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, 2023

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**
Warrants to purchase ordinary shares	**ENTXW**	**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 1, 2023, the registrant had 28,813,952 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, 2022 (the "2022 Annual Report"). Meaningful factors which could cause actual results to differ include, but are not limited to:

- Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates;

- The regulatory approval processes of the U.S. Food and Drug Administration ("FDA") and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed;

- Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all;

- Positive results from preclinical studies and early-stage clinical trials may not be predictive of future results. Initial positive results in any of our clinical trials may not be indicative of results obtained when the trial is completed or in later stage trials;

- The scope, progress and costs of developing our product candidates such as EB613 for Osteoporosis and EB612 for Hypoparathyroidism may alter over time based on various factors such as regulatory requirements, 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;

- We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors;

- 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 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 and hypoparathyroidism 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;

- The possibility that competing products or technologies may make any product candidates we may develop and commercialize or our oral delivery technology obsolete;

- Our ability to comply with laws and regulations that currently apply or become applicable to our business in Israel, the United States and internationally; and

- Our ability to manage growth.

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 or that are made on our behalf. 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, of this Quarterly Report and Item 1A of our 2022 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, 2023
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ENTERA BIO LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share data)
(Unaudited)

	March 31, 2023	December 31, 2022
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	10,691	12,309
Accounts receivable	29	246
Other current assets	653	294
TOTAL CURRENT ASSETS	11,373	12,849
NON-CURRENT ASSETS:		
Property and equipment, net	136	139
Operating lease right-of-use assets	48	90
Deferred income taxes	43	43
Funds in respect of employee rights upon retirement	6	6
TOTAL NON-CURRENT ASSETS	233	278
TOTAL ASSETS	11,606	13,127
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	150	17
Accrued expenses and other payables	1,296	1,233
Current maturities of operating lease	48	91
TOTAL CURRENT LIABILITIES	1,494	1,341
NON-CURRENT LIABILITIES:		
Liability for employee rights upon retirement	32	32
TOTAL NON-CURRENT LIABILITIES	32	32
TOTAL LIABILITIES	1,526	1,373
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.0000769 par value: Authorized - as of March 31, 2023 and December 31, 2022, 140,010,000 shares; issued and outstanding - as of March 31, 2023 and December 31, 2022, 28,809,922	*	*
Additional paid-in capital	107,726	107,210
Accumulated other comprehensive income	41	41
Accumulated deficit	(97,687)	(95,497)
TOTAL SHAREHOLDERS' EQUITY	10,080	11,754
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	11,606	13,127

* Represents an amount less than one thousand US dollars

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,	
	2023	**2022**
REVENUES	-	68
COST OF REVENUES	-	54
GROSS PROFIT	-	14
OPERATING EXPENSES:		
Research and development	931	1,690
General and administrative	1,294	2,171
Other income	(13)	(12)
TOTAL OPERATING EXPENSES	2,212	3,849
OPERATING LOSS	2,212	3,835
FINANCIAL INCOME, NET	(22)	(44)
LOSS BEFORE INCOME TAX	2,190	3,791
INCOME TAX BENEFIT	-	(7)
NET LOSS	2,190	3,784
LOSS PER SHARE BASIC AND DILUTED	0.08	0.13
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	28,809,922	28,804,411

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, 2022	28,804,411	*	104,950	41	(82,426)	22,565
Net loss	-	-	-	-	(3,784)	(3,784)
Share-based compensation	-	-	964	-	-	964
BALANCE AT March 31, 2022	28,804,411	*	105,914	41	(86,210)	19,745
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

* 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:	**2023**	**2022**
Net loss	(2,190)	(3,784)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	14	16
Deferred income taxes	-	(33)
Share-based compensation	516	964
Finance income, net	(3)	(39)
Changes in operating asset and liabilities:		
Decrease (increase) in accounts receivable	217	(27)
Increase in other current assets	(359)	(1,099)
Increase in accounts payable	133	33
Increase (decrease) in accrued expenses and other payables	63	(808)
Decrease in contract liabilities	-	(15)
Net cash used in operating activities	(1,609)	(4,792)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(11)	(23)
Net cash used in investing activities	(11)	(23)
DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS	(1,620)	(4,815)
CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS AT BEGINNING OF THE PERIOD	12,376	24,964
CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS AT END OF THE PERIOD	10,756	20,149
Reconciliation in amounts on consolidated balance sheets:		
Cash and cash equivalents	10,691	20,109
Restricted deposits included in other current assets	65	40
Total cash and cash equivalents and restricted deposits	10,756	20,149

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 under the laws of the State of Israel and commenced operation on June 1, 2010. On January 8, 2018, the Company incorporated Entera Bio Inc., a wholly owned subsidiary incorporated in Delaware United States. The Company is a leader in the development and commercialization of orally delivered large molecule therapeutics for use in areas with significant unmet medical need where adoption of injectable therapies is limited due to cost, convenience and compliance challenges for patients. The Company's most advanced product candidates, EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism, are based on its proprietary technology platform and are both in clinical development. Additionally, the Company intends to license its oral delivery 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. On December 10, 2018, the Company entered into a research collaboration and license agreement with Amgen (the "Amgen Agreement") for the use of the Company's oral delivery platform in the field of inflammatory disease and other serious illnesses. Pursuant to the Amgen Agreement, the Company and Amgen had agreed to use the Company's proprietary drug delivery platform to develop oral formulations for one preclinical large molecule program that Amgen had selected. Amgen is responsible for the clinical development, regulatory approval, manufacturing and worldwide commercialization of the programs. On May 2, 2023, the Company and Amgen agreed to terminate the Amgen Agreement in accordance with its terms, effective on such date.

The Company granted Amgen an exclusive, worldwide, sublicensable license under certain of its intellectual property relating to its drug delivery technology to develop, manufacture and commercialize the applicable products. The Company will retain all intellectual property rights to its drug delivery technology, and Amgen will retain all rights to its large molecules and any subsequent improvements, and ownership of certain intellectual property developed through the performance of the agreement is to be determined by U.S. patent law.

d. 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 $97.7million as of March 31, 2023 and negative cash flows from operating activities. The Company's management is of the opinion that its available funds as of March 31, 2023 will allow the Company to operate under its current plans into the third quarter of 2024. This assumes the use of the Company's capital to fund its ongoing operations, including R&D and the completion of the Phase 1 study related to the new formulation EB612. This does not include the capital required to fund the Company's proposed Phase 3 study for EB613 in osteoporosis and comparative study. These factors raise substantial doubt as to the Company's ability to continue as a going concern. Management is in the process of evaluating various financing alternatives in the public or 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 fund raising. However, there is no certainty about the Company's ability to obtain such funding. The financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

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, 2023, and the consolidated results of operations, statements of changes in shareholders' equity and cash flows for the three-month periods ended March 31, 2023 and 2022.

The consolidated results for the three-month period ended March 31, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements of the Company for the year ended December 31, 2022, as filed with the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 31, 2023. The comparative balance sheet at December 31, 2022 has been derived from the audited annual financial statements at that date but does not include all disclosures required by U.S. GAAP for annual financial statements.

b. Loss per share

Basic loss per share is computed on the basis of the net loss, adjusted to recognize the effect of a down-round feature when it is triggered, for the period divided by the weighted average number of outstanding ordinary shares during the period.

Diluted loss per share is based upon the weighted average number of ordinary shares and dilutive ordinary shares equivalents outstanding. Ordinary share equivalents include outstanding stock options and warrants, which are included under the treasury stock method when dilutive. The calculation of diluted loss per share does not include options and warrants, exercisable into 7,116,583 shares and 6,238,605 shares for the periods ended March 31, 2023 and 2022, respectively, because the effect would have been anti-dilutive.

c. Newly issued and recently adopted accounting pronouncements:

Recently issued accounting pronouncements adopted

1) In June 2016, the FASB issued ASU 2016-13 "Financial Instruments—Credit Losses—Measurement of Credit Losses on Financial Instruments." This guidance replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance is effective for Smaller Reporting Companies (as defined by the SEC) for the fiscal year beginning on January 1, 2023, including interim periods within that year. The adoption of this guidance did not have material impact on the Company's consolidated financial statements.

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

NOTE 3 - SHARE-BASED COMPENSATION

On January 2, 2023, options to purchase an aggregate of 534,246 ordinary shares were granted to six non-executive board members with an exercise price of $0.73 per share which was the share price on the grant day. The options vest over one year in four equal quarterly installments starting on the date of grant. 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 $253. The fair value of each option granted is estimated at the date of grant using the Black-Scholes option-pricing model, with the following weighted average assumptions:

	Three months ended March 31, 2023
Exercise price	$ 0.73
Dividend yield	-
Expected volatility	74%
Risk-free interest rate	3.98%
Expected life - in years	5.3

NOTE 4 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

Accrued expenses and other payables:	March 31, 2023	December 31, 2022
Employees and employees related	182	154
Provision for vacation	163	146
Accrued expenses	951	933
	1,296	1,233

NOTE 5 - SUBSEQUENT EVENTS

a. In April 2023, the Company entered into an amendment to its office lease agreement from 2014 to extended the period of the lease agreement for additional five years, expiring on June 30, 2028, with two options for early termination subject to a notice period. The monthly lease fee is a total of $15.

b. On April 24, 2023, the Company's Board of Directors approved the following option grants:

i. Options to purchase 851,000 ordinary shares to employees, executive officers and service providers with an exercise price of $0.795 per share.

ii. Options to purchase 350,000 ordinary shares to the Company's Chief Executive Officer with an exercise price of $0.795 per share. This grant is subject to shareholders' approval.

These options vest over four years from the date of grant; 25% vest on the first anniversary of the date of grant and the remaining 75% of the option will vest in twelve equal quarterly installments following the first anniversary of the grant date.

iii. Options to purchase 30,000 ordinary shares to a service provider with an exercise price of $0.795 per share. These options vest immediately at the service inception date.

c. On May 2, 2023, the Company and Amgen agreed to terminate the Amgen Agreement in accordance with its terms, effective on such date.

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 and Item 1A-Risk Factors in this Quarterly Report and in our 2022 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 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 our 2022 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 biopharmaceutical company and a leader in the development of orally delivered macromolecule therapeutics, including peptides and therapeutic proteins. 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. Furthermore, from a technical standpoint, oral delivery of therapeutic proteins has historically been challenging due to enzymatic degradation within the gastrointestinal tract, poor absorption into the blood stream and variable drug exposures. Entera's proprietary technology is designed to deliver orally administered proteins with sufficient bioavailability to meet treatment goals, using white mini tablets (around 6mm in diameter) of the desired protein.

We strategically focus on underserved, chronic medical conditions where oral administration of a mini tablet peptide or peptide replacement therapy has the potential to significantly shift a treatment paradigm.

We currently have two product candidates in the clinical stage of development: EB613 and EB612. Both candidates are first-in-class daily mini tablets of human parathyroid hormone (hPTH (1-34), teriparatide). To date, Entera's proprietary PTH tablets have been safely administered to a total of 72 healthy subjects in Phase 1 studies and 153 patients across Phase 2 studies in osteoporosis and hypoparathyroidism, two diseases that remain underserved with the current standard of care and which disproportionately affect women.

In addition to these product candidates, we have various internal early stage research programs targeting GLP-2, kappa opioid receptors and hGH..

Osteoporosis

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, which leads to greater fragility of bones and an increase in fracture risk. Osteoporosis is most frequently associated with menopause in women, aging in both women and men and glucocorticoid steroid use (greater than three months). The bone remodeling cycle can be separated into two distinct processes: (i) bone resorption, where cells called osteoclasts function in the resorption of mineralized tissue; and (ii) bone formation, where cells called osteoblasts are responsible for bone matrix synthesis and subsequent mineralization of the bone. In healthy individuals, bone resorption is matched by new bone formation. Osteoporosis develops as the balance between bone resorption by osteoclasts and bone formation by osteoblasts is not maintained, and not enough bone tissue is formed, leading to frail and fracture-prone bones.

Current osteoporosis drugs may be divided into two categories: antiresorptive and anabolic. Drugs that inhibit bone resorption include oral and injectable options such as estrogen (for postmenopausal women), oral and intravenous bisphosphonates, selective estrogen receptor modulators (SERMs), the RANK-ligand inhibitor (denosumab) and (salmon) calcitonin. The three currently approved osteoanabolic drugs that stimulate bone formation all require daily or monthly subcutaneous injections: teriparatide (hPTH[1-34]); abaloparatide (a PTH-related protein analog); and romosozumab (an antibody that inhibits sclerostin and also inhibits bone resorption). There are currently no FDA-approved oral anabolic treatments for osteoporosis.

To date, we have completed two Phase 1 clinical trials and a six-month Phase 2 double-blind, placebo-controlled dose-ranging trial of EB613 in patients with osteoporosis in Israel. The dose ranging Phase 2 study in postmenopausal women with low bone mass met its primary —change in P1NP at Month 3 — and key secondary endpoints including bone mineral density (BMD) at Month 6 and was presented in a late-breaker oral presentation at the 2021 ASBMR Annual Meeting.

In November 2018, we had a Pre-Investigational New Drug ("Pre-IND") meeting with the FDA to discuss our EB613 program for the treatment of osteoporosis. In December 2020, we announced that the FDA had approved our 2020 IND Application. In December 2021, we held an end-of-Phase 2 meeting with the FDA to review the six-month phase 2 results and a proposed Head-to-Head Non-Inferiority Phase 3 study protocol vs. Forteo®, our nonclinical and clinical development plan and the use of BMD, rather than fracture incidence, as the primary endpoint to support a potential NDA submission. In our End of Phase 2 Meeting Minutes received in January 2022, the FDA expressed concern that a Head-to-Head study phase 3 design vs. Forteo® may not be favorable to support an NDA for EB613.

During early 2022 and considering FDA's suggestions and emerging data from the ASBMR-FNIH SABRE program1, we redesigned our pivotal phase 3 study for EB613 as a placebo-controlled trial with a total hip (TH) BMD primary endpoint. A Type C meeting with the FDA in relation to Entera's re-designed Phase 3 registrational study was held in August 2022 and in October 2022, we announced FDA's concurrence on the major design elements of the protocol; and that (1) a single Phase 3 placebo-controlled study with a TH BMD primary endpoint along with (2) a comparative PK study vs. Forteo® could support an NDA submission of EB613 (oral hPTH (1-34), teriparatide tablets) under the 505(b)(2) regulatory pathway.

In February 2023, we submitted the revised phase 3 protocol as part of a Type D meeting with FDA in February 2023. On April 3rd, 2023, we reported the outcome of our Type D meeting and the FDA's written responses to our two questions. On the first question, "Based on the FDA's feedback provided in the Type C meeting written response August 19, 2022, and subsequent teleconference held on September 27, 2022, the Sponsor has updated the Phase 3 protocol design including the use of Total Hip Bone Mineral Density (BMD) as the primary endpoint. Does the FDA concur that the revised protocol meets its expectations?" the FDA responded that it is not opposed to the use of BMD as a surrogate for fracture, including initiating a study under the proposed Foundation for the National Institutes of Health Bone Quality Project (FNIH BQP) pathway, which is undergoing review. The FDA re-confirmed to Entera that a 24-month placebo-controlled phase 3 trial with the primary efficacy analysis at 24 months was acceptable and provided some guidance on the statistical evaluation of the study.

On the second question, "Does FDA agree that the design of the population PK (pharmacokinetic) and exposure response evaluation incorporated in the draft Phase 3 study protocol meets FDA expectations?" FDA responded that the Company's proposed PK sampling scheme in the phase 3 study seems reasonable.

On April 3rd, the Company announced that it plans on continuing its dialogue with FDA in light of its review of the FNIH-BQP criteria and will not plan to initiate a phase 3 study for EB613 until such a time that FDA provides final guidance on the evaluation of its primary endpoint.

Hypoparathyroidism

Hypoparathyroidism is a rare condition in which the body either fails to produce sufficient amounts of PTH or the PTH produced lacks normal biologic activity. Individuals with a deficiency of parathyroid hormone may exhibit hypocalcemia and hyperphosphatemia. Hypocalcemia can cause weakness, muscle cramps, excessive nervousness, headaches and uncontrollable twitching and tetany. Hyperphosphatemia can result in soft tissue calcium deposition, which may lead to severe issues, including damage to the circulatory and central nervous systems. The most common cause of hypoparathyroidism is damage to, or removal of, the parathyroid glands due to surgery for another condition.

Our product candidate for hypoparathyroidism, EB612, is the first oral formulation of PTH (1-34, teriparatide) hormone replacement treatment developed in a mini tablet form. The FDA and the European Medicines Agency have granted EB612 orphan drug designation for the treatment of hypoparathyroidism. We believe that EB612 may have inherent advantages compared to injectable forms, including convenience of administration without any special preparation of the medication, as well as convenience of storage (room temperature or refrigeration for long term storage). In 2015, we successfully completed a Phase 2a trial for EB612. Although this pilot four-month Phase 2a trial involved a smaller number of patients, was conducted for a shorter duration and did not include an initial dose optimization in comparison to the design of the pivotal trial used for regulatory approval of Natpara® (the REPLACE trial), our study achieved its primary and secondary endpoints, including a reduction in calcium supplements, reductions in serum phosphate and 24-hour urine calcium excretion, maintenance of ACa within the reference range, and an improvement in quality of life.

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1 FNIH BQP is also known as the ASBMR FNIH-SABRE, American Society for Bone and Mineral Research-Foundation for the National Institutes of Health (FNIH) Strategy to Advance BMD as a Regulatory Endpoint (SABRE)

We have since developed an improved formulation of EB612 based on new intellectual property, optimization of its PK profile and the potential for reduced daily dosing for hypoparathyroidism. We expect to carry out a PK study for the new formulation of EB612 in the first half of 2023. If successful, the phase 2b/3 clinical trial of EB612 in hypoparathyroidism may potentially support a submission for regulatory approval of EB612.

Patent Transfer, Licensing Agreements and Grant Funding

Oramed Patent Transfer Agreement

In 2011, we entered into a patent transfer agreement with Oramed, or 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. 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.

Amgen Research Collaboration and License Agreement

On December 10, 2018, we entered into a research collaboration and license agreement with Amgen, which we refer to as the Amgen Agreement. Pursuant to the Amgen Agreement, we and Amgen had agreed to use our proprietary drug delivery platform to develop oral formulations for one preclinical large molecule program that Amgen has selected. In exchange for entering into the agreement, Amgen paid us a non-refundable and non-creditable initial access fee of $725 thousand in the first quarter of 2019, of which $500 thousand was attributed to the right to use the intellectual property and $225 thousand was attributed to the pre-clinical R&D services that we were obligated to perform under the Amgen Agreement. Since 2019, Amgen has paid $1.2 million for pre-clinical R&D services. Under certain circumstances, Amgen had been required to make aggregate payments to us of up to $270 million upon achievement of various clinical and commercial milestones or its exercise of options to select the additional two programs to include in the collaboration.

On May 2, 2023, the Company and Amgen agreed to terminate the Amgen Agreement in accordance with its terms, effective on such date. See Part II, Item 5 of this Quarterly Report for more information.

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, or 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, including EB613, EB612 and any other oral PTH product candidates we may develop. 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 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. Moreover, a payment of up to 600% of the grant received may be required upon the transfer of any IIA-funded 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 thereon. Following the signing of the Amgen Agreement, we were required to pay 5.38% of each payment by Amgen and up to 600% of the grant received plus interest. Through March 31, 2023, we had paid royalties to the IIA in the amount of $95 thousand related to the Amgen Agreement and other Master Service Agreements ("MTA").

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.

Financial Overview

Since our inception, we have raised a total of $84.7 million from a combination of public and private equity offerings, grants and the exercise of options and warrants. Since inception, we have incurred significant losses. For the three months ended March 31, 2023 and 2022, our operating losses were $2.2 million and $3.8 million, respectively, and we expect to continue to incur significant expenses and losses for the foreseeable future. As of March 31, 2023, we had an accumulated deficit of $97.7 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 payments under any future collaborations into which we may enter.

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. 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, 2022, 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. If we are unable to raise the requisite funds, we will need to delay certain program initiation, curtail or cease operations. See "Item 1A-Risk Factors-Risks Related to Our Financial Position and Need for Additional Capital" contained in our 2022 Annual Report.

As of March 31, 2023, we had cash and cash equivalents of $10.7 million. We believe that our existing cash resources will be sufficient to meet our projected operating requirements into the third quarter of 2024, which includes the capital required to fund our ongoing operations, including R&D and the completion of the Phase 1 PK study related to the new formulation EB612. However, this does not include the capital required to fund our proposed Phase 3 pivotal study for EB613 in osteoporosis and comparative PK study of EB613 and Forteo®. Our ability to commence such studies will depend on finalizing discussions with the FDA 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 2023, we had 18 full-time employees and five consultants who provide services to us on a part-time basis. 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.

Under the Amgen Agreement, from 2019 through March 31, 2023, we received an aggregate amount of $1.7 million.

We recognize revenues, including revenues under the Amgen Agreement, according to ASC 606, "Revenues from Contracts with Customers".

According to ASC 606, a performance obligation is a promise to provide a distinct good or service or a series of distinct goods or services. Goods and services that are not distinct are bundled with other goods or services in the contract until a bundle of goods or services that is distinct is created. A good or service promised to a customer is distinct if the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. Options granted to the customer that do not provide a material right to the customer that it would not receive without entering into the contract do not give rise to performance obligations. We identified two performance obligations in the agreement: the license to use the Company's proprietary drug delivery platform and pre-clinical research and development services ("pre-clinical R&D services"). The license to our intellectual property has significant standalone functionality because we are not required to continue to support, develop or maintain the intellectual property transferred and will not undertake any activities to change the standalone functionality of the intellectual property. Therefore, we recognized the revenues related to this performance obligation in December 2018 at the point in time that control of the license was transferred to Amgen. The preclinical R&D services that we provide from time-to-time under the Amgen Agreement include discovery, research and design preclinical activities relating to the programs selected by Amgen. Revenues attributed to the preclinical R&D services are recognized during the period the pre-clinical R&D services are provided according to the input model method on a cost-to-cost basis. Each of these items met the definition of distinct performance obligation.

Under ASC 606, the consideration that we would be entitled to upon the achievement of contractual milestones, which are contingent upon the occurrence of future events of development and commercial progress, are a form of variable consideration. When assessing the portion, if any, of such milestone-related consideration to be included in the transaction price, we first assess the most likely outcome for each milestone, and exclude the consideration related to milestones of which the occurrence is not considered the most likely outcome. We then evaluate if any of the variable consideration determined in the first step is constrained. Variable consideration is included in the transaction price if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of our anticipated performance and all information (historical, current and forecasted) that is reasonably available. We did not recognize any revenues from milestone payments.

An entity should recognize revenue for a sales-based or usage-based royalty promised in exchange for a license of intellectual property only when (or as) the later of the following events occurs:

- The subsequent sale or usage occurs; and
- The performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

We did not recognize any revenues from royalties because royalties are payable based on future commercial sales, as defined in the Amgen Agreement and there were no commercial sales as of March 31, 2023.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of our drug delivery technology and our product candidates. Those expenses include:

- 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 EB613 and EB612 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. For the three months ended March 31, 2023 and 2022, our research and development expenses were $0.9 million and $1.7 million, respectively. Research and development expenses for the three months ended March 31, 2023 and 2022 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, 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 and/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 principally 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, patent counseling and portfolio maintenance and business development expenses.

We expect that our general and administrative expenses will increase in the future as we increase our headcount and expand our administrative function to support our operations.

Financial Income, Net

Financial income, net is composed primarily of 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, 2023, we had carry-forward tax losses of $69.2 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, 2023, Entera Bio Inc. had tax loss carry-forwards of $26 thousand.

Results of Operations

Comparison of Three Months Ended March 31, 2023 and 2022

	Three Months Ended March 31,		Increase (Decrease)	
	2023	**2022**	**$**	**%**
	(In thousands, except for percentage information)			
Revenues	$ -	$ 68	$ (68)	(100)%
Cost of revenues	$ -	$ 54	(54)	(100)%
Operating expenses:				
Research and development expenses	$ 931	$ 1,690	$ (759)	(45)%
General and administrative expenses	$ 1,294	$ 2,171	$ (877)	(40)%
Other income	$ (13)	$ (12)	$ (1)	(8)%
Operating loss	$ 2,212	$ 3,835	$ (1,623)	(42)%
Financial income, net	$ (22)	$ (44)	$ 22	(50)%
Income tax benefit	$ -	$ (7)	$ 7	(10)%
Net loss	$ 2,190	$ 3,784	$ (1,594)	(42)%

Revenue

Revenues for the three months ended March 31, 2022 of $68,000 were mainly attributable to pre-clinical R&D services provided to Amgen under the Amgen Agreement. We did not recognize any revenue for the three months ended March 31, 2023 due to finalization of third year pre-clinical R&D services. We did not generate any revenues prior to entering into the Amgen Agreement.

Cost of Revenues

Cost of revenues for the three months ended March 31, 2022 of $54,000 were mainly attributable to pre-clinical R&D services provided to Amgen under the Amgen Agreement. The decrease in cost was due to the lack of revenues under the Amgen Agreement, as described above, for the three months ended March 31, 2023.

Research and Development Expenses

Research and development expenses for three months ended March 31, 2023 were $0.9 million, as compared to $1.7 million for the three months ended March 31, 2022. The decrease of $0.8 million was primarily due to a decrease of $0.6 million in continued materials and production costs and others consultants and a decrease of $0.2 million in employee compensation including share-based compensation.

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2023 were $1.3 million, as compared to $2.2 million for the three months ended March 31, 2022. The decrease of $0.9 million was mainly attributable to a decrease of $0.6 million in employee compensation, including share-based compensation, a decrease of $0.2 million in professional fees and a decrease of $0.1 million in D&O insurance costs.

Financial Income, Net

Financial income, net for the three months ended March 31, 2023 and 2022 was $22,000 and $44,000, respectively. Our financial income is composed mainly of 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, 2023 and 2022, our operating losses were $2.2 million and $3.8 million, respectively. As of March 31, 2023, we had an accumulated deficit of $97.7 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.

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. If we are unable to raise the requisite funds, we will need to curtail or cease operations. See in “Item 1A-Risk Factors” in our 2022 Annual Report.

Since our inception, we have raised a total of $84.7 million, including $25.3 million through completed or terminated at-the-market-offering (“ATM”) programs, $14.3 million in our December 2019 private placement, $11.2 million in our IPO in 2018 and $33.9 million in aggregate funding from a combination of grants, exercise of options and warrants and private placements of Ordinary Shares, preferred shares and debt prior to our IPO. In addition, as of March 31, 2023, we had received approximately $1.7 million under the Amgen Agreement. As of March 31, 2023, we had cash and cash equivalents of $10.7 million. Our primary uses of cash have been to fund research and development, general and administrative and working capital requirements, and we expect these will continue to be our primary uses of cash.

On September 2, 2022, we entered into a Sales Agreement with SVB Securities LLC, as sales agent, to implement an at-the-market offering program, under which we may from time to time offer and sell up to 5,000,000 Ordinary Shares (the “SVB 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 and reimbursement of expenses. As of March 31, 2023, we had not sold any shares under the SVB ATM Program.

Funding Requirements

We believe that our existing capital resources will be sufficient to meet our projected operating requirements into the third quarter of 2024, which includes the capital required to fund our ongoing operations, including R&D and the completion of the Phase 1 PK study related to the new formulation EB612. However, this does not include the capital required to fund our proposed Phase 3 pivotal study for EB613 in osteoporosis and comparative PK study of EB613 and Forteo®. Our ability to commence such studies will depend on finalizing discussions with the FDA 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 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 or grant rights to develop and market our oral PTH product candidates and any other product candidates that we would otherwise prefer to develop and market ourselves.

Our unaudited condensed consolidated financial statements as of and for the three months ended March 31, 2023 included elsewhere in this Quarterly Report note that there is substantial doubt about our ability to continue as a going concern as of such date. This means that our management has expressed substantial doubt about our ability to continue our operations without an additional infusion of capital from external sources. The unaudited condensed consolidated financial statements 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, 2023 compared to Three Months Ended March 31, 2022

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)	
	2023	**2022**
	(in thousands)	
Net Cash used in operating activities	$ (1,609)	$ (4,792)
Net Cash used in investing activities	(11)	(23)
Net Cash provided by financing activities	-	-
Net decrease in cash and cash equivalents	$ (1,620)	$ (4,815)

Net Cash Used in Operating Activities

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 and a decrease of $0.1 million in our working capital, which was partially offset by approximately $0.5 million of share-based compensation and depreciation expenses.

Net cash used in operating activities for the three months ended March 31, 2022 was $4.8 million, consisting primarily of our operating loss of $3.8 million and an increase of $2.0 million in our working capital, which was partially offset by approximately $1.0 million of share-based compensation and depreciation expenses.

The decrease of $3.2 million in cash used in operating activities for the three months ended March 31, 2023 compared to the same period in 2022 was mainly attributed to a decrease of $1.6 million in our operating loss, a decrease of $2.1 in working capital mainly due to a decrease in payments to suppliers and services providers, which were partially offset by a decrease of $0.5 million in share-based compensation.

Net Cash Used in Investing Activities

Net cash used in investing activities for the three months ended March 31, 2023 and 2022 consisted primarily of the purchase of property and equipment.

Net Cash Provided by Financing Activities

For the three months ended March 31, 2023 and 2022, no cash was used in or provided by financing activities.

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 2022 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 2022 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 2022 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 (our principal 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, 2023, 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

There have been no material changes with respect to the risk factors disclosed in Part I, Item 1A. of our 2022 Annual Report.

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

On May 2, 2023, the Company and Amgen agreed to terminate the Amgen Agreement in accordance with its terms, effective on such date.

Neither party incurred any termination penalty or fees in connection with the termination of the Amgen Agreement.

A brief description of the Amgen Agreement is set forth under the heading “Amgen Research Collaboration and License Agreement” contained in Part I, Item 2 of this Quarterly Report, and such description is incorporated by reference in this Item 5.

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, thereunto duly authorized.

ENTERA BIO LTD.

Date: May 5, 2023

/s/ Miranda Toledano

Miranda Toledano
Chief Executive Officer
(Principal Executive Officer)

Date: May 5, 2023

/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, 2023 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 5, 2023

/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, 2023 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 5, 2023

/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, 2023 (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 5, 2023

/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, 2023 (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 5, 2023

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