such grant.

These options vest over three years from the date of grant; 33.33% vest on the first anniversary of the date of grant and the remaining 66.67% of the options will vest in eight equal quarterly installments over the remaining two year period.

- 3) options to purchase an aggregate of 40,000 ordinary shares were granted to a board member with an exercise price of \$1.37 per share, which was the closing share price on the grant date. These options vest immediately at the date of grant. This grant is subject to shareholder approval and the filing of an S-8 registration statement registering the shares underlying such grant.
- 4) options to purchase an aggregate of 83,367 ordinary shares were granted to certain board members with an exercise price of \$1.37 per share, which was the closing share price on the grant date. These options vest over three years from the date of grant in twelve equal quarterly installments following the vesting commencement date. These grants are subject to shareholder approval and the filing of an S-8 registration statement registering the shares underlying such option grants.
- 5) options to purchase an aggregate of 86,418 ordinary shares were granted to certain board members with an exercise price of \$1.37 per share, which was the closing share price on the grant date. These options vest over one year ended December 31, 2026 in quarterly installments. This grant is subject to shareholder approval and the filing of an S-8 registration statement registering the shares underlying such option grants.

In addition, the board of directors approved the grant of 734,428 RSUs to executive officers and key consultants in lieu of a cash bonus and partial salary raise. The grant of 420,559 of these RSUs is subject to shareholder approval.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information we believe is relevant to an assessment and understanding of our results of operations, financial condition, liquidity and cash flows for the periods presented below. This discussion should be read in conjunction with the interim unaudited condensed consolidated financial statements and related notes contained elsewhere in this Quarterly Report, Part II, Item 1A-Risk Factors in this Quarterly Report, and Part I, Item 1A-Risk Factors in our 2025 Annual Report. As discussed in the section above titled "Cautionary Note Regarding Forward-Looking Statements," the following discussion contains forward-looking statements that are based upon our current expectations, including with respect to our future operations, revenues and operating results. Our actual results may differ materially from those anticipated in such forward-looking statements as a result of various factors. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included under Part II, Item 1A below, as well as in Part I, Item 1A-Risk Factors in our 2025 Annual Report.

Unless otherwise provided, references to the "Company," "we," "us" and "our" refer to Entera Bio Ltd. and its consolidated subsidiary.

Business Overview

Entera is a clinical stage company focused on developing first-in-class oral tablet formats of peptides or protein replacement therapies. We focus on underserved, chronic medical conditions for which oral administration of a protein therapy has the potential to significantly shift a treatment paradigm. Our pipeline includes differentiated, first-in-class oral peptide programs targeting PTH(1-34), GLP-1/Glucagon and GLP-2.

Currently, most protein therapies are administered via frequent intravenous, subcutaneous, or intramuscular injections. In chronic diseases where patients require persistent management, these cumbersome, often painful and high-priced injections can create a major treatment gap. From a technical standpoint, oral delivery of peptides and therapeutic proteins is challenging due to the enzymatic degradation within the gastrointestinal tract and poor absorption into the blood stream. We leverage our N-Tab[®] platform, which is designed to simultaneously stabilize large (4kD+) hydrophilic peptides in the gastrointestinal tract and promote their absorption into the bloodstream.

EB613 Program

Our most advanced product candidate, EB613, oral PTH(1-34), is being developed as the first oral, osteoanabolic (bone building) once-daily tablet treatment for osteoporosis. EB613 is intended to provide an oral anabolic treatment earlier in an osteoporosis patient's journey to increase skeletal mass, reduce the risk of fracture and limit the disease progression, and decrease disability and mortality. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (pharmacodynamic/bone turnover biomarker) and secondary endpoints (bone mineral density ("BMD")). In April 2024, the Phase 2 data was published in the Journal of Bone and Mineral Research (JBMR).

In July 2025, we announced that in a written response to a Type A meeting request, the FDA agreed that a new drug application ("NDA") filing for EB613 could be supported by a phase 3 study in women with postmenopausal osteoporosis, where change in total hip BMD is evaluated as the primary endpoint, and incidence of new or worsening vertebral fractures is evaluated as the key secondary endpoint at 24 months.

In December 2025, the FDA released the Determination for Qualification of BMD qualifying total hip BMD as a surrogate efficacy endpoint for fracture that could be used in future studies of new anti-osteoporosis therapies. The FDA's suggested a context of use (COU): "The percentage change from baseline at 24 months in total hip bone mineral density (BMD) assessed by dual-energy X-ray absorptiometry (DXA) can be used as a validated surrogate endpoint for the assessment of investigational therapies for postmenopausal women with osteoporosis at risk for fracture."

In February 2026, we submitted to the FDA a clinical amendment that included the EB613 Phase 3 protocol, statistical analysis plan and open-label extension synopsis. Subject to regulatory feedback, we are planning to initiate the Phase 3 study in the second half of 2026.

EB612 Program

Our product candidate, EB612, is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for patients with hypoparathyroidism.

In December 2025, we announced new in vivo PK/PD data supporting the development of a proprietary long-acting PTH (“LA-PTH”) analog utilizing our N-Tab[®] platform. Preclinical findings demonstrated a markedly prolonged plasma half-life and sustained elevation of serum calcium levels for more than three days following administration of a single oral tablet, in contrast to unmodified PTH(1-34) controls, which showed no calcium response. These data support the development of a once-daily oral PTH tablet for patients with hypoparathyroidism.

In February 2026, we announced the expansion of our collaboration with OPKO Biologics, Inc. (“OPKO Biologics”), a subsidiary of OPKO Health, Inc. (“OPKO”), and OPKO to jointly advance this LA-PTH program. Under the expanded collaboration, Entera and OPKO each hold a 50% pro-rata ownership interest in the LA-PTH hypoparathyroidism program, and each is responsible for 50% of development costs. We intend to accelerate development and currently expect to submit an IND application to the FDA in late 2026.

EB618 Program (Oral GLP-1/Glucagon)

In September 2023, we entered into a collaboration agreement with OPKO Biologics (the “2023 Collaboration Agreement”). Under the terms of this agreement, OPKO agreed to supply certain Oxymodulin (“OXM”) analogs for the development of oral tablet candidates using our proprietary N-Tab[®] platform.

The EB618 program focuses on developing the first oral dual agonist GLP-1/Glucagon (OXM) peptide as a potential once-daily tablet treatment for patients with obesity and metabolic disorders using the N-Tab[®] platform. Currently, there are no approved dual GLP-1/Glucagon agonists available. Currently, there are no approved dual GLP-1/Glucagon agonists available.

In September 2024, we and OPKO jointly announced topline PK/PD results for the OXM program. 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 an additional collaboration agreement with OPKO and OPKO Biologics (the “2025 Collaboration Agreement”) to collaborate with respect to the preclinical and clinical development and decision making related to the Oral OXM program for the treatment of obesity, metabolic and fibrotic disorders in humans.

In February 2026, we amended and restated the 2025 Collaboration Agreement (the “A&R Collaboration Agreement”) to expand the scope of the agreement to include the collaboration with respect to the preclinical and clinical development of a daily LA-PTH tablet for the treatment of hypoparathyroidism.

OPKO is planning to initiate a single ascending dose (SAD) and multiple ascending dose (MAD) Phase 1 clinical study with the subcutaneous injection formulation in 2027. We plan to file an IND for the oral OXM tablet formulation thereafter.

For additional information regarding our collaboration agreements with OPKO, see Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Patent Transfer, Licensing Agreements and Grant Funding—OPKO Collaboration and License Agreements, contained in this Quarterly Report.

Oral GLP-2

This program focuses on developing the first GLP-2 peptide tablet alternative for patients suffering from short bowel syndrome and additional disorders involving mucosal inflammation and nutrient malabsorption.

In connection with the 2023 Collaboration Agreement we and OPKO completed proof-of-concept pharmacokinetic studies in rodents and minipigs. Oral GLP-2 tablets exhibited significant systemic exposure with plasma levels about 10-fold higher than therapeutic plasma concentrations reported for subcutaneously administered teduglutide (Gattex® label). Rodent repeat-dose PK/PD studies showed clear pharmacologic activity in intestinal tissue. Systemic exposure was maintained for more than 24 hours with relatively low variability, supporting once-daily oral dosing.

Given the challenging compliance rates attributed to injectable GLP-2 therapy and heterogeneity of 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.

Patent Transfer, Licensing Agreements and Grant Funding

OPKO Collaboration and License Agreements

2023 Collaboration Agreement

In September 2023, we entered into the 2023 Collaboration Agreement with OPKO Biologics. Under the terms of this agreement, OPKO has agreed to supply its proprietary long-acting GLP-2 peptide and certain OXM analogs for the development of oral tablet candidates using our proprietary N-Tab® platform. Under this agreement, we and OPKO have each agreed to be responsible for specific phases of development of the two oral peptides to the point of demonstrated in vivo feasibility

2025 Collaboration Agreement

In March 2025, we entered into the 2025 Collaboration Agreement with OPKO and OPKO Biologics to collaborate with respect to the preclinical and clinical development and decision making related to the Oral OXM program for the treatment of obesity, metabolic and fibrotic disorders in humans (the “Program”).

Under the 2025 Collaboration Agreement, we granted to OPKO an exclusive, sublicensable and non-transferable, worldwide license to certain of our intellectual property and technology solely to develop, manufacture, and commercialize any GLP-1/Glucagon dual agonist as an oral treatment form for the treatment of obesity, metabolic, cardiovascular, and fibrotic disorders in humans, and OPKO has granted to us a non-exclusive, non-sublicensable and non-transferable license to certain of its intellectual property and technology to the extent necessary for us to perform our obligations in relation to the Program, in each case subject to the exceptions contained therein.

Under the terms of the 2025 Collaboration Agreement, we and OPKO will retain 40% and 60%, respectively, of all proceeds deriving from the EB618 Program, and will be responsible for 40% and 60% of the Program’s development costs, respectively. Following the completion of the Phase 1 stage, we may continue to fund our 40% share of the Program to maintain our right to proceeds or to opt-out (the “Opt-Out”). If we Opt-Out, then we and OPKO will retain 15% and 85%, respectively, of all proceeds deriving from the Program, while OPKO will be solely responsible for ongoing development and commercialization funding of the Program.

In connection with the execution of the 2025 Collaboration Agreement, we issued and sold to OPKO an aggregate of 3,685,226 Ordinary Shares for a purchase price of \$8.0 million, the proceeds of which we have agreed to use solely to fund our development cost obligations under the 2025 Collaboration Agreement, subject to the expiration or termination of the agreement.

Amended And Restated Collaboration Agreement

In February 2026, we entered into the A&R Collaboration Agreement with OPKO which amends and restates the 2025 Collaboration Agreement to expand the scope of the agreement to include the collaboration with respect to the preclinical and clinical development of a daily LA-PTH for the treatment of hypoparathyroidism (EB612 Program) and other indications in addition to the original oral dual agonist GLP-1/glucagon peptide program. Development costs incurred by the parties with respect to the development of the LA-PTH EB612 program will be shared equally between the Company and OPKO.

Oramed Patent Transfer Agreement

In 2011, we entered into a patent transfer agreement with Oramed Ltd. ("Oramed"), which we refer to as the Patent Transfer Agreement, pursuant to which Oramed assigned to us all of its rights, title and interest in the patent rights Oramed licensed to us when we were originally organized, subject to a worldwide, royalty-free, exclusive, irrevocable, perpetual and sub-licensable license granted to Oramed under the assigned patent rights to develop, manufacture and commercialize products or otherwise exploit such patent rights in the fields of diabetes and influenza. Additionally, we agreed not to engage, directly or indirectly, in any activities in the fields of diabetes and influenza that involve the use of, or utilize, the patents underlying the Patent Transfer Agreement. Under the terms of the Patent Transfer Agreement, we agreed to pay Oramed royalties equal to 3% of our net revenues generated, directly or indirectly, from our exploitation of the assigned patent rights, including the sale, lease or transfer of the assigned patent rights or sales of products or services covered by the assigned patent rights. On March 27, 2025, we entered into a Novation Agreement with Oramed, and Oramed NewCo Inc. ("Oramed NewCo") pursuant to which Oramed NewCo replaced Oramed as a party to the Patent Transfer Agreement. Under the Novation Agreement, Oramed NewCo assumed all of Oramed's rights and obligations under the Patent Transfer Agreement accruing on or after the effective date, Oramed was released from any obligations and liabilities owed to us under the Patent Transfer Agreement accruing or arising after such date, and we were released from any obligations and liabilities owed to Oramed accruing or arising after such date. All other provisions of the Patent Transfer Agreement remain in full force and effect.

Israeli Innovation Authority Grants

We have received grants of approximately \$0.5 million from the Israeli Innovation Authority ("IIA") to partially fund our PTH research and development for Osteoporosis. The grants are subject to certain requirements and restrictions under the Israeli Encouragement of Research, Development and Technological Innovation in Industry Law 5477 1984 (the "Research Law"). In general, until the grants are repaid with interest, royalties are payable to the Israeli government in the amount of 3% on revenues derived from sales of products or services developed in whole or in part using the IIA grants. The royalty rate may increase to 5%, with respect to approved applications filed following any year in which we achieve sales of over \$70 million.

The amount that must be repaid may be increased up to six times the amount of the grant received and the interest. The rate of royalties may be accelerated and the royalty liability may increase (up to three times the amount of the grant amount and the interest), if manufacturing of the products developed with the grant money is transferred outside of the State of Israel. Moreover, a payment of up to 600% of the grant received may be required upon the transfer of any IIA-related know-how to a non-Israeli entity. We signed a contract with a U.K.-based contract manufacturing organization to produce and supply pills for trials performed worldwide. We believe that, because this production is not for commercial purposes, it will not affect the royalty rates to be paid to the IIA. Should the IIA successfully take a contrary position, the maximum royalties to be paid to the IIA will be approximately \$1.5 million, which is three times the amount of the original grant (plus interest on the entire increased amount). Under a collaboration agreement that was previously mutually terminated in May 2023, from 2019 through March 31, 2023, we recognized an aggregate amount of \$1.7 million of revenue in accordance with ASC 606, "Revenues from Contracts with Customers" with respect to revenue generated from the collaboration agreement. Prior to its termination, we had been required to pay to the IIA 5.38% of each payment made to us under such collaboration agreement with an ultimately liability of up to 600% of the grant received plus interest. As of March 31, 2026, we had paid royalties to the IIA in the amount of \$96 thousand.

In addition to paying any royalties due, we must abide by other restrictions associated with receiving such grants under the Research Law that continue to apply following repayment to the IIA.

Recent Developments

April 2026 Private Placement

On April 1, 2026, we entered into a securities purchase agreement with certain funds affiliated with BVF Partners LP (collectively, the “Purchaser”), providing for the private placement (the “April 2026 Private Placement”) to the Purchaser of an aggregate of 7,916,879 units (the “2026 Units”), each 2026 Unit consisting of (i) one Ordinary Share (or, in lieu thereof, one pre-funded warrant to purchase one Ordinary Share (the “2026 Pre-Funded Warrants”)) and (ii) one warrant to purchase one and one-half Ordinary Shares (the “2026 Ordinary Share Warrants”), for aggregate proceeds of approximately \$10.0 million (or \$1.2775 per 2026 Unit). On April 2, 2026 (the “Closing Date”), the Company issued 2,425,000 Ordinary Shares, 5,402,789 2026 Pre-Funded Warrants, and 11,741,683 2026 Ordinary Share Warrants in connection with the April 2026 Private Placement.

Each 2026 Ordinary Share Warrant has an exercise price of \$1.24 per share, becomes exercisable six months following the Closing Date, expires five years from the date of issuance, and is subject to customary adjustments. The 2026 Ordinary Share Warrants are exercisable only for cash so long as we have an effective registration statement registering the shares underlying the 2026 Ordinary Share Warrants. The 2026 Pre-Funded Warrants have an exercise price of NIS 0.0000769 per share, are immediately exercisable and may be exercised at any time and have no expiration date.

Israel-Hamas War and Regional Conflicts

In October 2023, Israel was attacked by Hamas, a terrorist organization and entered a state of war. Since the commencement of these events, there have been additional active hostilities, including with Hezbollah in Lebanon, the Houthi movement which controls parts of Yemen, and with Iran. In response to ongoing Iranian aggression and support of proxy attacks against Israel, on June 12, 2025, Israel conducted a series of preemptive defensive air strikes in Iran targeting Iran’s nuclear program and military commanders. On June 21, 2025, U.S. President Donald Trump announced that the United States had conducted air strikes against three nuclear sites within Iran. On October 9, 2025, a ceasefire had been reached. Israel, Hamas, the United States and other countries in the region agreed to a framework for a ceasefire in Gaza between Israel and Hamas. On February 28, 2026, following the breakdown of diplomatic efforts and heightened regional tensions, the United States and Israel conducted a series of preemptive strikes targeting Iranian military infrastructure and strategic assets. Immediately thereafter, Iran launched extensive retaliatory ballistic missile and drone attacks against multiple locations across Israel, including central and southern population centers, critical infrastructure facilities and military installations. On March 2, 2026, Hezbollah resumed hostilities, ending the November 2024 ceasefire, by launching projectiles into northern Israel, prompting Israeli airstrikes in Lebanon targeting Hezbollah operatives and assets. Since the outbreak of these hostilities, Israel has implemented nationwide emergency measures, including restrictions on public gatherings and large-scale reserve duty call-ups affecting the civilian workforce.

In early April 2026, a two-week ceasefire between the United States and Iran was agreed and on April 21, 2026, U.S. President Donald Trump announced that the United States would extend the ceasefire with Iran, to allow Iran's leadership to present a unified proposal for negotiations. However, the ceasefire's durability remains uncertain. The United States has maintained a naval blockade of Iranian ports, and Iran has responded by intermittently restricting commercial vessel passage through the Strait of Hormuz, declaring that the waterway would remain effectively closed until the blockade is lifted. There can be no assurance that this ceasefire will hold or be extended, and hostilities between the United States, Israel and Iran could resume at any time. On April 16, 2026, following direct talks between Israeli and Lebanese officials in Washington, D.C., a 10-day cessation of hostilities between Israel and Lebanon was announced, brokered by the United States. The parties have requested that the United States facilitate further direct negotiations with the objective of achieving a comprehensive agreement for lasting security and peace. Israeli forces remain stationed in southern Lebanon and Hezbollah has not accepted the terms as binding, stating that its fighters will remain deployed and will respond to any violations. The ceasefire remains fragile, with reports of continued military operations by both sides in southern Lebanon.

The Company's research personnel and management personnel are located in Israel, however other core activities including clinical, regulatory and supply chain are located outside of Israel. Currently, such activities in Israel remain largely unaffected. During the three months ended March 31, 2026 and March 31, 2025, the impact of this war on the Company's results of operations and financial condition was immaterial. See Item 1.A. "Risk Factors—Security, political and economic instability in the Middle East may harm our business."

Financial Overview

From our inception through March 31, 2026, we have raised a total of \$111.8 million from a combination of public and private equity offerings, IIA grants and the issuance of Ordinary Shares upon the exercise of options and warrants. Since inception, we have incurred significant losses. For the three months ended March 31, 2026 and 2025, our operating losses were \$3.5 million and \$2.6 million, respectively, and we expect to continue to incur significant expenses and losses for the foreseeable future.

As of March 31, 2026, we had an accumulated deficit of \$128.9 million. Our losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials, our expenditures on research and development activities and any third-party collaborations into which we may enter.

The Company is engaged in research and development activities, and it has not derived significant income from its activities and has incurred an accumulated deficit and negative cash flows from operating activities since inception. These factors raise substantial doubt as to the Company's ability to continue as a going concern. The unaudited condensed consolidated financial statements included herein have been prepared assuming that we will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty. See Part I, Item 1A-Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital contained in our 2025 Annual Report.

As of March 31, 2026, we had cash and cash equivalents and restricted cash of \$11.9 million, of which \$7.8 million has been designated to fund the collaboration activity with OPKO under the A&R Collaboration Agreement. In April 2026, we consummated the April 2026 Private Placement and received gross proceeds of approximately \$10.0 million. Based on our current cash position and operating plan, we believe that our existing cash resources will be sufficient to fund our projected operating requirements through the first quarter of 2027, including activities related to the preparation for our planned Phase 3 registrational study of EB613. However, the Company's ability to commence and complete the Phase 3 clinical study of EB613 in osteoporosis is dependent on its ability to obtain additional funding, which may not be available on acceptable terms, or at all. Any delay or our inability to secure such funding will delay or prevent the commencement of these studies. These factors raise substantial doubt as to our ability to continue as a going concern.

In order to fund further operations, we will need to raise additional capital. We may raise these funds through a variety of means, including private or public equity offerings, debt financings, strategic collaborations and licensing arrangements. Additional financing may not be available when we need it or may not be available on terms that are favorable to us.

As of March 31, 2026, we had a total of 22 employees, of whom 20 are full-time employees, and all are based in Israel. In addition, we employ a number of specialized clinical, non-clinical, statistical, regulatory and development advisors based in the United States, the United Kingdom and Europe. Our operations are located in Jerusalem, Israel.

Revenue

To date, we have not generated any revenue from sales of our products, and we do not expect to receive any revenue from any product candidates that we develop unless and until we obtain regulatory approval and successfully commercialize our products.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of our N-Tab[®] platform and our product candidates. We expense both internal and external research and development expenses to operations for the periods in which they are incurred. We mapped the majority of external research and development costs incurred for our product candidates and development programs.

Internal and certain general external research and development expenses that support multiple programs include:

- employee-related expenses, including salaries, bonuses and share-based compensation expenses for employees and service providers in the research and development function;
- costs associated with our research and development platform used across programs, process development, manufacturing, consulting fees and preclinical development for earlier stage programs and new technologies;
- expenses incurred in operating our laboratories including our small-scale manufacturing facility; and
- depreciation of research and development equipment, allocated overhead, rent and facilities-related expenses.

External research and development expenses for our main clinical development programs include:

- expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials;
- other costs associated with pre-clinical and clinical activities;
- supply, development and manufacturing costs relating to clinical trial materials; and
- certain consulting and advisory services related to the program.

Research and development activities are our primary focus. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase significantly in future periods as we advance our clinical candidates into later stages of clinical development and invest in additional preclinical candidates.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including due to the timing of initiation of clinical trials and the enrolment of patients in clinical trials. For the three months ended March 31, 2026 and 2025, our research and development expenses were \$2.3 million and \$1.1 million, respectively. Research and development expenses for the three months ended March 31, 2026 were primarily for the development of EB613 and the next-generation of EB613 and our collaboration with OPKO related to the EB618 (OXM) and EB612 (LA-PTH) programs. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from any of our product candidates. This is due to numerous risks and uncertainties associated with developing drugs, including:

- the uncertainty of the scope, rate of progress, results and cost of our clinical trials, nonclinical testing and other related activities;
- the cost of manufacturing clinical supplies and establishing commercial supplies of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;

- the cost and timing of establishing any sales, marketing, and distribution capabilities; and
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any milestone and royalty payments thereunder.

A change in the outcome of any of these variables with respect to the development of EB613, EB612 and EB618 or any other product candidate that we may develop could significantly change the costs and timing associated with the development of any such product candidate. For example, if the FDA or other regulatory authority were to require us to conduct preclinical or clinical studies beyond those that we currently anticipate will be required for the completion of clinical development, if we experience significant delays in enrolment in any clinical trials or if we encounter difficulties in manufacturing our clinical supplies, then we could be required to expend significant additional financial resources and time on the completion of the clinical development.

Our research and development expenses for the three months ended March 31, 2026 and March 31, 2025 are summarized as follows:

	Three Months Ended Month 31,	
	(unaudited)	
	2026	2025
	(In thousands)	
External Expenses related to EB613	780	373
Internal and External expenses related to collaboration with OPKO	523	—
Internal and External expenses related to other development program:		
Payroll and related expenses	435	395
Share-based compensation	313	176
Rent and related expenses	128	123
Other development expenses	72	56
Research and development expenses, net	<u>2,251</u>	<u>1,123</u>

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related expenses, share-based compensation and related costs for directors and personnel in executive and finance functions. Other general and administrative expenses include D&O insurance and other insurance, communication expenses, professional fees for legal and accounting services, costs associated with maintaining and prosecuting our intellectual property portfolio and business development expenses.

Financial Income, Net

Financial income, net is composed primarily of interest income from bank deposits and exchange rate differences of certain currencies against our functional currency, which is the U.S. Dollar.

Taxes on Income

We have not generated taxable income since our inception, and, as of March 31, 2026, we had carryforward tax losses of \$93.9 million.

We anticipate that we will be able to carry forward these tax losses indefinitely to future tax years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carryforward tax losses. We provided a full valuation allowance with respect to the deferred tax assets related to these carryforward losses.

The Company's subsidiary, Entera Bio, Inc., is taxed separately under U.S. tax laws. As of March 31, 2026, Entera Bio Inc. had tax loss carryforwards of \$0.2 million.

Results of Operations

Comparison of Three Months Ended March 31, 2026 and 2025

	Three Months Ended		Increase (Decrease)	
	March 31,		\$	%
	2026	2025		
	(In thousands, except for percentage information)			
Revenues	\$ —	\$ 42	(42)	(100)%
Cost of Revenues	\$ —	\$ 42	(42)	(100)%
Gross Profit	\$ —	\$ —	\$ —	
Operating expenses:				
Research and development expenses	\$ 2,251	\$ 1,123	1,128	100%
General and administrative expenses	\$ 1,288	\$ 1,440	(152)	(11)%
Operating loss	\$ 3,539	\$ 2,563	976	38%
Financial expenses (income), net	\$ (34)	\$ 4	(38)	(950)%
Net loss	\$ 3,505	\$ 2,567	938	37%

Revenues

Revenues for the three months ended March 31, 2025 were \$42 thousand, which were attributable to research services we provided pursuant to a research services agreement with an external party. The Company completed its obligations under the research services agreement in the first quarter of 2025. We did not recognize any revenue for the three months ended March 31, 2026.

Cost of Revenues

Cost of revenues for the three months ended March 31, 2025 were \$42 thousand, which was attributable to research services we provided pursuant to a research services agreement with an external party. For the three months ended March 31, 2026, we did not recognize any cost of revenues.

Research and Development Expenses

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. The increase in expenses of \$1.2 million was mainly attributable to an increase of \$0.5 million related to our Phase 1 safety and PK bridging study for the Next Generation of EB613, an increase of \$0.5 million in connection with our collaboration programs with OPKO for EB618 and EB612 and an increase of \$0.2 million in compensation mainly due to unfavorable foreign exchange rate changes.

General and Administrative Expenses

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. The decrease of \$0.1 million was mainly attributable to a decrease in consultants and legal fees.

Financial Income, Net

Financial income, net for the three months ended March 31, 2026 was \$34 thousand as compared to financial expenses, net of \$4 thousand for the three months ended March 31, 2025. Our financial income mainly included interest income from bank deposits and exchange rate differences of certain currencies against our functional currency, which is the U.S. Dollar.

Liquidity and Capital Resources

Since inception, we have incurred significant losses from operations and negative cash flows from operating activities. For the three months ended March 31, 2026 and 2025, our operating losses were \$3.5 million and \$2.6 million, respectively. As of March 31, 2026, we had an accumulated deficit of \$128.9 million. We expect to continue to incur significant expenses and losses for the next several years as we advance our products through development and provide administrative support for our operations. These factors raise substantial doubt about our ability to continue as a going concern. The unaudited condensed consolidated financial statements contained in this Quarterly Report have been prepared on a going concern basis and do not include any adjustments that may be necessary should we be unable to continue as a going concern.

Since our inception and through March 31, 2026, we have raised a total of \$111.8 million from a combination of public and private equity offerings, IIA grants, the issuance of Ordinary Shares upon the exercise of options and warrants, and the issuance of \$36.4 million of Ordinary Shares through at-the-market-offering (“ATM”) programs.

As of March 31, 2026, we had cash and cash equivalents and restricted cash of \$11.9 million, of which \$7.8 million has been designated to fund our obligations under the A&R Collaboration Agreement. In April 2026, we consummated the April 2026 Private Placement and received gross proceeds of approximately \$10.0 million. Our primary uses of cash have been to fund research and development, general and administrative and working capital requirements, including activities related to the preparation for and initiation of its Phase 3 registration study of EB613 and our collaboration programs with OPKO (EB612 and EB618) and we expect these will continue to be our primary uses of cash.

Equity Offerings

On September 2, 2022, we entered into a Sales Agreement with Leerink Partners LLC (f/k/a SVB Securities LLC), as sales agent, to implement an ATM program (the “Leerink ATM Program”) under which we were originally able to sell up to 5,000,000 Ordinary Shares in an at-the-market offering registered under the Securities Act. The sales agent is entitled to a fixed commission of 3% of the aggregate gross proceeds as well as reimbursement of expenses. As of March 31, 2026, we had sold 4,940,156 Ordinary Shares under the Leerink ATM Program for aggregate proceeds of \$9.8 million, net of issuance costs. We currently have the ability, but not the obligation, to sell up to an additional 30,000,000 Ordinary Shares under the Leerink ATM Program under our currently effective Registration Statement on Form S-3.

On December 20, 2023, we entered into a securities purchase agreement with certain investors, providing for the private placement (the “December 2023 Private Placement”) of an aggregate of 7,916,879 units, each consisting of (i) one Ordinary Share (or, in lieu thereof, one pre-funded warrant to purchase one Ordinary Share (the “2023 Pre-Funded Warrants”)) and (ii) one warrant to purchase one Ordinary Share (the “2023 Ordinary Share Warrant”), for aggregate proceeds of approximately \$6.6 million. The December 2023 Private Placement was priced at the market under applicable Nasdaq rules and closed on December 22, 2023.

Each 2023 Ordinary Share Warrant has an exercise price of \$1.00 per share and expires five years from the date of issuance.

In connection with our entering into the 2025 Collaboration Agreement with OPKO, we issued to OPKO an aggregate of 3,685,226 Ordinary Shares for a purchase price of \$8.0 million, representing a purchase price per share equal to approximately \$2.17, which was the volume weighted average price per share for the 30 trading days immediately preceding the date of such agreement. We have agreed to use the proceeds from the issuance of such Ordinary Shares solely to fund our development cost obligations under the A&R Collaboration Agreement.

On April 2, 2026, we consummated the April 2026 Private Placement. See “—Recent Developments—April 2026 Private Placement.”

As of March 31, 2026, we had received approximately \$0.6 million of net proceeds from the exercise of outstanding 2023 Ordinary Share Warrants. If all remaining 2023 Ordinary Share Warrants and all 2026 Ordinary Share Warrants were exercised for cash, then the Company would receive additional proceeds of approximately \$22.3 million. There can be no assurance that the holders will exercise any of such warrants.

Funding Requirements

Given our current plans, we believe that our existing cash resources will be sufficient to support our operations through the first quarter of 2027, including activities related to the preparation for our planned Phase 3 registrational study of EB613. However, our ability to commence and complete the Phase 3 clinical study of EB613 in osteoporosis is dependent on our ability to obtain additional funding, which may not be available on acceptable terms, or at all. Any delay or our inability to secure such funding will delay or prevent the commencement of these studies. Our expectations are based on management’s current assumptions, clinical development plans and regulatory submission timelines, which may prove to be wrong, and we could spend our available financial resources much faster than we currently expect.

We have based these estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our product candidates, and the extent to which we may enter into additional collaborations with third parties for development of these or other product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current and future product candidates. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of clinical trials for, and regulatory review of our oral peptide programs, including EB613 for osteoporosis and collaborations with OPKO related to EB612 for hypoparathyroidism and EB618 for obesity and metabolic disorders or other oral peptides for obesity, metabolic disorders and gastrointestinal rare diseases and any other product candidates we may develop;
- the costs of development activities for any other product candidates we may pursue;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- our ability to establish collaborations on favorable terms, if at all.

We continuously evaluate various financing alternatives in the public or private equity markets or through license of our N-Tab[®] platform to additional external parties through partnerships or research collaborations as we will need to finance future research and development activities, general and administrative expenses and working capital through fund raising. However, there is no certainty about our ability to obtain such funding.

Other than the Leerink ATM Program, we do not have any committed external sources of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our then-existing shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that may adversely affect our existing shareholders’ rights as shareholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may include requirements to hold minimum levels of funding. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financing or collaborations, when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

Cash Flows

Three Months Ended March 31, 2026 compared to Three Months Ended March 31, 2025

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Three Months Ended March 31, (unaudited)	
	2026	2025
	(In thousands)	
Net Cash used in operating activities	\$ (3,090)	\$ (1,404)
Net Cash used in investing activities	\$ —	\$ (8)
Net Cash provided by financing activities	\$ 130	\$ 13,337
Effect of Exchange Rate change on cash and cash equivalents	\$ 4	—
Net increase (decrease) in cash and cash equivalents	<u>\$ (2,956)</u>	<u>\$ 11,925</u>

Net Cash Used in Operating Activities

Net cash used in operating activities for the three months ended March 31, 2026 was \$3.1 million, consisting primarily of our operating expenses of \$3.5 million, which was partially offset by approximately \$0.7 million of share-based compensation and depreciation expenses and a decrease of approximately \$0.3 million in our net operating assets and liabilities.

Net cash used in operating activities for the three months ended March 31, 2025 was \$1.4 million, consisting primarily of our operating expenses of \$2.6 million, which was partially offset by approximately \$0.6 million of share-based compensation and depreciation expenses and a decrease of \$0.6 million in our operating assets and liabilities.

The change in cash used in operating activities for three months ended March 31, 2026 compared to the same period in 2025 was mainly attributed to an increase of \$0.9 million in our net loss, an increase of \$0.9 million in our net operating assets and liabilities and an increase of \$0.1 million of share-based compensation and depreciation expense.

Net Cash Used in Investing Activities

There was no net cash used in or provided by investing activities for the three months ended March 31, 2026.

Net cash used in investing activities for the three months ended March 31, 2025 consisted primarily of the purchase of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2026 consisted of the net proceeds of \$0.1 million from the issuance of Ordinary Shares upon the exercise of options.

Net cash provided by financing activities for the three months ended March 31, 2025 consisted of the net proceeds of \$6.0 million from the issuance of Ordinary Shares under the Leerink ATM Program, \$0.2 million from the issuance of Ordinary Shares upon the exercise of warrants and \$7.2 million from issuance of Ordinary Shares under the 2025 Collaboration Agreement.

Contractual Obligations

There have not been any material changes in our assessment of material contractual obligations and commitments as set forth in Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our 2025 Annual Report.

Critical Accounting Policies and Estimates

See Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies” and our consolidated financial statements and related notes included in the 2025 Annual Report for accounting policies and related estimates we believe are the most critical to understanding our consolidated financial statements, financial condition and results of operations and which require complex management judgment and assumptions, or involve uncertainties. The preparation of consolidated financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. There have been no changes to our critical accounting policies or their application since the date of the 2025 Annual Report.

Recently Issued Accounting Pronouncements

Certain recently issued accounting pronouncements are discussed in Note 2 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required for smaller reporting companies.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2026, which we refer to as the Evaluation Date. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION.

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

Except as set forth below in this Item 1A, there have been no material changes with respect to the risk factors disclosed in Part I, Item 1A. of our 2025 Annual Report.

Security, political and economic instability in the Middle East may harm our business.

Our principal research facilities are located in Israel. In addition, most of our key employees, officers and two directors are residents of Israel. Accordingly, political, economic and military conditions in the Middle East may affect our business directly. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries, Hamas (an Islamist militia and political group in the Gaza Strip), Hezbollah (an Islamist militia and political group in Lebanon), and Iran.

On October 7, 2023, thousands of Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of lethal attacks on Israeli civilians and some military targets. Hamas also launched extensive rocket attacks on the Israeli civilian population and industrial centers located along Israel's border with the Gaza Strip and across the State of Israel. These attacks resulted in thousands of deaths and injuries, and Hamas additionally kidnapped over 250 Israeli civilians and soldiers. Following the attack, Israel's security cabinet commenced a counter-offense military campaign against Hamas in Gaza. Since the onset of these events, hostilities have persisted across Israel, along Israel's northern border with Lebanon, primarily involving the Hezbollah terror organization, as well as other extremist groups in the region, including the Houthis in Yemen and various militia groups in Syria and Iraq. Israel has conducted multiple targeted strikes against these terror organizations.

In addition, since April 2024, Israel has experienced direct attacks from Iran, involving hundreds of drones and ballistic missiles launched towards mostly densely populated civilian towns across Israel and some military bases, threatening continued aggression while also exerting considerable influence over regional militia groups encouraging them to launch attacks against Israel. The Israeli defense systems, aided by international allies, successfully intercepted the majority of the ballistic missile attacks, minimizing physical damage and casualties. Additionally, since October 2023, the Houthis, a military organization based in Yemen, have launched a series of attacks on global shipping routes in the Red Sea, as well as direct attacks on various parts of Israel. Such incidents contribute to regional instability and could potentially escalate into broader conflicts with Iran and its proxies in the Middle East, affecting Israel's political and trade relations, especially with neighboring countries and global allies. The situation remains fluid, and the potential for further escalation exists. In October 2024, Israel initiated both air and ground operations against Hezbollah in Lebanon, culminating in a ceasefire agreement between Israel and Lebanon on November 27, 2024, the results of which remain uncertain. In response to ongoing Iranian aggression and support of proxy attacks against Israel, on June 12, 2025, Israel conducted a series of preemptive defensive air strikes in Iran targeting Iran's nuclear program and military commanders. On June 21, 2025, U.S. President Donald Trump announced that the United States had conducted air strikes against three nuclear sites within Iran. On October 9, 2025, a ceasefire had been reached. Israel, Hamas, the United States and other countries in the region agreed to a framework for a ceasefire in Gaza between Israel and Hamas.

On February 28, 2026, following the breakdown of diplomatic efforts and heightened regional tensions, the United States and Israel conducted a series of preemptive strikes targeting Iranian military infrastructure and strategic assets. Immediately thereafter, Iran launched extensive retaliatory ballistic missile and drone attacks against multiple locations across Israel, including central and southern population centers, critical infrastructure facilities and military installations. On March 2, 2026, Hezbollah resumed hostilities, ending the November 2024 ceasefire, by launching projectiles into northern Israel, prompting Israeli airstrikes in Lebanon targeting Hezbollah operatives and assets. Since the outbreak of these hostilities, Israel has implemented nationwide emergency measures, including restrictions on public gatherings and large-scale reserve duty call-ups affecting the civilian workforce.

In early April 2026, a two-week ceasefire between the United States and Iran was agreed. However, the ceasefire's durability remains uncertain. The United States has maintained a naval blockade of Iranian ports, and Iran has responded by intermittently restricting commercial vessel passage through the Strait of Hormuz, declaring that the waterway would remain effectively closed until the blockade is lifted. There can be no assurance that this ceasefire will hold or be extended, and hostilities between the United States, Israel and Iran could resume at any time.

On April 16, 2026, following direct talks between Israeli and Lebanese officials in Washington, D.C., a 10-day cessation of hostilities between Israel and Lebanon was announced, brokered by the United States. The parties have requested that the United States facilitate further direct negotiations with the objective of achieving a comprehensive agreement for lasting security and peace. Israeli forces remain stationed in southern Lebanon and Hezbollah has not accepted the terms as binding, stating that its fighters will remain deployed and will respond to any violations. The ceasefire remains fragile, with reports of continued military operations by both sides in southern Lebanon.

How long and how severe the current conflicts in Gaza, Northern Israel, Lebanon, Iran or the broader region become is unknown at this time and any continued clash among Israel, Hamas, Hezbollah, Iran or other countries or militant groups in the region may escalate in the future into a greater regional conflict.

While we have a few employees who are in active military service, the ongoing war, the escalation of Hezbollah's attacks on Northern Israel, and the direct offensives from Iran and its proxies have not, to date, materially impacted our business or operations. Furthermore, we do not expect any delays to any of our programs as a result of such conflicts. While research and some management are located in Israel, other core activities including clinical, regulatory and our supply chain are not. However, we cannot currently predict the intensity or duration of Israel's war against Hamas, Hezbollah and Iran, and its proxies, nor can we predict how such conflicts will ultimately affect our business and operations or Israel's economy in general.

Additionally, political uprisings, social unrest and violence in various other countries in the Middle East, including Israel's neighboring countries Syria, Lebanon, Egypt and Jordan, are affecting the political stability of those countries. This instability may lead to deterioration of the political relationships that exist between Israel and certain countries and have raised concerns regarding security in the region and the potential for a broader regional armed conflict. Since February 2026, there has been a significant escalation in hostilities involving the U.S., Israel, Iran and several other countries in the middle east, including direct military exchanges. These developments have increased regional instability and may further escalate into more severe and prolonged hostilities, which could affect Israel and us.

Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could have a material adverse effect on our business. Although such hostilities did not have a material adverse impact on our business in the past, we cannot guarantee that hostilities will not be renewed and have such an effect in the future. These or other Israeli political or economic factors could harm our operations and product development. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could adversely affect our operations. We could experience disruptions if acts associated with such conflicts result in any serious damage to our facilities.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

During the quarter ended March 31, 2026, none of our officers or directors adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any "non-Rule 10b5-1 trading arrangement", as defined in Item 408 of Regulation S-K.

ITEM 6. EXHIBITS

Exhibit No.	Description of Exhibits
<u>31.1</u>	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>31.2</u>	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>32.1**</u>	<u>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
<u>32.2**</u>	<u>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

** Furnished herewith.

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, hereunto duly authorized.

ENTERA BIO LTD.

Date: May 8, 2026

/s/ Miranda Toledano

Miranda Toledano
Chief Executive Officer
(Principal Executive Officer)

Date: May 8, 2026

/s/ Dana Yaacov-Garbeli

Dana Yaacov-Garbeli
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Miranda Toledano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2026 of Entera Bio Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2026

/s/ Miranda Toledano
Miranda Toledano
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Dana Yaacov-Garbeli, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2026 of Entera Bio Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2026

/s/ Dana Yaacov Garbeli
Dana Yaacov-Garbeli
Chief Financial Officer
(Principal Financial and Accounting)

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES OXLEY ACT OF 2002

I, Miranda Toledano, Chief Executive Officer of Entera Bio Ltd. (the “Company”), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350 that, to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2026 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 8, 2026

/s/ Miranda Toledano
Miranda Toledano
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES OXLEY ACT OF 2002

I, Dana Yaacov-Garbeli, Chief Financial Officer of Entera Bio Ltd. (the “Company”), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350 that, to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2026 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 8, 2026

/s/ Dana Yaacov Garbeli
Dana Yaacov-Garbeli
Chief Financial Officer
(Principal Financial and Accounting)
