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 2021

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 16, 2021, 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 and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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

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/ Spiros Jamas, Sc.D
Name: Spiros Jamas
Title: Chief Executive Officer and Director

Date: August 16, 2021

Exhibit 99.1

ENTERA BIO LTD.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF JUNE 30, 2021

ENTERA BIO LTD.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF JUNE 30, 2021

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ENTERA BIO LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

	June 30 2021	December 31 2020
	U.S. dollars in thousands	
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	26,926	8,593
Accounts receivable	116	255
Other current assets	863	261
TOTAL CURRENT ASSETS	27,905	9,109
NON-CURRENT ASSETS:		
Property and equipment	168	192
Right of use assets	261	356
Intangible assets	605	605
TOTAL NON-CURRENT ASSETS	1,034	1,153
TOTAL ASSETS	28,939	10,262
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable:		
Trade	289	164
Other	1,473	1,330
Current maturities of lease liabilities	184	189
Warrants to purchase ordinary shares	1,395	1,432
Contract liabilities	8	158
TOTAL CURRENT LIABILITIES	3,349	3,273
NON-CURRENT LIABILITIES:		
Lease liabilities	187	243
Severance pay obligations, net	88	81
TOTAL NON-CURRENT LIABILITIES	275	324
TOTAL LIABILITIES	3,624	3,597
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.0000769 par value:		
Authorized - as of June 30, 2021 and December 31, 2020, 140,010,000 shares; issued and outstanding: as of June 30, 2021, and December 31, 2020 28,286,111 and 21,057,922 shares, respectively	*	*
Accumulated other comprehensive income	41	41
Other reserves	9,722	8,924
Additional paid in capital	103,089	70,595
Accumulated deficit	(87,537)	(72,895)
TOTAL SHAREHOLDERS' EQUITY	25,315	6,665
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	28,939	10,262

* 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	
	2021	2020	2021	2020
	U.S. dollars in thousands			
REVENUE	266	94	109	52
COST OF REVENUE	121	73	63	31
RESEARCH AND DEVELOPMENT EXPENSES, NET	2,417	3,616	1,258	2,011
GENERAL AND ADMINISTRATIVE EXPENSES	2,759	2,827	1,450	1,537
OTHER INCOME	(22)	-	(12)	-
OPERATING LOSS	5,009	6,422	2,650	3,527
FINANCIAL EXPENSES (INCOME):				
Loss (income) from change in fair value of financial liabilities at fair value	9,530	(318)	2,427	(366)
Other financial expenses, net	25	4	37	29
FINANCIAL EXPENSES (INCOME), NET	9,555	(314)	2,464	(337)
NET LOSS BEFORE TAXES	14,564	6,108	5,114	3,190
TAXES ON INCOME	78	-	40	-
NET COMPREHENSIVE LOSS FOR THE PERIOD	14,642	6,108	5,154	3,190
	U.S. dollars		U.S. dollars	
LOSS PER ORDINARY SHARE:				
Basic	0.63	0.34	0.21	0.17
Diluted	0.63	0.34	0.21	0.17
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:				
Basic	23,377,668	18,142,016	24,716,608	18,234,191
Diluted	23,377,668	18,142,016	24,716,608	18,234,191

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, 2020							
CHANGES DURING THE SIX MONTHS ENDED JUNE 30, 2020:	17,864,684	*	41	11,398	63,392	(62,912)	11,919
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
BALANCE AT JANUARY 1, 2021							
CHANGES DURING THE SIX MONTHS ENDED JUNE 30, 2021:	21,057,922	*	41	8,924	70,595	(72,895)	6,665
Net loss for the period		-	-			(14,642)	(14,642)
Exercise of warrants to ordinary shares	3,175,050	*	-		12,725	-	12,725
Exercise of options to ordinary shares	99,974	*	-	(139)	413	-	274
Issuance of shares under the ATM program, net of issuance costs	3,946,265	*	-	-	19,343	-	19,343
Vested restricted share units	7,000	-	-	(13)	13	-	-
Share-based compensation	-	-	-	950	-	-	950
BALANCE AT JUNE 30, 2021	28,286,211	*	41	9,722	103,089	(87,537)	25,315

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, 2020							
CHANGES DURING THE THREE MONTHS ENDED JUNE 30, 2020:	18,234,191	*	4	11,598	64,206	(65,830)	10,015
Net loss for the period	-	-	-	-	-	(3,190)	(3,190)
Exercise of options to ordinary Shares							
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
BALANCE AT APRIL 1, 2021							
CHANGES DURING THE THREE MONTHS ENDED JUNE 30, 2021:	23,776,785	*	41	9,128	80,827	(82,383)	7,613
Net loss for the period	-	-	-			(5,154)	(5,154)
Exercise of warrants to ordinary shares	3,080,832	*	-	-	12,701	-	12,701
Exercise of options to ordinary shares	28,594	*	-	(29)	77	-	48
Issuance of shares under the ATM program, net of issuance costs	1,400,000	*	-	-	9,484	-	9,484
Share-based compensation	-	-	-	623	-	-	623
BALANCE AT JUNE 30, 2021	28,286,211	*	41	9,722	103,089	(87,537)	25,315

* 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	
	2021	2020
	(Unaudited)	
	U.S dollars in thousands	
CASH FLOWS USED IN OPERATING ACTIVITIES:		
Net loss for the period	(14,642)	(6,108)
Adjustments required to reflect net cash used in operating activities (see appendix A)	10,249	(74)
Net cash used in operating activities	(4,348)	(6,182)
CASH FLOWS USED IN INVESTING ACTIVITIES:		
Purchase of property and equipment	-	(29)
Net cash used in investing activities	-	(29)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares and warrants, net of issuance costs	-	797
Issuance of shares due to the ATM program, net of issuance costs	19,343	-
Proceeds from exercise of options and warrants	3,432	68
Principle element of lease payments	(94)	(72)
Net cash provided by financing activities	22,681	793
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	18,333	(5,418)
CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	8,593	15,185
CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	26,926	9,767

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	
	2021	2020
	(Unaudited)	
	U.S dollars in thousands	
APPENDIX A:		
Adjustments required to reflect net cash used in operating activities:		
Depreciation	150	101
Change in fair value of financial liabilities at fair value through profit or loss	9,530	(318)
Financial expenses	19	19
Net changes in severance pay obligation	7	5
Share-based compensation	950	777
	10,656	584
Changes in working capital:		
Decrease in accounts receivables	139	278
Increase in other current assets	(602)	(504)
Increase (decrease) in accounts payable and accruals:		
Trade	125	(285)
Other	143	(34)
Decrease in contract liabilities	(150)	(94)
	(345)	(639)
Cash used for operating activities -		
Interest paid	(17)	(19)
	10,294	(74)
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	31	23
Exercise of warrants	9,567	-
Cashless exercise of warrants	*	-
Vested restricted shares units	*	-

* Represents an amount less than one thousand US dollars.

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 large molecule therapeutics for use in areas with significant unmet medical need where adoption of injectable therapies is limited due to cost, convenience and compliance challenges for patients. The Company's most advanced product candidates, EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism, are based on its proprietary technology platform and are both in 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.

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 $87.5 million through June 30, 2021 and negative cash flows from operating activities. The Company's management is of the opinion that its available funds as of June 30, 2021 will allow the Company to operate under its current plans into the fourth quarter of 2022. 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 as the Company will need to finance future research and development activities, general and administrative expenses and working capital through fund raising. However, there is no certainty about the Company's ability to obtain such funding.

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 12, 2021.

NOTE 2 - BASIS OF PREPARATION

The Company’s condensed consolidated interim financial statements as of June 30, 2021 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, 2020 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, 2021 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, 2020 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, 2021 and 2020 since their effect was anti-dilutive. The total number of ordinary shares which were excluded from the calculation of diluted loss per share was 7,804,106 and 7,613,633 for the six months ended June 30, 2021 and 2020 respectively.

All outstanding options and warrants have been excluded from the calculation of the diluted profit per share for the three months ended June 30, 2021 and 2020 since their effect was anti-dilutive. The total number of ordinary shares which were excluded from the calculation of diluted loss per share was 7,718,887 and 7,864,992 for the three months ended June 30, 2021 and 2020 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, 2020.

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, 2021, and December 31, 2020, 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, 2021:			
Trade and other payable	—	1,762	1,762
Warrants to purchase ordinary shares (level 1) (1)	1,395	—	1,395
Lease liabilities	—	371	371
	1,395	2,133	3,528
As of December 31, 2020:			
Trade and other payable	—	1,494	1,494
Warrants to purchase ordinary shares (level 1) (1)	239	—	239
Warrants to purchase ordinary shares (level 3) (2)	1,193	—	1,193
Lease liabilities		432	432
	1,432	1,926	3,358

(1) Tradable warrants presented above are valuated based on the market price (a level 1 valuation) as of June 30, 2021.

(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. As of June 30, 2021, all these warrants were exercised, see additional information in Note 61d.

NOTE 6 - SHARE CAPITAL:

1. Equity:

a. In February and March 2021, the Company issued additional 2,546,265 ordinary shares for net proceeds of $9.9 million at a weighted average price of $3.99 per ordinary share through the Company's ATM Program established in July 2020.

b. In March 2021, 4,500 tradable warrants were exercised into 2,250 ordinary shares of the Company for a total consideration of $13 thousand at an exercise price of $5.85.

c. During the six months ended June 30, 2021, several employees and service providers exercised 99,974 options into 99,974 ordinary shares of the Company for a total consideration of $274 thousand at a weighted average price of $2.76.

NOTE 6 - SHARE CAPITAL (Continued):

d. On April 21, 2021, upon satisfaction of the sale price condition pursuant to the subscription agreement signed in December 2019, the Company's Board of Directors decided to accelerate the termination date of the Investors and Broker warrants issued in December 2019 and February 2020. In accordance with the terms of the agreement, as of the notice date and until June 23, 2021 (the "Early Termination Exercise Period"), the holders may exercise their warrants and following such Early Termination Exercise Period, these warrants shall be deemed terminated.

During the six months ended June 30, 2021, the warrants holders, including our Chairman of the board and D.N.A Biomedical Solutions Ltd. ("DNA") exercised 3,300,645 warrants into 3,172,800 ordinary shares through cash or cashless mechanism. The total consideration from the exercise of these warrants was $3,145 thousand at an exercise price of $1.05.

e. On May 7, 2021, the Company entered into new At-the-market equity program (the "Second ATM Program") that allows the Company to issue up to additional 5 million ordinary shares, at the Company's discretion. Distributions of the ordinary shares through the Second ATM Program were made pursuant to the terms of an equity distribution agreement dated May 7, 2021 among the Company and B. Riley Securities, Inc (the "Agent").

In June 2021, the Company issued 1,400,000 ordinary shares for net proceeds of $9.5 million at a weighted average price of $7.02 per ordinary share through the Company's Second ATM Program established in May 2021.

2. Options Grants

a. On January 4, 2021 options to purchase 1,314,218 ordinary shares were granted to the Chief Executive officer of the Company, with an exercise price of $1.24. 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% of the option will vest in twelve equal quarterly installments following the first anniversary of the grant date. The grant was subject to the approval by the shareholders of the Company, which approved the grant in March 2021. The fair value of the options at the date of grant was $1,320 thousand.

b. On April 7, 2021, the Company's Board of Directors approved the following option grants:

i. Options grant to purchase 150,000 ordinary shares to the new US-based CFO, with an exercise price of $3.61 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% of the option will vest in twelve equal quarterly installments following the first anniversary of the grant date. This grant is subject to shareholders approval. The fair value of the options at the date of grant was $647 thousand.

ii. Options grants to purchase 213,000 ordinary shares to certain employees and 70,000 options granted to service providers, with an exercise price of $3.61 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% of the option will vest in twelve equal quarterly installments following the first anniversary of the grant date. The fair value of the options at the date of grant was $646 thousand.

NOTE 6 - SHARE CAPITAL (Continued):

iii. Options grant to purchase 33,368 ordinary shares to a non-executive director of the Company, with an exercise price of $3.61. The options will vest over 3 years in twelve equal quarterly instalments starting on the vesting commencement date. This grant is subject to shareholders approval. The fair value of the options at the date of grant was $142 thousand.

c. On April 21, 2021, options to purchase 345,000 ordinary shares were granted to several executive officers of the Company, with an exercise price of $3.15. 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% of the option will vest in twelve equal quarterly installments following the first anniversary of the grant date. This grant is subject to shareholders approval. The fair value of the options at the date of grant was $1,532 thousand.

NOTE 7 - REVENUE FROM COLLABORATION AND LICENSE AGREEMENT

During the second quarter, the Company extended the agreement of the research collaboration and license agreement (the "Amgen Agreement") with Amgen Inc. Pursuant to the terms, Amgen is required to pay for the third year of preclinical R&D services to be provided by the Company for a total consideration of $450 thousand and reimburse the Company for further expenses as shall be agreed between the parties.

NOTE 8 - SUBSEQUENT EVENTS

a. In July and August 2021, the Company issued 440,463 ordinary shares for net proceeds of $2.5 million at a weighted average price of $5.84 per ordinary share through the Company's Second ATM Program established in May 2021.

b. In July 2021, a former employee exercised 20,257 options into 20,257 ordinary shares of the Company for a total consideration of $51 thousand at a weighted average price of $2.53.

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-month period ended June 30, 2021 and 2020 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, 2020 filed with the Securities and Exchange Commission on March 18, 2021. 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 260 healthy volunteers and patients, have received multiple doses of various formulations of our oral PTH (1-34).

We met with the 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, placebo-controlled 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, was 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 evaluated multiple bone markers, such as P1NP – a bone formation marker, CTX – a bone resorption marker, BMD, and various additional safety endpoints.

In March 2021, we announced the final 3-month biomarker results. The trials primary efficacy endpoint was met - the complete 3-month results from the trial showed a significant increase in the P1NP biomarker in the 2.5 mg dose group after 3 months of treatment ($P < 0.04$) as compared to placebo. P1NP is a biomarker that indicates the rate of new bone formation and the change at 3-months is the primary endpoint in this Phase 2 trial.

Secondary endpoints in the trial comprised the effect of treatment on several additional serum bone biomarkers at 3-months including, Osteocalcin and CTX. Similar to P1NP, Osteocalcin is a biomarker for bone formation by osteoblasts, the cells that build new bone. CTX is a biomarker that indicates the rate of bone resorption by osteoclasts, the cells that remove old bone. An osteoanabolic, or bone building effect, is based on the difference in bone formation and bone resorption. An increase in P1NP or Osteocalcin, for example, associated with a smaller increase (or decrease) in CTX, usually indicates an increase in bone mass.

Similar to the increase in P1NP, a significant increase in Osteocalcin was also observed in the 2.5 mg group after 3 months ($P < 0.01$). In line with a potential anabolic effect, a significant decrease in CTX was observed after 3 months of treatment ($P < 0.015$). The decrease in CTX taken together with the increase in P1NP and Osteocalcin would indicate a potential positive impact on BMD and a reduced risk of fractures, which is the goal of an anabolic osteoporosis treatment.

In June 2021, we announced the final 6-month bone mineral density (BMD) results from the completed Phase 2 clinical trial of EB613. The most important BMD endpoint — change in lumbar spine (LS) BMD after 6 months — was met. There were statistically significant dose-related trends in the increases in LS BMD as well as femoral neck and total hip BMD, with the largest increases observed in subjects treated with EB613 2.5 mg. Dose dependent increases in biochemical markers of bone formation were previously reported. A significant increase in lumbar spine (LS) BMD was observed in the 1.5 mg group, the non-titrated 2.5 mg group (those who received 2.5 mg for the full 6 months) and the titrated 2.5 mg group (who received lower doses during titration and 2.5 mg for 4 months). An increase in LS BMD is the primary endpoint for the 505(b)(2) pathway as was described by the FDA in Entera's pre-IND meeting. At present it is believed that the single Phase 3 Pivotal study necessary under the 505b2 pathway would require a 12-month head-to-head study against Forteo® (the "reference drug"), designed to achieve non inferiority for increase in BMD of the lumbar spine.

The trials primary efficacy endpoint was met - the complete 3-month results from the trial showed a significant increase in the P1NP biomarker in the 2.5 mg dose group after 3 months of treatment (P <0.04) as compared to placebo. P1NP is a biomarker that indicates the rate of new bone formation and the change at 3-months is the primary endpoint in this Phase 2 trial.

Increases in LS BMD versus placebo observed at 6 months in previous Forteo® studies conducted with similar patient populations, were in the 3.9% range. In the current study LS BMD increased 3.78% (p<0.008) in the group treated with 2.5 mg for the full 6 months. When this group was combined with the titrated 2.5 mg group (who received lower doses during titration and 2.5 mg for just 4 months) LS spine BMD increased, 2.73% (p<0.002).

Furthermore, EB613 had a significant impact on both femoral neck and total hip BMD at 6 months. The 2.5 mg EB613 treatment group had a 2.76% (p<0.002) increase in femoral neck, and a 1.84% (p<0.02) increase in total hip at 6 months, as compared to placebo. In contrast, significant increases in BMD of the femoral neck and total hip are usually not observed with Forteo® treatment at 6 months. Increases in hip BMD have been shown to correlate with decreases in non-vertebral fracture risk.

In December 2020, the FDA approved our Investigational New Drug Application (IND) for EB613 for the treatment of osteoporosis. With the successful completion of the Phase 2 study, Entera will request an End-of-Phase-2 Meeting with the FDA to review the company's EB613 Phase 2 results and proposed single Phase 3 protocol under the 505(b)(2) pathway to demonstrate non-inferiority to Forteo in BMD increase. The start of the single Phase 3 clinical trial in osteoporosis patients using sites in, the United States, Israel and other territories is planned for 2022. We believe that the study design to achieve the BMD endpoint, to be 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. This data led to a number of Phase 2 studies evaluating different formulations of EB612 in hypoparathyroidism patients including a multicenter Phase 2a clinical trial of EB612 in hypoparathyroidism patients. The endpoints in the Phase 2trials, 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 February 2021 Entera announced a new research program for an oral glucagon-like peptide-2 (GLP-2) analog based on the Company's platform technology. GLP-2, a peptide produced in the intestine and the central nervous system via the brainstem and hypothalamus, is known to enhance intestinal absorption, specifically the increased absorption of nutrients.

The only GLP-2 analog currently on the market, teduglutide, was approved in 2012 as a once daily injection for the treatment of short bowel syndrome in the U.S. and Europe, registering global sales of $574 million in 2019. In preclinical models, Entera's oral formulation of a GLP-2 analog has shown a comparable pharmacokinetic profile to a subcutaneous injection. The ability of GLP-2 analogs to improve intestinal function, combined with new findings about the gut-bone and gut-brain connections, indicates these peptides may also have a role in the treatment of other diseases.

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. We may sign additional licensing or collaboration agreements in the future. To fuel our business development efforts we have signed Material Transfer Agreements ("MTA") with three companies to demonstrate our oral delivery platform on proprietary molecules.

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 sales of our Ordinary Shares under our Equity Distribution Agreement with Canaccord Genuity LLC and B. Riley Securities, Inc in connection with the Company's ATM Programs, sales of Ordinary Shares in our IPO, private placements of our Ordinary Shares and preferred shares, warrants, convertible debt, government grants and through revenues generated from research collaboration and our license agreement with Amgen. We have no products that have received regulatory approval and have never generated revenue from sales of any product.

Since inception, we have incurred significant losses. For the six months ended June 30, 2021 and 2020, our operating losses were $5.0 million and $6.4 million, respectively and we expect to continue to incur significant expenses and losses for the next several years. As of June 30, 2021, we had an accumulated deficit of $87.5 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, 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 2020 Annual Report on Form 20-F filed with the SEC on March 18, 2021.

As of August 8, 2021, we had cash and cash equivalents of $28.1 million. In order to fund further operations, including initiating Phase 3 study, 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 B. Riley, debt financings, government grants, strategic collaborations, partnership for Phase 3 financing and licensing arrangements. Additional financing may not be available when we need it or may not be available.

We believe that our existing cash and cash equivalents, will be sufficient to meet our projected operating requirements into the fourth quarter of 2022.

As of August 8, 2021, we had 19 employees and five consultants who provide 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 2020 Annual Report on Form 20-F filed with the SEC on March 18, 2021.

Results of Operations

Comparison of Six Months period Ended June 30, 2021 and 2020

	(unaudited) Six Months Ended June 30,		Increase (Decrease)	
	2021	**2020**	**$**	**%**
	(In thousands, except for percentage information)			
Revenues	$ 266	$ 94	$ 172	183
Cost of revenues	121	73	48	66
Operating expenses:				
Research and development expenses, net	2,417	3,616	(1,199)	(33)
General and administrative expenses	2,759	2,827	(68)	(2.4)
Other income	22	-	22	-
Operating loss	5,009	6,422	(1,413)	(22)
Financial expenses (income), net	9,555	(314)	9,870	3,142
Taxes on income	78	-	78	-
Net loss	$ 14,642	$ 6,108	$ 8,534	140

Revenue

Revenues for the six months ended June 30, 2021 and 2020 were $266,000 and $94,000, respectively. In this period, the majority of our 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, 2021 were $121,000 compared to $73,000 for the six months ended June 30, 2020 and were primarily attributed to 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, 2021 were $2.4 million, compared to $3.6 million for the six months ended June 30, 2020, a decrease of $1.2 million. The decrease was primarily due to a decrease of $0.6 in professional and consulting services expenses due to submission of the IND in 2020 and a decrease of $0.6 million in EB613 clinical trial related expenses including materials and production costs, which was completed in June 2021.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2021 and 2020 were $2.8 million. The changes in General and administrative expenses for the six months ended June 30, 2021, compared to the same period previous year, were mainly attributed to a decrease of $0.2 million in professional fees which were offset by an increase of $0.1 million in share-based compensation and an increase of $0.1 million in D&O insurance costs.

Financial Expenses (income), Net

Financial expenses (income), net for the six months ended June 30, 2021 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. The financial expenses of $9.9 million in the six months ended June 30, 2021, is attributed to the increase in the fair value of the warrants mainly due to an increase in our market share price, as well as to the exercise of all warrants issued as part private placement in December 2019 which included a second closing in February 2020 during the six months ended June 30, 2021.

Cash Flows

Comparison of Six Months period Ended June 30, 2021 and June 30, 2020

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,	
	2021	**2020**
	(in thousands)	
Cash used in operating activities	$ (4,348)	$ (6,182)
Cash used in investing activities	-	(29)
Cash provided by financing activities	22,681	793
Net increase (decrease) in cash and cash equivalents	$ 18,333	$ (5,418)

Net Cash Used in Operating Activities

Net Cash used in operating activities for the six months ended June 30, 2021 was $4.3 million consisting primarily of our operating loss of $5.0 million and an increase of $0.3 million in our working capital which were partially offset by $0.9 million of share-based compensation expense and $0,1 in depreciation expenses.

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 partially offset by $0.8 million of share-based compensation expense and $0.1 million of depreciation expense. We currently planning on the Phase 3 clinical trial for EB613 to commence in the second quarter of 2022 and anticipate that net cash used in operating activities will increase significantly as a result of that trial.

The decrease in cash used in operating activities for the six months ended June 30, 2021 compared to the same period in 2020, was mainly attributed to a decrease of $1.4 million in our operating expenses, a decrease of $0.3 in working capital mainly due to a decrease in payments to suppliers and services providers and an increase in cash received from Amgen, which were partially offset by an increase in payments to D&O insurance.

Net Cash Used in Investing Activities

Net Cash used in investing activities for the six months ended June 30, 2020 were attributed to purchase of property and equipment. For the six months ended June 30, 2021, no cash was used in or provided by investing activities.

Net Cash Provided by Financing Activities

Net Cash provided by financing activities for the six months ended June 30, 2021 consisted primarily of the net proceeds of $22.7 million from the issuance of Ordinary shares under our ATM Programs, exercise of options and warrants.

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.

Comparison of Three Months period Ended June 30, 2021 and 2020

	(unaudited) Three Months Ended June 30,		Increase (Decrease)	
	2021	2020	$	%
	(In thousands, except for percentage information)			
Revenues	$ (109)	$ (52)	$ (57)	110%
Cost of revenues	63	31	32	103
Operating expenses:				
Research and development expenses, net	1,258	2,011	(753)	(37)
General and administrative expenses	1,450	1,537	(87)	(6)
Other income	(12)	*	(12)	-
Operating loss	2,650	3,527	(877)	(25)
Financial expenses (income), net	2,464	(337)	2,801	831
Taxes on income	40	-	40	-
Net loss	$ 5,154	$ 3,190	$ 1,964	62%

Revenue

Revenues for the three months ended June 30, 2021 and 2021 were $109,000 and $52,000 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, 2021 and 2020 were $63,000 and $31,000 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, 2021 were $1.3 million, compared to $2 million for the three months ended June 30, 2020. The decrease was primarily due to a decrease of $0.4 in professional and consulting services expenses due to submission of the IND in 2020 and a decrease of $0.3 million in EB613 clinical trial related expenses including materials and production costs, which was completed in June 2021.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2021 and 2020 were $1.5 million. The changes in General and administrative expenses for the three months ended June 30, 2021, compared to the same period previous year, were mainly attributed to a decrease of $0.2 million in professional fees which were offset by an increase of $0.2 million in D&O insurance costs

Financial Expenses (income), Net

Financial expenses (income), net for the three months ended June 30, 2021 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. The increase in financial expenses of $2.8 million in the three months ended June 30, 2021, is attributed to the increase in the fair value of the warrants mainly due to an increase in our market share price, as well as to the exercise of all warrants issued as part private placement in December 2019 which included a second closing in February 2020 during the three months ended June 30, 2021

Liquidity and Capital Resources

Since our inception through June 30, 2021, we have funded our operations primarily through private and public offerings, including through our ATM programs, convertible loans, grants from governmental authorities and payments under our collaboration with Amgen.

Our cash and cash equivalents as of June 30, 2021 were approximately $26.9 million, compared to approximately $8.6 million as of December 31, 2020.

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, 2020, 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 18, 2021. For the six months ended June 30, 2021 and June 30, 2020, our operating losses were $5.0 million and $6.4 million, respectively. We expect to continue to incur significant expenses and losses for the next several years. As of June 30, 2021, we had an accumulated deficit of $87.5 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 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, including initiating Phase 3 study into the fourth quarter of 2022.

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 project. 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 continue to evaluate 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 their 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 months ended June 30, 2021, 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 18, 2021.

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 18, 2021.

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 18, 2021.

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 18, 2021.

Foreign Private Issuer Status

As of June 30, 2021, we are no longer considered a foreign private issuer and accordingly, such change in status will require us, as of January 1, 2022, to comply with all periodic disclosures and reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We may also be required to modify certain of our policies to comply with governance practices associated with U.S. domestic issuers. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities more time consuming and costly.

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, including via our At The Market, or ATM, Program;

- 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 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 expectations regarding licensing, business transactions and strategic collaborations, including our ongoing collaboration with Amgen;
- our ability to use and expand our drug delivery technology to additional product candidates;
- our operation as a development stage company with limited operating history and a history of operating losses and our ability to fund our operations going forward;
- our ability to continue as a going concern absent access to sources of liquidity;
- our ability to obtain and maintain regulatory approval for any of our product candidates;
- our competitive position, 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;
- 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, 2020.

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, 2020 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.