

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

FORM 10-Q

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

For the quarterly period ended June 30, 2025

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 <hr/> (State or other jurisdiction of incorporation or organization)	Not applicable <hr/> (I.R.S. Employer Identification No.)
Kiryat Hadassah Minrav Building – Fifth Floor Jerusalem, Israel <hr/> (Address of principal executive offices)	9112002 <hr/> (Zip Code)

Registrant's telephone number, including area code: 972-2-532-7151

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 August 4, 2025, the registrant had 45,663,381 ordinary shares, par value NIS 0.0000769 per share ("Ordinary Shares") outstanding.

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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, 2024 (the “2024 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 or other oral peptides for hypoparathyroidism 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 drug delivery technology (“N-Tab™”) 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, 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 duration and intensity of the ongoing Israel-Hamas War, and escalation of Hezbollah's conflict since October 2023 as well as the developing conflict with Iran and its proxies in the Middle East, such as the Houthis in Yemen and militias in Iraq and Syria, and their impact on our operations and workforce.

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 2024 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 JUNE 30, 2025

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

Assets	June 30, 2025	December 31, 2024
CURRENT ASSETS:		
Cash and cash equivalents	10,858	8,660
Accounts receivable	-	126
Restricted cash	8,015	-
Other current assets	438	186
TOTAL CURRENT ASSETS	19,311	8,972
NON-CURRENT ASSETS:		
Property and equipment, net	79	57
Operating lease right-of-use assets	190	275
Restricted deposit	81	80
Funds in respect of employee rights upon retirement	6	6
TOTAL NON-CURRENT ASSETS	356	418
TOTAL ASSETS	19,667	9,390
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	383	132
Accrued expenses and other payables	1,267	874
Current maturities of operating lease	194	170
TOTAL CURRENT LIABILITIES	1,844	1,176
NON-CURRENT LIABILITIES:		
Operating lease liabilities	9	102
Other long-term liability	524	-
Liability for employee rights upon retirement	34	32
TOTAL NON-CURRENT LIABILITIES	567	134
TOTAL LIABILITIES	2,411	1,310
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.0000769 par value: Authorized - as of June 30, 2025 and December 31, 2024, 140,010,000 shares; issued and outstanding as of June 30, 2025 and December 31, 2024, 45,452,167 and 38,837,220 shares, respectively	1	1
Additional paid-in capital	136,364	121,965
Accumulated other comprehensive income	41	41
Accumulated deficit	(119,150)	(113,927)
TOTAL SHAREHOLDERS' EQUITY	17,256	8,080
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	19,667	9,390

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)

	Six Months Ended June 30,		Three Months Ended June 30,	
	2025	2024	2025	2024
REVENUES	42	57	-	57
COST OF REVENUES	42	48	-	48
GROSS PROFIT	-	9	-	9
OPERATING EXPENSES:				
Research and development, net	2,643	1,821	1,520	1,086
General and administrative	2,588	2,415	1,148	1,088
TOTAL OPERATING EXPENSES	5,231	4,236	2,668	2,174
OPERATING LOSS	5,231	4,227	2,668	2,165
FINANCIAL INCOME, NET	(8)	(65)	(12)	(20)
NET LOSS	5,223	4,162	2,656	2,145
LOSS PER SHARE BASIC AND DILUTED	0.12	0.11	0.06	0.06
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	45,146,415	36,913,725	46,836,700	37,090,160

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				
BALANCE AT JANUARY 1, 2025	38,837,220	1	121,965	41	(113,927)	8,080
Net loss	-	-	-	-	(5,223)	(5,223)
Exercise of warrants to Ordinary Shares	149,700	*	150	-	-	150
Exercise of options to Ordinary Shares	23,952	*	24	-	-	24
Issuance of Ordinary Shares under collaboration agreement, net	3,685,226	*	7,115	-	-	7,115
Issuance of Ordinary Shares under ATM program, net of issuance costs	2,700,000	*	5,997	-	-	5,997
Vested restricted share units	56,069	*	-	-	-	-
Share-based compensation	-	-	1,113	-	-	1,113
BALANCE AT JUNE 30, 2025	<u>45,452,167</u>	<u>1</u>	<u>136,364</u>	<u>41</u>	<u>(119,150)</u>	<u>17,256</u>
BALANCE AT APRIL 1, 2025	45,420,677	1	135,831	41	(116,494)	19,379
Net loss	-	-	-	-	(2,656)	(2,656)
Exercise of options to Ordinary Shares	23,952	*	24	-	-	24
Vested restricted share units	7,538	*	-	-	-	-
Share-based compensation	-	-	509	-	-	509
BALANCE AT JUNE 30, 2025	<u>45,452,167</u>	<u>1</u>	<u>136,364</u>	<u>41</u>	<u>(119,150)</u>	<u>17,256</u>
BALANCE AT JANUARY 1, 2024	35,476,341	1	114,730	41	(104,386)	10,386
Net loss	-	-	-	-	(4,162)	(4,162)
Exercise of warrants to Ordinary Shares	89,820	*	90	-	-	90
Exercise of options to Ordinary Shares	447,292	*	555	-	-	555
Issuance of Ordinary Shares under ATM program, net of issuance costs	236,126	*	601	-	-	601
Vested restricted share units	65,000	*	-	-	-	-
Share-based compensation	-	-	1,062	-	-	1,062
BALANCE AT JUNE 30, 2024	<u>36,314,579</u>	<u>1</u>	<u>117,038</u>	<u>41</u>	<u>(108,548)</u>	<u>8,532</u>
BALANCE AT APRIL 1, 2024	35,526,281	1	115,224	41	(106,403)	8,863
Net loss	-	-	-	-	(2,145)	(2,145)
Exercise of warrants to Ordinary Shares	59,880	*	60	-	-	60
Exercise of options to Ordinary Shares	447,292	*	555	-	-	555
Issuance of Ordinary Shares under the ATM program, net of issuance costs	236,126	*	601	-	-	601
Vested restricted share units	45,000	*	-	-	-	-
Share-based compensation	-	-	598	-	-	598
BALANCE AT JUNE 30, 2024	<u>36,314,579</u>	<u>1</u>	<u>117,038</u>	<u>41</u>	<u>(108,548)</u>	<u>8,532</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)

	Six months ended June 30,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	(5,223)	(4,162)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	15	24
Share-based compensation	1,113	1,062
Finance expenses (income), net	18	(14)
Changes in operating asset and liabilities:		
Increase in other current assets	(252)	(232)
Decrease (increase) in accounts receivable	126	(57)
Increase (decrease) in accounts payable	251	(14)
Increase in accrued expenses and other payables and other long-term liability	917	196
Net cash used in operating activities	<u>(3,035)</u>	<u>(3,197)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(37)	-
Net cash used in investing activities	<u>(37)</u>	<u>-</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of Ordinary Shares under ATM program	6,183	620
Issuance cost	(261)	(19)
Issuance of Ordinary Shares, under collaboration agreement	7,190	-
Exercise of warrants and options to Ordinary Shares	174	645
Net cash provided by financing activities	<u>13,286</u>	<u>1,246</u>
INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH AND DEPOSITS	10,214	(1,951)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AND DEPOSITS AT BEGINNING OF THE PERIOD	8,740	11,085
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AND DEPOSITS AT END OF THE PERIOD	<u>18,954</u>	<u>9,134</u>
Reconciliation in amounts on consolidated balance sheets:		
Cash and cash equivalents	10,858	9,056
Restricted cash and deposits	8,096	78
Total cash and cash equivalents and restricted cash and deposit	<u>18,954</u>	<u>9,134</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOW TRANSACTIONS:		
Interest received	57	66
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Operating lease right of use assets obtained in exchange for new operating lease liabilities	-	33

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)
(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 low bone mineral density ("BMD") and high-risk osteoporosis with no prior fracture. The Company is preparing to initiate a Phase 3 registrational study for EB613 pursuant to the FDA's qualification of a quantitative BMD endpoint.

The Company's product candidate, EB612, is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for hypoparathyroidism. Additionally, the Company intends to license its N-Tab™ technology to biopharmaceutical companies for use with their proprietary compounds.

In addition, OPK-88006 is being developed pursuant to a collaboration and license agreement between OPKO Health, Inc. ("OPKO") and the Company pursuant to which the companies are advancing a proprietary novel dual agonist GLP-1/glucagon peptide as a once-daily tablet treatment and as a weekly subcutaneous injection for patients with obesity, metabolic and fibrotic disorders. The oral program combines OPKO's proprietary long-acting oxyntomodulin ("OXM") analog (OPK-88006) and Entera's proprietary N-Tab™ technology.

- 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, since its inception in 2009, the Company has incurred an accumulated deficit in the amount of \$119.2 million as of June 30, 2025 and negative cash flows from operating activities. For the three months ended June 30, 2025 and 2024, our operating losses were \$2.7 million and \$2.2 million, respectively. For the six months ended June 30, 2025 and 2024, our operating losses were \$5.2 million and \$4.2 million, respectively. The Company's management is of the opinion that its available funds as of June 30, 2025 will be sufficient to support the Company's operations under its current plans through the middle of the third quarter of 2026. This assumes the use of the Company's capital to fund its ongoing operations, including regulatory and intellectual property expenses, optimization related to the preparation of the EB613 phase 3 program in osteoporosis, ongoing N-Tab™ research and development, the completion of an additional Phase 1 PK study related to the Company's new generation of EB613 and completion of SAD and MAD Phase 1 proposed studies of oral OXM (GLP1/Glucagon tablet) in collaboration with OPKO. The Company's current capital resources do not include the capital required to 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.

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

NOTE 1 - DESCRIPTION OF BUSINESS (Cont.)

- 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 with Iran. As of the date of these condensed consolidated financial statements, the war with Hamas is ongoing and continues to evolve. 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 June 24, 2025, U.S. President Donald Trump announced that a ceasefire had been reached and, since such date, there has been no further escalation of hostilities between Israel and Iran; however, there is no assurance that the ceasefire will be upheld and military activity and or escalate. The Company's research personnel and some 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. During the six months ended June 30, 2025 and as of December 31, 2024, the impact of such events on the Company's results of operations and financial condition was immaterial.

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 June 30, 2025, the consolidated results of operations and statements of changes in shareholders' equity for the three and six-month periods ended June 30, 2025 and 2024, and cash flows for the six-month periods ended June 30, 2025 and 2024.

The consolidated results of operations for the three and six months ended June 30, 2025 are not necessarily indicative of the results to be expected for the year ending December 31, 2025.

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, 2024, as filed with the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 28, 2025.

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

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 and pre-funded warrants 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 restricted share units (“RSUs”), which are included under the treasury stock method when dilutive. The calculation of diluted loss per share does not include options, warrants and RSUs exercisable into 16,562,467 shares and into 16,785,585 shares for the six months ended June 30, 2025 and 2024, respectively, and 16,859,160 shares and 17,068,031 shares for the three months ended June 30, 2025 and 2024, 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 December 2023, the FASB issued ASU 2023-09 “Income Taxes (Topic 740): Improvements to Income Tax Disclosures”. This guidance is intended to enhance the transparency and decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the U.S. and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 and may be applied either retrospectively or prospectively, at the Company’s discretion. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

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 condensed consolidated financial statements disclosures.

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

NOTE 3 - EQUITY AND SHARE-BASED COMPENSATION

Changes in Share Capital:

- a. On September 2, 2022, the Company entered into a sales agreement with Leerink Partners LLC (formerly known as SVB Securities LLC), as sales agent, to implement an ATM program under which the Company had originally been able from time to time offer and sell up to 5,000,000 ordinary shares (the “Leerink ATM Program”).

On January 3, 2025, the Company issued an aggregate of 2,700,000 ordinary shares pursuant to the Leerink ATM Program for net proceeds of \$5,997 at a weighted average price of \$2.29 per ordinary share. On January 10, 2025, the Company filed a supplement to the prospectus supplement relating to the Leerink ATM Program, which provides the Company the ability to sell up to an additional 30,000,000 ordinary shares under the Leerink ATM Program.

- b. In January 2025, 149,700 warrants were exercised for an aggregate of 149,700 ordinary shares for a total consideration of \$150.
- c. On January 15, 2025, the Company issued 40,993 ordinary shares to five non-executive members of the board of directors in lieu cash board fees for the fourth quarter of 2024, which was approved by the Company’s shareholders at a meeting of the Company’s shareholders held on July 31, 2024.
- d. In March 2025, in connection with the execution of a collaboration and license agreement (the “2025 Collaboration Agreement”) with OPKO, the Company issued and sold to OPKO an aggregate of 3,685,226 ordinary shares for a total 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 the 2025 Collaboration Agreement. For additional information, see Note 5b.
- e. In April 2025, the Chairman of the board of directors exercised warrants for an aggregate of 23,952 ordinary shares for a total consideration of \$24.

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

NOTE 3 - EQUITY AND SHARE-BASED COMPENSATION (Cont.)

Share-based Compensation:

- a. On January 15, 2025, an aggregate of 142,545 options to purchase ordinary shares were granted to five non-executive board members with an exercise price of \$2.28 per share. The options will vest over one year in four equal quarterly installments starting on January 1, 2025. 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 \$226.
- b. On April 28, 2025, the board of directors approved the following options grants:
 - (i) options to purchase an aggregate of 954,000 ordinary shares were granted to employees, executive officers and a service provider with an exercise price of \$2.28 per share, which was the closing share price on the grant date. The fair value of the options at the grant date was \$1,545; and
 - (ii) options to purchase an aggregate of 830,000 ordinary shares were granted to the Company's Chief Executive Officer and other executive officers with an exercise price of \$2.28 per share which was the closing share price on grant date. This grant was subject to shareholder approval, which was obtained at a meeting of the Company's shareholders held on July 16, 2025.

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 following the first anniversary of the grant date.

In addition, the board of directors approved the grant of 259,650 RSUs to executive officers, of which grant 233,334 RSUs were subject to shareholder approval, which was obtained at a meeting of the Company's shareholders held on July 16, 2025. The RSUs vest in four equal quarterly installments over a one-year period that started on April 28, 2025. The fair value of each option granted was estimated at the date of grant using the Black-Scholes option-pricing model, using the following assumptions:

	Six months ended June 30, 2025
Exercise price	\$2.28
Dividend yield	-
Expected volatility	81.2%-82.2%
Risk-free interest rate	3.9%-4.45%
Expected life - in years	5.3-5.87

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

NOTE 5 - COLLABORATION AND RESEARCH AGREEMENTS (Cont.)

Under the terms of the 2025 Collaboration Agreement, the Company and OPKO will retain 40% and 60%, respectively, of all proceeds deriving from the Program, and will be responsible for 40% and 60% of the Program's development costs, respectively. Following the completion of the Phase 1 stage, the Company may continue to fund its 40% share of the Program to maintain its right to proceeds or to opt-out (the "Opt-Out"). If the Company exercises the Opt-Out, then the Company 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, the Company issued and sold to OPKO an aggregate of 3,685,226 ordinary shares for a total 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 the 2025 Collaboration Agreement.

OPKO has agreed to a customary lockup with respect to such shares, and may not sell or otherwise transfer them for a period of 12 months following the date of the 2025 Collaboration Agreement, and OPKO has additionally agreed to a customary "standstill" provision, pursuant to which, for a 24-month period following the date of the 2025 Collaboration Agreement, OPKO may not acquire additional equity in the Company or otherwise take certain other actions, in each case without the Company's consent.

The Company has agreed to use the proceeds from the sale of the foregoing ordinary shares solely to fund its development cost obligations under the 2025 Collaboration Agreement, and has entered into an escrow arrangement, together with OPKO and an escrow agent, into which such proceeds in an amount of \$8,000 have been deposited. Such proceeds are presented under restricted cash in the condensed consolidated balance sheet, and will be disbursed to fund such development costs. If the 2025 Collaboration Agreement expires or is terminated for any reason, any funds remaining in such escrow will be disbursed to the Company.

The Company determined that the agreement is a collaboration agreement under the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. The consideration received was allocated to the collaboration component and the equity component.

The Company recognized as equity the fair value of the ordinary shares issued to OPKO net of issuance costs (issuance costs of \$75) based on the fair value of the Company's ordinary shares, which was the Nasdaq closing share price as of the agreement date. The remaining consideration was allocated to the agreement and presented under current other payables (an amount of 295\$) and Other long-term liabilities (an amount of 515\$) in the balance sheet and will be recognized as the program is performed.

For the three and the six months ended June 30, 2025, the Company recognized net expenses of \$120 relating to this agreement.

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)
(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.
- b. Segment information:

	Six Months Ended June 30,		Three Months Ended June 30,	
	2025	2024	2025	2024
Revenues	\$ 42	\$ 57	-	\$ 57
Less:				
<i>Research and development, net:</i>				
Sub-contractors and consulting expense (EB613)	\$ 972	\$ 152	\$ 599	\$ 30
Net expenses related to OPKO Collaboration Agreement	120	-	120	-
Payroll and related expenses	766	735	372	356
Share-based compensation	470	414	294	328
Rent and related expenses	226	214	103	134
Other development expenses*	89	306	32	235
Other segment expenses**	2,622	2,398	1,136	1,119
Segment net loss	<u>\$ 5,223</u>	<u>\$ 4,162</u>	<u>\$ 2,656</u>	<u>\$ 2,145</u>

* Other development expenses include materials and productions and others.

** Other segment expenses include payroll and related expenses, share-based compensation, legal and audit and related fees and others.

NOTE 7 - SUBSEQUENT EVENTS

In July 2025, 179,640 warrants were exercised for an aggregate of 179,640 ordinary shares for a total consideration of \$180.

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 2024 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 2024 Annual Report.

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

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 five differentiated, first-in-class oral peptide programs targeting PTH(1-34), GLP-1 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 therapeutic proteins is challenging due to the enzymatic degradation within the gastrointestinal tract and poor absorption into the blood stream due to the proteins' polarity and molecular weight. We leverage our N-Tab™ platform which is designed to simultaneously stabilize the peptide in the gastrointestinal tract and promote its 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 post-menopausal women with low bone mineral density ("BMD") and high-risk 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 consequently limit the progression of the disease, and its associated 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 (BMD). In April 2024, the phase 2 data was published in the Journal of Bone and Mineral Research (JBMR).

Following Type C and Type D meetings with the FDA, we announced in 2023 the FDA's concurrence that a 2-year, placebo-controlled phase 3 (registrational) study with Total Hip BMD as primary endpoint could support a new drug application ("NDA") for EB613; however, the BMD endpoint remained unqualified as a surrogate endpoint by the FDA. In November 2023, the American Society for Bone and Mineral Research (ASBMR) announced that the Study to Advance BMD as a Regulatory Endpoint (SABRE) project team had submitted its full qualification plan to the FDA for the use of BMD as a surrogate endpoint for fractures in future trials of new anti-osteoporosis drugs. In March 2024, the ASBMR announced that the FDA had communicated to the SABRE project team that a ruling to qualify the treatment-related change in BMD as a surrogate endpoint for fractures in future trials of new anti-osteoporosis drugs would be provided within 10 months. The EB613 osteoporosis clinical program has been developed under the auspices of this new approach to osteoporosis drug development.

On July 28, 2025, we announced that in a written response to a Type A meeting request, the FDA agreed with our proposal that the NDA filing for EB613 (oral PTH (1-34), teriparatide) would be supported by a single multinational, randomized, double-blind, placebo-controlled, 24-month 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.

While the FDA's anticipated qualification of SABRE is still expected in 2025, the FDA's concurrence with our proposal allows us to advance our clinical program without having to wait for such qualification.

EB612 Program

Our product candidate, EB612, is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for patients with hypoparathyroidism. With respect to our EB612 program, we are currently testing new generations of our N-Tab™ Technology with the naked PTH(1-34) peptide to assess the effectiveness of once or twice a day dosing regimens, as well as collaborating with a third party on another peptide in this field. In June 2024, Phase 1 clinical data for EB612 was presented at the Endocrine Society ENDO 2024 Annual Meeting.

To date, Entera's proprietary PTH tablets have been safely administered to a total of 102 healthy subjects in Phase 1 studies and 153 patients in Phase 2 studies in osteoporosis and hypoparathyroidism, two diseases that remain underserved with the current standard of care and which disproportionately affect women. We believe these product candidates, if approved, hold the potential to become standards of care for patients with osteoporosis and hypoparathyroidism.

Our ability to deliver our oral PTH(1-34) peptide in a simple mini tablet format with reproducible, dose dependent pharmacokinetics and rapid biological responses across gender, age, and health status was highlighted as part of two poster sessions at the ASBMR 2023 Annual Meeting. We believe our work to date has built the foundation for our oral PTH (1-34) tablets to potentially treat diverse patient populations, including younger men and women athletes at risk of stress fractures.

Oral GLP-2 and Oral GLP-1/Glucagon Programs in Collaboration with OPKO Biologics

In September 2023, we entered into collaboration agreement with OPKO Biologics, Inc., a subsidiary of OPKO Health, Inc. (collectively, "OPKO"). Under the terms of this agreement, OPKO has agreed to supply its proprietary long-acting GLP-2 peptide and certain oxyntomodulin (OXM) analogs for the development of oral tablet candidates using our proprietary N-Tab™ technology. 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.

In March 2024, we announced positive in vivo pharmacokinetic (PK) results from our collaborative research, combining a proprietary long acting GLP-2 agonist developed by OPKO with Entera's proprietary N-Tab™ technology. The program is focused on developing the first and only GLP-2 peptide tablet alternative for patients suffering from short bowel syndrome and additional disorders involving mucosal inflammation and nutrient malabsorption.

OXM is a naturally occurring peptide hormone found in the colon, with glucagon-like-peptide 1 (GLP-1) and glucagon dual agonist activity that suppresses appetite and induces weight loss. OPKO has developed several proprietary, modified OXM analogs as potential candidates for treating obesity, including an injectable pegylated peptide which demonstrated safety in over 430 subjects and significant reductions in weight loss and decreased plasma triglyceride levels in over 110 subjects in completed phase 2 studies.

In September 2024, we jointly announced with OPKO topline pharmacokinetic/pharmacodynamic (PK/PD) results for the OXM program. The program is focused on developing the first oral dual agonist GLP-1/Glucagon peptide as a potential once-daily tablet treatment for patients with obesity and metabolic disorders using the N-Tab™ platform. Oral OXM exhibited significant systemic exposure across two in vivo models, a favorable PK profile and bioavailability. The high plasma concentrations with prolonged systemic exposure were consistent with the reported half-life for semaglutide (Rybelsus®), the only approved oral GLP-1 analog. Oral OXM showed a statistically significant reduction in plasma glucose levels compared with placebo.

Additionally, in March 2025, we and OPKO entered into the 2025 Collaboration Agreement (as defined and further described below under “Patent Transfer, Licensing Agreements and Grant Funding—Collaboration and License Agreement with OPKO”) 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.

Given the scarcity of oral peptide treatments and potential safety challenges attributed to small molecule approaches, we believe oral OXM may address a significant number of patients suffering from chronic metabolic diseases. We plan to file an Investigational New Drug (IND) application with the FDA later this year.

Patent Transfer, Licensing Agreements and Grant Funding

Collaboration and License Agreement with OPKO

On March 16, 2025, we entered into a collaboration and license agreement (the “2025 Collaboration Agreement”) with OPKO 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”). The Program combines OPKO’s proprietary long-acting oxyntomodulin (OXM, dual targeted GLP-1/Glucagon agonist, OPK-88006) analog and Entera’s proprietary N-Tab™ technology.

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 Program, and will be responsible for 40% and 60% of the Program’s development costs, respectively. Following the completion of the Phase I 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, 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. OPKO has agreed to a customary lockup with respect to such shares, and may not sell or otherwise transfer them for a period of 12 months following the date of the 2025 Collaboration Agreement, and OPKO has additionally agreed to a customary “standstill” provision, pursuant to which, for a 24-month period following the date of the 2025 Collaboration Agreement, OPKO may not acquire additional equity in us or otherwise take certain other actions, in each case without our consent.

We have agreed to use the proceeds from the sale of the foregoing Ordinary Shares solely to fund our development cost obligations under the 2025 Collaboration Agreement, and we have entered into an escrow arrangement, together with OPKO and an escrow agent, into which such proceeds have been deposited, and from which such proceeds will be disbursed to fund such development costs. If the 2025 Collaboration Agreement expires or is terminated for any reason, any funds remaining in such escrow will be disbursed to us.

Oramed Patent Transfer Agreement

In 2011, we entered into the Patent Transfer Agreement with Oramed, pursuant to which Oramed assigned to us all of its rights, title and interest in the patent rights that 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 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.

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 June 30, 2025, 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 Potentially Affecting Our Business

On July 28, 2025, we announced that in a written response to a Type A meeting request, the FDA agreed with our proposal that the NDA filing for EB613 (oral PTH (1-34), teriparatide) would be supported by a single multinational, randomized, double-blind, placebo-controlled, 24-month 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.

While the FDA’s anticipated qualification of SABRE is still expected in 2025, the FDA’s concurrence with our proposal allows us to advance our clinical program without having to wait for such qualification.

Israel's multi-front war with terrorist groups in neighboring countries, such as Hezbollah in Lebanon and Hamas in the Gaza Strip, and state actors such as Iran, and Israel's responses thereto.

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 continuous rocket strikes across Israel, including with Hezbollah in Lebanon, the Houthi movement which controls parts of Yemen, and with Iran. As of the date of this Quarterly Report, the war with Hamas is ongoing and continues to evolve. 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 June 24, 2025, U.S. President Donald Trump announced that a ceasefire had been reached and, since such date, there has been no further escalation of hostilities between Israel and Iran; however, there is no assurance that the ceasefire will be upheld, and military activity and hostilities may continue or escalate. The Company's research personnel and some management personnel are located in Israel; however, other core activities including clinical, regulatory and supply chain are outside of Israel.

Currently, such activities in Israel remain largely unaffected by the foregoing events. During the six months ended June 30, 2025 and as of December 31, 2024, the impact of such events on the Company's results of operations and financial condition was immaterial.

Financial Overview

From our inception through June 30, 2025, we have raised a total of \$111.1 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 June 30, 2025 and 2024, our operating losses were \$2.7 million and \$2.2 million, respectively. For the six months ended June 30, 2025 and 2024, our operating losses were \$5.2 million and \$4.2 million, respectively, and we expect to continue to incur significant expenses and losses for the foreseeable future.

As of June 30, 2025, we had an accumulated deficit of \$119.2 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 2024 Annual Report.

As of June 30, 2025, we had cash and cash equivalents and restricted cash of \$18.9 million, of which \$8.0 million has been designated to fund our obligations under the 2025 Collaboration Agreement. Given our current cash position and plans, we believe that our existing cash resources will be sufficient to meet our projected operating requirements through the middle of the third quarter of 2026, which include the capital required to fund our ongoing operations, including regulatory and intellectual property expenses, optimization related to the preparation of the EB613 phase 3 program in osteoporosis, ongoing N-TabTM research and development, the completion of an additional Phase 1 PK study related to the Company's new generation of EB613 and completion of SAD and MAD Phase 1 proposed studies of oral OXM (GLP1/Glucagon tablet) in collaboration with OPKO. Our ability to commence the Phase 3 program of EB613 in osteoporosis will require additional funding, which may not be available on reasonable terms, or at all. Any delay or our inability to secure such funding will delay or prevent the commencement of this study.

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 and strategic collaborations. Additional financing may not be available when we need it or may not be available on terms that are favorable to us.

As of June 30, 2025, we had a total of 21 employees, of whom 19 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 our product candidates 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™ technology 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 support multiple product candidate research and development 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 the primary focus of our business. 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 enrollment of patients in clinical trials. Research and development expenses for the three and six months ended June 30, 2025 were primarily for the development of EB613 and our collaboration with OPKO related to OXM and for the three and six months ended June 30, 2024 were primarily for the development of EB613. 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, OXM 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 enrollment 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 and six months ended June 30, 2025 and June 30, 2024 are summarized as follows:

	Six Months Ended June 30,		Three Months Ended June 30,	
	(unaudited)		(unaudited)	
	2025	2024	2025	2024
	(In thousands)		(In thousands)	
External Expenses related to EB613	\$ 972	\$ 152	\$ 599	\$ 30
Internal and External expenses related to OXM collaboration with OPKO	120	-	120	-
Internal and External expenses related to other development program:				
Payroll and related expenses	766	735	372	356
Share-based compensation	470	414	294	328
Rent and related expenses	226	214	103	134
Other development expenses	89	306	32	235
Research and development expenses, net	<u>\$ 2,643</u>	<u>\$ 1,821</u>	<u>\$ 1,520</u>	<u>\$ 1,086</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 June 30, 2025, we had carryforward tax losses of \$87.7 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 June 30, 2025, Entera Bio, Inc. had tax loss carryforwards of \$174 thousand.

Results of Operations

Comparison of Three Months Ended June 30, 2025 and 2024

	Three Months Ended		Increase (Decrease)	
	June 30,		\$	%
	2025	2024		
	(In thousands, except for percentage information)			
Revenues	\$ -	\$ 57	\$ (57)	(100)%
Cost of Revenues	\$ -	\$ 48	\$ (48)	(100)%
Gross Profit	\$ -	\$ 9	\$ (9)	(100)%
Operating expenses:				
Research and development expenses	\$ 1,520	\$ 1,086	\$ 434	40%
General and administrative expenses	\$ 1,148	\$ 1,088	\$ 60	6%
Operating loss	\$ 2,668	\$ 2,165	\$ 503	23%
Financial income, net	\$ (12)	\$ (20)	\$ 8	(40)%
Net loss	\$ 2,656	\$ 2,145	\$ 511	24%

Revenues

Revenues for the three months ended June 30, 2024 were \$57 thousand, which were attributable to research services we provided pursuant to a material transfer and research project agreement entered into in April 2024 (the “research services agreement”). The Company completed the first stage of its obligations under the research services agreement in the first quarter of 2025. As a result, we did not recognize any revenue for the three months ended June 30, 2025.

Cost of Revenues

Cost of revenues for the three months ended June 30, 2025 was zero, as compared to \$48 thousand for the three months ended June 30, 2024, which were attributable to research services we provided pursuant to the research services agreement. The Company completed the first stage of its obligations under the research services agreement in the first quarter of 2025, resulting in no revenue recognized for the three months ended June 30, 2025.

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2025 were \$1.5 million, as compared to \$1.1 million for the three months ended June 30, 2024. The increase of \$0.4 million was primarily due to an increase of \$0.3 million in other consulting fees, including regulatory required in connection with filing of a type A meeting and ongoing optimization processes related to the preparation of the EB613 phase 3 program and \$0.1 million in connection with our internal programs and collaboration programs.

General and Administrative Expenses

General and administrative expenses for both the three months ended June 30, 2025 and 2024 were \$1.1 million. There were no material changes for the three months ended June 30, 2025 as compared to the same period in the previous year.

Financial Income, Net

Financial income, net for the three months ended June 30, 2025 was \$12 thousand as compared to \$20 thousand for the three months ended June 30, 2024. Our financial income mainly included income from bank deposits and exchange rate differences of certain currencies against our functional currency, which is the U.S. Dollar.

Comparison of Six Months Ended June 30, 2025 and 2024

	Six Months Ended June 30,		Increase (Decrease)	
	2025	2024	\$	%
	(In thousands, except for percentage information)			
Revenues	\$ 42	\$ 57	\$ (15)	(26)%
Cost of Revenues	\$ 42	\$ 48	\$ (6)	(12)%
Gross Profit	\$ -	\$ 9	\$ (9)	(100)%
Operating expenses:				
Research and development expenses	\$ 2,643	\$ 1,821	\$ 822	45%
General and administrative expenses	\$ 2,588	\$ 2,415	\$ 173	7%
Operating loss	\$ 5,231	\$ 4,227	\$ 1,004	24%
Financial income, net	\$ (8)	\$ (65)	\$ 57	(88)%
Net loss	\$ 5,223	\$ 4,162	\$ 1,061	25%

Revenues

Revenues for the six months ended June 30, 2025 and 2024 were \$42 thousand and \$57 thousand, respectively, which were attributable to research services we provided pursuant to the research services agreement. The Company completed the first stage of its obligations under the research services agreement in the first quarter of 2025.

Cost of Revenues

Cost of revenues for the six months ended June 30, 2025 and 2024 was \$42 thousand and \$48 thousand, respectively, which was attributable to research services we provided pursuant to the research services agreement. The Company completed the first stage of its obligations under the research services agreement in the first quarter of 2025.

Research and Development Expenses

Research and development expenses for six months ended June 30, 2025 were \$2.6 million as compared to \$1.8 million for the six months ended June 30, 2024. The increase of \$0.8 million was primarily due to an increase of \$0.6 million in other consulting fees, including regulatory required in connection with filing of a type A meeting and ongoing optimization processes related to the preparation of the EB613 phase 3 program and \$0.2 million in connection with our internal programs and collaboration programs.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2025 were \$2.6 million as compared to \$2.4 million for the six months ended June 30, 2024. The increase was primarily due to an increase of \$0.2 million in legal expenses related to the OPKO collaboration agreement and other potential strategic agreements.

Financial Income, Net

Financial income, net for the six months ended June 30, 2025 and 2024 was \$8 thousand and \$65 thousand, respectively. Our financial income was composed mainly of 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, negative cash flows from operating activities and lack of liquidity. For the three months ended June 30, 2025 and 2024, our operating losses were \$2.7 million and \$2.2 million, respectively. For the six months ended June 30, 2025 and 2024, our operating losses were \$5.2 million and \$4.2 million, respectively. As of June 30, 2025, we had an accumulated deficit of \$119.2 million. We expect to continue to incur significant expenses and losses for the next several years as we advance our product candidates through development and provide administrative support for our operations. These factors raise substantial doubt about our ability to continue as a going concern. Given our current plans, we believe that our existing cash resources will be sufficient to meet our projected operating requirements through the middle of the third quarter of 2026 without additional funding, excluding the initiation of Phase 3 program of EB613 in osteoporosis.

From our inception through June 30, 2025, we have raised a total of \$111.1 million, including \$36.3 million through at-the-market-offering (“ATM”) programs, an aggregate of \$28.9 million in private placements since our IPO, \$11.2 million in our IPO in 2018 and \$34.7 million in aggregate funding from a combination of IIA grants, exercise of options and warrants and private placements of Ordinary Shares, preferred shares and debt prior to our IPO.

As of June 30, 2025, we had cash and cash equivalents and restricted cash of \$18.9 million, of which \$8.0 million has been designated to fund our obligations under the 2025 Collaboration Agreement. Our primary uses of cash have been to fund research and clinical development, general and administrative expenses and working capital requirements, 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 under our currently effective Registration Statement on Form S-3 and a related prospectus supplement forming a part thereof. The sales agent is entitled to a fixed commission of 3% of the aggregate gross proceeds as well as and reimbursement of expenses. In January 2025, we sold an additional 2,700,000 Ordinary Shares at \$2.29 per share to Point 72 Asset Management, L.P. for aggregate proceeds of \$6.0 million, net of issuance costs. As of June 30, 2025, we had sold 4,940,156 shares under the Leerink ATM Program for aggregate proceeds of \$9.8 million, net of issuance costs. In order to refresh the Leerink ATM program, in January 2025, we filed a supplement to the prospectus supplement, which provides us the ability, but not the obligation, to sell up to an additional 30,000,000 Ordinary Shares under the Leerink ATM Program.

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. The proceeds received are not reflected in our cash balance as of December 31, 2024, as we have escrowed such proceeds and agreed to use them solely to fund our development cost obligations under the 2025 Collaboration Agreement.

Funding Requirements

Given our current plans, we believe that our existing cash resources will be sufficient to support the Company's operations through the middle of the third quarter of 2026. This assumes the use of the Company's capital to fund our ongoing operations, including regulatory and intellectual property expenses, optimization related to the preparation of the EB613 phase 3 program in osteoporosis, ongoing N-TabTM research and development, the completion of an additional Phase 1 PK study related to the Company's new generation of EB613 and completion of SAD and MAD Phase 1 proposed studies of oral OXM (GLP1/Glucagon tablet) in collaboration with OPKO. Our ability to commence the Phase 3 program of EB613 in osteoporosis will require additional funding, which may not be available on reasonable 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 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, EB613, EB612 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™ technology 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 product candidates, 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 financings or collaborations, when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

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. As of the date of this Quarterly Report, we believe that our existing cash resources will be sufficient to support the Company's operations under its current plans through the middle of the third quarter of 2026. These factors raise substantial doubt as to the Company's 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. If we are unable to finance our operations, our business would be in jeopardy, and we might not be able to continue operations and might have to liquidate our assets. In that case, investors might receive less than the value at which those assets are carried on our financial statements, and it is likely that investors would lose all or a part of their investment.

Cash Flows

Six Months Ended June 30, 2025 compared to Six Months Ended June 30, 2024

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

	Six Months Ended June 30,	
	(unaudited)	
	2025	2024
	(In thousands)	
Net Cash used in operating activities	\$ (3,035)	\$ (3,197)
Net Cash used in investing activities	\$ (37)	\$ -
Net Cash provided by financing activities	\$ 13,286	\$ 1,246
Net increase (decrease) in cash and cash equivalents	<u>\$ 10,214</u>	<u>\$ (1,951)</u>

Net Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2025 was \$3.0 million, consisting primarily of our operating loss of \$5.2 million, which was partially offset by approximately \$1.1 million of share-based compensation and depreciation expenses and a decrease of \$1.1 million in our net operating assets and liabilities.

Net cash used in operating activities for the six months ended June 30, 2024 was \$3.2 million, consisting primarily of our operating loss of \$4.2 million and an increase of \$0.1 million in our net operating assets and liabilities, which was partially offset by approximately \$1.1 million of share-based compensation and depreciation expenses.

The change in cash used in operating activities for the six months ended June 30, 2025 compared to the same period in 2024 was mainly attributed to an increase of \$1.0 million in our operating loss which was offset by a decrease of \$0.9 million in our net operating assets and liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2025 consisted primarily of the purchase of property and equipment.

There was no net cash used in or provided by investing activities for the six months ended June 30, 2024.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the six months ended June 30, 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 \$7.1 million from issuance of Ordinary Shares under the 2025 Collaboration Agreement.

Net cash provided by financing activities for the six months ended June 30, 2024 consisted of the net proceeds of \$0.6 million from the issuance of Ordinary Shares under the Leerink ATM Program and \$0.6 million from the issuance of Ordinary Shares upon the exercise of options and warrants.

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 2024 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 2024 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 2024 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 June 30, 2025, which we refer to as the Evaluation Date. Based on such evaluation, those officers 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 2024 Annual Report.

Israel's multi-front war with terrorist groups in neighboring countries, such as Hezbollah in Lebanon and Hamas in the Gaza Strip, and state actors such as Iran, and Israel's responses thereto, may have an effect on our business.

Our research personnel and some management personnel are located in Israel; however, other core activities including clinical, regulatory and supply chain are outside of Israel. Accordingly, political, economic and military conditions in the Middle East may affect our business directly.

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 continuous rocket strikes across Israel, including with Hezbollah in Lebanon, the Houthi movement which controls parts of Yemen, and with Iran. As of the date of this Quarterly Report, the war with Hamas is ongoing and continues to evolve. 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 June 24, 2025, U.S. President Donald Trump announced that a ceasefire had been reached, since such date, there has been no further escalation of hostilities between Israel and Iran; however, there is no assurance that the ceasefire will be upheld, and military activity and hostilities may continue or escalate. The Company's research personnel and some management personnel are located in Israel; however, other core activities including clinical, regulatory and supply chain are outside of Israel.

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.

Currently, such activities in Israel remain largely unaffected by the foregoing events. During the six months ended June 30, 2025 and as of December 31, 2024, the impact of such events on the Company's results of operations and financial condition was immaterial.

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 armed conflict. Iran is also believed to have a strong influence over various proxy militias across the Middle East, and among the Hamas and Hezbollah, in addition to its readiness to engage in conflict with Israel directly. These situations may potentially escalate in the future into more violent events which may 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. In light of the intensity of the ongoing Israel-Hamas War, the escalation of Hezbollah's and Iran's attack of Israeli civilian and military sites, in September 2024, the international rating agency Moody's downgraded Israel's credit rating from A2 to Baa1, reflecting heightened geopolitical risks. This lowered credit rating, as well as the ongoing war and conflicts described above, could make it more difficult for us to raise capital, if needed, and negatively influence the market price of our Ordinary Shares. 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 June 30, 2025, 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

<u>Exhibit No.</u>	<u>Description of Exhibits</u>
<u>10.1</u>	<u>Amendment No. 1 to Sales Agreement, dated June 5, 2025, by and between Entera Bio Ltd. and Leerink Partners LLC</u>
<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: August 8, 2025

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

Date: August 8, 2025

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

AMENDMENT NO. 1
TO
SALES AGREEMENT

June 5, 2025

Leerink Partners LLC
1301 Avenue of the Americas, 5th Floor
New York, New York 10019

Ladies and Gentlemen:

Entera Bio Ltd., a company organized under the laws of Israel (the “Company”), and Leerink Partners LLC (the “Agent”) are parties to that certain Sales Agreement dated September 2, 2022 (the “Original Agreement”). All capitalized terms not defined herein shall have the meanings ascribed to them in the Original Agreement. The parties hereto, intending to be legally bound, hereby amend the Original Agreement as follows:

1. The first and second paragraphs of Section 1 of the Original Agreement shall be deleted in their entirety, and the following shall be inserted in lieu thereof:

“Issuance and Sale of Shares. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through the Agent ordinary shares, par value NIS 0.0000769 per share, of the Company (the “**Ordinary Shares**”), subject to the limitations set forth in Section 5(c) (the “**Placement Shares**”). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this Section 1 on the aggregate gross sales price or total number of Placement Shares that may be issued and sold under this Agreement from time to time shall be the sole responsibility of the Company, and that the Agent shall have no obligation in connection with such compliance except for compliance with the parameters set forth in a Placement Notice (as defined below). The issuance and sale of Placement Shares through the Agent will be effected pursuant to the Registration Statement (as defined below) filed by the Company with the Securities and Exchange Commission (the “**Commission**”), although nothing in this Agreement shall be construed as requiring the Company to issue any Placement Shares.

The Company originally prepared and filed, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the “**Securities Act**”), with the Commission a registration statement on Form S-3 (File No. 333-265286), including a base prospectus, relating to certain securities, including the Ordinary Shares, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the “**Exchange Act**”). The Company originally prepared a prospectus supplement to the base prospectus included as part of such registration statement at the time the registration statement became effective, which prospectus supplement specifically relates to the Placement Shares to be issued from time to time pursuant to this Agreement (the “**Prospectus Supplement**”). The Company will furnish to the Agent, for use by the Agent, copies of the base prospectus included as part of such registration statement at the time it became effective, as supplemented by the Prospectus Supplement. Except where the context otherwise requires, such registration statement, and any post effective amendment thereto, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B of the Securities Act, or any subsequent registration statement on Form S-3 filed under the Securities Act, which replaces such initial registration statement, is herein called the “**Registration Statement**.” The base prospectus, including all documents incorporated therein by reference to the extent such information has not been superseded or modified in accordance with Rule 412 under the Securities Act (as qualified by Rule 430B(g) of the Securities Act), included in the Registration Statement, as it may be supplemented by the Prospectus Supplement or replaced by a subsequent prospectus relating to the Placement Shares, in the form in which such Prospectus Supplement and/or prospectus have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any “issuer free writing prospectus” (as used herein, as defined in Rule 433 under the Securities Act (“**Rule 433**”), relating to the Placement Shares that (i) is required to be filed with the Commission by the Company or (ii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case, in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g), is herein called the “**Prospectus**.”

2. All references to “September 2, 2022” set forth in Schedule 1 and Exhibit 7(m) of the Original Agreement are revised to read “September 2, 2022 (as amended by Amendment No. 1 to Sales Agreement, dated June 5, 2025)”.

3. All references to “SVB Securities LLC” in the Original Agreement are revised to read “Leerink Partners LLC”.

4. All references to “SVB Securities” in the Original Agreement are revised to read “Leerink Partners”.

5. Except as specifically set forth herein, all other provisions of the Original Agreement shall remain in full force and effect.

6. Entire Agreement; Amendment; Severability. This Amendment No. 1 to the Original Agreement together with the Original Agreement (including all schedules and exhibits attached hereto and thereto and Placement Notices issued pursuant hereto and thereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. All references in the Original Agreement to the “Agreement” shall mean the Original Agreement as amended by this Amendment No. 1; *provided, however*, that all references to “date of this Agreement” in the Original Agreement shall continue to refer to the date of the Original Agreement.

7. Governing Law and Time; Waiver of Jury Trial. THIS AMENDMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAWS. SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME. EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AMENDMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

8. Consent to Jurisdiction. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan, for the adjudication of any dispute hereunder or in connection with any of the transactions contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum, or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy (certified or registered mail, return receipt requested) to such party at the address in effect for notices under Section 12 of the Original Agreement and agrees that such service shall constitute good and sufficient notice of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.

9. Counterparts. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Amendment by one party to the other may be made by facsimile or electronic transmission. Counterparts may be delivered via facsimile, electronic mail (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[Remainder of Page Intentionally Blank]

If the foregoing correctly sets forth the understanding among the Company and the Agent, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding amendment to the Original Agreement between the Company and the Agent.

Very truly yours,

ENTERA BIO LTD.

By: /s/ Miranda Toledano

Name: Miranda Toledano

Title: Chief Executive Officer

LEERINK PARTNERS LLC

By: /s/ Peter M. Fry

Name: Peter M. Fry

Title: Head of Alternative Equities

[Signature page to Amendment No. 1 to Sales Agreement]

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 June 30, 2025 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: August 8, 2025

/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 June 30, 2025 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: August 8, 2025

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

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 June 30, 2025 (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: August 8, 2025

/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 June 30, 2025 (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: August 8, 2025

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