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

FORM 10-Q

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

For the quarterly period ended June 30, 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**

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 August 7, 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. 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 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 JUNE 30, 2023

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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	**June 30, 2023**	**December 31, 2022**
CURRENT ASSETS:		
Cash and cash equivalents	9,135	12,309
Accounts receivable	29	246
Prepaid expenses and other current assets	650	294
TOTAL CURRENT ASSETS	9,814	12,849
NON-CURRENT ASSETS:		
Property and equipment, net	122	139
Operating lease right-of-use assets	460	90
Deferred income taxes	43	43
Funds in respect of employee rights upon retirement	6	6
TOTAL NON-CURRENT ASSETS	631	278
TOTAL ASSETS	10,445	13,127
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	240	17
Accrued expenses and other payables	1,485	1,233
Current maturities of operating lease	140	91
TOTAL CURRENT LIABILITIES	1,865	1,341
NON-CURRENT LIABILITIES:		
Operating lease liabilities	316	-
Liability for employee rights upon retirement	32	32
TOTAL NON-CURRENT LIABILITIES	348	32
TOTAL LIABILITIES	2,213	1,373
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.0000769 par value: Authorized - as of June 30, 2023 and December 31, 2022, 140,010,000 shares; issued and outstanding - as of June 30, 2023 and December 31, 2022, 28,813,952 and 28,809,922 shares, respectively	*	*
Additional paid-in capital	108,203	107,210
Accumulated other comprehensive income	41	41
Accumulated deficit	(100,012)	(95,497)
TOTAL SHAREHOLDERS' EQUITY	8,232	11,754
TOTAL LIABILITIES AND SHAREHOLDERS’ EQUITY	10,445	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)

	Six Months Ended June 30,		Three Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
REVENUES	-	112	-	44
COST OF REVENUES	-	87	-	33
GROSS PROFIT	-	25	-	11
OPERATING EXPENSES:				
Research and development	2,140	3,084	1,209	1,394
General and administrative	2,429	4,052	1,135	1,880
Other income	(27)	(27)	(14)	(14)
TOTAL OPERATING EXPENSES	4,542	7,109	2,330	3,260
OPERATING LOSS	4,542	7,084	2,330	3,249
FINANCIAL INCOME, NET	(27)	(104)	(5)	(60)
LOSS BEFORE INCOME TAX	4,515	6,980	2,325	3,189
INCOME TAX BENEFIT	-	(11)	-	(4)
NET LOSS	4,515	6,969	2,325	3,185
LOSS PER SHARE BASIC AND DILUTED	0.16	0.24	0.08	0.11
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	28,811,162	28,806,217	28,812,375	28,808,023

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	-	-	-	-	(4,515)	(4,515)
Issuance of shares under the ATM program, net of issuance costs	4,030	*	5	-	-	5
Share-based compensation	-	-	988	-	-	988
BALANCE AT JUNE 30, 2023	28,813,952	*	108,203	41	(100,012)	8,232
BALANCE AT APRIL 1, 2023	28,809,922	*	107,726	41	(97,687)	10,080
Net loss	-	-	-	-	(2,325)	(2,325)
Issuance of shares under the ATM program, net of issuance costs	4,030	*	5	-	-	5
Share-based compensation	-	-	472	-	-	472
BALANCE AT JUNE 30, 2023	28,813,952	*	108,203	41	(100,012)	8,232
BALANCE AT JANUARY 1, 2022	28,804,411	*	104,950	41	(82,426)	22,565
Net loss	-	-	-	-	(6,969)	(6,969)
Exercise of options to ordinary shares	5,511	*	13	-	-	13
Share-based compensation	-	-	1,660	-	-	1,660
BALANCE AT JUNE 30, 2022	28,809,922	*	106,623	41	(89,395)	17,269
BALANCE AT APRIL 1, 2022	28,804,411	*	105,914	41	(86,210)	19,745
Net loss	-	-	-	-	(3,185)	(3,185)
Exercise of options to ordinary shares	5,511	*	13	-	-	13
Share-based compensation	-	-	696	-	-	696
BALANCE AT JUNE 30, 2022	28,809,922	*	106,623	41	(89,395)	17,269

* 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)

	Six months ended June 30,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	(4,515)	(6,969)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	29	32
Deferred income taxes	-	(63)
Share-based compensation	988	1,660
Finance income, net	(6)	(71)
Changes in operating asset and liabilities:		
Decrease (increase) in accounts receivable	217	(42)
Increase in other current assets	(356)	(704)
Increase (decrease) in accounts payable	223	(57)
Increase (decrease) in accrued expenses and other payables	252	(1,390)
Decrease in contract liabilities	-	(15)
Net cash used in operating activities	(3,168)	(7,619)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(12)	(42)
Net cash used in investing activities	(12)	(42)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares under the ATM program, net of issuance costs	5	-
Exercise of options and warrants into shares	-	13
Net cash provided by financing activities	5	13
DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS	(3,175)	(7,648)
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	9,201	17,316
Reconciliation in amounts on consolidated balance sheets:		
Cash and cash equivalents	9,135	17,279
Restricted deposits included in other current assets	66	37
Total cash and cash equivalents and restricted deposits	9,201	17,316
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	449	-

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. 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 $100.0 million as of June 30, 2023 and negative cash flows from operating activities. The Company's management is of the opinion that its available funds as of June 30, 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 the related 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. These condensed consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

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 the information and notes required by U.S. GAAP for annual financial statements. In the opinion of management, these unaudited condensed consolidated financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of the Company's consolidated financial position as of June 30, 2023, the consolidated results of operations and statements of changes in shareholders' equity for the three and six-month periods ended June 30, 2023 and 2022 and cash flows for the six-month periods ended June 30, 2023 and 2022.

The consolidated results for the three and six-month periods ended June 30, 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 net loss 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 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 7,360,374 shares and 6,326,180 shares for the six months ended June 30, 2023 and 2022, respectively and 7,604,195 shares and 6,473,863 shares for the three months ended June 30, 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

a. 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 date. 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 January 2, 2023 was $253.

b. On April 24, 2023**,** options to purchase an aggregate of 881,000 ordinary shares were granted to employees, executive officers and service providers with an exercise price of $0.795 per share which was the share price on the grant date. 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. The fair value of the options at the date of grant was $485.

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

	Six months ended June 30, 2023
Exercise price	$0.73-$0.79
Dividend yield	-
Expected volatility	74%-76%
Risk-free interest rate	3.58%-3.98%
Expected life - in years	5.3-6.11

c. On April 24, 2023**,** options to purchase an aggregate of 350,000 ordinary shares were granted to the Company’s Chief Executive Officer with an exercise price of $0.795 per share which was the share price on that day. 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. This grant is subject to the Company's shareholders' approval.

d. On June 4, 2023, options to purchase an aggregate of 33,638 ordinary shares were granted to non-executive board member with an exercise price of $0.89 per share which was the share price on that day. The options will vest over three years in 12 equal quarterly installments starting on the date of grant. This grant is subject to the Company's shareholders' approval.

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

NOTE 4 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

	June 30, 2023	December 31, 2022
Prepaid expenses and other current assets:		
Prepaid expenses	296	86
Other current assets	354	208
	650	294

	June 30, 2023	December 31, 2022
Accrued expenses and other payables:		
Employees and employees related	170	154
Provision for vacation	193	146
Accrued expenses	1,122	933
	1,485	1,233

NOTE 5 - EVENTS DURING THE PERIOD

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

As of June 30,2023, the Company recorded the related asset and obligation at the present value of lease payments over the expected terms, discounted using the lessee's incremental borrowing rate, which was 13.84%. The Company lease agreements do not provide a readily determinable implicit rate. Therefore, the Company estimated the incremental borrowing rate to discount the lease payments based on information available at lease commencement.

As of June 30, 2023, the maturity of lease liabilities under our non-cancelable operating leases were as follows:

2023	96
2024	180
2025	180
2026	86
Total future minimum lease payments	542
Less: interest	(86)
Present value of operating lease liabilities	456

b. 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. Additionally, the Company had 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.

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.

NOTE 6 - SUBSEQUENT EVENTS

a. In connection with the Company's initial public offering ("IPO") in July 2018, the Company issued 1,400,000 IPO warrants to purchase 700,000 ordinary shares, and these warrants were listed for trading on Nasdaq Capital Market ("Nasdaq") since August 12, 2018. The IPO warrants were immediately exercisable at an initial exercise price of $8.40 per ordinary share for a period of five years, unless earlier repurchased by the Company as described in the warrant agreement. These IPO warrants expired on July 2, 2023, in accordance with their original terms, and Nasdaq removed them from listing.

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 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 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 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, in a simple tablet format (around 6mm in diameter).

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, among other peptides. On May 2, 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) - A Novel Approach for Injection-Free Treatment of Short Bowel Syndrome." We believe GLP-2 represents a strong candidate for our oral delivery platform and warrants further development as an injection -free alternative to patients suffering from short bowel syndrome and other disorders requiring parenteral nutrition.

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.

Osteoporosis is a significant health issue facing our aging population. In the United States, with respect to hip fractures alone, 21% of women who suffer a hip fracture do not survive beyond one year, even after it is surgically repaired. Without surgery, the one-year mortality rate is approximately 70%. Post-menopausal osteoporosis afflicts more women globally than cancer and cardiovascular disease .

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). It is estimated that less than 10% of currently treated osteoporosis patients agree to injectable osteoanabolic treatment despite guideline recommendations and the approval of generics. There are currently no FDA-approved oral anabolic treatments for osteoporosis. EB613 is positioned to potentially be the first, once daily osteoanabolic mini tablet treatment for women with high risk post-menopausal osteoporosis and no prior fractures.

To date, we have completed two Phase 1 clinical trials and a phase 2, 6-month, 161-patient, placebo-controlled study in which daily oral EB613 tablets produced rapid dose-proportional increases in biochemical markers of bone formation (primary endpoint), reductions in markers of bone resorption, and increased lumbar spine, total hip, and femoral neck Bone Mineral Density (BMD, key secondary endpoint) in postmenopausal women with low BMD or osteoporosis. Results were reported at ASBMR 2021 as a LB oral presentation.

In November 2018, we had a Pre-Investigational New Drug 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 (EOP2) with the FDA to review the six-month phase 2 results and a proposed Head-to-Head, Non-Inferiority (NI) Phase 3 study design vs. Forteo® , using BMD as the primary endpoint to support an NDA submission under the 505(b)2 pathway. In the minutes from our EOP2 meeting, which we received in January 2022, the FDA agreed that the use of BMD as a primary endpoint in our proposed phase 3 study could support an NDA and that a new fracture study would not be required. However, the FDA expressed concern that a NI Head-to-Head phase 3 study design vs. Forteo® may not be favorable. The FDA also remarked that the ASBMR-FNIH SABRE[1] program was evaluating BMD as a surrogate endpoint for fracture risk reduction across placebo-controlled studies; and that the FNIH framework could provide another approach to support a potential NDA for EB613.

In early 2022, we redesigned our pivotal phase 3 study for EB613 as a placebo-controlled study with a total hip (TH) BMD primary endpoint, following the FDA's EOP2 remarks and emerging data from the ASBMR-FNIH SABRE program. In August 2022, we held a Type C meeting with the FDA, and in October 2022, we announced the 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 a NDA submission of EB613 under the 505(b)(2) regulatory pathway.

In February 2023, we submitted a revised phase 3 protocol for EB613 as part of a Type D meeting with the FDA with further detail on the statistical evaluation of our TH BMD endpoint. On April 3, 2023, we reported that the FDA would not be opposed to Entera initiating the Phase 3 study under the proposed FNIH BQP pathway and that the Company's proposed PK sampling scheme seemed reasonable. Also on April 3, 2023, we announced that we plan to continue our dialogue with the FDA and await the final qualification of the FNIH-BQP criteria and their guidance on the statistical evaluation of our BMD endpoint before initiating a phase 3 study for EB613.

[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);

Hypoparathyroidism

Hypoparathyroidism is a rare condition in which the body either fails to produce sufficient amounts of endogenous PTH or the PTH produced lacks normal biologic activity. Individuals with a deficiency of PTH 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 experimental daily injectable treatments, including convenience of administration, storage, and the potential for a flexible titration schedule. In 2015, we successfully completed a Phase 2a trial for EB612, which was an open-label, multicenter pilot study, evaluating the safety, tolerability and PK of EB612 in 19 patients who had been diagnosed with hypoparathyroidism for at least a year and were taking ≥1gr/day of calcium and alfa-calcidol 25(OH)D 20ng/ml supplementation. Patients received PTH (1-34) 0.75 mg/dose tablets qid for 4 months (NCT02152228). The study achieved its primary and secondary endpoints, including a significant reduction in calcium supplementation (42% reduction from baseline, (p=0.001), a decline of 23% (p=0.0003) in median serum phosphate levels two hours following the first dose that was maintained for the duration of the study, improvement in quality of life score and maintenance of median calcium levels above the lower target level for hypoparathyroidism patients (>7.5 mg/dL) throughout the study. There were no treatment emergent adverse events of hypercalcemia reported and no treatment-emergent serious adverse events.

We have since developed what we believe could be an improved formulation of EB612 based on new intellectual property, tailored to optimize its PK profile and the potential for reduced daily dosing. We initiated a PK study in May 2023, which is testing various potential drug candidates based on our new platform, including several which could be developed for the treatment of hypoparathyroidism. We expect to begin reporting our results from this study during the second half of 2023.

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.

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 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 global 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 June 30, 2023, we had paid royalties to the IIA in the amount of $95 thousand related to our former research collaboration and license agreement with Amgen (the "Amgen Agreement") and other master service 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.

Financial Overview

Since our inception, we have raised a total of $84.7 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 June 30, 2023 and 2022, our operating losses were $2.3 million and $3.3 million, respectively. For the six months ended June 30, 2023 and 2022, our operating losses were $4.5 million and $7.1 million, respectively, and we expect to continue to incur significant expenses and losses for the foreseeable future.

As of June 30, 2023, we had an accumulated deficit of $100.0 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.

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 the initiation of certain programs and otherwise 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 June 30, 2023, we had cash and cash equivalents of $9.1 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 our new generation platform and new formulations for 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 June 30 2023, we had 19 full-time employees, two part-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 recognized an aggregate amount of $1.7 million in accordance with ASC 606, "Revenues from Contracts with Customers”. As previously reported, we and Amgen mutually terminated the Amgen Agreement in May 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 June 30, 2023 and 2022, our research and development expenses were $1.2 million and $1.4 million, respectively. For the six months ended June 30, 2023 and 2022, our research and development expenses were $2.1 million and $3.1 million, respectively. Research and development expenses for the three and six months ended June 30, 2023 and 2022 were primarily for the development of EB613 and EB612. 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 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, 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 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 June 30, 2023, we had carry-forward tax losses of $71.3 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 June 30, 2023, Entera Bio Inc. had tax loss carry-forwards of $26 thousand.

Results of Operations

Comparison of Three Months Ended June 30, 2023 and 2022

	Three Months Ended June 30,		Increase (Decrease)	
	2023	2022	$	%
	(In thousands, except for percentage information)			
Revenues	$ -	$ 44	$ (44)	(100)%
Cost of revenues	$ -	$ 33	$ (33)	(100)%
Operating expenses:				
Research and development expenses	$ 1,209	$ 1,394	$ (185)	(13)%
General and administrative expenses	$ 1,135	$ 1,880	$ (745)	(40)%
Other income	$ (14)	$ (14)	$ -	-%
Operating loss	$ 2,330	$ 3,249	$ (919)	(28)%
Financial income, net	$ (5)	$ (60)	$ 55	(92)%
Income tax benefit	$ -	$ (4)	$ 4	(100)%
Net loss	$ 2,325	$ 3,185	$ (860)	(27)%

Revenue

Revenues for the three months ended June 30, 2022 of $44,000 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 June 30, 2023 due to termination of the Amgen Agreement, effective May 2, 2023, under which we provided no revenue-generating services for 2023. We did not generate any revenues prior to entering into the Amgen Agreement.

Cost of Revenues

Cost of revenues for the three months ended June 30, 2022 of $33,000 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 June 30, 2023.

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2023 were $1.2 million, as compared to $1.4 million for the three months ended June 30, 2022. We reduced pre-clinical costs by $0.2 million, which was offset by an increase of $0.2 million in materials and production costs in preparation of our Phase 3 clinical trial for EB613. There were no special one-time payments in the current period such as the $0.2 million payment made to a former employee pursuant to the terms of his separation agreement.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2023 were $1.1 million, as compared to $1.9 million for the three months ended June 30, 2022. The decrease of $0.8 million was mainly attributable to a decrease of $0.2 million in employee compensation, including share-based compensation, a decrease of $0.3 million in professional fees and other consultants and a decrease of $0.2 million in D&O insurance costs.

Financial Income, Net

Financial income, net for the three months ended June 30, 2023 and 2022 was $5,000 and $60,000, respectively. Our financial income is composed mainly of exchange rate differences of certain currencies against our functional currency, which is the U.S. Dollar.

Comparison of Six Months Ended June 30, 2023 and 2022

	Six Months Ended June 30,		Increase (Decrease)	
	2023	2022	$	%
	(In thousands, except for percentage information)			
Revenues	$ -	$ 112	$ (112)	(100)%
Cost of revenues	$ -	$ 87	$ (87)	(100)%
Operating expenses:				
Research and development expenses	$ 2,140	$ 3,084	$ (944)	(31)%
General and administrative expenses	$ 2,429	$ 4,052	$ (1,623)	(40)%
Other income	$ (27)	$ (27)	$ -	-%
Operating loss	$ 4,542	$ 7,084	$ (2,542)	(36)%
Financial income, net	$ (27)	$ (104)	$ 77	(74)%
Income tax benefit	$ -	$ (11)	$ 11	(100)%
Net loss	$ 4,515	$ 6,969	$ (2,454)	(35)%

Revenue

Revenues for the six months ended June 30, 2022 of $112,000 were mainly attributable to pre-clinical R&D services provided to Amgen under the Amgen Agreement. We did not recognize any revenue for the six months ended June 30, 2023 due to finalization of third year pre-clinical R&D services and termination of the Amgen Agreement, effective May 2, 2023. We did not generate any revenues prior to entering into the Amgen Agreement.

Cost of Revenues

Cost of revenues for the six months ended June 30, 2022 of $87,000 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 six months ended June 30, 2023.

Research and Development Expenses

Research and development expenses for six months ended June 30, 2023 were $2.1 million, as compared to $3.1 million for the six months ended June 30, 2022. The decrease of $1.0 million was primarily due to a decrease of $0.4 million in pre-clinical activity, a decrease of $0.1 million in share-based compensation and a decrease of $0.5 million related to a one-time payment made to a former employee pursuant to the terms of his separation agreement.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2023 were $2.4 million, as compared to $4.1 million for the six months ended June 30, 2022. The decrease of $1.7 million was mainly attributable to a decrease of $0.3 million in employee compensation and $0.5 million in share-based compensation, a decrease of $0.6 million in professional fees and other consultants and a decrease of $0.3 million in D&O insurance costs.

Financial Income, Net

Financial income, net for the six months ended June 30, 2023 and 2022 was $27,000 and $104,000, 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 June 30, 2023 and 2022, our operating losses were $2.3 million and $3.2 million, respectively. For the six months ended June 30, 2023 and 2022, our operating losses were $4.5 million and $7.1 million, respectively. As of June 30, 2023, we had an accumulated deficit of $100.0 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 June 30, 2023, we had received approximately $1.7 million under the Amgen Agreement, which has since been terminated. As of June 30, 2023, we had cash and cash equivalents of $9.1 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.

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 reimbursement of expenses.

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 and six months ended June 30, 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

Six Months Ended June 30, 2023 compared to Six Months Ended June 30, 2022

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

	Six Months Ended June 30, (unaudited)	
	2023	**2022**
	(In thousands)	
Net Cash used in operating activities	$ (3,168)	$ (7,619)
Net Cash used in investing activities	(12)	(42)
Net Cash provided by financing activities	5	13
Net decrease in cash and cash equivalents	$ (3,175)	$ (7,648)

Net Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2023 was $3.2 million, consisting primarily of our operating loss of $4.5 million, which was partially offset by an increase of $0.3 million in our working capital and $1.0 million of share-based compensation and depreciation expenses.

Net cash used in operating activities for the six months ended June 30, 2022 was $7.6 million, consisting primarily of our operating loss of $7.1 million and a decrease of $2.2 million in our working capital, which was partially offset by approximately $1.7 million of share-based compensation and depreciation expenses.

The decrease of $4.4 million in cash used in operating activities for the six months ended June 30, 2023 compared to the same period in 2022 was mainly attributed to a decrease of $2.6 million in our operating loss and an increase of $2.5 million in working capital, primarily due to a decrease in payments to suppliers and services providers, which were partially offset by a decrease of $0.7 million in share-based compensation.

Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2023 and 2022 consisted primarily of the purchase of property and equipment.

Net Cash Provided by Financing Activities

Net Cash provided by financing activities for the six months ended June 30, 2023 consisted of the net proceeds of $5 thousand from the issuance of Ordinary Shares under the SVB ATM Program.

Net Cash provided by financing activities for the six months ended June 30, 2022 consisted of the net proceeds of $13 thousand from the issuance of Ordinary Shares due to exercise of options .

Contractual Obligations

On April 17, 2023, we entered into an amendment to our lease for our principal offices in Israel to extend the lease term by five years, or through 2028. As amended, the Company has the option to exit the lease earlier, in December 2024 and in June 2026. The average rent over the new five-year extension is $180 thousand per year.

Other than as disclosed above, 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 June 30, 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

During the quarter ended June 30, 2023, 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: August 11, 2023

/s/ Miranda Toledano

Miranda Toledano
Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 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 June 30, 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: August 11, 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 June 30, 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: August 11, 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 June 30, 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: August 11, 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 June 30, 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: August 11, 2023

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