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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of May 2020

Commission file number: 001-38556

ENTERA BIO LTD.

(Exact Name of Registrant as Specified in Its Charter)

Kiryat Hadassah
Minrav Building – Fifth Floor
Jerusalem, Israel
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

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This report on Form 6-K of the registrant consists of a press release issued by the registrant on May 21, 2020, attached hereto as an exhibit and incorporated by reference herein.

Exhibit

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.
(Registrant)

By: /s/Adam Gridley
Name: Adam Gridley
Title: Chief Executive Officer

Date: May 21, 2020

Exhibit 99.1

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(UNAUDITED)

AS OF MARCH 31, 2020

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(UNAUDITED)

AS OF MARCH 31, 2020

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ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(UNAUDITED)

	March 31 2020	December 31 2019
	U.S. dollars in thousands	
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	13,328	15,185
Accounts receivable	-	278
Other current assets	786	173
TOTAL CURRENT ASSETS	14,114	15,636
NON-CURRENT ASSETS:		
Property and equipment	214	202
Right of use assets	250	260
Intangible assets	605	605
TOTAL NON-CURRENT ASSETS	1,069	1,067
TOTAL ASSETS	15,183	16,703
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable:		
Trade	431	334
Other	1,443	1,370
Current maturities of lease liabilities	152	177
Warrants to purchase ordinary shares	2,714	2,444
Contract liabilities	225	267
TOTAL CURRENT LIABILITIES	4,965	4,592
NON-CURRENT LIABILITIES:		
Lease liabilities	130	122
Severance pay obligations, net	73	70
TOTAL NON-CURRENT LIABILITIES	203	192
TOTAL LIABILITIES	5,168	4,784
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.0000769 par value:		
Authorized - as of March 31, 2020 and December 31, 2019, 140,010,000 shares; issued and outstanding: as of March 31, 2020, and December 31, 2019 18,234,191 and 17,864,684 shares, respectively	*	*
Accumulated other comprehensive income	41	41
Other reserves	11,598	11,398
Additional paid in capital	64,206	63,392
Accumulated deficit	(65,830)	(62,912)
TOTAL SHAREHOLDERS' EQUITY	10,015	11,919
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	15,183	16,703

* Represents an amount less than one thousand US dollars.

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

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended March 31	
	2020	2019
	U.S. dollars in thousands	
REVENUE	42	-
COST OF REVENUE	42	-
RESEARCH AND DEVELOPMENT EXPENSES, net	1,605	2,035
GENERAL AND ADMINISTRATIVE EXPENSES	1,290	1,056
OPERATING LOSS	2,895	3,091
FINANCIAL EXPENSES (INCOME):		
Loss (income) from change in fair value of financial liabilities at fair value	46	(112)
Other financial expenses (income), net	(23)	16
FINANCIAL EXPENSES (INCOME), net	23	(96)
NET COMPREHENSIVE LOSS FOR THE PERIOD	2,918	2,995
	U.S. dollars	
LOSS PER ORDINARY SHARE -		
Basic and diluted	0.16	0.26
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING -		
Basic and diluted	18,048,827	11,459,780

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

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF SHAREHOLDERS' EQUITY (UNAUDITED)

	Number of Ordinary Shares	Ordinary Shares- Amount	Accumulated other comprehensive income	Other reserve	Additional paid in capital	Accumulated deficit	Total
	U.S dollars in thousands						
BALANCE AT JANUARY 1, 2019	11,459,780	*	41	13,019	49,173	(52,117)	10,116
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2019:							
Net loss for the period	-	-	-	-	-	(2,995)	(2,995)
Share-based compensation	-	-	-	541	-	-	541
BALANCE AT MARCH 31, 2019	11,459,780	*	41	13,560	49,173	(55,112)	7,662
BALANCE AT JANUARY 1, 2020	17,864,684	*	41	11,398	63,392	(62,912)	11,919
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2020:							
Net loss for the period	-	-	-	-	-	(2,918)	(2,918)
Exercise of options to ordinary shares	31,954	*	-	(35)	103	-	68
Issuance of shares and warrant due to a private placement, net of issuance costs	337,553	*	-	-	573	-	573
Expiration of options				(138)	138		-
Share-based compensation	-	-	-	373	-	-	373
BALANCE AT MARCH 31, 2020	18,234,191	*	41	11,598	64,206	(65,830)	10,015

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

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31	
	2020	2019
	(Unaudited)	
	U.S dollars in thousands	
CASH FLOWS USED IN OPERATING ACTIVITIES:		
Net loss for the period	(2,918)	(2,995)
Adjustments required to reflect net cash used in operating activities (see appendix A)	262	1,062
Net cash used in operating activities	(2,656)	(1,933)
CASH FLOWS USED IN INVESTING ACTIVITIES:		
Purchase of property and equipment	(29)	(33)
Net cash used in investing activities	(29)	(33)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares and warrants, net of issuance costs	797	-
Proceeds from exercise of options	68	-
Principle element of lease payments	(37)	(23)
Net cash provided by (used in) financing activities	828	(23)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,857)	(1,989)
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR	15,185	7,506
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	13,328	5,517

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

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31	
	2020	2019
	(Unaudited)	
	U.S dollars in thousands	
APPENDIX A:		
Adjustments required to reflect net cash used in operating activities:		
Depreciation	50	56
Change in fair value of financial liabilities at fair value through profit or loss	46	(112)
Financial expenses (income)	4	(2)
Net changes in severance pay obligation	3	2
Share-based compensation	373	541
	476	485
Changes in working capital:		
Decrease in accounts receivables	278	725
Increase in other current assets	(613)	(389)
Increase (decrease) in accounts payable and accruals:		
Trade	97	326
Other	73	(73)
Decrease in contract liabilities	(42)	-
	(207)	589
Cash used for operating activities -		
Interest paid	(7)	(12)
	262	1,062
APPENDIX B:		
Supplementary information on investing and financing activities not involving cash flows:		
Right of use assets obtained in exchange for new operating lease liabilities	23	

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

NOTE 1 - GENERAL INFORMATION:

a. General:

1) Entera Bio Ltd. (collectively with its subsidiary, the "Company") was incorporated on September 30, 2009 and commenced operation on June 1, 2010. On January 8, 2018 the Company incorporated Entera Bio Inc., a fully owned subsidiary incorporated in Delaware USA. The Company is a leader in the development and commercialization of orally delivered macromolecule therapeutics for use in areas with significant unmet medical need where adoption of injectable therapies is limited due to cost, convenience and compliance challenges for patients. The Company's most advanced product candidates, EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism, are based on its proprietary technology platform and are both in Phase 2 clinical development. The Company also licenses its technology to biopharmaceutical companies for use with their proprietary compounds and, to date, has completed one such collaboration with Amgen Inc.

2) The Company's securities have been listed for trading on the Nasdaq Capital Market since the Company's initial public offering in July 2018, where a total of 1,400,000 new ordinary shares were issued in consideration of net proceeds of $9.6 million, after deducting offering expenses.

3) On December 10, 2018, the Company entered into a research collaboration and license agreement (the "Amgen Agreement") with Amgen Inc. ("Amgen") in inflammatory disease and other serious illnesses. Pursuant to the Amgen Agreement, the Company and Amgen 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 collaboration. 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 will retain all intellectual property rights to its drug delivery technology, and Amgen will retain all rights to its large molecules and any subsequent improvements, and ownership of certain intellectual property developed through the performance of the collaboration is to be determined by U.S. patent law.

b. Since 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 $65.8 million through March 31, 2020 and negative cash flows from operating activities. The Company's management is of the opinion that its available funds as of March 31, 2020 will allow the Company to operate under its current plans into the second quarter of 2021, due to delays in certain activities as a result of the recent coronavirus (COVID-19) outbreak. 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, government grants or through license of the company's technology to additional external parties through partnerships or research collaborations. The Company will need to finance future research and development activities, general and administrative expenses and working capital through financing or external partnership. However, there is no certainty about the Company's ability to obtain such funding.

NOTE 1 - GENERAL INFORMATION (Continued)**:**

The financial information has been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. If the Company does not raise the requisite funds, it will need to curtail or cease operations. These financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

c. Approval of financial statements

These financial statements were approved by the Company's Board of Directors on May 18, 2020.

NOTE 2 - BASIS OF PREPARATION

The Company’s condensed consolidated interim financial statements as of March 31, 2020 and for the three months then ended (the “interim financial statements”) have been prepared in accordance with International Accounting Standard No. 34, “Interim Financial Reporting” (“IAS 34”). These interim financial statements, which are unaudited, do not include all disclosures necessary for a complete presentation of financial position, comprehensive loss, changes in shareholders' equity and cash flows in conformity with generally accepted accounting principles. The condensed consolidated interim financial statements should be read in conjunction with the Company’s annual financial statements as of December 31, 2019 and for the year then ended and their accompanying notes, which have been prepared in accordance with International Financial Reporting Standards (“IFRS”) as issued by the IASB.

The results of operations for the three months ended March 31, 2020 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

NOTE 3 - SIGNIFICANT ACCOUNTING POLICIES

The accounting policies and calculation methods applied in the preparation of the interim financial statements are consistent with those applied in the preparation of the annual financial statements as of December 31, 2019 and for the year then ended.

Loss per ordinary share

Basic and diluted loss per share are computed by dividing the loss for the period by the weighted average number of ordinary shares outstanding for each period.

All outstanding options and warrants have been excluded from the calculation of the diluted loss per share for the three months ended March 31, 2020 and 2019 since their effect was anti-dilutive. The total number of ordinary shares which were excluded from the calculation of diluted loss per share was 8,047,941 and 5,857,338 for the three months ended March 31, 2020 and 2019 respectively.

NOTE 4 - FINANCIAL RISK FACTORS

The Company's activities expose it to a variety of financial risks.

The condensed interim financial statements do not include all financial risk information and disclosures required in the annual financial statements; they should be read in conjunction with the Company's annual financial statements as of December 31, 2019.

There have been no changes in the risk management policies since the year end.

NOTE 5 - FAIR VALUE MEASUREMENT

The Company measures fair value and discloses fair value measurements for financial assets. Fair value is based on the price that would be received to sell an asset in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

As of March 31, 2020, and December 31, 2019, the fair value of cash and cash equivalents, accounts receivable, other receivables and accounts payable approximates their carrying value.

NOTE 5 - FAIR VALUE MEASUREMENT (Continued):

	Financial liabilities at fair value through profit or loss	Financial liabilities at amortized cost	Total
	U.S. dollars in thousands		
As of March 31, 2020:			
Trade and other payable	-	1,874	1,874
Warrants to purchase ordinary shares (level 1) (1)	532	-	532
Warrants to purchase ordinary shares (level 3) (2)	2,182	-	2,182
	2,714	1,874	4,588
As of December 31, 2019:			
Trade and other payable	-	1,704	1,704
Warrants to purchase ordinary shares (level 1)	266	-	266
Warrants to purchase ordinary shares (level 3)	2,178	-	2,178
	2,444	1,704	4,148

(1) Tradable warrants presented above are valuated based on the market price (a level 1 valuation) as of March 31, 2020.

(2) Warrants to purchase ordinary shares issued in December 2019 and February 2020 presented are valuated based on the Monte-Carlo pricing model (a level 3 valuation) as of March 31, 2020. The main assumptions used are as follows:

	March 31 2020
Price per share	$3.08
Volatility	67%
Expected term (years)	2.75-3.00
Risk free interest rate	0.29%
Expected dividend	0%

NOTE 6 - SHARE CAPITAL

1. **Equity:**
   a. In January 2020, a consultant exercised 31,954 options into 31,954 ordinary shares for a total consideration of $68,000.

   b. On December 11, 2019 and December 18, 2019, the Company entered into subscription agreements with a select group of accredited investors, including certain board members or its affiliates for the private placement of 5,710,153 ordinary shares for aggregate subscription proceeds to the Company of $13.5 million at $2.37 price per share (the "Private Placement"). In addition, the Company granted 2,855,095 warrants, exercisable over a three-years period from the date of issuance, to purchase 2,855,095 ordinary shares at a per share exercise price of $2.96.

   On December 13, 2019, D.N.A Biomedical Solutions Ltd. ("DNA"), an existing shareholder of the Company, subscribed to the Private Placement (the "DNA Private Placement") to purchase 337,553 ordinary shares for aggregate consideration of $800,000. In connection with the transaction, the Company granted DNA warrants, exercisable over a three-year period from the date of issuance, to purchase 168,776 ordinary shares at a per share exercise price of $2.96. This investment was approved by the shareholders of the Company on February 18, 2020.

   The 168,776 warrants issued in connection with the DNA Private Placement together with the 2,855,095 warrants issued in connection with the Private Placement are the "Investors Warrants"

   Prior to the exercise of the Investors Warrants the number of ordinary shares issuable upon their exercise and the exercise price are subject to customary adjustments, including in the events of reorganizations or reclassifications of the Company's capital stock, upon payment of dividends or distributions to the Company's shareholders, and upon any subsequent issuance of the Company's share capital at or below a price of $2.37. In addition, the Investors Warrants have a cashless exercise mechanism. Therefore, for accounting purposes, the Investors Warrants were classified as a financial liability.

2. **Options Grants**

   On March 16, 2020, the Company's Board of Directors approved the following options grants:

   a. An options grant to purchase 201,600 ordinary shares to certain employees and 7,500 options granted to a service provider, with an exercise price of $2.14 per share. The options vest over 4 years from the date of grant; 25% vest on the first anniversary of the date of grant and the remaining 75% vest in twelve equal quarterly installments following the first anniversary of the applicable grant date. The fair value of the options as of the date of the grant was $274,000.

   b. An options grant to purchase 250,000 ordinary shares to certain executive officers of the Company, with an exercise price of $2.14. The options vest over 4 years from the date of grant; 25%vest on the first anniversary of the date of grant and the remaining 75% vest in twelve equal quarterly installments following the first anniversary of the applicable grant date. The grant is subject to the approval by the shareholders of the Company. The fair value of the option at March 31, 2020, was $322,000.

NOTE 7 - SUBSEQUENT EVENTS

On April 20, 2020, the Company's Board of Directors approved options grant to purchase 31,502 ordinary shares to the CEO with an exercise price of $1.98 per share. The options vest over 4 years from the date of grant; 25% vest on the first anniversary of the date of grant and the remaining 75% vest in twelve equal quarterly installments following the first anniversary of the applicable grant date. The grant is subject to the approval by the shareholders of the Company.

Exhibit 99.2

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This management's discussion and analysis is designed to provide you with a narrative explanation of our financial condition and results of operations. We recommended that you read this in conjunction with our unaudited condensed consolidated financial statements for the three-month period ended March 31, 2020 and 2019 and the related notes to the condensed consolidated financial statements, which are included in this Report of Foreign Private Issuer on form 6-K. You should also read the following discussion in conjunction with the information contained in our annual report on Form 20-F for the year ended December 31, 2019 filed with the Securities and Exchange Commission on March 26, 2020. We have prepared our financial statements in accordance with IFRS as issued by IASB.

All references to "we," "us," "our," "Entera", "the Company" and "our Company" in this Report of Foreign Private Issuer on Form 6-K are to Entera Bio Ltd. and its U.S. subsidiary Entera Bio Inc., unless the context otherwise requires.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of orally delivered macromolecule therapeutics for use in areas with significant unmet medical need where adoption of injectable therapies is limited due to cost, convenience and compliance challenges for patients. Our current strategy for our lead product candidates is to use our technology to develop an oral formulation of human parathyroid hormone (1-34), or PTH, which has been approved in the United States in injectable form for over a decade. Our lead oral PTH product candidates are EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism. In both of these indications, the leading products are daily injectable formulations of PTH. In total, more than 180 healthy volunteers and patients, have received multiple doses of various formulations of our oral PTH (1-34).

We met with the Food and Drug Administration (FDA) in the fourth quarter of 2018 to discuss the development and regulatory pathway for EB613 for the treatment of osteoporosis. In addition to discussing various aspects of the nonclinical and clinical development plan, the meeting focused on the use of the 505(b)(2) regulatory pathway and the use of BMD rather than fracture incidence as the primary endpoint to support an NDA. Based on the FDA's response, we believe that we may be able to use BMD as the primary efficacy endpoint for a Phase 3 trial and that a fracture endpoint trial will not be required. In July 2019, we initiated a Phase 2 multi-center dose-ranging trial of EB613 in approximately 160 osteoporosis patients, at 4 leading osteoporosis centers in Israel. This trial, which includes a treatment period of 6 months, is being conducted to evaluate both the safety of EB613 and to identify the optimal dose that we will select to advance into a single Phase 3 pivotal trial. In this trial, we are evaluating, multiple bone markers, such as P1NP – a bone formation marker, CTX – a bone resorption marker, BMD, and various additional safety endpoints. Based on directives from the Israeli Ministry of Health and our affiliated medical institutions implemented in March 2020 due to COVID-19, we temporarily suspended enrollment of new patients in our ongoing Phase 2 clinical trial, and in May 2020 we started to re-initiate enrollment activities based on the initial updated directives by the Israeli Ministry of Health. At this time, we have 102 patients currently enrolled in this trial. We continued to collect patient data from the currently enrolled patients in this trial through various monitoring means established by the regulatory authorities.

In May 2020, we announced interim data from the Phase 2 clinical trial of EB613. Based on the interim data, EB613 demonstrated statistically significant effects on the P1NP biomarker after one month of treatment ($p<0.001$) as compared to placebo, and meaningful increases at months two and three as compared to placebo with the highest EB613 dose (1.5 mg). There was also a dose response at one month, with those trends continuing at two months. The two lower doses (0.5 mg and 1.0 mg) demonstrated suboptimal increases that likely do not warrant further clinical advancement after the completion of this trial. We believe that the maximum efficacious dose has not yet been achieved, and will continue the evaluation of the data from the existing patients including 6-month bone mineral density (BMD) results. Based on the favorable safety profile for patients on EB613 in the ongoing Phase 2 study, we intend to evaluate additional doses greater than 1.5mg to advance into a potential Phase 3 study, if appropriate.

In parallel, we are conducting several nonclinical safety assessment studies to support our regulatory filings, including a planned Investigational New Drug Application, or IND, with the FDA to facilitate various IND-enabling trials, and subsequently, to enable the start of a single Phase 3 clinical trial in approximately 600-700 osteoporosis patients using sites in, the United States, Israel and other territories, subject to positive data from our ongoing Phase 2 trial of EB613, pending the determination of the impact of COVID-19 on the trial enrollment and its impact on such data. We believe that the study design to achieve the BMD endpoint, as discussed with the FDA, will have a much smaller number of patients and be significantly shorter in duration than a pathway that utilizes a placebo-controlled bone fracture endpoint.

Our lead product candidate for hypoparathyroidism, EB612, is an oral formulation of PTH (1-34). We believe that EB612, if approved, has the potential to become the standard of care for hypoparathyroidism. We have tested several formulations of our oral PTH (1-34) in multiple Phase 1 clinical trials to test different manufacturing technologies, formulations, administration parameters and dosing regimens. These data led to a number of Phase 2 studies evaluating different formulations of EB612 including a multicenter Phase 2a clinical trial of EB612 in hypoparathyroidism patients. The endpoints in these trials, included examination of the PK/PD levels of EB612, as well as serum calcium, serum phosphate, urinary calcium and urinary phosphate. In these trials, EB612 was generally well tolerated and achieved the targeted blood levels of PTH, serum calcium, serum phosphate, and the hormonal metabolite of vitamin D (1,25- dihydroxyvitamin D)

In addition, we intend to use our technology as a platform for the oral delivery of other protein and large molecule therapeutics as well as novel therapeutics. For example, in the fourth quarter of 2018, we signed a license agreement with Amgen and may sign additional licensing or collaboration agreements in the future. We intend to utilize future funds, as available, to advance EB613 and EB612 through clinical development and ultimately towards regulatory approval. To date, we have funded our operations through our IPO, private placements of our ordinary shares and preferred shares, warrants, convertible debt, government grants and through revenues generated from research collaborations and our license agreement with Amgen, Inc. (Amgen). We have no products that have received regulatory approval and have never generated revenue from sales of any product. Since our inception, we have raised a total of $56.9 million, including $14.3 million in our December 2019 private placement, $11.2 in our IPO in 2018 and $31.3 in funding from grants, private placements of Ordinary Shares, preferred shares and debt prior to our IPO.

Since inception, we have incurred significant losses. For the three months ended March 31, 2020 and 2019, our operating losses were $2.9 million and $3.0 million, respectively and we expect to continue to incur significant expenses and losses for the next several years. As of March 31, 2020, we had an accumulated deficit of $65.8 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 any other research and development activities, the receipt of government grants and payments under the collaboration with Amgen or any future collaborations into which we may enter.

As a result of our recurring losses from operations, negative cash flows and lack of liquidity, management is of the opinion that there is substantial doubt as to the Company's ability to continue as a going concern. If we are unable to raise the requisite funds, we will need to curtail or cease operations. See “Item 3.D.–Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital on our Annual Report on Form 20-F filed with the SEC on March 26, 2020.

As of May 12, 2020, we had cash and cash equivalents of $11.5 million. In order to fund further operations, we will need to raise additional capital. We may raise these funds through private and/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 of May 12, 2020, we had 21 employees and five consultants who provide consulting services to us on a part-time basis. Our operations are located in Jerusalem, Israel and in the United States, just outside of Boston in Wellesley Massachusetts.

Patent Transfer, Licensing Agreements and Grant Funding

There have been no material changes to our patent transfer, licensing agreements and grant funding from those reported in “Item 5.A.– Results of Operations” our Annual Report on Form 20-F filed with the SEC on March 26, 2020.

Results of Operations

Comparison of Three Months period Ended March 31, 2020 and 2019

	(unaudited) Three Months Ended March 31,		Increase (Decrease)	
	2020	2019	$	%
	(In thousands, except for percentage information)			
Revenues	$ (42)	$ -	$ (42)	(100)
Cost of revenues	42	-	42	100
Operating expenses:				
Research and development expenses, net	1,605	2,035	(430)	(21.1)
General and administrative expenses	1,290	1,056	234	22.2
Operating loss	2,895	3,091	(196)	(6.3)
Financial expenses (income), net	23	(96)	119	(124)
Net loss	$ 2,918	$ 2,995	$ (77)	(2.6)

Revenue

Revenues for the three months ended March 31, 2020 were $42,000 and were attributable to research and development, or R&D, services provided to Amgen under our 2018 collaboration agreement. We did not generate any revenue in the three months ended March 31, 2019 as we had not yet started providing R&D services to Amgen.

Cost of Revenue

The cost of revenues for the three months ended March 31, 2020 were $42,000 and were comprised of salaries and related expenses in connection with the R&D services provided to Amgen. We did not have any cost of revenues in the three months ended March 31, 2019.

Research and Development Expenses, Net

Research and development expenses for the three months ended March 31, 2020 were $1.6 million, compared to $2.0 million for the three months ended March 31, 2019. The decrease of $0.4 million was primarily due to reductions in materials and production costs and compensation-related expenses of $0.6 and $0.2 million, respectively. These decreases were partially offset by an increase of $0.4 million in consulting fees and other expenses related to the preparation of our IND application for EB613 and our Phase 2 clinical trial of EB613. The decline in materials and production costs was driven primarily by significant manufacturing activities during the three months ended March 31, 2019 to support our clinical trials and related pre-clinical activities that were not repeated during the same period in 2020. The decline in compensation-related expenses was primarily due to a reduction in headcount and non-cash compensation expense.

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2020 were $1.3 million, compared to $1.1 million for the three months ended March 31, 2019. The increase of $0.2 million was primarily due to increases of $0.2 million in compensation-related expenses, $0.1 million in professional fees and $0.1 million in insurance costs all of which were partially offset by a decrease of $0.1 million in legal fees and investor relations expenses. The increase in compensation-related expenses was primarily due to an increase in headcount related to executive hires in the second half of 2019.

Financial Expenses (Income), Net

Financial expenses (income), net for the three months ended March 31, 2019 and 2020 are mainly resulting from the re-measurement of warrants issued in connection with our 2018 initial public offering and our private placement in December 2019 which included a second closing in February 2020.

Cash Flows

Comparison of Three Months period Ended March 31, 2020 and 2019

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

	(unaudited) three months ended March 31,	
	2020	**2019**
	(in thousands)	
Cash used in operating activities	$ (2,656)	$ (1,933)
Cash used in investing activities	(29)	(33)
Cash provided by (used in) financing activities	828	(23)
Net decrease in cash and cash equivalents	$ (1,857)	$ (1,989)

Net Cash Used in Operating Activities

Net Cash used in operating activities for the three months ended March 31, 2020 was $2.7 million consisting primarily of our operating loss of $2.9 million and an increase of $0.2 million in working capital which were partially offset by $0.4 million of share-based compensation expense and $0.1 million of depreciation expense.

Net Cash used in operating activities for the three months ended March 31, 2019 was $1.9 million, consisting primarily of our operating loss of $3.0 million which was partially offset by $0.5 million of share-based compensation expense, and a $0.6 million decrease in our working capital and $0.1 million of depreciation expense.

The increase in cash used in operating activities for the three months ended March 31, 2020 compared to the same period in 2019, was mainly due to a decrease in $0.4 cash received from Amgen in 2020 and increased payments of $0.4 mainly for D&O insurance and account payables.

Net Cash Used in Investing Activities

Net Cash used in investing activities for the three months ended March 31, 2020 and 2019 were $29,000 and $33,000, respectively consisted of purchase of property and equipment.

Net Cash Provided by Financing Activities

Net Cash provided by financing activities for the three months ended March 31, 2020 consisted primarily of the net proceeds of $0.8 million from the issuance of the Ordinary Shares and Warrants in the final closing of our December 2019 private placement offering.

Net Cash used in financing activities for the three months ended March 31, 2020 and 2019 consisted primarily of facility lease payments.

Liquidity and Capital Resources

Since our inception through March 31, 2020, we have funded our operations primarily through private offerings, convertible loans, our Initial Public Offering in 2018, grants from governmental authorities and payments under our collaboration with Amgen.

Our cash and cash equivalents as of March 31, 2020 were approximately $13.3 million, compared to approximately $15.2 million as of December 31, 2019.

Since inception, we have incurred significant losses. 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, 2019, expressing the existence of substantial doubt about our ability to continue as a going concern on our Annual Report on Form 20-F filed with the SEC on March 26, 2020. For the three months ended March 31, 2019 and March 31, 2020, our operating losses were $3.0 million and $2.9 million, respectively. We expect to continue to incur significant expenses and losses for the next several years. As of March 31, 2020, we had an accumulated deficit of $65.8 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 any other research and development activities, the receipt of government grants and payments under our collaboration with Amgen or any future collaborations into which we may enter.

Funding Requirements

We believe that our existing capital resources, not including potential milestone payments, will be sufficient to meet our projected operating requirements into the second quarter of 2021.

We have based these estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our product candidates, and the extent to which we may enter into collaborations with third parties for development of these or other product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current and future product candidates. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of clinical trials for, and data 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, once known, 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, government grants or through the 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. However, there is no certainty about our ability to obtain such financing.

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 your rights as a shareholder. 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 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 months ended March 31, 2020, included on Report of Foreign Private Issuer on form 6-K , note that there is substantial doubt about our ability to continue as a going concern as of such date; This means that our management expressed substantial doubt about our ability to continue our operations without an additional infusion of capital from external sources. The 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.

For more information as to the risks associated with our future funding needs, see “Risk Factors” in our Annual Report on Form 20-F filed with the SEC on March 26, 2020.

Contractual Obligations and Commitments

As of the date of this discussion and analysis, there are no material changes to our contractual obligations from those reported under “Item 5.F.–Contractual Obligations” in our Annual Report on Form 20-F filed with the SEC on March 26, 2020.

Off-Balance Sheet Arrangements

As of the date of this discussion and analysis, we do not have any, and during the periods presented we did not have any, off-balance sheet arrangements other than operating leases as described under “Item 5.E.– Off-Balance Sheet Arrangements” in our Annual Report on Form 20-F filed with the SEC on March 26, 2020.

Critical Accounting Policies Estimates

There have been no material changes to the significant accounting policies and estimates described in “Item 5.A.– Results of Operations–Critical Accounting Policies and Estimates” in our Annual Report on Form 20-F filed with the SEC on March 26, 2020.

Cautionary Statement Regarding Forward Looking Statements

This Report of Foreign Private Issuer on Form 6-K of Entera Bio Ltd. includes forward looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include all statements that are not historical facts and can be identified by words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “targets,” “likely,” “will,” “would,” “could,” and similar expressions or phrases. 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 include, but are not limited to, statements about:

- 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 ongoing Phase 2 clinical trial of EB613 or the need for additional clinical trials or development work based on further analysis of the interim data from the ongoing EB613 Phase 2 clinical trial;
- 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;
- our ability to develop, advance product candidates into, and successfully complete, clinical studies such as our ongoing Phase 2 clinical trial of EB613 in osteoporosis;
- our reliance on third parties to conduct our clinical trials and on third-party suppliers to supply or produce our product candidates;
- our expectations regarding licensing, business transactions and strategic collaborations, including our ongoing collaboration with Amgen;
- 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 interpretation of 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 ability to obtain and maintain regulatory approval for any of our product candidates;
- our competitive position, especially with respect to Forteo® and other products on the market or in development for the treatment of osteoporosis;
- 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 sufficient amounts of material to support our clinical trials and any potential future commercial requirements;
- our ability to use and expand our drug delivery technology to additional product candidates;
- 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;
- the duration and severity of the recent coronavirus (COVID-19) outbreak, 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, preclinical studies and clinical trials; and
- other risk factors discussed under “Risk Factors" in our Annual report on Form 20-F for the year ended December 31, 2019.

All forward-looking statements in this Report of Foreign Private Issuer on Form 6-K involve risks, assumptions and uncertainties and are made as of the date of this Report of Foreign Private Issuer on Form 6-K. You should not rely upon forward-looking statements as predictors of future events. The occurrence of the events described, and the achievement of expected results, depend on many events, some or all of which are not predictable or within our control. Actual results may differ materially from expected results. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations” below and “Risk Factors” in our Form 20-F for the year ended December 31, 2019 for a more complete discussion of these risks, assumptions and uncertainties and for other risks and uncertainties. These risks, assumptions and uncertainties are not necessarily all of the important factors that could cause actual results to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results. All of the forward-looking statements we have included in this Report of Foreign Private Issuer on Form 6-K are based on information available to us on the date of this Report of Foreign Private Issuer on Form 6-K. We undertake no obligation, and specifically decline any obligation, to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this Report of Foreign Private Issuer on Form 6-K or in our Prospectus might not occur.