
**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 November 2019

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 November 21, 2019, attached hereto as an exhibit and incorporated by reference herein.

Exhibit

[Exhibit 99.1: Unaudited Condensed Consolidated Interim Financial Information for the Period Ended September 30, 2019.](#)

[Exhibit 99.2: Management's Discussion and Analysis of Financial Condition and Results of Operation for the Period Ended September 30, 2019.](#)

[Exhibit 99.3: Press release dated November 21, 2019.](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ENTERA BIO LTD.

(Registrant)

By: /s/Adam Gridley

Name: Adam Gridley

Title: Chief Executive Officer

Date: November 21, 2019

ENTERA BIO LTD.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF SEPTEMBER 30, 2019

ENTERA BIO LTD.
CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)
AS OF SEPTEMBER 30, 2019

TABLE OF CONTENTS

| | Page |
|---|-------------|
| CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) – U.S DOLLARS IN THOUSANDS (\$): | |
| <u>Condensed consolidated statements of financial position</u> | 2 |
| <u>Condensed consolidated statements of comprehensive loss</u> | 3 |
| <u>Condensed consolidated statements of changes in shareholders' equity</u> | 4-5 |
| <u>Condensed consolidated statements of cash flows</u> | 6-7 |
| <u>Notes to the condensed consolidated financial statements</u> | 8-16 |

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

| | <u>September 30</u> | <u>December 31</u> |
|---|----------------------------------|--------------------|
| | <u>2019</u> | <u>2018</u> |
| | <u>U.S. dollars in thousands</u> | |
| A s s e t s | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | 5,907 | 7,506 |
| Short-term bank deposits | - | 4,015 |
| Accounts receivable | - | 725 |
| Other current assets | 297 | 220 |
| TOTAL CURRENT ASSETS | <u>6,204</u> | <u>12,466</u> |
| NON-CURRENT ASSETS: | | |
| Property and equipment | 217 | 224 |
| Right to use assets | 295 | - |
| Intangible assets | 607 | 651 |
| TOTAL NON-CURRENT ASSETS | <u>1,119</u> | <u>875</u> |
| TOTAL ASSETS | <u>7,323</u> | <u>13,341</u> |
| Liabilities and shareholders' equity | | |
| CURRENT LIABILITIES: | | |
| Accounts payable: | | |
| Trade | 594 | 473 |
| Other | 1,501 | 1,090 |
| Lease liabilities | 156 | - |
| Contract liabilities | 91 | 225 |
| TOTAL CURRENT LIABILITIES | <u>2,342</u> | <u>1,788</u> |
| NON-CURRENT LIABILITIES: | | |
| Warrants to purchase ordinary shares | 700 | 1,372 |
| Lease liabilities | 173 | - |
| Severance pay obligations, net | 70 | 65 |
| TOTAL NON-CURRENT LIABILITIES | <u>943</u> | <u>1,437</u> |
| TOTAL LIABILITIES | <u>3,285</u> | <u>3,225</u> |
| COMMITMENTS AND CONTINGENCIES | | |
| SHAREHOLDERS' EQUITY: | | |
| Ordinary Shares, NIS 0.0000769 par value: | | |
| Authorized - as of September 30, 2019 and December 31, 2018, 140,010,000 shares; issued and outstanding: as of September 30, 2019, and December 31, 2018 – 12,153,980 shares and 11,459,780 shares, respectively. | * | * |
| Accumulated other comprehensive income | 41 | 41 |
| Other reserves | 11,912 | 13,019 |
| Additional paid in capital | 51,557 | 49,173 |
| Accumulated deficit | (59,472) | (52,117) |
| TOTAL SHAREHOLDERS' EQUITY | <u>4,038</u> | <u>10,116</u> |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | <u>7,323</u> | <u>13,341</u> |

* 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)

| | Nine months ended September 30 | | Three months ended September 30 | |
|--|-----------------------------------|-----------|------------------------------------|------------|
| | 2019 | 2018 | 2019 | 2018 |
| | U.S. dollars in thousands | | | |
| REVENUE | (134) | - | (60) | - |
| COST OF REVENUE | 102 | - | 40 | - |
| RESEARCH AND DEVELOPMENT EXPENSES, NET | 5,234 | 6,464 | 1,786 | 1,806 |
| GENERAL AND ADMINISTRATIVE EXPENSES | 2,757 | 1,914 | 1,073 | 1,060 |
| OPERATING LOSS | 7,959 | 8,378 | 2,839 | 2,866 |
| FINANCIAL EXPENSES (INCOME): | | | | |
| Loss (income) from change in fair value of financial liabilities at fair value | (672) | (719) | 122 | 2,177 |
| Other financial expenses , net | 68 | - | 33 | 23 |
| FINANCIAL EXPENSES (INCOME), net | (604) | (719) | 155 | 2,200 |
| NET COMPREHENSIVE LOSS FOR THE PERIOD | 7,355 | 7,659 | 2,994 | 5,066 |
| | U.S. dollars | | U.S. dollars | |
| LOSS PER ORDINARY SHARE: | | | | |
| Basic | 0.63 | 1.13 | 0.25 | 0.45 |
| Diluted | 0.63 | 1.14 | 0.25 | 0.45 |
| WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING: | | | | |
| Basic | 11,750,868 | 6,777,841 | 12,045,115 | 11,277,503 |
| Diluted | 11,750,868 | 6,825,532 | 12,045,115 | 11,277,503 |

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)

| | <u>Number of Ordinary Shares</u> | <u>Ordinary Shares-Amount</u> | <u>Accumulated other comprehensive income</u> | <u>Other reserve</u> | <u>Additional paid in capital</u> | <u>Accumulated deficit</u> | <u>Total</u> |
|--|--|-----------------------------------|---|--------------------------|---|--------------------------------|---------------|
| | U.S dollars in thousands | | | | | | |
| BALANCE AT JANUARY 1, 2018 | 4,490,720 | * | 41 | 7,361 | 2,853 | (41,813) | (31,558) |
| CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2018: | | | | | | | |
| Net loss for the period | - | - | - | - | - | (7,659) | (7,659) |
| Share-based compensation | - | - | - | 933 | - | - | 933 |
| Issuance of shares and warrants, net | 1,410,000 | * | - | 427 | 8,011 | - | 8,438 |
| Conversion of Preferred shares into Ordinary shares | 4,905,420 | * | - | - | 32,621 | - | 32,621 |
| Conversion of convertible loan into Ordinary shares | 622,180 | * | - | - | 4,138 | - | 4,138 |
| Conversion of Warrants to purchase preferred shares and shares into Warrants to purchase ordinary shares and shares | - | - | - | 5,548 | - | - | 5,548 |
| Reclassification due to share-based compensation expired | - | - | - | (1,090) | 1,090 | - | - |
| contribution from controlling shareholder | - | - | - | (51) | 51 | - | - |
| BALANCE AT SEPTEMBER 30, 2018 | <u>11,428,320</u> | <u>*</u> | <u>41</u> | <u>13,128</u> | <u>48,764</u> | <u>(49,472)</u> | <u>12,461</u> |
| BALANCE AT JANUARY 1, 2019 | 11,459,780 | * | 41 | 13,019 | 49,173 | (52,117) | 10,116 |
| CHANGES FOR NINE MONTHS ENDED SEPTEMBER 30, 2019: | | | | | | | |
| Net loss for the period | - | - | - | - | - | (7,355) | (7,355) |
| Issuance of shares due to exercise of options by employees and consultant | 661,700 | * | - | (586) | 724 | - | 138 |
| Issuance of shares due to exercise of right to purchase ordinary shares | 32,500 | * | - | (99) | 199 | - | 100 |
| Reclassification due to share-based compensation and warrants expired | - | - | - | (1,461) | 1,461 | - | - |
| Share-based compensation | - | - | - | 1,039 | - | - | 1,039 |
| BALANCE AT SEPTEMBER 30, 2019 | <u>12,153,980</u> | <u>*</u> | <u>41</u> | <u>11,912</u> | <u>51,557</u> | <u>(59,472)</u> | <u>4,038</u> |

* 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 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 JUNE 30, 2018 | 4,490,720 | * | 41 | 7,896 | 2,915 | (44,406) | (33,554) |
| CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2018: | | | | | | | |
| Net loss for the period | - | - | - | - | - | (5,066) | (5,066) |
| Share-based compensation | - | - | - | 336 | - | - | 336 |
| Issuance of shares and warrants, net | 1,410,000 | * | - | 427 | 8,011 | - | 8,438 |
| Conversion of Preferred shares into Ordinary shares | 4,905,420 | * | - | - | 32,621 | - | 32,621 |
| Conversion of convertible loan into Ordinary shares | 622,180 | * | - | - | 4,138 | - | 4,138 |
| Conversion of Warrants to purchase preferred shares and shares into Warrants to purchase ordinary shares | - | - | - | 5,548 | - | - | 5,548 |
| Reclassification due to share-based compensation expired | - | - | - | (1,079) | 1,079 | - | - |
| BALANCE AT SEPTEMBER 30, 2018 | <u>11,428,320</u> | <u>*</u> | <u>41</u> | <u>13,128</u> | <u>48,764</u> | <u>(49,472)</u> | <u>12,461</u> |
| BALANCE AT JUNE 30, 2019 | 11,899,159 | * | 41 | 13,563 | 49,342 | (56,478) | 6,468 |
| CHANGES FOR THREE MONTHS ENDED SEPTEMBER 30, 2019: | | | | | | | |
| Net loss for the period | - | - | - | - | - | (2,994) | (2,994) |
| Issuance of shares due to exercise of options by employees and consultant | 222,321 | * | - | (443) | 555 | - | 112 |
| Reclassification due to share-based compensation and warrants expired | - | - | - | (1,461) | 1,461 | - | - |
| Issuance of shares due to exercise of right to purchase ordinary shares | 32,500 | - | - | (99) | 199 | - | 100 |
| Share-based compensation | - | - | - | 352 | - | - | 352 |
| BALANCE AT SEPTEMBER 30, 2019 | <u>12,153,980</u> | <u>*</u> | <u>41</u> | <u>11,912</u> | <u>51,557</u> | <u>(59,472)</u> | <u>4,038</u> |

* 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)

| | Nine months ended September 30 | |
|--|---------------------------------------|----------------------|
| | 2019 | 2018 |
| | (Unaudited) | |
| | U.S dollars in thousands | |
| CASH FLOWS USED IN OPERATING ACTIVITIES: | | |
| Net loss for the period | (7,355) | (7,659) |
| Adjustments required to reflect net cash used in operating activities (see appendix A) | 1,640 | 215 |
| Net cash used in operating activities | <u>(5,715)</u> | <u>(7,444)</u> |
| CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES: | | |
| Short-term bank deposits | 4,000 | |
| Purchase of property and equipment | (40) | (68) |
| Net cash provided by (used in) investing activities | <u>3,960</u> | <u>(68)</u> |
| CASH FLOWS PROVIDED BY FINANCING ACTIVITIES: | | |
| Principle element of lease payments | (82) | - |
| Issuance of ordinary shares and tradable warrants, net of issuance costs | | 9,624 |
| Proceeds from exercise of warrants | 100 | - |
| Proceeds from exercise of options | 138 | - |
| Net cash provided by financing activities | <u>156</u> | <u>9,624</u> |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | (1,599) | 2,112 |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD | 7,506 | 11,746 |
| CASH AND CASH EQUIVALENTS AT END OF THE PERIOD | <u>5,907</u> | <u>13,858</u> |

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

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

**Nine months
ended September 30**

| 2019 | 2018 |
|---------------------------------|-------------|
| (Unaudited) | |
| U.S dollars in thousands | |

APPENDIX A:

| | | |
|--|-------|-------|
| Adjustments required to reflect net cash used in operating activities: | | |
| Depreciation and amortization | 185 | 37 |
| Change in fair value of financial liabilities at fair value | (672) | (719) |
| Financial expenses, net | 78 | 36 |
| Issuance costs | | 270 |
| Changes in severance pay obligations, net | 5 | (3) |
| Share-based compensation | 1,039 | 933 |
| | 635 | 554 |
| Changes in working capital: | | |
| Decrease in accounts receivables | 725 | - |
| Increase in other current assets | (77) | 273 |
| Decrease in contract liability | (134) | - |
| Increase (decrease) in accounts payable and accruals: | | |
| Trade | 121 | (193) |
| Other | 411 | (383) |
| | 1,046 | (303) |
| Cash used for operating activities - | | |
| Interest paid | (41) | (36) |
| | 1,640 | 215 |

APPENDIX B:

| | |
|---|--------|
| Supplementary information on financing activities not involving cash flows: | |
| Conversion of preferred shares into ordinary shares | 32,621 |
| Conversion of convertible loan into ordinary shares | 4,138 |
| | 36,759 |

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

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)

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 based in Delaware USA. The Company is a clinical-stage biopharmaceutical company, focused on the development and commercialization of orally delivered large molecule therapeutics for use in orphan indications and other areas with significant unmet medical needs. Currently the Company is focused on the development of oral capsules for the treatment of osteoporosis and hypoparathyroidism. Our lead oral PTH product candidates are EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism.
- 2) Initial Public Offering (IPO)–
The Company filed final prospectus with the Securities and Exchange Commission ("SEC") which became effective on June 27, 2018. On July 2, 2018 the Company Completed the IPO in the Nasdaq Capital Market (the "Nasdaq").
- 3) 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 \$59,472 thousand through September 30, 2019 and negative cashflows from operating activities. As a result of these losses and negative cash flows from operations, along with the Company's current cash position, the Company has sufficient resources to fund its operations through the middle of the first quarter of 2020. 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.

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.

- 4) 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 will 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.

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)

NOTE 1 - GENERAL INFORMATION (Cont.):

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.

Pursuant to the terms of the Amgen Agreement, Amgen is required to make aggregate payments of up to \$270 million upon achievement of various clinical and commercial milestones or its exercise of options to select additional two programs to include in the collaboration, as well as tiered royalty payments ranging from the low to mid-single digits based on the level of Amgen's net sales of the applicable products. Amgen is required to pay for the initial program \$450,000 for the second year of preclinical services to be provided by the Company and must reimburse the Company for further expenses as shall be agreed between the parties. In January 2019, as required by the Amgen Agreement, Amgen paid the Company a non-refundable and non-creditable initial technology access fee of \$725,000.

As of December 31, 2018, the company recognized \$500,000 in revenue. The company will recognize the remaining \$225,000 received from Amgen according to the input method. During the nine months ended September 30, 2019, the Company recorded revenues in the amount of \$134 thousand.

Amgen's obligation to pay royalties with respect to a product in a particular country commences upon the first commercial sale of such product in such country and expires on a country-by-country and product-by-product basis on the later of (a) the date on which the sale of the product is no longer covered by a valid claim of a patent licensed to Amgen under the Amgen Agreement, and (b) the tenth anniversary of the first commercial sale of such product in such country.

The term of the Amgen Agreement commenced on December 10, 2018, and unless earlier terminated, shall continue in full force and effect, on a product-by-product basis, until expiration of the last-to-expire royalty term with respect to such product.

b. Approval of financial statements

These financial statements were approved by the Company's Board of Directors on November 18, 2019.

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)

NOTE 2 - BASIS OF PREPARATION

The Company's condensed consolidated interim financial statements as of September 30, 2019 and for the nine 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, 2018 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 nine months ended September 30, 2019 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, 2018 and for the year then ended.

NOTE 3 - SIGNIFICANT ACCOUNTING POLICIES

Newly issued and recently adopted Accounting Pronouncements

IFRS 16, "Leases"

- a. Adjustments recognized on adoption of IFRS 16

The Company has adopted IFRS 16 retrospectively from January 1, 2019 but has not restated comparatives for the 2018 reporting period, as permitted under the specific transitional provisions in the standard. On adoption of IFRS 16, the Company recognized lease liabilities in relation to leases which had previously been classified as "operating leases" under the principles of IAS 17, "Leases". These liabilities were measured at the present value of the remaining lease payments, discounted using the lessee's incremental borrowing rate as of January 1, 2019, which was 16%. The remeasurements to the lease liabilities were recognized as adjustments to the related right-of-use assets immediately after the date of initial application. The associated right-of-use assets for facility leases were measured on a retrospective adjusted basis.

Following is the composition of right-of-use assets by type:

| | January 1, 2019 | September 30, 2019 |
|--------------------------|----------------------------|-------------------------------|
| Facility | 151 | 288 |
| Vehicles | 15 | 7 |
| Total right-of-use asset | <u>166</u> | <u>295</u> |

ENTERA BIO LTD.
NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
(UNAUDITED)

NOTE 3 - SIGNIFICANT ACCOUNTING POLICIES (Cont.):

The following table summarize the contractual obligations:

| | Payments due by period | | |
|---|-------------------------------|-----------------------------|--------------------|
| | Total | Less than 1 year | 1 - 3 years |
| | (In thousands) | | |
| Operating leases for facility and vehicles as of December 31, 2018 | \$ 123 | \$ 87 | \$ 36 |
| Operating leases for facility and vehicles as of September 30, 2019 | \$ 389 | \$ 179 | \$ 210 |

b. Practical expedients applied on adoption of IFRS 16

In applying IFRS 16 for the first time, the Company had used the following practical expedients permitted by the standard:

- Use of a single discount rate to a portfolio of leases with reasonably similar characteristics;
- Reliance on previous assessments on whether leases are onerous;
- Exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application;
- Use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

The Company has also elected not to reassess whether a contract is, or contains, a lease at the date of initial application. Instead, for contracts entered into before the transition date, the Company relied on its assessment made applying IAS 17 and IFRIC 4, "Determining whether an Arrangement contains a Lease."

c. Other information relating to IFRS 16

In January 2019, the Company entered into a new lease agreement for the building it uses in consideration of approximately additional \$98 thousand per year. The new lease started in February 2019. The annual lease consideration is in total amount of \$164 thousand.

As part of the new agreement, the whole lease agreement will expire on June 30, 2023 with a one-time option for the Company to early terminate the agreement on December 31, 2021 subject to a notice period of six months.

As of September 30, 2019, the Company provided bank guarantees of approximately \$30 thousand, in the aggregate, to secure the fulfillment of its obligations under the lease agreements.

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

NOTE 3 - SIGNIFICANT ACCOUNTING POLICIES (Cont.):

| | nine months ended | Three months ended |
|--|------------------------------|-----------------------------------|
| | September 30, 2019 | |
| Depreciation expense: | | |
| Facility | 86 | 31 |
| Vehicles | 8 | 2 |
| Financial expense | 41 | 14 |
| Cash paid for amounts included in the measurement of lease liabilities | 123 | 44 |
| Right of use assets obtained in exchange for new operating lease liabilities | 223 | - |

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, 2018.

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.

The fair value of the financial instruments included in the working capital of the Company is usually identical or close to their carrying value. The fair value of warrants to purchase ordinary shares is based on level 1 measurement as of September 30, 2019 and September 30, 2018.

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

NOTE 6 – SHARE CAPITAL:

1) Options grants

- a) On January 17, 2019, the Company granted options to purchase 124,000 ordinary shares to certain employees, with an exercise price of \$3.97. The options vest over 4 years from the date of grant; 25% will vest on the first anniversary of the date of grant and the remaining 75% options shall 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 \$341 thousand.
- b) On January 17, 2019, the Company's Board of Directors approved to grant options to purchase 25,000 ordinary shares to the CMO, with an exercise price of \$3.97. From the total options, 25% will vest on March 1, 2019 and the remaining 75% options shall vest in twelve equal quarterly installments over the next three years starting January 17, 2019. The grant was subject to the approval by the shareholders' of the Company, which approved the grant in May 2019. The fair value of the options at the date of grant was \$68 thousand.
- c) On January 17, 2019, the Company's Board of Directors approved to grant options to purchase 201,828 ordinary shares to non-executive directors of the Company, with an exercise price of \$3.97. The options will vest over 3 years in twelve equal quarterly instalments starting in the vesting commencement date (as described in each agreement). The grant was subject to the approval by the shareholders' of the Company, which approved the grant in May 2019. The fair value of the options at the date of grant was \$531 thousand.
- d) On August 5, 2019, the Company's Board of Directors approved to grant options to purchase 696,587 ordinary shares to the new CEO, with an exercise price of \$2.75 per share. The options vest over 4 years from the date of grant. 25% will vest on the first anniversary of the date of grant and the remaining 75% options shall 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 October 2019. The fair value of the options at the date of grant was \$1,074 thousand.

2) Exercise of options

During the nine months ended September 30, 2019, Executive officers and a former Executive officer exercised 661,700 options into 661,700 ordinary shares for a total consideration of \$138 thousand dollars.

- 3) In July 2019, one of the Company' shareholders' exercised his right to acquire 32,250 ordinary shares for a total consideration of \$100 thousands (upon achievement of the second milestone) in accordance with its preferred share A purchase agreement signed in 2014 and its following amendments.
- 4) On July 20, 2019, the 443,950 warrants to purchase 443,950 ordinary shares for a purchase price of \$3.69 per share (upon achievement of the second milestone) in accordance with preferred share A purchase agreement signed in 2014 and its following amendments have expired. Following the expiration, the Company classified \$1,352 thousand from Other Reserves to Additional paid in Capital.

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

NOTE 7 – BASIC AND DILUTED LOSS PER SHARE

Basic

Basic loss per share is calculated by dividing the result attributable to equity holders of the Company by the weighted average number of Ordinary Shares in issue during the period.

Diluted

All outstanding options and warrants have been excluded from the calculation of the diluted loss per share for the nine and three months ended September 30, 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 5,083,073 and 5,165,706 for the nine and three months ended September 30, 2019, respectively.

All outstanding options, 2012 Convertible Loan, preferred shares, warrants to issue preferred shares A, warrants to issue preferred shares B and warrants to issue ordinary shares have been excluded from the calculation of the diluted loss per share for the nine months ended September 30, 2018 since their effect was anti-dilutive. The total number of shares related to the outstanding options, 2012 Convertible Loan, preferred shares, warrants to issue preferred shares A, warrants to issue preferred shares B and warrants to issue ordinary shares excluded from the calculation of diluted loss per share was 10,608,063 for the nine months ended September 30, 2018.

All outstanding options, 2012 Convertible Loan, preferred shares, warrants to issue preferred shares A, warrants to issue preferred shares B, warrants to issue preferred shares B-1, and warrants to issue ordinary shares have been excluded from the calculation of the diluted income per share for the three months ended September 30, 2018 since their effect was anti-dilutive. The total number of shares related to the outstanding options, 2012 Convertible Loan, preferred shares, warrants to issue preferred shares A, warrants to issue preferred shares B, warrants to issue preferred shares B-1, and warrants to issue ordinary shares excluded from the calculation of diluted income per share was 11,093,195 for the three months ended September 30, 2018.

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

NOTE 7 – BASIC AND DILUTED LOSS PER SHARE (Cont.):

| | Nine months ended September 30 | | Three months ended September 30 | |
|---|--|-----------|------------------------------------|------------|
| | 2019 | 2018 | 2019 | 2018 |
| | U.S. dollars in thousand (except for share numbers) | | | |
| Loss attributable to equity holders of the Company | 7,355 | 7,659 | 2,994 | 5,066 |
| Less: | | | | |
| Income from change in fair value of financial liabilities at fair value | - | 135 | - | - |
| Loss used for the computation of diluted loss per share | 7,355 | 7,794 | 2,994 | 5,066 |
| Weighted average number of Ordinary Shares used in the computation of basic loss per share | 11,750,868 | 6,777,841 | 12,045,115 | 11,277,503 |
| Add: | | | | |
| Weighted average number of additional shares issuable upon the assumed conversion/ exercise of: | | | | |
| Warrants to issue preferred shares and shares | - | 47,691 | - | - |
| | - | 47,691 | - | - |
| Weighted average number of shares used in the computation of diluted loss per share | 11,750,868 | 6,825,532 | 12,045,115 | 11,277,503 |
| Basic loss per Share | 0.63 | 1.13 | 0.25 | 0.45 |
| Diluted loss per Share | 0.63 | 1.14 | 0.25 | 0.45 |

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

NOTE 8 - SUBSEQUENT EVENTS

- a) On November 18, 2019, the Company's Board of Directors approved options grants as follows:
 - i) An options grant to purchase 30,385 ordinary shares to the new US-based CFO, with an exercise price of \$2.53 per share. The options will vest over two years in equal monthly installments following the grant date. The grant is subject to the approval by the shareholders of the Company.
 - ii) An options grant to purchase 33,638 ordinary shares a non-executive director of the Company, with an exercise price of \$2.53. The options will vest over 3 years in twelve equal quarterly instalments starting in the vesting commencement date (as described in the agreement). The grant is subject to the approval by the shareholders of the Company.
- b) On November 2019, The Board of Directors approved options grant to a services provider in accordance with business development and advisory services agreement. Under the terms of the agreement, the Company agreed to grant options to purchase 62,393 ordinary shares at an exercise price of \$2.53. The options will vest over six months in six equal monthly instalments starting in the effective date (as described in the agreement).

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

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the related notes to the 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, 2018 filed with the Securities and Exchange Commission on March 28, 2019. We have prepared our financial statements in accordance with IFRS as issued by IASB.

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:

- 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 secure additional funding as may be needed, including, without limitation, to fund our ongoing operations and complete the clinical trials for our product development candidates.
 - our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern;
 - our ability to develop and advance product candidates into, and successfully complete, clinical studies;
 - uncertainty surrounding whether any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized, including that we will be able to demonstrate to regulators the noninferiority of EB613 in comparison to Forteo as part of a 505(b)(2) submission or that we will be able to demonstrate to regulation the clinical superiority of EB612 over Natpara, which is required to overcome Natpara's drug exclusivity;
 - our competitive position, with respect to Natpara, our key competitor for hypoparathyroidism treatment, and certain injectable anabolic treatments such as Forteo®, or newer products recently launched for osteoporosis treatment;
 - our ability to use and expand our drug delivery technology to other product candidates;
 - our reliance on third parties to conduct our clinical trials and on third-party suppliers to supply or produce our product candidates; our being subject to ongoing regulatory obligations if our products secure regulatory approval;
 - our ability to develop sales, marketing and distribution infrastructure;
 - the pricing and reimbursement of our product candidates, if approved;
 - our ability to achieve market acceptance for our product candidates;
 - our ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights;
-

- our ability to retain key personnel and recruit additional qualified personnel;
- our expectations about cash use;
- our ability to manage growth; and
- other risk factors discussed under “Risk Factors” in our annual report on Form 20-F for the year ended December 31, 2018.

All forward-looking statements in this Report of Foreign Private Issuer on Form 6-K involve risks, assumptions and uncertainties and 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 the sections below “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Form 20-F for the year ended December 31, 2018 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.

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 large molecule therapeutics for use in orphan indications and other areas with significant unmet medical need. We are initially applying our technology to develop an oral formulation of parathyroid hormone, (PTH), which has been approved in the United States in injectable form for over a decade. Following Food and Drug Administration (FDA) guidance received in the fourth quarter of 2018, indicating that a fracture study would not be required for a 505(b)(2) approval pathway in osteoporosis, we decided to accelerate our development of EB613 for osteoporosis. As planned, a phase 2, dose ranging study was initiated at the end of Q2 2019. This double blinded, placebo controlled, study will evaluate three different doses in postmenopausal women with low bone mass. The study is being developed to include up to 160 patients dosed once daily for a period of 6 months. Human PTH (1-34) is a known anabolic treatment currently available as a daily subcutaneous injection, Forteo[®] (marketed by Eli Lilly[®]) with a known effect on bone formation biomarkers and bone mineral density (BMD). The primary endpoint of this study will be bone formation biomarkers at 3 months with an additional evaluation at 6 months, along with a BMD readout. The study was approved by the Israeli Ministry of Health and is planned to be conducted at the osteoporosis clinics of 4 leading medical centers in Israel. These clinics have participated in a number of multinational osteoporosis trials for large pharmaceutical companies. All lab tests will be processed by an accredited central lab and BMD measurements will be monitored and analyzed in the US by a leading US contract research organization (CRO).

The 3-month biomarker results are expected to provide preliminary insight into the efficacy of the oral PTH treatments and preliminary results may be obtained once the first half of the study population has been dosed for this period, followed by the full 3-month biomarker results. A full study report will be generated upon completion of the 6-month biomarker and BMD analysis. Based on feedback from the FDA in late 2018, the Company has initiated created a Phase 3 study outline and currently envisages a trial with a partner comparing EB613 to Forteo, enrolling 600 to 800 patients and with a primary endpoint based on non-inferiority in BMD outcome. Other details, including the EB613 dose and the length of the study, are expected to be finalized based on the results obtained from the Phase 2 study.

We are also developing an additional oral PTH product candidate, EB612, which has successfully completed a Phase 2a trial for hypoparathyroidism, a rare condition in which the body fails to produce sufficient amounts of PTH. We completed a clinical trial to evaluate the PK/PD profile of various EB612 dose regimens and Natpara. Results of the Phase 2 PK/PD study of Oral PTH (1-34) in patients with hypoparathyroidism were presented at the American Society for Bone and Mineral Research Annual Meeting in September 2019. These data suggest favorable pharmacologic and pharmacokinetic profiles of Entera's Oral PTH formulation with a flexible oral dosing regimen vs. an injectable form of PTH. Based on these data, the Company is determining final formulations and our Phase 2b/Phase 3 clinical development strategy which would potentially support a submission for regulatory approval of EB612. The FDA and the EMA have granted EB612 orphan drug designation for the treatment of hypoparathyroidism.

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. We have 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 for advanced clinical studies and ultimately for regulatory approval.

Financial Results

Comparison of Nine-Month Period Ended September 30, 2019 and 2018

| | (unaudited) Nine Months Ended September 30, | | Increase (Decrease) | |
|-------------------------------|---|----------|---------------------|-------|
| | 2019 | 2018 | \$ | % |
| | (In thousands, except for percentage information) | | | |
| Revenues | \$ (134) | \$ - | \$ (134) | 100% |
| Cost of revenues | 102 | - | 102 | 100% |
| Operating Expenses: | | | | |
| Research and development, net | 5,234 | 6,464 | (1,230) | (19)% |
| General and administrative | 2,757 | 1,914 | 843 | 44% |
| Operating loss | 7,959 | 8,378 | (419) | (5)% |
| Financial income, net | (604) | (719) | 115 | (16)% |
| Net loss | \$ 7,355 | \$ 7,659 | \$ 304 | 3.9% |

Revenues. Revenues for the nine months ended September 30, 2019 were \$134 thousand from services provided to Amgen under the license agreement. The cost of revenues recorded are comprised of related salaries and related expenses.

Research and development, net expenses. Research and development expenses for the nine months ended September 30, 2019 were \$5.2 million, compared to \$6.5 million for the nine months ended September 30, 2018, a decrease of \$1.2 million, or 19%. The decrease in research and development expenses was primarily attributed to a decrease of \$1.3 million in materials, clinical manufacturing and production for clinical trials and a decrease of \$0.5 million in share-based compensation expenses due to higher fair value of the options granted to the previous CMO in the same period last year. The decrease was partially offset by an increase of \$0.5 million in subcontractors and CRO expenses and an increase of \$0.1 million in salaries and related expenses mainly due to hiring new employees in the US and in Israel.

General and administrative expenses. General and administrative expenses for the nine months ended September 30, 2019 were \$2.7 million, compared to \$1.9 million for the nine months ended September 30, 2018, an increase of \$0.8 million, or 44%. The increase in general and administrative expenses was primarily attributed to an increase of \$0.7 million in salaries and related expenses as well as share-based compensation expenses mainly due to hiring of our new CEO. In the same period previous year, we recorded income due to a reversal of share based compensation due to the termination of services of our previous Chairman of the board. In addition, there was an increase of \$0.2 million for insurance expenses and investor relation expenses due to the requirements of a public company.

Financial income, net. Financial income, net for the nine months ended September 30, 2019 was \$0.6 million, compared to f \$0.7 million for the nine months ended September 30, 2018, a decrease of \$0.1 million. Financial income, net for the nine months ended September 30, 2019 resulted mainly from the change in the fair value of warrants to purchase ordinary shares that were recorded as a financial liability at fair value through profit or loss. During the same period last year, the Company recognized financial income from changes in fair value of financial liabilities comprised of convertible loans, preferred shares and warrants which were converted or recorded as equity upon completion of our initial public offering (IPO).

Comprehensive loss. Comprehensive loss for the nine months ended September 30, 2019 was approximately \$7.4 million, compared with approximately \$7.7 million in the same period in 2018, a decrease of approximately \$0.3 million, or 3.9%.

Basic and diluted Loss per share. Basic and dilutive loss per share for the nine months ended September 30, 2019 was \$0.63, compared with \$1.13 and \$1.14, respectively, for the nine months ended September 30, 2018.

Comparison of Three-Month Period Ended September 30, 2019 and 2018

| | (unaudited) Three Months Ended September 30, | | Increase (Decrease) | |
|-------------------------------|--|----------|---------------------|---------|
| | 2019 | 2018 | \$ | % |
| | (In thousands, except for percentage information) | | | |
| Revenues | \$ (60) | | \$ (60) | 100% |
| Cost of revenue | 40 | | 40 | 100% |
| Expenses: | | | | |
| Research and development, net | 1,786 | \$ 1,806 | \$ (20) | (1.1)% |
| General and administrative | 1,073 | 1,060 | 13 | 1.2% |
| Operating loss | 2,839 | 2,866 | (27) | (0.9)% |
| Financial expenses , net | 155 | 2,200 | (2,045) | (93)% |
| Net loss | \$ 2,994 | \$ 5,066 | \$ (2,072) | (40.9)% |

Revenues. Revenues for the three months ended September 30, 2019 were \$60 thousand from services provided to Amgen under the license agreement. The cost of revenues recorded are comprised of related salaries and related expenses.

Research and development, net expenses. Research and development expenses for the three months ended September 30, 2019 and 2018 were \$1.8 million. The research and development expenses for the three months ended September 30, 2019 primarily consisted of salaries and related expenses and materials and clinical trials expenses (mainly subcontractors and CRO) related to our Phase 2 study in Osteoporosis and preparation for IND submission. In the same period in the previous year, the research and development expenses consisted of salaries and related expenses and materials and clinical trials expenses (mainly manufacturing and subcontractors) related to Phase 2 PK/PD Study in Hypoparathyroidism.

General and administrative expenses. General and administrative expenses for the three months ended September 30, 2019 and 2018 were \$1.1 million. General and administrative expenses were mainly consisting of salaries and related expenses, including share-based compensation, legal, audit and other public company related expenses. During the three months ended September 30, 2019 salaries and related expenses and other public company related expenses (D&O insurance and Investor Relations) increased compared to the same period previous year. The increase was offset by a decrease in accounting and legal fees related to our initial public offering (IPO) completed on July 2, 2018.

Financial expenses, net. Financial expenses, net for the three months ended September 30, 2019 were \$0.2 million, compared to \$2.2 million for the three months ended September 30, 2018. Financial expense, net for the three months ended September 30, 2019 resulted mainly from the change in the fair value of warrants to purchase ordinary shares that recorded as a financial liability at fair value through profit or loss. During the three months ended September 30, 2018, financial expenses, net resulted mainly from the change in fair value of convertible loans, preferred shares and warrants to purchase preferred shares that were recorded as a financial liability at fair value through profit or loss until July 2, 2018 when they were converted into ordinary shares and warrants to purchase ordinary shares classified as equity.

Comprehensive loss, net. Comprehensive loss for the three months ended September 30, 2019, was approximately \$3.0 million, compared with a comprehensive income of approximately \$5.1 million in the same period in 2018, a decrease of \$2.1 million, or 40.9%.

Basic and diluted Loss per share. Basic and dilutive loss per share for the three months ended September 30, 2019 and September 30, 2018 was \$0.25, compared with \$0.45, respectively.

Liquidity and Capital Resources

Since our inception through September 30, 2019, we have funded our operations primarily through private offerings, convertible loans, IPO and grants from governmental authorities.

As of September 30, 2019, we had positive working capital of approximately \$3.9 million, including cash and cash equivalents of approximately \$5.9 million. As of December 31, 2018, we had cash and cash equivalents and short-term bank deposit of approximately \$11.5 million.

Net Cash Used in Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2019 was \$5.7 million, consisting primarily of our operating loss of \$7.9 million arising mainly from research and development expenses and general and administrative expenses, partially offset by \$1.0 million in share-based compensation expense, and a \$1.0 million decrease in working capital. Net Cash used in operating activities for the nine months ended September 30, 2018 was \$7.4 million, consisting primarily of our operating loss of \$8.4 million arising mainly from research and development expenses and general and administrative expenses, partially offset by \$0.9 million of share-based compensation, \$0.2\$ issuance costs related to our IPO and by a \$0.3 million increase in working capital.

The decrease in cash used in operating activities for the nine months ended September 30, 2019 compared to the same period of 2018, was mainly due to a decrease of \$0.8 million for materials, clinical manufacturing and production capabilities, the payment received from Amgen of \$0.7 million which was offset by other working capital due to an increase in professional services and other expenses related to regulation and the requirements of a public company.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2019 were \$4.0 million consisting of the release of a short-term bank deposit and purchase of property and equipment.

Net Cash used in investing activities for the nine months ended September 30, 2018 were \$70 thousand consisting of purchase of property and equipment.

Net Cash provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2019 was mainly consisted of proceeds in the amount of \$238 thousand received due to exercise of options granted to employees, consultant and exercise of right to invest held by an investor, the cash provided by financing activities was partially offset by operating leases payments.

Net Cash provided by financing activities for the nine months ended September 30, 2018 was mainly consisted of proceeds in the amount of \$9.6 million received from issuance of ordinary shares and warrants as part of our Initial Public Offering (IPO) which was completed on July 2, 2018.

Entera Bio Reports Third Quarter 2019 Financial Results and Provides Operating Update

- Enrollment Continues for Phase 2 study for oral PTH in Osteoporosis; Top-line 3-month Biomarker Data expected in mid 2020
- Presented Positive Results of a Phase 2 PK/PD study in Hypoparathyroidism patients.
- Conference call and live webcast today at 8:30 am Eastern Time

BOSTON, Massachusetts & JERUSALEM, Israel (November 21, 2019)– Entera Bio Ltd. (NASDAQ: ENTX) today provided a corporate update and reported financial results for the third quarter ended September 30, 2019.

“Since joining the organization in August 2019, we’ve made significant progress on our strategic priorities in both our lead internal programs and potential future R&D opportunities as we build Entera into one of the leading oral delivery companies of large molecules and biologics,” stated Adam Gridley, CEO of Entera. “Enrollment is advancing rapidly in our Phase 2 study of our lead program EB613 for Osteoporosis, and our investigators are pleased to be involved in this landmark study for an oral alternative to injectables. We also presented further positive confirmatory data from our Phase 2 study of EB612 for Hypoparathyroidism in September 2019 and are currently determining our strategies to advance a final formulation into advanced registration studies.”

“Our ongoing business development and collaboration discussions are also advancing across all three pillars of our partnering strategy. Our partnership with Amgen is tracking well, and we’ve developed additional data regarding the utility of our synergistic technology platform in other molecules outside of hormones. This has led to discussions with several large pharmaceutical companies to test our technologies together. There has been considerable interest in Asia for our lead program and new molecules, and we’re starting to engage with leaders in the Osteoporosis space regarding our commercial partnering strategies both in U.S. and on a regional basis,” continued Mr. Gridley. “As we look forward to 2020, we have a number of important data read-outs for our ongoing Osteoporosis study that we believe will rapidly lead us into FDA discussions to finalize our Phase III study design. Further, we are building our financial, business development and investor focused teams and strategies to elevate Entera’s profile with the investment and partnering community”.

Clinical and Corporate Highlights:

Phase 2 Study for Oral PTH in osteoporosis: Following input from the U.S. Food and Drug Administration (FDA) in our pre-IND meeting held in 2018, the Company initiated a dose-ranging, placebo-controlled, Phase 2 study in June 2019, and enrollment is well underway. This study will enroll 160 postmenopausal women with osteoporosis or low bone mineral density at four internationally recognized clinical sites in Israel.

The primary endpoint of this study is bone formation biomarkers (serum P1NP, a biochemical marker that is correlated with bone formation rate) at 3 months with an additional evaluation at 6 months, of bone mineral density (BMD).

The Company expects the following milestones to be achieved in 2020:

- Full patient enrollment to be completed by the end of the first quarter of 2020
- Top-line data from the interim (50%) 3-month biomarker endpoint in the second quarter of 2020
- Top-line data from the full 3-month biomarker endpoint in the third quarter of 2020
- Bone mineral density data at 6 months are expected to be completed in fourth quarter 2020

We believe that these data will further inform the design of our registrational Phase 3 study, which the Company has already discussed with FDA. We expect it to be approximately 600-700 patients with similar endpoints as the Phase 2 study being conducted currently. The Company expects to also file an IND to the FDA in 2020 to support the selection of our final dose and formulation for our potential upcoming Phase 3 study.

Phase 2b Study for Oral PTH in hypoparathyroidism: Oral PTH for hypoparathyroidism is Entera's second major proprietary pipeline program. Entera completed in 2018 a two-part Phase 2 trial in patients with hypoparathyroidism that was designed to evaluate the pharmacokinetic (PK) and pharmacodynamic (PD) profiles of its oral PTH drug and injectable PTH (Natpara®).

Results from Part 1 of this study, reported in 2018, demonstrated a positive impact of Oral PTH on three metabolic parameters - serum calcium, phosphate, and 1,25-dihydroxyvitamin D ("active" vitamin D) - in patients with hypoparathyroidism. There was also a decrease in 24-hour urine calcium in the patients treated with Oral PTH.

The recently reported 16 patient Phase 2 PK/PD Study was open-label, and employed a 2-period partial crossover design to evaluate the PK and PD profiles of two doses, 0.75 mg and 2.25 mg, and three regimens (BID, TID and QID) of Oral hPTH (1-34) and included subcutaneous Natpar® [hPTH (1-84)] 100 µg once daily.

The conclusions of the poster presentation indicate that:

- Oral hPTH(1-34) 2.25 mg QID for one day is associated with an increase in serum albumin-corrected calcium and 1,25(OH)₂D (1,25-dihydroxyvitamin D), a decrease in serum phosphate, and a decrease in urinary calcium in patients with hypoparathyroidism. The patients also received calcium supplements and either alfacalcidol or calcitriol.
- Oral PTH produced similar biological effects to Natpara® 100 µg QD, the highest dose of hPTH (1-84) currently indicated for use in patients with hypoparathyroidism, on serum calcium, phosphate and Vit D. Additionally, Oral hPTH (1-34) effected a decrease in urinary calcium. These changes in serum PD parameters were sustained over the 24-hour period of observation from time zero.
- BID, TID and QID regimens showed a dose-dependent increase in 1,25(OH)₂D indicating that the long-term treatment, even with the less frequent regimens, may be an effective treatment option for those patients suffering from less severe hypoparathyroidism.
- Treatment with Oral hPTH (1-34) dosed at multiple times during the day has the potential to reduce calciuria generally associated with maintenance of serum calcium within the normal range using calcium supplements and calcitriol analogs alone.
- There were no treatment-emergent adverse events of hypercalcemia, as well as no treatment-emergent Serious Adverse Events reported in the study.

These data will provide input for the design of the Company's anticipated Phase 3 registration clinical trials.

Board Appointment:

Adam Gridley, our CEO was appointed as a member of the Company's Board of Directors.

Financial Results for the Nine Months Ended September 30, 2019

Revenues. Revenues for the nine months ended September 30, 2019 were \$134 thousand from services provided to Amgen under the license agreement. The cost of revenues recorded are comprised of related salaries and related expenses.

Research and development, net expenses. Research and development expenses for the nine months ended September 30, 2019 were \$5.2 million, compared to \$6.5 million for the nine months ended September 30, 2018, a decrease of \$1.2 million, or 19%. The decrease in research and development expenses was primarily attributed to a decrease of \$1.3 million in materials, clinical manufacturing and production for clinical trials and a decrease of \$0.5 million in share-based compensation expenses due to higher fair value of the options granted to the previous CMO in the same period last year. The decrease was partially offset by an increase of \$0.5 million in subcontractors and CRO expenses and an increase of \$0.1 million in salaries and related expenses mainly due to hiring new employees in the US and in Israel.

General and administrative expenses. General and administrative expenses for the nine months ended September 30, 2019 were \$2.8 million, compared to \$1.9 million for the nine months ended September 30, 2018, an increase of \$0.8 million, or 44%. The increase in general and administrative expenses was primarily attributed to an increase of \$0.7 million in salaries and related expenses, as well as share-based compensation expenses mainly due to hiring of our new CEO. In addition, there was an increase of \$0.2 million for insurance expenses and investor relation expenses due to the requirements of being a public company.

Financial income, net. Financial income, net for the nine months ended September 30, 2019 was \$0.6 million, compared to f \$0.7 million for the nine months ended September 30, 2018, a decrease of \$0.1 million. Financial income, net for the nine months ended September 30, 2019 and 2018 resulted mainly from the change in the fair value of financial liabilities measured at fair value through profit or loss.

Comprehensive loss. Comprehensive loss for the nine months ended September 30, 2019 was approximately \$7.4 million, compared with approximately \$7.7 million in the same period in 2018, a decrease of approximately \$0.3 million

Basic and diluted Loss per share. Basic and dilutive loss per share for the nine months ended September 30, 2019 was \$0.63, compared with \$1.13 and \$1.14, respectively, for the nine months ended September 30, 2018.

Conference call and webcast, Thursday, November 2nd, 2019 @ 8:30 am Eastern Time

From the US: 1 855 547-3865
International: 1 409 217-8787
From Israel: 1 809 315 362
Conference ID: 3677455
Webcast: <https://edge.media-server.com/mmc/p/i5yx6yjqw>

About Entera Bio Ltd.

Entera Bio is a clinical-stage biopharmaceutical company focused on the development and commercialization of orally delivered large molecule therapeutics for use in orphan indications and other areas with significant unmet medical needs. The Company is initially applying its technology to develop an oral formulation of a human parathyroid hormone analog, Oral PTH (1-34), for treatment of hypoparathyroidism and osteoporosis.

Entera has developed a proprietary platform technology that enables oral delivery of biologicals and large molecule drugs, which are typically delivered via injections and or other non-oral pathways. However, oral drug delivery is the easiest method for self-administering medications, offers patients greater dosing flexibility, and has the highest patient acceptance and compliance rates as compared to all other routes of drug administration. The Company employs this technology for its own pipeline products and may enter into licensing agreements with biopharma companies for application of the technology to their proprietary compounds, such as the Amgen strategic research collaboration. For more information on Entera Bio, visit www.enterabio.com.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, often signify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information that the Company has when those statements are made or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Those risks and uncertainties, include, but are not limited to, the timing and conduct of our clinical trials, the clinical utility of our product candidates, the timing and likelihood of regulatory filings and approvals, our intellectual property position, and our financial position. For a discussion of these and other risks that could cause such differences and that may affect the realization of forward-looking statements, please refer to the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" in the Company's Annual Report on Form 20-F and other filings with the Securities and Exchange Commission (SEC). Investors and security holders are urged to read these documents free of charge on the SEC's web site at <http://www.sec.gov>. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

Entera Bio Ltd.

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

| | <u>September 30</u> | <u>December 31</u> |
|---|----------------------------------|--------------------|
| | <u>2019</u> | <u>2018</u> |
| | <u>U.S. dollars in thousands</u> | |
| Assets | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | 5,907 | 7,506 |
| Short-term bank deposits | - | 4,015 |
| Accounts receivable | - | 725 |
| Other current assets | 297 | 220 |
| TOTAL CURRENT ASSETS | <u>6,204</u> | <u>12,466</u> |
| NON-CURRENT ASSETS: | | |
| Property and equipment | 217 | 224 |
| Right to use assets | 295 | - |
| Intangible assets | 607 | 651 |
| TOTAL NON-CURRENT ASSETS | <u>1,119</u> | <u>875</u> |
| TOTAL ASSETS | <u>7,323</u> | <u>13,341</u> |
| Liabilities and shareholders' equity | | |
| CURRENT LIABILITIES: | | |
| Accounts payable: | | |
| Trade | 594 | 473 |
| Other | 1,501 | 1,090 |
| Lease liabilities | 156 | - |
| Contract liabilities | 91 | 225 |
| TOTAL CURRENT LIABILITIES | <u>2,342</u> | <u>1,788</u> |
| NON-CURRENT LIABILITIES: | | |
| Warrants to purchase ordinary shares | 700 | 1,372 |
| Lease liabilities | 173 | - |
| Severance pay obligations, net | 70 | 65 |
| TOTAL NON-CURRENT LIABILITIES | <u>943</u> | <u>1,437</u> |
| TOTAL LIABILITIES | <u>3,285</u> | <u>3,225</u> |
| COMMITMENTS AND CONTINGENCIES | | |
| SHAREHOLDERS' EQUITY: | | |
| Ordinary Shares, NIS 0.0000769 par value: | | |
| Authorized - as of September 30, 2019 and December 31, 2018, 140,010,000 shares; issued and outstanding: as of September 30, 2019, and December 31, 2018 – 12,153,980 shares and 11,459,780 shares, respectively. | * | * |
| Accumulated other comprehensive income | 41 | 41 |
| Other reserves | 11,912 | 13,019 |
| Additional paid in capital | 51,557 | 49,173 |
| Accumulated deficit | (59,472) | (52,117) |
| TOTAL SHAREHOLDERS' EQUITY | <u>4,038</u> | <u>10,116</u> |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | <u>7,323</u> | <u>13,341</u> |

* 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)

| | Nine months ended September 30 | | Three months ended September 30 | |
|--|-----------------------------------|-----------|------------------------------------|------------|
| | 2019 | 2018 | 2019 | 2018 |
| | U.S. dollars in thousands | | | |
| REVENUE | (134) | - | (60) | - |
| COST OF REVENUE | 102 | - | 40 | - |
| RESEARCH AND DEVELOPMENT EXPENSES, NET | 5,234 | 6,464 | 1,786 | 1,806 |
| GENERAL AND ADMINISTRATIVE EXPENSES | 2,757 | 1,914 | 1,073 | 1,060 |
| OPERATING LOSS | 7,959 | 8,378 | 2,839 | 2,866 |
| FINANCIAL EXPENSES (INCOME): | | | | |
| Loss (income) from change in fair value of financial liabilities at fair value | (672) | (719) | 122 | 2,177 |
| Other financial expenses , net | 68 | - | 33 | 23 |
| FINANCIAL EXPENSES (INCOME), net | (604) | (719) | 155 | 2,200 |
| NET COMPREHENSIVE LOSS FOR THE PERIOD | 7,355 | 7,659 | 2,994 | 5,066 |
| | U.S. dollars | | U.S. dollars | |
| LOSS PER ORDINARY SHARE: | | | | |
| Basic | 0.63 | 1.13 | 0.25 | 0.45 |
| Diluted | 0.63 | 1.14 | 0.25 | 0.45 |
| WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING: | | | | |
| Basic | 11,750,868 | 6,777,841 | 12,045,115 | 11,277,503 |
| Diluted | 11,750,868 | 6,825,532 | 12,045,115 | 11,277,503 |

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