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 August 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): ☐

CONTENTS

This report on Form 6-K of the registrant consists of a press release issued by the registrant on August 20, 2020, attached hereto as an exhibit and incorporated by reference herein.

This report on Form 6-K and Exhibits 99.1 and 99.2 hereto shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number: 333-238988) and Form F-3 (Registration Number: 333-239843) of Entera Bio Ltd. and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit

Exhibit 99.1: Unaudited Condensed Consolidated Interim Financial Information for the Period Ended June 30, 2020.

Exhibit 99.2: Management's Discussion and Analysis of Financial Condition and Results of Operation for the Period Ended June 30, 2020.

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/ Dr. Roger Garceau
Name: Roger Garceau
Title: Chief Executive Officer

Date: August 20, 2020

Exhibit 99.1

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(UNAUDITED)

AS OF JUNE 30, 2020

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

(UNAUDITED)

AS OF JUNE 30, 2020

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ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(UNAUDITED)

	June 30 2020	December 31 2019
	U.S. dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	9,767	15,185
Accounts receivable	-	278
Other current assets	677	173
TOTAL CURRENT ASSETS	10,444	15,636
NON-CURRENT ASSETS:		
Property and equipment	199	202
Right of use assets	214	260
Intangible assets	605	605
TOTAL NON-CURRENT ASSETS	1,018	1,067
TOTAL ASSETS	11,462	16,703
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable:		
Trade	49	334
Other	1,336	1,370
Current maturities of lease liabilities	169	177
Warrants to purchase ordinary shares	2,350	2,444
Contract liabilities	173	267
TOTAL CURRENT LIABILITIES	4,077	4,592
NON-CURRENT LIABILITIES:		
Lease liabilities	81	122
Severance pay obligations, net	75	70
TOTAL NON-CURRENT LIABILITIES	156	192
TOTAL LIABILITIES	4,233	4,784
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.0000769 par value: Authorized - as of June 30, 2020 and December 30, 2019, 140,010,000 shares; issued and outstanding: as of June 30, 2020, and December 31, 2019 18,234,191 and 17,864,684 shares, respectively	*	*
Accumulated other comprehensive income	41	41
Other reserves	10,468	11,398
Additional paid in capital	65,740	63,392
Accumulated deficit	(69,020)	(62,912)
TOTAL SHAREHOLDERS' EQUITY	7,229	11,919
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	11,462	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)

	Six months ended June 30		Three months ended June 30	
	2020	2019	2020	2019
	U.S. dollars in thousands			
REVENUE	94	74	52	74
COST OF REVENUE	73	62	31	62
RESEARCH AND DEVELOPMENT EXPENSES, NET	3,616	3,448	2,011	1,413
GENERAL AND ADMINISTRATIVE EXPENSES	2,827	1,684	1,537	628
OPERATING LOSS	6,422	5,120	3,527	2,029
FINANCIAL INCOME:				
Income from change in fair value of financial liabilities at fair value	(318)	(794)	(366)	(682)
Other financial expenses, net	4	35	29	19
FINANCIAL INCOME, NET	(314)	(759)	(337)	(663)
NET COMPREHENSIVE LOSS FOR THE PERIOD	6,108	4,361	3,190	1,366
	U.S. dollars		U.S. dollars	
LOSS PER ORDINARY SHARE:				
Basic	0.34	0.38	0.17	0.12
Diluted	0.34	0.38	0.17	0.12
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:				
Basic	18,142,016	11,601,289	18,234,191	11,742,797
Diluted	18,142,016	11,601,289	18,234,191	11,742,797

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 DURING THE SIX MONTHS ENDED JUNE 30, 2019:							
Net loss for the period	-	-	-	-	-	(4,361)	(4,361)
Exercise of options to ordinary shares	439,379	*	-	(143)	169	-	26
Share-based compensation	-	-	-	687	-	-	687
BALANCE AT JUNE 30, 2019	11,899,159	*	41	13,563	49,342	(56,478)	6,468
BALANCE AT JANUARY 1, 2020	17,864,684	*	41	11,398	63,392	(62,912)	11,919
CHANGES DURING THE SIX MONTHS ENDED JUNE 30, 2020:							
Net loss for the period	-	-	-	-	-	(6,108)	(6,108)
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 and warrants	-	-	-	(1,672)	1,672	-	-
Share-based compensation	-	-	-	777	-	-	777
BALANCE AT JUNE 30, 2020	18,234,191	*	41	10,468	65,740	(69,020)	7,229

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

ENTERA BIO LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN 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 APRIL 1, 2019	11,459,780	*	41	13,560	49,173	(55,112)	7,662
CHANGES DURING THE THREE MONTHS ENDED JUNE 30, 2019:							
Net loss for the period	-	-	-	-	-	(1,366)	(1,366)
Exercise of options to ordinary Shares	439,379	*	-	(143)	169	-	26
Share-based compensation	-	-	-	146	-	-	146
BALANCE AT JUNE 30, 2019	11,899,159	*	41	13,563	49,342	(56,478)	6,468
BALANCE AT APRIL 1, 2020	18,234,191	*	41	11,598	64,206	(65,830)	10,015
CHANGES DURING THE THREE MONTHS ENDED JUNE 30, 2020:							
Net loss for the period	-	-	-	-	-	(3,190)	(3,190)
Expiration of warrants	-	-	-	(1,534)	1,534	-	-
Share-based compensation	-	-	-	404	-	-	404
BALANCE AT JUNE 30, 2020	18,234,191	*	41	10,468	65,740	(69,020)	7,229

* 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 CASH FLOW STATEMENTS

(UNAUDITED)

	Six months ended June 30	
	2020	2019
	(Unaudited)	
	U.S dollars in thousands	
CASH FLOWS USED IN OPERATING ACTIVITIES:		
Net loss for the period	(6,108)	(4,361)
Adjustments required to reflect net cash used in operating activities (see appendix A)	(74)	304
Net cash used in operating activities	(6,182)	(4,057)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES:		
Short-term bank deposits	-	4,000
Purchase of property and equipment	(29)	(37)
Net cash provided by (used in) investing activities	(29)	3,963
CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares and warrants, net of issuance costs	797	-
Proceeds from exercise of options	68	26
Principle element of lease payments	(72)	(52)
Net cash provided by (used in) financing activities	793	(26)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(5,418)	(120)
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	15,185	7,506
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	9,767	7,386

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

ENTERA BIO LTD.
CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	Six months ended June 30	
	2020	2019
	(Unaudited)	
	U.S dollars in thousands	
APPENDIX A:		
Adjustments required to reflect net cash used in operating activities:		
Depreciation	101	122
Change in fair value of financial liabilities at fair value through profit or loss	(318)	(794)
Financial expenses	19	58
Net changes in severance pay obligation	5	3
Share-based compensation	777	687
	584	76
Changes in working capital:		
Decrease in accounts receivables	278	725
Increase in other current assets	(504)	(266)
Increase (decrease) in accounts payable and accruals:		
Trade	(285)	21
Other	(34)	(151)
Decrease in contract liabilities	(94)	(74)
	(639)	255
Cash used for operating activities -		
Interest paid	(19)	(27)
	(74)	304
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 $69 million through June 30, 2020 and negative cash flows from operating activities. The Company's management is of the opinion that its available funds as of June 30, 2020 will allow the Company to operate under its current plans into the second quarter of 2021. 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 collaborations. 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 August 18, 2020.

NOTE 2 - BASIS OF PREPARATION

The Company’s condensed consolidated interim financial statements as of June 30, 2020 and for the six 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 six months ended June 30, 2020 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

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.

NOTE 3 - SIGNIFICANT ACCOUNTING POLICIES

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 six months ended June 30, 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 7,613,633 and 5,529,645 for the six months ended June 30, 2020 and 2019 respectively.

All outstanding options and warrants have been excluded from the calculation of the diluted loss per share for the three months ended June 30, 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 7,864,992 and 5,450,825 for the three months ended June 30, 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 June 30, 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 June 30, 2020:			
Trade and other payable	-	1,385	1,385
Warrants to purchase ordinary shares (level 1) (1)	560	-	560
Warrants to purchase ordinary shares (level 3) (2)	1,790	-	1,790
	2,350	1,385	3,735
As of December 31, 2019:			
Trade and other payable	-	1,704	1,704
Warrants to purchase ordinary shares (level 1) (1)	266	-	266
Warrants to purchase ordinary shares (level 3) (2)	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 June 30, 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 June 30, 2020 the fair value of one warrant is $0.59-$0.62. The main assumptions used are as follows:

	June 30 2020
Price per share	$1.84
Volatility	67%
Expected term (years)	2.5-2.7
Risk free interest rate	0.16%-0.18%
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.

c. On June 13, 2020, 687,960 warrants to purchase 687,960 ordinary shares for a purchase price of $6.99 per share in accordance with the Series B preferred share purchase agreement signed in 2016 and its following amendments have expired. Following the expiration, the Company classified $1,5 million from Other Reserves to Additional paid in Capital.

2. Options Grants

The Company's Board of Directors approved the following options grants:

a. On March 16, 2020, options 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.

NOTE 6 - SHARE CAPITAL (Continued)

b. On March 16, 2020, options 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 was subject to the approval by the shareholders of the Company, which approved the grant in June 2020. The fair value of the options as of the date of the grant was $316,000

c. On April 20, 2020, options 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 was subject to the approval by the shareholders of the Company, which approved the grant in June 2020. The fair value of the options as of the date of the grant was $37,000

d. On April 20 2020, the Company entered into a separate investor relations services, agreement. Under the terms of the agreement, the Company agreed to pay a monthly fees of $5,000 and to issue the consultant 28,000 Restricted Share Units (“RSU”), of which the first 7,000 shares vested on the signing date and the remaining 21,000 shares will vest in three equal installments until January 8, 2021. As of June 30, 2020, 7,000 shares were fully vested. The fair value of the RSU was $53,200 using the fair value of the shares at the grant date. $13,300 was recognized during the six months ended June 30, 2020.

NOTE 7 - SUBSEQUENT EVENTS

a. In July 2020, 340,210 warrants to purchase 340,210 ordinary shares for a purchase price of $3.69 per share in accordance with the Series A preferred share purchase agreement expired.

b. On July 4, 2020, the Company established a primary registration statement under form F-3 and at-the-market equity program (the "ATM Program") that allowed the Company to issue up to $13.9 million of ordinary shares, at the Company's discretion. Distributions of the ordinary shares through the ATM Program were made pursuant to the terms of an equity distribution agreement dated July 13, 2020 among the Company, Canaccord Genuity LLC (the "Agent").

In July 2020, the Company issued 106,806 ordinary shares for gross proceeds of $218 thousand at a weighted average price of $2.04 per ordinary share. This transaction triggered adjustment to the exercise price of the warrant issued as part of the Private Placement held in December and February 2020. See also Note 6(1)b.

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 six and three month periods ended June 30, 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 200 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 but continued to collect patient data from those patients already enrolled in the trial through various monitoring means established by the regulatory authorities.

In May 2020 we started to re-initiate enrollment activities based on the initial updated directives by the Israeli Ministry of Health and announced limited interim biomarker data from the Phase 2 clinical trial of EB613. Based on the interim biomarker data, EB613 demonstrated statistically significant effects on the P1NP biomarker after one month of treatment ($p<0.001$) compared to the placebo, and meaningful increases at months two and three compared to the 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. Based on the interim data, we amended the Phase 2 protocol in July 2020 and discontinued the two lower doses (0.5mg and 1.0mg) and added a 2.5mg dose of EB613. The clinical trial is enrolling patients in the 2.5mg, 1.5mg and placebo groups. There are currently 131 patients enrolled out of the targeted 160 patients in the trial, including in the new high-dose group. The Company expects to complete enrollment for the trial in the third quarter of 2020.

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 global Phase 3 clinical trial in approximately 600-700 osteoporosis patients, subject to positive data from our ongoing Phase 2 trial of EB613 (including any 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 $57.1 million, including $0.2 million through our Equity Distribution Agreement (ATM Agreement), $14.3 million in our December 2019 private placement, $11.2 in our IPO in 2018 and $31.4 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 six months ended June 30, 2020 and 2019, our operating losses were $6.4 million and $5.1 million, respectively and we expect to continue to incur significant expenses and losses for the next several years. As of June 30, 2020, we had an accumulated deficit of $69.0 million. Our losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials, our expenditures on 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 2019 Annual Report on Form 20-F filed with the SEC on March 26, 2020.

As of August 12, 2020, we had cash and cash equivalents of $8.9 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, including the sale of common stock through our ATM Agreement with Canaccord Genuity LLC (Canaccord), 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 August 12, 2020, we had 19 employees and five services providers who provide consulting services to us on a part-time basis. Our operations are located in Jerusalem, Israel and in the United States.

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 2019 Annual Report on Form 20-F filed with the SEC on March 26, 2020.

Results of Operations

Comparison of Six Months period Ended June 30, 2020 and 2019

	(unaudited) Six Months Ended June 30,		Increase (Decrease)	
	2020	2019	$	%
	(In thousands, except for percentage information)			
Revenues	$ (94)	$ (74)	$ 20	27.0%
Cost of revenues	73	62	11	17.7
Operating expenses:				
Research and development expenses, net	3,616	3,448	168	4.9
General and administrative expenses	2,827	1,684	1,143	67.9
Operating loss	6,422	5,120	1,302	25.4
Financial income, net	(314)	(759)	445	(58.6)
Net loss	$ 6,108	$ 4,361	$ 1,747	40.1%

Revenue

Revenues for the six months ended June 30, 2020 were $94,000 compared to $74,000 for the six months ended June 30, 2019. Revenues were attributable to research and development, or R&D, services provided to Amgen under our 2018 collaboration agreement.

Cost of Revenue

The cost of revenues for the six months ended June 30, 2020 were $73,000 compared to $62,000 for the six months ended June 30, 2019 and were comprised of salaries and related expenses in connection with the R&D services provided to Amgen.

Research and Development Expenses, Net

Research and development expenses for the six months ended June 30, 2020 were $3.6 million, compared to $3.4 million for the six months ended June 30, 2019. The increase of $0.2 million was primarily due to an increase of $0.6 million related predominantly to the Phase 2 clinical trial of EB613 and an increase of $0.3 million in consulting fees and other expenses related to the preparation of our IND application for EB613. The increases were partially offset by a reduction in materials and production costs of $0.5 due to significant manufacturing activities during the six months ended June 30, 2019 to support our clinical trials and related pre-clinical activities that were not repeated during the same period in 2020 and a decline of $0.2 in compensation-related expenses.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2020 were $2.8 million, compared to $1.7 million for the six months ended June 30, 2019. The increase of $1.1 million was primarily due to increases of $0.7 million in compensation-related expenses, $0.3 million in legal fees, $0.1 million in insurance costs and an increase of $0.1 of other costs all of which were partially offset by a decrease of $0.1 million in investor relations. 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 Income, Net

Financial income, net for the six months ended June 30, 2019 and 2020 are primarily due to 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 Six Months period Ended June 30, 2020 and 2019

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

	(unaudited) six months ended June 30,	
	2020	**2019**
	(in thousands)	
Cash used in operating activities	$ (6,182)	$ (4,057)
Cash Provided by (used in) investing activities	(29)	3,963
Cash provided by (used in) financing activities	793	(26)
Net decrease in cash and cash equivalents	$ (5,418)	$ (120)

Net Cash Used in Operating Activities

Net Cash used in operating activities for the six months ended June 30, 2020 was $6.2 million consisting primarily of our operating loss of $6.4 million and an increase of $0.6 million in working capital which were offset by $0.8 million of share-based compensation expense and $0.1 million of depreciation expense.

Net cash used in operating activities for the six months ended June 30, 2019 was $4.1 million, consisting primarily of our operating loss of $5.1 million which was offset by $0.7 million in share-based compensation and a $0.3 million decrease in working capital.

The increase in cash used in operating activities for the six months ended June 30, 2020 compared to the same period in 2019, was mainly due to an increase of $1.2 million in operating expenses and a decrease of $0.9 in our working capital primarily resulting from a decrease in cash received from Amgen in 2020, and an increase in payments related to D&O insurance and accounts payable.

Net Cash Used in Investing Activities

Net Cash used in investing activities for the six months ended June 30, 2020 are $29 thousand and consisted of purchase of property and equipment.

Net cash provided by investing activities for the six months ended June 30, 2019 were $4.0 million primarily attributed to the release of a short-term bank deposit.

Net Cash Provided by Financing Activities

Net Cash provided by financing activities for the six months ended June 30, 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 six months ended June 30, 2019 was primarily due to lease payments which were partially offset by cash received from the exercise of options granted to employees.

Comparison of Three Months period Ended June 30, 2020 and 2019

	(unaudited) Three Months Ended June 30,		Increase (Decrease)	
	2020	**2019**	**$**	**%**
	(In thousands, except for percentage information)			
Revenues	$ (52)	$ (74)	$ (22)	(29.7)%
Cost of revenues	31	62	(31)	(50)
Operating expenses:				
Research and development expenses, net	2,011	1,413	598	42.3
General and administrative expenses	1,537	628	909	144.7
Operating loss	3,527	2,029	1,498	73.83
Financial income, net	(337)	(663)	326	(49.2)
Net loss	$ 3,190	$ 1,366	$ 1,824	133.5%

Revenue

Revenues for the three months ended June 30, 2020 and 2019 were $52,000 and $74,000 and were attributable R&D services provided to Amgen under our 2018 collaboration agreement.

Cost of Revenue

The cost of revenues for the three months ended June 30, 2020 and 2019 were $31,000 and $62,000 and were comprised of salaries and related expenses in connection with the R&D services provided to Amgen.

Research and Development Expenses, Net

Research and development expenses for the three months ended June 30, 2020 were $2.0 million, compared to $1.4 million for the three months ended June 30, 2019. The increase of $0.6 million was primarily due to an increase of $0.4 million in consulting fees related to the preparation of our IND application for EB613, an increase of $0.2 million in clinical trial expenses relating to our Phase 2 clinical trial of EB613 and an increase of $0.1 million in material and production expenses.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2020 were $1.5 million, compared to $0.6 million for the three months ended June 30, 2019. The increase of $0.9 million was primarily due to increases of $0.5 million in compensation-related expenses, $0.4 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 investor relations and other expenses.

Financial Income, Net

Financial income, net for the three months ended June 30, 2019 and 2020 are primarily due to 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.

Liquidity and Capital Resources

Since our inception through June 30, 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 June 30, 2020 were approximately $9.8 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 in our 2019 Annual Report on Form 20-F filed with the SEC on March 26, 2020. For the six months ended June 30, 2020 and June 30, 2019, our operating losses were $6.4 million and $5.1 million, respectively. We expect to continue to incur significant expenses and losses for the next several years. As of June 30, 2020, we had an accumulated deficit of $69.0 million. Our losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials, our expenditures on 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 including the sale of common stock through our ATM Agreement with Canaccord, 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 six and three months ended June 30, 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 2019 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 2019 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 2019 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 2019 Annual Report on Form 20-F filed with the SEC on March 26, 2020.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our financial condition, liquidity, or results of operations will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets.

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 2019 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.