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, 2022

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 August 8, 2022, the registrant had 28,809,922 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. 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, including statements 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, 2021 (the "2021 Annual Report"). Meaningful factors which could cause actual results to differ include, but are not limited to:

- the scope, progress and costs of developing our product candidates such as EB613 for osteoporosis and EB612 for hypoparathyroidism, including without limitation any changes to the design of the Phase 3 clinical trial of EB613;
- the Food and Drug Administration (FDA) and other regulatory agencies' acceptance of the proposed design for the Phase 3 clinical trial of EB613 and the outcome of future studies for EB612;
- the accuracy of our estimates regarding expenses, capital requirements, the sufficiency of our cash resources and the need for additional financing;
- our ability to raise additional funds on commercially reasonable terms, including via our Amended ATM Program (as defined in Part I, Item 2 "Management's Discussion and Analysis of Financial Condition and Results of Operation—Liquidity and Capital Resources" of this Quarterly Report);
- 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 U.S. Food and Drug Administration (the "FDA") feedback and guidance and how such guidance may impact our clinical development plans, specifically our ability to utilize the 505(b)(2) pathway for the development and potential approval of EB613 and any other product candidates we may develop;
- our expectations regarding licensing, business transactions and strategic collaborations, including our ongoing collaboration with Amgen;
- 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 ability to continue as a going concern absent access to sources of liquidity;

- our ability to obtain and maintain regulatory approval for any of our product candidates;
- our competitive position with respect to other products on the market or in development for the treatment of osteoporosis and hypoparathyroidism;
- our ability to establish and maintain development and commercialization collaborations;
- any potential commercial launch of current or future product candidates, and the timing, cost or other aspects of such commercialization;
- our ability to manufacture and supply, in conjunction with our third-party supply chain partners, sufficient amounts of material to support our clinical trials and any potential future commercial requirements;
- the safety and efficacy of therapeutics marketed by competitors that are targeted toward indications for which we are developing product candidates;
- 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;
- the pricing and reimbursement of our product candidates, if approved;
- our ability to develop a sales, marketing and distribution infrastructure, if any;
- our ability to manage growth; and
- the duration and severity of the coronavirus (COVID-19) pandemic, the actions that may be required to contain the coronavirus or treat its impact, and its impact on our operations and workforce, including our research and development and clinical trials.

All forward-looking statements contained in this Quarterly Report are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely too 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 may file with the Securities and Exchange Commission ("SEC").

We encourage you to read Item 1A of this Quarterly Report and our 2021 Annual Report, 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, 2022

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ENTERA BIO LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS

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

	June 30, 2022	December 31, 2021
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	17,279	24,892
Accounts receivable	225	183
Other current assets	922	254
TOTAL CURRENT ASSETS	18,426	25,329
NON-CURRENT ASSETS:		
Property and equipment, net	166	156
Operating lease right-of-use assets	170	239
Deferred income taxes	280	217
Funds in respect of employee rights upon retirement	46	46
TOTAL NON-CURRENT ASSETS	662	658
TOTAL ASSETS	19,088	25,987
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable	109	166
Accrued expenses and other payables	1,411	2,801
Current maturities of operating lease	172	179
Contract liabilities	-	15
TOTAL CURRENT LIABILITIES	1,692	3,161
NON-CURRENT LIABILITIES:		
Operating lease liabilities	5	123
Liability for employee rights upon retirement	122	138
TOTAL NON-CURRENT LIABILITIES	127	261
TOTAL LIABILITIES	1,819	3,422
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.0000769 par value: Authorized - as of June 30, 2022 and December 31, 2021, 140,010,000 shares; issued and outstanding: - as of June 30, 2022 and December 31, 2021, 28,809,922 and 28,804,411 shares, respectively	*	*
Additional paid-in capital	106,623	104,950
Accumulated other comprehensive income	41	41
Accumulated deficit	(89,395)	(82,426)
TOTAL SHAREHOLDERS' EQUITY	17,269	22,565
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	19,088	25,987

* 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,	
	2022	2021	2022	2021
REVENUES	112	266	44	109
COST OF REVENUES	87	172	33	99
GROSS PROFIT	25	94	11	10
OPERATING EXPENSES:				
Research and development	3,084	2,351	1,394	1,227
General and administrative	4,052	2,674	1,880	1,364
Other income	(27)	(22)	(14)	(11)
TOTAL OPERATING EXPENSES	7,109	5,003	3,260	2,580
OPERATING LOSS	7,084	4,909	3,249	2,570
FINANCIAL (INCOME) LOSS ,NET	(104)	(5)	(60)	24
LOSS BEFORE INCOME TAX	6,980	4,904	3,189	2,594
INCOME TAX BENEFIT	(11)	(31)	(4)	(17)
NET LOSS	6,969	4,873	3,185	2,577
LOSS PER SHARE BASIC AND DILUTED	0.24	0.21	0.11	0.1
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE	28,806,217	23,377,668	28,808,023	24,716,608

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		Additional paid-in capital	Accumulated other Comprehensive income	Accumulated deficit	Total
	Number of shares issued	Amounts				
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
BALANCE AT JANUARY 1, 2021	21,057,922	*	77,708	41	(70,239)	7,510
Net loss	-	-	-	-	(4,873)	(4,873)
Issuance of shares due to the ATM program, net of issuance costs	3,946,265	*	19,342	-	-	19,342
Exercise of options to ordinary shares	99,974	*	275	-	-	275
Exercise of warrants to ordinary shares	3,175,050	*	3,158	-	-	3,158
Share-based compensation	-	-	865	-	-	865
Vested restricted share units	7,000	-	-	-	-	-
BALANCE AT JUNE 30, 2021	28,286,211	*	101,348	41	(75,112)	26,277
BALANCE AT APRIL 1, 2021	23,776,785	*	88,144	41	(72,535)	15,650
Net loss	-	-	-	-	(2,577)	(2,577)
Issuance of shares due to the ATM program, net of issuance costs	1,400,000	*	9,484	-	-	9,484
Exercise of options to ordinary shares	28,594	*	48	-	-	48
Exercise of warrants to ordinary shares	3,080,832	*	3,134	-	-	3,134
Share-based compensation	-	-	538	-	-	538
BALANCE AT JUNE 30, 2021	28,286,211	*	101,348	41	(75,112)	26,277

* 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 CASH FLOWS

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

	Six months ended June 30,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	(6,969)	(4,873)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	32	24
Deferred income taxes	(63)	(109)
Share-based compensation	1,660	865
Finance income, net	(71)	(4)
Changes in operating asset and liabilities:		
Decrease (increase) in accounts receivable	(42)	139
Increase in other current assets	(704)	(602)
Increase (decrease) in accounts payable	(57)	125
Increase (decrease) in accrued expenses and other payables	(1,390)	143
Decrease in contract liabilities	(15)	(150)
Net cash used in operating activities	(7,619)	(4,442)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(42)	-
Net cash used in investing activities	(42)	-
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares through ATM programs, net of issuance costs	-	19,342
Exercise of options and warrants into shares	13	3,433
Net cash provided by financing activities	13	22,775
INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(7,648)	18,333
CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS AT BEGINNING OF THE PERIOD	24,964	8,663
CASH, CASH EQUIVALENTS AND RESTRICTED DEPOSITS AT END OF THE PERIOD	17,316	26,996
Reconciliation in amounts on consolidated balance sheets:		
Cash and cash equivalents	17,279	26,926
Restricted deposits included in other current assets	37	70
Total cash and cash equivalents and restricted cash	17,316	26,996
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	-	31

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 of orally delivered macromolecule therapeutics, including peptides and other therapeutic proteins. The Company applies its platform 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. Entera established such a collaboration with Amgen Inc. ("Amgen") in December 2018, for the use of the Company's oral delivery platform in the field of inflammatory diseases.

b. The Company's ordinary shares, NIS 0.0000769 par value per share ("ordinary shares"), have been listed for trading on the Nasdaq Capital Market since the Company's initial public offering in July 2018, in which total of 1,400,000 ordinary shares and 1,400,000 warrants to purchase up to 700,000 ordinary shares were issued in consideration for net proceeds of $9.6 million, after deducting offering expenses.

c. On December 10, 2018, the Company entered into a research collaboration and license agreement (the "Amgen Agreement") with Amgen 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 have agreed to use the Company's proprietary drug delivery platform to develop oral formulations for one preclinical large molecule program that Amgen has selected. Amgen also has options to select up to two additional programs to include in the Amgen Agreement. Amgen is responsible for the clinical development, regulatory approval, manufacturing and worldwide commercialization of the programs.

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 has retained all intellectual property rights to its drug delivery technology, and Amgen has retained 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 accumulated losses in the amount of $89.4 million through June 30, 2022 and negative cash flows from operating activities. The Company's management is of the opinion that its available funds as of June 30, 2022 will allow the Company to operate under its current plans through the second quarter of 2023. 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 or through the license of the Company's technology [1]

NOTE 1 - DESCRIPTION OF BUSINESS (continued):

e. **Covid-19**

In March 2020, the World Health Organization declared the outbreak of COVID-19 to be a pandemic. The COVID-19 pandemic is having widespread, rapidly evolving, and unpredictable impacts on global society, economies, financial markets, and business practices. During 2021, there was a broad distribution of several vaccinations and medicines to overcome the pandemic. The Company has adjusted its operations to co-exist with the pandemic and has encouraged its employees to get vaccinated against COVID-19. Though the Company sees great progress to overcome the COVID-19 pandemic, the COVID-19 pandemic may continue to impact the Company's business operations, with outbursts of new variants of the COVID-19 from time to time, and there is uncertainty in the nature and degree of its continued effects over time.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:

a. Basis of presentation of the financial statements

These unaudited interim condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") for interim financial statements. Accordingly, they do not include all of the information and notes required by U.S. GAAP for annual financial statements. In the opinion of management, these unaudited condensed consolidated financial statements reflect all adjustments, which include normal recurring adjustments, necessary for a fair statement of the Company's consolidated financial position as of June 30, 2022, the consolidated results of operations, statements of changes in shareholders' equity for the three and six-month periods ended June 30, 2022 and 2021 and cash flows for the six-month periods ended June 30, 2022 and 2021.

The consolidated results for the three and six-month periods ended June 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022.

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, 2021 as filed with the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 8, 2022. The comparative balance sheet at December 31, 2021 has been derived from the audited financial statements at that date but does not include all disclosures required by U.S. GAAP for annual financial statements.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

b. Loss per share

Basic loss per share is computed on the basis of the 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 of ordinary shares equivalents outstanding when dilutive. 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 6,326,180 shares and 7,804,106 shares for the six months ended June 30, 2022 and 2021, respectively and 6,473,863 shares and 7,718,887 shares for the three months ended June 30, 2022 and 2021, respectively, because the effect would be anti-dilutive.

c. Newly issued and recently adopted accounting pronouncements:

Recently issued accounting pronouncements adopted

1) In November 2021, the FASB issued ASU 2021-10 "Government Assistance (Topic 832)", which requires annual disclosures that increase the transparency of transactions involving government grants, including (1) the types of transactions, (2) the accounting for those transactions, and (3) the effect of those transactions on an entity's financial statements. The amendments in this update are effective for financial statements issued for annual periods beginning after December 15, 2021. The adoption of this guidance did not have material impact on the Company's consolidated financial statements.

2) In August 2020, the FASB issued ASU 2020-06 "Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)." This guidance simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The amendments to this guidance are effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. The adoption of this guidance did not have material impact on the Company's consolidated financial statements.

NOTE 3 - SHARE-BASED COMPENSATION:

a. On August 23, 2021, the Company's Board of Directors approved the following option grants which were approved by the shareholders of the Company on October 4, 2021:

i. Grants of options to purchase ordinary shares with a total fair value 0f $195 for each of the seven non-executive board members on January 1, 2022. The options will vest over 3 years in twelve equal quarterly instalments starting on January 1, 2022 the vesting commencement date. On January 1, 2022, which is considered the awards grant date, the Company granted 752,899 ordinary shares to non-executive directors with an exercise price of $2.815 per share.

ii. Grants of options to purchase ordinary shares with a total fair value 0f $65 for each of the seven non-executive board members on January 1, 2022. The options will vest over 1 year in four equal quarterly instalments starting on January 1, 2022 the vesting commencement date. On January 1, 2022, which is considered the awards grant date, the Company granted 250,964 ordinary shares to non-executive directors with an exercise price of $2.815 per share.

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

NOTE 3 - SHARE-BASED COMPENSATION (continued):

b. On March 31, 2022, the Company's Board of Directors approved option grants to purchase 115,000 ordinary shares to certain executive officers and 20,000 options granted to a service provider, in each case with an exercise price of $2.86 per share. The 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 $147. Of these options, 55,000 are subject to the approval of the shareholders of the Company and as such, are not included as part of the fair value.

c. On April 28, 2022, the Company's Board of Directors approved options grants to purchase 220,000 ordinary shares to employees with an exercise price of $2.57 per share. The 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 $364.

d. On May 11, 2022, the Company's Board of Directors approved a grant of options to purchase 500,000 ordinary shares to the Company's Chief Financial Officer, who has since been appointed the Company's Chief Executive Officer. These options have an exercise price of $2.02 per share and 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. These options are subject to the approval of the shareholders of the Company.

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:

	Six months ended June 30, 2022
Exercise price	$2.57-$2.86
Dividend yield	-
Expected volatility	69%-70%
Risk-free interest rate	1.35%-2.87%
Expected life - in years	5.5-6.5

e. On June 15, 2022 the Company signed on a separation agreement with Dr. Phillip Schwartz, the Company's former President of R&D, under which he agreed to continue to provide services to the Company until July 21, 2022 (the "Separation Date"). Pursuant to the terms of the separation agreement and subject to approval of the Company's shareholders, Dr. Schwartz is entitled to receive a full acceleration of the options to purchase 100,000 ordinary shares granted in April 2021, such that 68,750 outstanding options to acquire ordinary shares that not already vested will be deemed to have vested as of the Separation date. These options, together with 357,500 options to purchase ordinary shares, granted in 2017 will remain exercisable, consistent with the original exercise periods.

In addition, the separation agreement provides for the following payments to Dr. Schwartz, all of which would have otherwise been payable in accordance with either Israeli law or pursuant to his existing employment agreement: a one-time cash separation payment in an amount equal to NIS 537,600 (approximately $155,900) and additional payments of approximately NIS 737,771 (approximately $213,952) in respect of all other ongoing accrued benefits, subject to any mandatory deductions. The foregoing payments were recognized in the research and development expenses.

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

NOTE 4 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

Accrued expenses and other payables:	June 30, 2022	December 31, 2021
Employees and employees related	182	147
Income tax	20	134
Provision for vacation	260	308
Accrued expenses	949	2,212
	1,411	2,801

NOTE 5 - SUBSEQUENT EVENTS:

a. On July 15, 2022, the Company's Board of Directors appointed Ms. Miranda Toledano as the Company's new CEO and approved a grant of additional (see also note 3d) options to purchase 600,000 ordinary shares at an exercise price of $1.40 per share. The 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 applicable grant date.

In addition, upon the occurrence of a Triggering Event (as defined below), the Board of Directors will grant Ms. Toledano options to purchase 200,000 ordinary shares.

"Triggering Event" shall mean the earlier of the following events: (i) the execution by the Company of a binding strategic or partnership agreement with a strategic partner to fund the Company's Phase III FDA Trial; or (b) raising sufficient funding to complete the Company's Phase III FDA Trial, in each case as such event was approved by the Board of Directors.

The foregoing option grants are subject to the Company's shareholders' approval.

b. On July 15, 2022, the Company entered into a mutual separation agreement with Dr. Spiros Jamas, the Company's former CEO. Pursuant to the separation agreement, Dr. Jamas received the following benefits: (i) a one-time lump sum payment of his annual base salary for a period of 13 months, for a total gross amount equal to $411,666.67; and (ii) an extension of the exercise period for the vested portion of the options granted to Dr. Jamas on January 4, 2021, representing collectively 492,832 ordinary shares, through the end of a two-year period commencing on July 15, 2022. All of Dr. Jamas' remaining unvested options, totaling 821,386 options, were forfeited.

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

The following discussion and analysis provide 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 consolidated financial statements and related notes contained elsewhere in this Quarterly Report and Item 1A-Risk Factors in this Quarterly Report and our 2021 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 2021 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 leader in the development of orally delivered macromolecule therapeutics, including peptides and other therapeutic proteins. We apply our platform 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. We were organized under the laws of the State of Israel on September 30, 2009 and commenced operations on June 1, 2010.

Oral delivery of most therapeutic proteins is challenging due to poor absorption into the blood stream, enzymatic degradation within the gastrointestinal tract, and variable drug exposure. Entera's proprietary, oral drug delivery technology is designed to address these technical challenges using a synthetic absorption enhancer and protease inhibitors to prevent enzymatic degradation and support delivery to targeted tissues. Our platform has been tested pre-clinically and/or clinically on several molecules of broad characteristics and size. The Company's most advanced product candidates, EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism, are in clinical development. The Company completed a phase 2 dose ranging study for EB613 in 2021. A Type C meeting with the FDA in relation to Entera's proposed Phase 3 registrational study is expected in the second half of 2022. Additionally, the Company aims to license its oral delivery technology to biopharmaceutical companies for use with their proprietary compounds. Entera established such a collaboration with Amgen Inc., referred to as Amgen, in December 2018, for the use of Entera's oral delivery platform in the field of inflammatory diseases.

Parathyroid hormone (PTH) is an 84-amino acid hormone and the primary regulator of calcium and phosphate metabolism in bone and in the kidney. Our lead product candidates are EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism. Both EB613 and EB612 are first in class oral formulations of synthetic human PTH (1-34), (teriparatide), a peptide consisting of the first 34 amino acids of PTH, which represent the functional region of the hormone. In total, more than 260 subjects have participated in Entera's clinical trials to date. Entera's oral PTH (1-34) formulations have been administered collectively to a total of 225 subjects in two Phase 1 studies and three phase 2 studies (including 35 in two phase 2 hypoparathyroidism studies). Subjects in the phase 2 osteoporosis study received EB613 daily for up to six months.

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 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.

Current osteoporosis pharmacologic treatment is segmented into anti-resorptive agents that suppress osteoclast-mediated bone resorption and anabolic agents that promote new bone formation by activating osteoblasts. Current anti-resorptive standards of care treatments include bisphosphonates, a rank-ligand inhibitor (such as Amgen's denosumab, Prolia®), SERMS, estrogen/HRT and calcitonin. Current anabolic standard of care treatments include PTH receptor agonists (such as Forteo® and Tymlos®) and Evenity®, Amgen's anti-sclerostin monoclonal antibody. In contrast to the anti-resorptive drugs available, there are currently no oral anabolic treatments for osteoporosis.

Forteo®, a once-daily subcutaneous injectable form of PTH (1-34), (teriparatide), marketed by Eli Lilly and Company ("Eli Lilly"), is considered one of the most effective treatments in osteoporosis therapy due to its ability to build bone (anabolic mechanism of action). Forteo® had peak sales surpassing $1.7 billion globally in 2017, prior to patent expiry. Entera's EB613 has the same amino acid sequence as Forteo.® In February 2022, we engaged a third-party firm to conduct primary market research with endocrinologist and general practice clinicians who treat osteoporosis patients. According to these surveys, it is estimated that less than 10% of osteoporosis patients use current anabolic drugs (including PTH receptor activators currently available). Despite the validated mechanism of action of these treatments, patients are deterred by their high cost and injectable mode of administration. Furthermore, healthcare providers indicated that they would support the use of an oral PTH anabolic therapy earlier in the treatment paradigm due to its validated PTH receptor-activating bone formation mechanism of action and patients' preference for an oral route of administration. Because our PTH product candidate, EB613, is delivered in a patient-friendly, oral tablet formulation, we believe it will lead to significantly higher patient and physician acceptance compared to the injectable PTH standard treatments, thus addressing this significant unmet clinical need.

To date, we have completed two, Phase 1 clinical trials and a six-month placebo-controlled Phase 2 double-blind, 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 and key secondary endpoints and was presented in a late-breaker oral presentation at the 2021 ASBMR Annual Meeting. For the primary efficacy endpoint: a statistically significant increase in P1NP (a bone formation marker) at 3 months was achieved. A significant dose response was observed for 0.5, 1.0, 1.5 and 2.5 mg oral PTH doses on P1NP, Osteocalcin and bone mineral density ("BMD"). Subjects receiving the 2.5 mg dose of EB613 showed significant dose-related increases in BMD at the lumbar spine, total hip, and femoral neck at 6 months. Subjects receiving the 2.5 mg dose of EB613 daily for 6 months had a significant placebo adjusted increase of 3.78% in lumbar spine BMD ($p<0.008$) which is similar to the 3.9% increase in lumbar spine BMD seen with Forteo® at 6 months in clinical studies reported in published literature. Increases in total hip and femoral neck BMD were greater than those previously reported with Forteo.® EB613 exhibited was well tolerated, with no drug related serious adverse events. The most common adverse events included mild nausea, moderate back pain, moderate headache, and moderate upper abdominal pain.

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 reviewed our October 2020 IND Application and informed us that we may proceed with our U.S. clinical pharmacology study. In December 2021 we held an end-of-Phase 2 meeting with the FDA to review the six-month phase 2 results and our proposed Phase 3 study protocol, our nonclinical and clinical development plan and the use of BMD, rather than fracture incidence, as the primary endpoint to support a New Drug Application ("NDA").

Following our End of Phase 2 Meeting with the FDA, Entera redesigned the pivotal phase 3 study for EB613 based on the FDA's suggestion to explore a placebo-controlled trial. The study proposed is an 18-month randomized, double-blind, multicenter study comparing the effects of oral PTH (1-34), (teriparatide), EB613 compared to placebo in post-menopausal women with osteoporosis at high risk of fracture, followed by a six-month open-label extension where all patients will be transitioned to alendronate, a standard of care anti-resorptive therapy. Patients will be randomized in a 2:1 ratio to receive blinded treatments with either EB613 (N=400) 2.5 mg dose of oral PTH or Placebo (N=200). The six-month extension phase of the study is intended to provide information on the transition from EB613 to a standard anti-resorptive therapy which has been shown to maintain or augment the increases in BMD following injectable PTH therapies, to preserve blinding of the prior therapy and to ensure that patients randomized to the placebo arm also receive an osteoporosis treatment.

The primary endpoint of the phase 3 study is the percent change in total hip BMD over 18 months of daily oral EB613 treatment as compared to the placebo. Change in total hip BMD is incorporated as the primary endpoint, in line with the Foundation for the National Institutes of Health - American Society for Bone and Mineral Research Study to Advance Bone Mineral Density as a Regulatory Endpoint (FNIH-ASBMR SABRE). The FNIH-ASBMR SABRE submitted a Qualification Plan for percentage change in total hip bone BMD as a surrogate endpoint for fracture. This plan has been accepted by FDA's Biomarker Qualification Program, with a request for submission of a Full Qualification Package. According to the FNIH's June 1, 2022 press release, the FNIH-ASBMR SABRE plans to submit the Full Qualification Package, for final approval by the FDA, by the end of the year. The FNIH-ASBMR SABRE project investigators published meta-regression analyses based on patient-level BMD and fracture incidence data from 23 placebo-controlled fracture-endpoint studies across many classes of osteoporosis drugs, including subcutaneous teriparatide injection.

The FNIH-ASBMR SABRE project evaluations indicate that changes in total hip BMD (in comparison to lumbar spine or femoral neck BMD) is the best surrogate marker of an osteoporosis drug's effects on vertebral, nonvertebral, all site and hip fracture risk. The FNIH-ASBMR SABRE proposal is that changes in total hip BMD that equal or exceed Surrogate Threshold Effects (STEs) indicate fracture risk reduction. In the planned oral PTH EB613 phase 3 study, statistical methods will compare the observed treatment effect of EB613 versus placebo, compared to the FNIH-ASBMR SABRE defined STEs associated with vertebral fracture, all site fracture and nonvertebral fracture risk reduction. The study will also look at secondary endpoints including changes in lumbar spine and femoral neck BMD and EB613's effects on biochemical markers of bone formation and resorption.

In the first half of 2022, Entera submitted to the FDA a Type C meeting request, briefing documents and its proposed Phase 3 design for a registrational study of EB613 based on this design. A Type C meeting with the FDA in relation to Entera's proposed Phase 3 registrational study is expected in the second half of 2022.

Hypoparathyroidism

Hypoparathyroidism is a rare condition in which the body fails to produce sufficient amounts of PTH or the PTH produced lacks normal biologic activity. Historically, the treatments for hypoparathyroidism have been calcium supplements, calcitriol or "active vitamin D" analogs and occasionally phosphate binders, the chronic use of which may result in serious side effects and significant costs to patients and healthcare systems.

Natpara® (injectable PTH 1-84) for the treatment of hypoparathyroidism was approved in the United States in 2015 and at least temporarily withdrawn from the U.S. market in September 2019 due to FDA's concern about the potential for rubber particulate formation in Natpara®. This concern is specific to their device and not part of EB612 given we are proposing a tablet form of PTH.

Our lead product candidate for hypoparathyroidism, EB612, is delivered orally and may be administered in customized doses several times a day. We believe EB612 has the potential to become a standard of care, if approved, for hypoparathyroidism because of its oral administration, which is preferred by most patients based on clinician and third-party commercial research to date.

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 trial showed the potential for similar clinical benefit of EB612. EB612 induced a rapid decline in median serum phosphate levels and maintenance of target calcium levels throughout the study, even as patients were able to meaningfully reduce their calcium and active vitamin D supplementation which is key to reducing common comorbidities of this disease.

In the third quarter of 2019, we reported the results of a second Phase 2 clinical trial that included one day of dosing with EB612 to evaluate the pharmacokinetic/pharmacodynamics, or PK/PD, profile of various EB612 dose regimens compared with Natpara®. The results from this study demonstrated that EB612 was effectively delivered into the blood stream and activated PTH-dependent biological pathways that are inadequately activated in patients with hypoparathyroidism. In addition, the various dosing regimens demonstrated positive impacts on serum calcium, urine calcium and serum phosphate levels. No serious adverse events were reported. The pilot 4-month Phase 2 results for EB612 were presented at ASBMR 2015 and published in a peer-reviewed journal, JBMR, in 2021. The Phase 2 PK-PD study versus Natpara® was presented at ASBMR 2019.

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. We anticipate that the outcome of the PK study will help determine the design of a pivotal Phase 2b or Phase 3 trial of EB612 in patients with hypoparathyroidism, in which the dose frequency would be titrated to control hypocalcemia, normalize serum phosphate and reduce renal calcium excretion. If successful, the phase 2b/3 clinical trial of EB612 in hypoparathyroidism may potentially support a submission for regulatory approval of EB612. Entera has received U.S. and European Union ("EU") orphan drug designation for EB612.

In addition to the utilization of our technology to develop our own internal drug candidates, we intend to use our technology as a platform for the oral delivery of additional approved and novel peptide and therapeutic proteins. We believe our proprietary technology has advantages over alternative delivery options and may enable us to create a potential pipeline of products across a range of therapeutic indications. We have generated data on a number of additional proteins and peptides in molecules as large as 150 kilodaltons, or kDa, and may develop these candidates further internally, or explore potential business development collaborations to advance these therapies through clinical development produce non-dilutive funding and diversify our revenue stream.

In December 2018, we entered into a research collaboration and license agreement with Amgen. Under the agreement, we and Amgen have agreed to collaborate on the development and discovery of clinical candidates in the field of inflammatory disease and other serious illnesses. Specifically, we and Amgen have agreed to use our proprietary drug delivery platform to help Amgen develop oral formulations for up to three large molecule drug candidates within Amgen's pipeline. Further, under the terms of the agreement, we have agreed to conduct preclinical development activities, at Amgen's expense, and Amgen will be responsible for research, clinical development, manufacturing and commercialization of any of the resulting programs, at its expense. We will be eligible to receive from Amgen aggregate payments of up to $270 million upon achievement of various clinical and commercial milestones or Amgen's exercise of its option to select up to two additional programs to include in the collaboration, as well as tiered royalty payments based on percentages ranging from the low to mid-single digits based on the level of Amgen's net sales of any applicable products, if approved. We will retain all intellectual property rights to our drug delivery technology, which under this collaboration will be licensed to Amgen exclusively for Amgen's selected drug targets. Amgen will retain all rights to its large molecules, including any subsequent improvements.

In February 2021, we announced that we had initiated a new research program for an oral glucagon-like peptide-2 (GLP-2) analog based on the Company's platform technology. GLP-2, a peptide produced in the intestine and the central nervous system via the brainstem and hypothalamus, is known to enhance intestinal absorption, specifically the increased absorption of nutrients. The only GLP-2 analog currently on the market, teduglutide, was approved in 2012 as a once daily injection for the treatment of short bowel syndrome in the United States and Europe, registering global sales of $613 million in 2020. In preclinical models, our oral formulation of a GLP-2 analog has shown a comparable pharmacokinetic profile to a subcutaneous injection. In addition, GLP-2 analogs are an important category of new therapies for many metabolic diseases and therefore we believe this product candidate is well positioned for partnering opportunities.

We intend to utilize future funds, as available, to advance EB613 and EB612 through clinical development and ultimately towards regulatory approval. In addition, we are currently evaluating the potential for a strategic transaction involving EB613's phase 3 clinical development and commercialization. To date, we have funded our operations through both public and private sales of our Ordinary Shares and other equity or equity-linked securities, convertible debt, government grants and through revenues generated from research collaboration and our license agreement with Amgen. We have no products that have received regulatory approval and have never generated revenue from product sales.

Since our inception, we have raised a total of $84.7 million in various public and private equity offerings, as well as from grants, and the exercise of options and warrants. Since inception, we have incurred significant losses. For the three months ended June 30, 2022 and 2021, our operating losses were $3.2 million and $2.6 million, respectively. In addition, for the six months ended June 30, 2022 and 2021, our operating losses were $7.1 and $4.9 million, respectively, and we expect to continue to incur significant expenses and losses for the foreseeable future. As of June 30, 2022, we had an accumulated deficit of $89.4 million. Our losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials, our expenditures on research and development activities and payments under the collaboration with Amgen or any future collaborations into which we may enter.

As of June 30, 2022, we had cash and cash equivalents of $17.3 million. We believe that our existing cash resources, not including potential milestone payments, will be sufficient to meet our projected operating requirements through the second quarter of 2023.

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, government grants, 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 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, 2021, 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 curtail or cease operations. See “Item 1A—Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital” in our 2021 Annual Report.

As of June 30, 2022, we had 22 full-time employees and four consultants who provide services to us on a part-time basis. Our operations are located in Jerusalem, Israel.

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, with respect to inflammatory disease and other serious illnesses. Pursuant to the Amgen Agreement, we and Amgen have 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 $725,000 in the first quarter of 2019, of which $500,000 was attributed to the right to use the intellectual property and $225,000 was attributed to the pre-clinical R&D services that we are obligated to perform under the Amgen Agreement. In addition, under the Amgen Agreement, Amgen reimburses us for additional expenses that we incur for any work we do under the collaboration. Thus far during our collaboration, Amgen has paid $968,000 for pre-clinical R&D services.

Amgen also has options, limited in time, to select up to two additional programs to include in the collaboration. Amgen is responsible for the clinical development, regulatory approval, manufacturing and worldwide commercialization of the programs. Pursuant to the terms of the Amgen Agreement, Amgen is required to make aggregate payments 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. In addition, Amgen is required to make tiered royalty payments ranging from the low to mid-single digits as a percentage of Amgen's net sales of the applicable products covered by the Amgen Agreement. Amgen's obligation to pay royalties with respect to a product in a particular country commences upon the first commercial sale of such product in such country and expires on a country-by-country and product-by-product basis on the later of (a) the date on which the sale of the product is no longer covered by a valid claim of a patent licensed to Amgen under the Amgen Agreement, and (b) the tenth anniversary of the first commercial sale of such product in such country.

Under the Amgen Agreement, we granted Amgen an exclusive, worldwide, sub-licensable license to certain of our intellectual property relating to our drug delivery technology to develop, manufacture and commercialize the applicable products. We have retained all intellectual property rights to our drug delivery technology, 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 collaboration is to be determined by U.S. patent law. Each party is responsible for the filing and prosecution of patents relating to its owned developments and, with respect to any jointly-owned developments, we are responsible for the filing and prosecution of patents solely claiming improvements to our drug delivery technology and Amgen is responsible for the filing and prosecution of any other jointly-owned developments. Amgen has the primary right to enforce any such patents against third-party infringement with respect to a product that has the same mechanism of action as one of the collaboration programs, subject to involvement by us in certain circumstances.

During certain periods covered by the Amgen Agreement, we may not alone, or with a third party, research, develop, manufacture or commercialize certain products that interact with the targets of the applicable collaboration programs. The collaboration is governed by a joint research committee, or JRC, made up of equal representatives of us and Amgen. The JRC may establish additional subcommittees to oversee particular projects or activities. Subject to certain limitations, if the JRC is unable to make a decision by consensus, the disagreement is to be resolved through escalation to specified senior executive officers of the parties, although Amgen has the final decision-making ability with respect to certain pre-defined issues.

The term of the Amgen Agreement commenced on December 10, 2018, and unless earlier terminated, continues in full force and effect, on a product-by-product basis, until expiration of the last-to-expire royalty term with respect to such product. At any point in the research, development or commercialization process, subject to certain conditions, Amgen can terminate the Amgen Agreement in its entirety or with respect to a specific development program. Both parties can terminate the agreement for a material breach by the other party that goes uncured, subject to a 90-day notice period.

The Israeli Innovation Authority Grants

We have received grants of approximately $0.5 million from the Israeli Innovation Autority ("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, referred to as 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, and the rate of royalties may be accelerated, 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. Following the signing of the Amgen Agreement, we have been required to pay 5.38% of each payment by Amgen and up to 600% of the grant received. As of June 30, 2022, we had paid royalties to the IIA in the amount of $79,000 related to the Amgen Agreement.

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

Financial Overview

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, through June 30, 2022, we had received an aggregate amount of $968,000 from Amgen for research and development services. In addition, we have several Material Transfer Agreements, or MTA agreements, under which we generate revenue.

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. The Company evaluated the standalone selling price of the pre-clinical R&D services at $225,000 and the right to use the intellectual property at $500,000.

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 have been no commercial sales.

For the three months ended June 30, 2022 and 2021, we recognized revenues from the Amgen Agreement and other MTA agreements in the total amounts of $44 thousand and $109 thousand, respectively. In addition, we recognized $112 thousand and $266 thousand under these agreements for the six months ended June 30, 2022 and 2021, respectively.

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.

Research expenses are generally recognized as incurred. An intangible asset arising from the development of our product candidates is recognized if certain capitalization conditions are met. For the three and six months ended June 30, 2022 and 2021, we did not capitalize any development costs.

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, 2022 and 2021, our research and development expenses were $1.4 million and $1.2 million, respectively. For the six months ended June 30, 2022 and 2021, our research and development expenses were $3.1 million and $2.4 million, respectively. Research and development expenses for both the three and six months ended June 30, 2022 and 2021 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 and related benefits, share-based compensation and related costs for employees and directors 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 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) Loss, Net

Financial (income), loss ,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, 2022, we had carry-forward tax losses of $61.5 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.

As of June 30, 2022, our subsidiary, Entera Bio Inc., had no carry forward tax losses.

Results of Operations

Comparison of Three Months Ended June 30, 2022 and 2021

	Three Months Ended June 30,		Increase (Decrease)	
	2022	2021	$	%
	(In thousands, except for percentage information)			
Revenues	$ 44	$ 109	$ (65)	(60)%
Cost of revenues	$ 33	$ 99	$ (66)	(67)%
Operating expenses:				
Research and development expenses	$ 1,394	$ 1,227	$ 167	14%
General and administrative expenses	$ 1,880	$ 1,364	$ 516	38%
Other income	$ (14)	$ (11)	$ (3)	27%
Operating loss	$ 3,249	$ 2,570	$ 679	26%
Financial (income) loss, net	$ (60)	$ 24	$ (84)	(350)%
Income tax benefit	$ (4)	$ (17)	$ 13	(76)%
Net loss	$ 3,185	$ 2,577	$ 608	24%

Revenue

Revenues for the three months ended June 30, 2022 and 2021 were $44,000 and $109,000, respectively. For both the three months ended June 30, 2022 and 2021, the majority of our revenues were attributable to pre-clinical R&D services provided to Amgen under the Amgen Agreement and other MTA agreements.

Cost of Revenues

Cost of revenues for the three months ended June 30, 2022 was $33,000 compared to $99,000 for the three months ended June 30, 2021 and was primarily attributed to salaries and related expenses in connection with the R&D services provided to Amgen and other MTA agreements.

Research and Development Expenses

Research and development expenses for three months ended June 30, 2022 were $1.4 million, as compared to $1.2 million for the three months ended June 30, 2021. The increase of $0.2 million was primarily due to an increase of $0.2 million in pre-clinical activity as part of the preparation for our Phase 3 clinical trial for EB613 and an increase of $0.2 million in employee's compensation mainly related to the separation agreement with the President of R&D, including share-based compensation, which was offset by a decrease of $0.2 million in other clinical trial expenses related to our Phase 2 trial for EB613 that was completed in June 2021.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2022 were $1.9 million compared to $1.4 million for the three months ended June 30, 2021. The increase of $0.5 million was mainly attributable to an increase of $0.2 million in share-based compensation granted to non-executive directors, an increase of $0.2 million in professional fees and an increase of $0.1 million in D&O insurance costs.

Financial (Income) Loss (Income), Net

Financial (income) loss, net for the three months ended June 30, 2022 and 2021 was $(60,000) and $24,000, 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, 2022 and 2021

	Six Months Ended June 30,		Increase (Decrease)	
	2022	2021	$	%
	(In thousands, except for percentage information)			
Revenues	$ 112	$ 266	$ (154)	(58)%
Cost of revenues	$ 87	$ 172	$ (85)	(49)%
Operating expenses:				
Research and development expenses	$ 3,084	$ 2,351	$ 733	31%
General and administrative expenses	$ 4,052	$ 2,674	$ 1,378	52%
Other income	$ (27)	$ (22)	$ (5)	23%
Operating loss	$ 7,084	$ 4,909	$ 2,175	44%
Financial income, net	$ (104)	$ (5)	$ (99)	1,980%
Income tax benefit	$ (11)	$ (31)	$ 20	(65)%
Net loss	$ 6,969	$ 4,873	$ 2,096	43%

Revenue

Revenues for the six months ended June 30, 2022 and 2021 were $112,000 and $266,000, respectively. For both the six months ended June 30, 2022 and 2021, the majority of our revenues were attributable to pre-clinical R&D services provided to Amgen under the Amgen Agreement and other MTA agreements.

Cost of Revenues

Cost of revenues for the six months ended June 30, 2022 was $87,000 compared to $172,000 for the six months ended June 30, 2021 and were primarily attributed to salaries and related expenses in connection with the R&D services provided to Amgen and other MTA agreements.

Research and Development Expenses

Research and development expenses for six months ended June 30, 2022 were $3.1 million, as compared to $2.4 million for the six months ended June 30, 2021. The increase of $0.7 million was primarily due to an increase of $0.7 million in materials, production costs and pre-clinical activity as part of the preparation for our Phase 3 clinical trial for EB613 and an increase of $0.4 million in employee's compensation mainly related to the separation agreement with our Former President of R&D, which was offset by a decrease of $0.4 million in other clinical trial expenses related to our Phase 2 trial for EB613 that was completed in June 2021.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2022 were $4.1 million compared to $2.7 million for the six months ended June 30, 2021. The increase of $1.4 million was mainly attributable to an increase of $0.8 million in share-based compensation granted to non-executive directors and employees, an increase of $0.4 million in legal, accounting fees and other consultant fees, and an increase of $0.2 million in D&O insurance costs.

Financial Income, Net

Financial income, net for the six months ended June 30, 2022 and 2021 was $104,000 and $5,000, 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, 2022 and 2021, our operating losses were $3.2 million and $2.6 million, respectively. In addition, for the six months ended June 30, 2022 and 2021, our operating losses were $7.1 and $4.9 million, respectively, and we expect to continue to incur significant expenses and losses for the foreseeable future. As of June 30, 2022, we had an accumulated deficit of $89.4 million. We expect to continue to incur significant expenses and losses for the next several years as we advance our products through development and provide administrative support for our operations.

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 2021 Annual Report.

Since our inception, we have raised a total of $84.7 million, including $25.3 million through our Prior ATM Program and our ATM Program (each as defined below), of which $21.8 million was raised in 2021, $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, through June 30, 2022, we had have received approximately $1.4 million under the Amgen Agreement.

As of June 30, 2022, we had cash and cash equivalents of $17.3 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.

In July 2020, we entered into an equity distribution agreement with Canaccord Genuity LLC, as sales agent, to implement an at-the-market offering program under which we, from time to time, were able to offer and sell our Ordinary Shares, having an aggregate offering amount of up to $13.9 million (the “Prior ATM Program”). Offers and sales under the Prior ATM Program had been registered on a registration statement on From F-3 (the “Prior Registration Statement”). The Prior ATM Program terminated in accordance with its terms following our sale of the full dollar amount of Ordinary Shares permitted thereunder. On May 7, 2021 we entered into an At Market Issuance Sales Agreement with B. Riley Securities, Inc., as sales agent, under which we, from time to time, may had been able to offer and sell up to 5,000,000 Ordinary Shares (the “ATM Program”). The sales agent is entitled to a fixed commission of 3% of the aggregate gross proceeds as well as and reimbursement of expenses. For the year ended December 31, 2021, we sold an aggregate of 2,546,265 Ordinary Shares under the Prior ATM Program and 1,764,860 Ordinary Shares under the ATM Program, the aggregate proceeds of which amounted to $21.8 million, net of issuance costs, in each case in offerings registered under the Prior Registration Statement.

Following our loss of foreign private issuer status on January 1, 2022, we were no longer able to effect offers and sales under our Prior Registration Statement; therefore, we filed a new shelf registration statement on Form S-3 (file no. 333-365286) on May 27, 2022 to, among other things, facilitate our use of the ATM Program. On May 27,2022 we entered into Amended Restated At Market Issuance Sales Agreement with B. Riley Securities, Inc., as sales agent, as a replacement to our May 2021 agreement, which we, from time to time, may had been able to offer and sell up to 5,000,000 Ordinary Shares (the “Amended ATM Program”). The sales agent is entitled to a fixed commission of 3% of the aggregate gross proceeds as well as and reimbursement of expenses. We have not sold any additional shares under the ATM Program or Amended ATM Program during the six months ended June 30, 2022.

Funding Requirements

We believe that our existing capital resources, not including potential milestone payments, will be sufficient to meet our projected operating requirements through the second quarter of 2023.

We have based these estimates on assumptions that maybe the different from the actual results, 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;
- the impact of COVID-19 on our clinical trials, regulatory timelines, business operations and financial stability; and
- our ability to establish collaborations on favorable terms, if at all.

We are in the process of evaluating various financing alternatives in the public or private equity markets, and through license of our technology to additional external parties through partnerships or research collaborations as we will need to finance future research and development activities, general and administrative expenses and working capital through fund raising. However, there is no certainty about our ability to obtain such funding.

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 for the three and six months ended June 30, 2022 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, 2022 compared to Six Months Ended June 30, 2021

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)	
	2022	**2021**
	(in thousands)	
Net Cash used in operating activities	$ (7,619)	$ (4,442)
Net Cash used in investing activities	$ (42)	-
Net Cash provided by financing activities	$ 13	22,775
Net (decrease) increase in cash and cash equivalents	$ (7,648)	$ 18,333

Net Cash Used in Operating Activities

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 an increase of $2.2 million in our working capital, which was partially offset by approximately $1.7 million of share-based compensation and depreciation expenses.

Net cash used in operating activities for the six months ended June 30, 2021 was $4.4 million consisting primarily of our operating loss of $4.9 million and an increase of $0.4 million in our working capital which were partially offset by $0.9 million of share-based compensation expense.

The increase of $3.2 million in cash used in operating activities for the six months ended June 30, 2022 compared to the same period in 2021 was mainly attributed to an increase of $2.2 million in our operating loss, an increase of $1.8 in working capital mainly due to payments to suppliers and services providers, which were partially offset by an increase of $0.8 million in share-based compensation.

Net Cash Used in Investing Activities

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

For the six months ended June 30, 2021, no cash was used in or provided by investing activities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2022 consisted net proceeds of $13 thousand from the exercise by a former employee of options to purchase Ordinary Shares.

Net cash provided by financing activities for the six months ended June 30, 2021 consisted primarily of the net proceeds of $19.4 million from the issuance of Ordinary Shares under our ATM Program and $3.4 million from exercise of options and warrants.

Contractual Obligations

There have not been any material changes in our assessment of material contractual obligations and commitments as set forth in Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our 2021 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 2021 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 2021 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, 2022, 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 2021 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

None.

ITEM 6. EXHIBITS

Exhibit No.	Description of Exhibits
10.1*	Employment Agreement, effective as of May 16, 2022 by and between Entera Bio Ltd. and Miranda J. Toledano (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 16, 2022 and incorporated herein by reference).
10.2**	Amended and Restated At Market Issuance Sales Agreement, dated May 27, 2022, by and between Entera Bio Ltd. and B. Riley Securities, Inc. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 27, 2022 and incorporated herein by reference).
10.3*	Mutual Separation Agreement, dated June 15, 2022, by and between Entera Bio Ltd. and Dr. Phillip Schwartz (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 17, 2022 and incorporated herein by reference).
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)

* Management contract or compensation plan or arrangement

** Pursuant to Item 601(a)(5) of Regulation S-K, schedules and similar attachments to this exhibit have been omitted because they do not contain information material to an investment or voting decision and such information is not otherwise disclosed in such exhibit. The Company will supplementally provide a copy of any omitted schedule or similar attachment to the U.S. Securities and Exchange Commission or its staff upon request.

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: August 11, 2022

/s/ Miranda J. Toledano

Miranda J. Toledano
Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2022

/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 J. Toledano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2022 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, 2022

/s/ Miranda J. Toledano
Miranda J. 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, 2022 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, 2022

/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 J. 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, 2022 (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, 2022

/s/ Miranda J. Toledano
Miranda J. 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, 2022 (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, 2022

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