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 March 31, 2024

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	Not applicable
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Kiryat Hadassah Minrav Building – Fifth Floor Jerusalem, Israel	**9112002**
(Address of principal executive offices)	**(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	☐	Accelerated filer	☐
Non-Accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

Yes ☐ No ☒

As of May 6, 2024, the registrant had 35,785,309 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 such as, 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 "Item 1A-Risk Factors" of this Quarterly Report and in "Item 1A-Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 (the "2023 Annual Report"). Meaningful factors which 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 in Israel, the United States and internationally;

- Our ability to manage growth; and

- The duration and intensity of the ongoing Israel-Hamas War, as well as the developing conflict with Iran and its proxies in the Middle East, and their impact on our operations and workforce, including our research and development and clinical trials.

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 any further disclosures we make on related subjects in any annual, quarterly or current reports that we file with the Securities and Exchange Commission ("SEC").

We encourage you to read Part II, Item 1A of this Quarterly Report and Item 1A of our 2023 Annual Report, each entitled "Risk Factors," and Part I, Item 2 "Management's Discussion and Analysis of Financial Condition and Results of Operation—Liquidity and Capital Resources" of this Quarterly Report for additional discussion of the risks and uncertainties associated with our business. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

PART I.

ITEM 1. FINANCIAL STATEMENTS

ENTERA BIO LTD.
UNAUDITED CONDENSED
CONSOLIDATED FINANCIAL STATEMENTS
AS OF MARCH, 31 2024

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ENTERA BIO LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands, except share data)
(Unaudited)

A s s e t s	**March 31, 2024**	**December 31, 2023**
CURRENT ASSETS:		
Cash and cash equivalents	9,189	11,019
Other current assets	562	238
TOTAL CURRENT ASSETS	9,751	11,257
NON-CURRENT ASSETS:		
Property and equipment, net	87	100
Operating lease right-of-use assets	381	388
Deferred income taxes	14	14
Funds in respect of employee rights upon retirement	6	6
TOTAL NON-CURRENT ASSETS	488	508
TOTAL ASSETS	10,239	11,765
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	66	83
Accrued expenses and other payables	902	874
Current maturities of operating lease	153	134
TOTAL CURRENT LIABILITIES	1,121	1,091
NON-CURRENT LIABILITIES:		
Operating lease liabilities	224	256
Liability for employee rights upon retirement	31	32
TOTAL NON-CURRENT LIABILITIES	255	288
TOTAL LIABILITIES	1,376	1,379
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.0000769 par value: Authorized - as of March 31, 2024 and December 31, 2023, 140,010,000 shares; issued and outstanding as of March 31, 2024 and December 31, 2023, 35,526,281 and 35,476,341 shares, respectively	1	1
Additional paid-in capital	115,224	114,730
Accumulated other comprehensive income	41	41
Accumulated deficit	(106,403)	(104,386)
TOTAL SHAREHOLDERS' EQUITY	8,863	10,386
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	10,239	11,765

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

ENTERA BIO LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(U.S. dollars in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
OPERATING EXPENSES:		
Research and development	735	931
General and administrative	1,327	1,294
Other income	-	(13)
TOTAL OPERATING EXPENSES	2,062	2,212
OPERATING LOSS	2,062	2,212
FINANCIAL INCOME, NET	(45)	(22)
NET LOSS	2,017	2,190
LOSS PER SHARE BASIC AND DILUTED	0.05	0.08
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	36,735,429	28,809,922

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)

	Ordinary shares					
	Number of shares issued	Amounts	Additional paid-in capital	Accumulated other Comprehensive income	Accumulated deficit	Total
BALANCE AT JANUARY 1, 2023	28,809,922	*	107,210	41	(95,497)	11,754
Net loss	-	-	-	-	(2,190)	(2,190)
Share-based compensation	-	-	516	-	-	516
BALANCE AT MARCH 31, 2023	28,809,922	*	107,726	41	(97,687)	10,080
BALANCE AT JANUARY 1, 2024	35,476,341	1	114,730	41	(104,386)	10,386
Net loss			-	-	(2,017)	(2,017)
Exercise of Warrants to ordinary shares	29,940	*	30	-	-	30
Vested restricted share units	20,000	*	-	-	-	-
Share-based compensation			464	-	-	464
BALANCE AT March 31, 2024	35,526,281	1	115,224	41	(106,403)	8,863

* 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, except share and per share data)
(Unaudited)

	Three months ended March 31,	
CASH FLOWS FROM OPERATING ACTIVITIES:	**2024**	**2023**
Net loss	(2,017)	(2,190)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	13	14
Share-based compensation	464	516
Finance income, net	(9)	(3)
Changes in operating asset and liabilities:		
Decrease in accounts receivable	-	217
Increase in other current assets	(324)	(359)
Increase (decrease) in accounts payable	(17)	133
Increase in accrued expenses and other payables	28	63
Net cash used in operating activities	(1,862)	(1,609)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	-	(11)
Net cash used in investing activities	-	(11)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of warrants into shares	30	-
Net cash provided by financing activities	30	-
DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS	(1,832)	(1,620)
CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS AT BEGINNING OF THE PERIOD	11,085	12,376
CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS AT END OF THE PERIOD	9,253	10,756
Reconciliation in amounts on consolidated balance sheets:		
Cash and cash equivalents	9,189	10,691
Restricted deposits included in other current assets	64	65
Total cash and cash equivalents and restricted deposits	9,253	10,756
SUPPLEMENTAL DISCLOSURE OF CASH FLOW TRANSACTIONS:		
Interest received	39	-
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	-

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

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 EB612 program 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.

b. The Company's ordinary shares, NIS 0.0000769 par value per share ("ordinary shares"), have been listed on the Nasdaq Capital Market since July 2018 under the symbol "ENTX".

c. Because the Company is engaged in research and development activities, it has not derived significant income from its activities and has incurred an accumulated deficit in the amount of $106.4 million as of March 31, 2024 and negative cash flows from operating activities. The Company's management is of the opinion that its available funds as of March 31, 2024 will allow the Company to operate under its current plans into the third quarter of 2025. This assumes the use of the Company's capital to fund its ongoing operations, including research and development, the completion of the Phase 1 PK study related to the Company's new generation platform and the GLP-2/OXM collaborative research the Company is conducting with OPKO Biologics, Inc., a subsidiary of OPKO Health Inc. The Company's current capital resources do not include the capital required to fund the Company's proposed Phase 3 study 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 in the public and private equity markets, debt financing and strategic collaborations, as the Company will need to finance future research and development activities, general and administrative expenses and working capital through capital raising. However, there is no certainty about the Company's ability to obtain such funding. These consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

d. In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on the Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in thousands of deaths and injuries, and Hamas additionally kidnapped many Israeli civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and commenced a military campaign against Hamas. In addition, in April 2024, Israel experienced a direct attack from Iran, involving hundreds of drones and missiles launched towards various parts of the country, mostly targeting military bases. The Israeli defense systems, aided by international allies, successfully intercepted the majority of these attacks, minimizing physical damage and casualties. Despite the effectiveness of Israel's missile defense systems, such incidents contribute to regional instability and could potentially escalate into broader conflicts with Iran and its proxies in the Middle East, affecting Israel's political and trade relations, especially with neighboring countries and global allies. The situation remains fluid, and the potential for further escalation exists. While the Company has a few employees who are in active military service, the ongoing war with Hamas and the conflict with Iran and its proxies have not, to date, materially impacted the Company's business or operations. Furthermore, the Company does not expect any delays to any of its programs as a result of such conflicts. While R&D and management are located in Israel, other core activities including clinical, regulatory and our supply chain are not. However, the Company cannot currently predict the intensity or duration of Israel's war against Hamas and/or the conflict with Iran and its proxies, nor can it predict how such conflicts will ultimately affect the Company's business and operations or Israel's economy in general.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation of the financial statements

These unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") for interim financial statements. Accordingly, they do not include all of the information and notes required by U.S. GAAP for annual financial statements. In the opinion of management, these unaudited condensed consolidated financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of the Company's consolidated financial position as of March 31, 2024, and the consolidated results of operations, statements of changes in shareholders' equity and cash flows for the three-month periods ended March 31, 2024 and 2023.

The consolidated results for the three-month period ended March 31, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024.

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, 2023, as filed with the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 8, 2024.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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.

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 Shares Units ("RSUs"), which are included under the treasury stock method when dilutive. The calculation of diluted loss per share excluded options, warrants and RSUs exercisable into 16,484,665 shares and 7,116,583 shares for the periods ended March 31, 2024 and 2023, respectively, because the effect would have been antidilutive.

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 United States and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis. Early adoption is permitted, with the option to apply the standard retrospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

In November 2023, the FASB issued ASU 2023-07 "Segment Reporting: Improvements to Reportable Segment Disclosures". This guidance expands public entities' segment disclosures primarily by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

(U.S. dollars in thousands, except share and per share data)

NOTE 3 - EQUITY AND SHARE-BASED COMPENSATION

1. Changes in Share Capital:

   In March 2024, 29,940 warrants issued in connection with the Company's December 2023 private placement (the "December 2023 PIPE") were exercised for 29,940 ordinary shares for a total consideration of $30.

2. Share-based Compensation:

	Three months ended March 31, 2024
Exercise price	$ 0.60
Dividend yield	-
Expected volatility	74.28%
Risk-free interest rate	3.93%
Expected life - in years	5.3

   a. On January 1, 2024, an aggregate of 758,331 options to purchase ordinary shares were granted to seven non-executive members of the Board of Directors with an exercise price of $0.60 per share. The options vest in equal quarterly installments over a one-year period that began on January 1, 2024. 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 $295.

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

   b. On February 1, 2024, the Company entered into a consulting agreement with an investor relations consulting firm. Under the terms of the agreement, the Company agreed to pay a monthly fee of $5 and issued to the consultant 25,000 RSUs. The RSUs vest in five equal monthly installments over a five-month period that began on February 1, 2024. As of March 31, 2024, 10,000 RSUs had vested. The fair value of the RSUs was $21,750 using the fair value of the RSU's on the board approval date, January 30, 2024, of which $15,433 was recognized as an expense during the period ended March 31, 2024.

   c. On February 15, 2024, the Company entered into a consulting agreement with an additional investor relations firm. Under the terms of the agreement, the Company agreed to issue the consultant 50,000 RSUs. The RSUs vest in five equal monthly installments over a five-month period that started on February 15, 2024. As of March 31, 2024, 10,000 RSUs had vested. The fair value of the RSUs was $52,550 using the fair value of the RSUs on the grant date, of which $30,659 was recognized as an expense during the period ended March 31, 2024.

(U.S. dollars in thousands, except share and per share data)

NOTE 4 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

Other current assets:	March 31, 2024	December 31, 2023
Prepaid expenses	384	34
Advance income tax	69	69
Restricted deposits	70	65
Other	39	70
	562	238

Accrued expenses and other payables:	March 31, 2024	December 31, 2023
Employees and employees related	177	159
Provision for vacation	254	215
Accrued expenses	471	500
	902	874

NOTE 5 - SUBSEQUENT EVENTS

1. 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 may from time to time offer and sell up to 5,000,000 ordinary shares (the "Leerink ATM Program").

   During April 2024, the Company issued 214,088 ordinary shares pursuant to the Leerink ATM Program for net proceeds of $545 at a weighted average price of $2.60 per ordinary share.

2. In April 2024, 29,940 warrants issued in connection with the December 2023 PIPE were exercised for 29,940 ordinary shares for a total consideration of $30.

3. On April 19, 2024, the board of directors approved the following options grants:

   a. options to purchase an aggregate of 768,000 ordinary shares were granted to employees, executive officers and service provider with an exercise price of $1.99 per share which was the share price on the grant date; and

   b. options to purchase an aggregate of 500,000 ordinary shares to the Company's Chief Executive Officer with an exercise price of $1.99 per share which was the share price on that day. This grant is subject to the shareholders' approval.

      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 option will vest in eight equal quarterly installments following the first anniversary of the grant date.

   c. options to purchase an aggregate of 90,000 ordinary shares to two advisory board members with an exercise price of $1.99 per share which was the share price on that day. These option vest immediately at the grant date.

   In addition, the board of directors approved the grant of 209,548 RSUs to executive officers in place of cash annual bonus, of which 124,121 RSUs that were granted to the CEO are subject to the shareholders' approval. The RSUs vest in four equal quarterly installments over one year that started on April 19, 2024.

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 Item 1A-Risk Factors in our 2023 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 Item 1A-Risk Factors in our 2023 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.

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™ oral delivery technology, which is designed to simultaneously stabilize the peptide in the gastrointestinal tract and promote its absorption into the bloodstream.

Oral PTH(1-34) Programs

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 with no prior fracture. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (pharmacodynamic/bone turnover biomarker) and secondary endpoints (BMD). Following the completion of a Type C and a Type D meeting with the U.S. Food and Drug Administration's (FDA), we announced 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. In November 2023, we reported that the American Society for Bone and Mineral Research (ASBMR) announced that the SABRE (Strategy to Advance BMD as a Regulatory Endpoint) 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, we reported that the ASBMR had announced that the FDA 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 of March 2024. We believe EB613 stands as the first program to potentially avail itself of the ASBMR-SABRE BMD endpoint.

The EB612 program is being developed as the first oral PTH(1-34) tablet peptide replacement tablet therapy for 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.

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 reproduceable, 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. We are exploring the use of our PTH(1-34) tablets for the treatment of stress fractures in athletes and an investigator sponsored phase 2 study is expected to be initiated with respect to this indication in the second half of 2024.

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

In May 2023, the results from our oral GLP-2 program were published in the International Journal of Peptide Research and Therapeutics, "Oral Delivery Technology Enabling Gastro-Mucosal Absorption of Glucagon-Like-Peptide-2 Analog (Teduglutide, Gattex®) - A Novel Approach for Injection-Free Treatment of Short Bowel Syndrome." We believe GLP-2 represents a strong candidate for our N-Tab™ technology and warrants further development as an injection-free alternative to patients suffering from short bowel syndrome and other gastrointestinal disorders where GLP-2 plays a role.

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

Oxyntomodulin (OXM) is a naturally occurring peptide hormone found in the colon, with glucagon-like-peptide 1 (GLP-1) and glucagon dual agonist activity which 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 significant reductions in weight loss and decreased plasma triglyceride levels in over 430 patients in phase 2/2B studies.

We expect additional in vivo PK/PD data from both the oral GLP-2 tablet program and the oral OXM tablet program in 2024. 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.

Patent Transfer, Licensing Agreements and Grant Funding

Oramed Patent Transfer Agreement

In 2011, we entered into a patent transfer agreement with Oramed, which we refer to as the Patent Transfer Agreement, pursuant to which Oramed assigned to us all of its rights, title and interest in the patent rights Oramed licensed to us when we were originally organized, subject to a worldwide, royalty-free, exclusive, irrevocable, perpetual and sub-licensable license granted to Oramed under the assigned patent rights to develop, manufacture and commercialize products or otherwise exploit such patent rights in the fields of diabetes and influenza. Additionally, we agreed not to engage, directly or indirectly, in any activities in the fields of diabetes and influenza that involve the use of, or utilize, the patents underlying the Patent Transfer Agreement. Under the terms of the Patent Transfer Agreement, we agreed to pay Oramed royalties equal to 3% of our net revenues generated, directly or indirectly, from our exploitation of the assigned patent rights, including the sale, lease or transfer of the assigned patent rights or sales of products or services covered by the assigned patent rights.

The Israeli Innovation Authority Grants

We have received grants of approximately $0.5 million from the Israeli Innovation Authority ("IIA") to partially fund our research and development. 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, which include EB613, EB612 and any other oral PTH product candidates that we may develop. The royalty rate may increase to 5% with respect to approved grant 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 plus 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. As of March 31, 2024, the total royalty amount that would be payable by the Company to the IIA, before interest and payments as described above, is approximately $460 thousand. As of March 31, 2024, we had paid royalties to the IIA in the amount of $96,000 related to a collaboration agreement and other material transfer agreements.

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

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on the Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in thousands of deaths and injuries, and Hamas additionally kidnapped hundreds Israeli civilians and soldiers, including infants, children and elderly men and women. Following the attack, Israel's security cabinet declared war against Hamas and commenced a military campaign against Hamas.

In April 2024, Israel experienced a direct attack from Iran, involving hundreds of drones and missiles launched towards various parts of the country, mostly targeting military bases. The Israeli defense systems, aided by international allies, successfully intercepted the majority of these attacks, minimizing physical damage and casualties. Despite the effectiveness of Israel's missile defense systems, such incidents contribute to regional instability and could potentially escalate into broader conflicts with Iran and its proxies in the Middle East, affecting Israel's political and trade relations, especially with neighboring countries and global allies. The situation remains fluid, and the potential for further escalation exists.

While we have a few employees who are in active military service, the ongoing war with Hamas and the conflict with 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 R&D and 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 and/or the conflict with Iran and its proxies, nor can we predict how such conflicts will ultimately affect our business and operations or Israel's economy in general.

Financial Overview

Since our inception, we have raised a total of $91.9 million from a combination of public and private equity offerings, IIA grants and the exercise of options and warrants. Since inception, we have incurred significant losses. For the three months ended March 31, 2024 and 2023, our operating losses were $2.1 million and $2.2 million, respectively, and we expect to continue to incur significant expenses and losses for the foreseeable future.

As of March 31, 2024, we had an accumulated deficit of $106.4 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.

Notwithstanding our current expectation that we will have sufficient capital to continue operations into the third quarter of 2025 without additional funding, as a result of our recurring losses from operations, negative cash flows and lack of liquidity, management is of the opinion that there is substantial doubt as to the Company's ability to continue as a going concern, and our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of, and for the year ended, December 31, 2023, expressing the existence of substantial doubt about our 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 “Item 1A-Risk Factors-Risks Related to Our Financial Position and Need for Additional Capital” contained in our 2023 Annual Report.

As of March 31, 2024, we had cash and cash equivalents of $9.2 million. We believe that our existing cash resources will be sufficient to meet our projected operating requirements into the third quarter of 2025, which include the capital required to fund our ongoing operations, including R&D, the completion of the Phase 1 PK study related to our new generation platform and the GLP-2/OXM collaborative research we are conducting with OPKO. Our ability to commence the Phase 3 study of EB613 in osteoporosis will depend on finalizing discussions with the FDA pursuant to their qualification of the total hip BMD endpoint and 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.

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

As of March 31, 2024, we had a total of 19 employees, of whom 17 are full-time employees, and all are based in Israel (including our Chief Executive Officer, EVP of Research and Development and Chief Operating Officer). In addition, we employ a number of specialized outside advisors and expert consultants 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 drug delivery technology and our product candidates, including:

- employee-related expenses, including salaries, bonuses and share-based compensation expenses for employees and service providers in the research and development function;
- expenses incurred in operating our laboratories including our small-scale manufacturing facility;
- expenses incurred under agreements with CROs, and investigative sites that conduct our clinical trials;

- expenses related to outsourced and contracted services, such as external laboratories, consulting and advisory services;
- supply, development and manufacturing costs relating to clinical trial materials; and
- other costs associated with pre-clinical and clinical activities.

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. Our research and development expenses were $0.7 million and $0.9 million for the three months ended March 31, 2024 and 2023, respectively, and were primarily for the development of EB613, EB612 and our collaboration with OPKO related to GLP-2 and OXM. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to numerous risks and uncertainties associated with developing drugs, including:

- the uncertainty of the scope, rate of progress, results and cost of our clinical trials, nonclinical testing and other related activities;
- the cost of manufacturing clinical supplies and establishing commercial supplies of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing any sales, marketing, and distribution capabilities; and
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any milestone and royalty payments thereunder.

A change in the outcome of any of these variables with respect to the development of EB613, EB612 or any other product candidate that we may develop could mean a significant change in the costs and timing associated with the development of such product candidate. For example, if the FDA or other regulatory authority were to require us to conduct preclinical or clinical studies beyond those which 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.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits, 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.

Taxes on Income

We have not generated taxable income since our inception, and as of March 31, 2024, we had carry-forward tax losses of $77.7 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 carry-forward losses of the Company.

The Company's subsidiary, Entera Bio, Inc., is taxed separately under U.S. tax laws. As of March 31, 2024, Entera Bio Inc. had tax loss carry-forwards of $154 thousand.

Results of Operations

Comparison of Three Months Ended March 31, 2024 and 2023

	Three Months Ended March 31,		Increase (Decrease)	
	2024	2023	$	%
	(In thousands, except for percentage information)			
Operating expenses:				
Research and development expenses	$ 735	$ 931	$ (196)	(21)%
General and administrative expenses	$ 1,327	$ 1,294	$ 33	2.6%
Other income	$ -	$ (13)	$ (13)	(100)%
Operating loss	$ 2,062	$ 2,212	$ (150)	(6.8)%
Financial income, net	$ (45)	$ (22)	$ 23	104.5%
Net loss	$ 2,017	$ 2,190	$ (173)	(7.9)%

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2024 were $0.7 million, as compared to $0.9 million for the three months ended March 31, 2023. The decrease was attributable to a decrease o f $0.2 million in clinical expenses for our Phase 1 PK study related to our new generation platform and new formulations for EB612 and related expenses.

General and Administrative Expenses

General and administrative expenses for both the three months ended March 31, 2024 and 2023 were $1.3 million. For the three months ended March 31, 2024, there was a decrease of $0.1 million in D&O insurance costs and an increase of $0.1 million in compensation, consultant and other fees.

Financial Income, Net

Financial income, net for the three months ended March 31, 2024 was $45 thousand as compared to $22 thousand for the three months ended March 31, 2023. Our financial income, net for the three months ended March 31, 2024 and 2023 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. For the three months ended March 31, 2024 and 2023, our operating losses were $2.1 million and $2.2 million, respectively. As of March 31, 2024, we had an accumulated deficit of $106.4 million. We expect to continue to incur significant expenses and losses for the next several years as we advance our products through development and provide administrative support for our operations.

Notwithstanding our current expectation that we will have sufficient capital to continue operations into the third quarter of 2025 without additional funding, as a result of our recurring losses from operations, negative cash flows and lack of liquidity, management is of the opinion that there is substantial doubt as to the Company's ability to continue as a going concern. See "Item 1A-Risk Factors-Risks Related to Our Financial Position and Need for Additional Capital" contained in our 2023 Annual Report.

Since our inception, we have raised a total of $91.9 million, including $25.9 million through at-the-market-offering ("ATM") programs, $20.9 million in private placements since our IPO, $11.2 million in our IPO in 2018 and $33.9 million in aggregate funding from a combination of grants, exercises of options and warrants and private placements of Ordinary Shares, preferred shares and debt prior to our IPO. In addition, as of March 31, 2024, we had received approximately $1.7 million under our previously terminated collaboration agreement.

As of March 31, 2024, we had cash and cash equivalents of $9.2 million. Our primary uses of cash have been to fund research and 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, under which we may from time to time offer and sell up to 5,000,000 Ordinary Shares (the "Leerink ATM Program") 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 reimbursement of expenses. As of March 31, 2024, we had sold an aggregate of 4,030 shares under the Leerink ATM Program for aggregate proceeds of $5 thousand, net of issuance costs. Through May 6, 2024, we had sold 218,118 shares under the Leerink ATM Program for aggregate proceeds of $0.5 million, net of issuance costs.

Funding Requirements

We believe that our existing capital resources will be sufficient to fund our operations into the third quarter of 2025, which include R&D, the completion of the Phase 1 PK study related to our new generation platform and the GLP-2/OXM collaborative research we are conducting with OPKO. Our ability to commence the Phase 3 study of EB613 in osteoporosis will depend on finalizing discussions with the FDA pursuant to their qualification of the total hip BMD endpoint and 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.

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 technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or collaborations, when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

Notwithstanding our current expectation that we will have sufficient capital to continue operations into the third quarter of 2025 without additional funding, as a result of our recurring losses from operations, negative cash flows and lack of liquidity, management is of the opinion that there is substantial doubt as to the Company's ability to continue as a going concern and our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of, and for the year ended, December 31, 2023, expressing the existence of substantial doubt about our ability to continue as a going concern. The unaudited condensed consolidated financial statements contained in this Quarterly Report have been prepared on a going concern basis and do not include any adjustments that may be necessary should we be unable to continue as a going concern. 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

Three Months Ended March 31, 2024 compared to Three Months Ended March 31, 2023

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

	Three Months Ended March 31, (unaudited)	
	2024	**2023**
	(In thousands)	
Net Cash used in operating activities	$ (1,862)	$ (1,609)
Net Cash used in investing activities	-	(11)
Net Cash provided by financing activities	30	-
Net decrease in cash and cash equivalents	$ (1,832)	$ (1,620)

Net Cash Used in Operating Activities

Net cash used in operating activities for the three months ended March 31, 2024 was $1.9 million, consisting primarily of our operating loss of $2.1 million and an increase of $0.3 million in our working capital, which was partially offset by $0.5 million of share-based compensation and depreciation expenses.

Net cash used in operating activities for the three months ended March 31, 2023 was $1.6 million, consisting primarily of our operating loss of $2.2 million, which was partially offset by a decrease of $0.1 million in our working capital and approximately $0.5 million of share-based compensation expense and depreciation expenses.

The increase of $0.3 million in cash used in operating activities for the three months ended March 31, 2024 compared to the same period in 2023 was mainly attributed to an increase of $0.4 million in working capital, which was partially offset by a decrease of $0.1 million in our operating loss.

Net Cash Used in Investing Activities

There was no net cash used in investing activities for the three months ended March 31, 2024. Net cash used in investing activities for the three months ended March 31, 2023 consisted primarily of the purchase of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2024 consisted of the net proceeds of $30 thousand from the issuance of Ordinary Shares due to exercise of outstanding warrants.

Contractual Obligations

There have not been any material changes in our assessment of material contractual obligations and commitments as set forth in Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our 2023 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 2023 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 2023 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 and regulations promulgated thereunder) as of March 31, 2024, 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 2023 Annual Report.

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

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

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on the Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in thousands of deaths and injuries, and Hamas additionally kidnapped many Israeli civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and commenced a military campaign against Hamas.

In April 2024, Israel experienced a direct attack from Iran, involving hundreds of drones and missiles launched towards various parts of the country, mostly targeting military bases. The Israeli defense systems, aided by international allies, successfully intercepted the majority of these attacks, minimizing physical damage and casualties. Despite the effectiveness of Israel's missile defense systems, such incidents contribute to regional instability and could potentially escalate into broader conflicts with Iran and its proxies in the middle east, affecting Israel's political and trade relations, especially with neighboring countries and global allies. The situation remains fluid, and the potential for further escalation exists.

While we have a few employees who are in active military service, the ongoing war with Hamas and the conflict with 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 R&D and 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 and/or the conflict with Iran and its proxies, nor can we predict how such conflicts will ultimately affect our business and operations or Israel's economy in general.

Additionally, political uprisings, social unrest and violence in various other countries in the Middle East, including Israel's neighboring countries Syria, Lebanon, Egypt and Jordan, are affecting the political stability of those countries. This instability may lead to deterioration of the political relationships that exist between Israel and certain countries and have raised concerns regarding security in the region and the potential for armed conflict. Iran is also believed to have a strong influence over various proxy militias across the Middle East, and among the Syrian government, 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. These situations, including conflicts which involved missile strikes against civilian and military targets in various parts of Israel, have, in the past, negatively affected business conditions in Israel.

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. The political and security situation in Israel may result in parties with whom we have contracts claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions. 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 and could make it more difficult for us to raise capital. We could experience disruptions if acts associated with such conflicts result in any serious damage to our facilities. Furthermore, several countries, as well as certain companies and organizations, continue to restrict business with Israel and Israeli companies, which could have an adverse effect on our business and financial condition in the future. Our business interruption insurance may not adequately compensate us for losses, if at all, that may occur as a result of an event associated with a security situation in the Middle East, and any losses or damages incurred by us could have a material adverse effect on our business.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

During the quarter ended March 31, 2024, none of our officers or directors adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any "non-Rule 10b5-1 trading arrangement", as defined in Item 408 of Regulation S-K.

ITEM 6. EXHIBITS

Exhibit No.	Description of Exhibits
31.1	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.
31.2	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.
32.1*	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.
32.2*	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.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ENTERA BIO LTD.

Date: May 10, 2024

/s/ Miranda Toledano

Miranda Toledano
Chief Executive Officer
(Principal Executive Officer)

Date: May 10, 2024

/s/ Dana Yaacov-Garbeli

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

Exhibit 31.1

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

I, Miranda Toledano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2024 of Entera Bio Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2024

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

Exhibit 31.2

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

I, Dana Yaacov-Garbeli, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2024 of Entera Bio Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2024

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

Exhibit 32.1

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

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

1. the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2024

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

Exhibit 32.2

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

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

1. the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2024

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