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

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended February 29, 2020

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 000-50298

ORAMED PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**98-0376008**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1185 Avenue of the Americas, Suite 228, New York, NY	**10036**
(Address of Principal Executive Offices)	(Zip Code)

844-967-2633
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.012	ORMP	The Nasdaq Capital Market, Tel Aviv Stock Exchange

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☒
Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of April 5, 2020, there were 23,093,978 shares of the issuer's common stock, $0.012 par value per share, outstanding.

ORAMED PHARMACEUTICALS INC.
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As used in this Quarterly Report on Form 10-Q, the terms "we," "us," "our" and the "Company" mean Oramed Pharmaceuticals Inc. and our wholly-owned subsidiaries, unless otherwise indicated. All dollar amounts refer to U.S. Dollars unless otherwise indicated.

On February 29, 2020, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.467 to $1.00. Unless indicated otherwise by the context, statements in this Quarterly Report on Form 10-Q that provide the dollar equivalent of NIS amounts or provide the NIS equivalent of dollar amounts are based on such exchange rate.

PART I – FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

ORAMED PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF FEBRUARY 29, 2020

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ORAMED PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. Dollars in thousands (except share and per share data)
(UNAUDITED)

	February 29, 2020	August 31, 2019
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	5,934	3,329
Short-term deposits	17,288	25,252
Marketable securities	5,704	3,701
Prepaid expenses and other current assets	563	1,042
Total current assets	29,489	33,324
LONG-TERM ASSETS:		
Long-term deposits	1	1
Marketable securities	250	1,295
Amounts funded in respect of employee rights upon retirement	17	19
Property and equipment, net	25	24
Operating lease right of use assets	99	-
Total long-term assets	392	1,339
Total assets	29,881	34,663
Liabilities and stockholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	2,377	2,541
Deferred revenues	2,703	2,703
Payable to related parties	43	64
Operating lease liabilities	32	-
Total current liabilities	5,155	5,308
LONG-TERM LIABILITIES:		
Deferred revenues	8,309	9,658
Employee rights upon retirement	17	22
Provision for uncertain tax position	11	11
Operating lease liabilities	67	-
Other liabilities	232	271
Total long-term liabilities	8,636	9,962
COMMITMENTS AND CONTINGENCIES (note 2)		
STOCKHOLDERS' EQUITY:		
Common stock, $0.012 par value (30,000,000 authorized shares; 23,093,978 and 17,383,359 shares issued and outstanding as of February 29, 2020 and August 31, 2019, respectively)	214	208
Additional paid-in capital	103,210	100,288
Accumulated deficit	(87,334)	(81,103)
Total stockholders' equity	16,090	19,393
Total liabilities and stockholders' equity	29,881	34,663

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

ORAMED PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF LOSS
U.S. Dollars in thousands (except share and per share data)
(UNAUDITED)

	Six months ended		Three months ended	
	February 29, 2020	February 28, 2019	February 29, 2020	February 28, 2019
REVENUES	$ 1,348	$ 1,340	$ 674	$ 666
COST OF REVENUES	-	90	-	55
RESEARCH AND DEVELOPMENT EXPENSES	5,342	7,461	3,320	3,114
GENERAL AND ADMINISTRATIVE EXPENSES	2,472	1,997	1,391	1,065
OPERATING LOSS	6,466	8,208	4,037	3,568
FINANCIAL INCOME	(369)	(559)	(169)	(273)
FINANCIAL EXPENSES	13	27	2	19
LOSS (GAIN) FROM CHANGES IN FAIR VALUE OF INVESTMENT	121	27	(182)	87
LOSS BEFORE TAXES ON INCOME	6,231	7,703	3,688	3,401
TAXES ON INCOME	-	300	-	300
NET LOSS FOR THE PERIOD	$ 6,231	$ 8,003	$ 3,688	$ 3,701
LOSS PER SHARE OF COMMON STOCK:				
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	$ 0.35	$ 0.46	$ 0.21	$ 0.21
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	17,645,372	17,451,411	17,818,429	17,454,109

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

ORAMED PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
U.S. Dollars in thousands
(UNAUDITED)

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	$			
	In thousands				
BALANCE AS OF AUGUST 31, 2019	17,383	$ 208	$ 100,288	$ (81,103)	$ 19,393
CHANGES DURING THE SIX MONTH PERIOD ENDED FEBRUARY 29, 2020:					
ISSUANCE OF COMMON STOCK, NET	441	5	2,311	-	2,316
SHARES ISSUED FOR SERVICES	8	*	30	-	30
EXERCISE OF WARRANTS AND OPTIONS	12	1	12	-	13
STOCK-BASED COMPENSATION	-	-	569	-	569
NET LOSS	-	-	-	(6,231)	(6,231)
BALANCE AS OF FEBRUARY 29, 2020	17,844	$ 214	$ 103,210	$ (87,334)	$ 16,090

	Common Stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	$				
	In thousands					
BALANCE AS OF AUGUST 31, 2018	17,369	$ 207	$ 99,426	$ 702	$ (69,223)	$ 31,112
INITIAL ADOPTION OF ASC 606					1,773	1,773
INITIAL ADOPTION OF ASU 2016-01				(702)	702	-
CHANGES DURING THE SIX MONTH PERIOD ENDED FEBRUARY 28, 2019:						
SHARES ISSUED FOR SERVICES	11	*	44	-	-	44
STOCK-BASED COMPENSATION	-	*	422	-	-	422
NET LOSS	-	-	-	-	(8,003)	(8,003)
BALANCE AS OF FEBRUARY 28, 2019	17,380	$ 207	$ 99,892	-	$ (74,751)	$ 25,348

* Represents an amount of less than $1.

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

ORAMED PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

U.S. Dollars in thousands

(UNAUDITED)

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	$			
	In thousands				
BALANCE AS OF NOVEMBER 30, 2019	17,400	$ 209	$ 100,597	$ (83,646)	$ 17,160
CHANGES DURING THE THREE MONTH PERIOD ENDED FEBRUARY 29, 2020:					
ISSUANCE OF COMMON STOCK, NET	441	5	2,311	-	2,316
SHARES ISSUED FOR SERVICES	3	*	13	-	13
EXERCISE OF WARRANTS AND OPTIONS	-	-	-	-	-
STOCK-BASED COMPENSATION	-	-	289	-	289
NET LOSS	-	-	-	(3,688)	(3,688)
BALANCE AS OF FEBRUARY 29, 2020	17,844	$ 214	$ 103,210	$ (87,334)	$ 16,090

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	$			
	In thousands				
BALANCE AS OF NOVEMBER 30, 2018	17,377	$ 207	$ 99,701	$ (71,050)	$ 28,858
CHANGES DURING THE THREE MONTH PERIOD ENDED FEBRUARY 28, 2019:					
SHARES ISSUED FOR SERVICES	3	*	8	-	8
STOCK-BASED COMPENSATION	-	*	183	-	183
NET LOSS	-		-	(3,701)	(3,701)
BALANCE AS OF FEBRUARY 28, 2019	17,380	$ 207	$ 99,892	$ (74,751)	$ 25,348

* Represents an amount of less than $1.

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

ORAMED PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars in thousands
(UNAUDITED)

	Six months ended	
	February 29, 2020	**February 28, 2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,231)	$ (8,003)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	2	4
Exchange differences and interest on deposits and held to maturity bonds	(17)	(83)
Changes in fair value of investments	121	27
Stock-based compensation	569	422
Shares issued for services	30	44
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	479	(376)
Accounts payable, accrued expenses and related parties	(186)	297
Deferred revenues	(1,349)	1,659
Liability for employee rights upon retirement	(5)	1
Other liabilities	(38)	(7)
Total net cash used in operating activities	(6,625)	(6,015)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of short-term deposits	(10,200)	(2,650)
Purchase of long-term deposits	-	(2,750)
Purchase of held to maturity securities	-	(397)
Proceeds from sale of short-term deposits	15,000	9,051
Proceeds from maturity of held to maturity securities	2,100	1,200
Funds in respect of employee rights upon retirement	3	(1)
Purchase of property and equipment	(3)	(8)
Total net cash provided by investing activities	6,900	4,445
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	2,316	-
Proceeds from exercise of options	13	-
Total net cash provided by financing activities	2,329	-
EFFECT OF EXCHANGE RATE CHANGES ON CASH	1	3
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,605	(1,567)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,329	4,996
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 5,934	$ 3,429
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -		
Interest received	$ 348	$ 461

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:

a. General:

1) Incorporation and operations

Oramed Pharmaceuticals Inc. (collectively with its subsidiary, the "Company," unless the context indicates otherwise) was incorporated on April 12, 2002, under the laws of the State of Nevada. From incorporation until March 3, 2006, the Company was an exploration stage company engaged in the acquisition and exploration of mineral properties. On February 17, 2006, the Company entered into an agreement with Hadasit Medical Services and Development Ltd. to acquire the provisional patent related to an orally ingestible insulin capsule to be used for the treatment of individuals with diabetes.

On May 14, 2007, the Company incorporated a wholly-owned subsidiary in Israel, Oramed Ltd. (the "Subsidiary"), which is engaged in research and development.

On March 11, 2011, the Company was reincorporated from the State of Nevada to the State of Delaware.

On July 30, 2019, the Subsidiary incorporated a wholly-owned subsidiary in Hong Kong, Oramed HK Limited. As of February 29, 2020, Oramed HK Limited has no operations.

On November 30, 2015, the Company entered into a Technology License Agreement with Hefei Tianhui Incubator of Technologies Co. Ltd. ("HTIT") and on December 21, 2015, the parties entered into an Amended and Restated Technology License Agreement that was further amended by the parties on June 3, 2016 and July 24, 2016 (the "License Agreement"). According to the License Agreement, the Company granted HTIT an exclusive commercialization license in the territory of the People's Republic of China, Macau and Hong Kong (the "Territory"), related to the Company's oral insulin capsule, ORMD-0801 (the "Product"). Pursuant to the License Agreement, HTIT will conduct, at its own expense, certain pre-commercialization and regulatory activities with respect to the Subsidiary's technology and ORMD-0801 capsule, and will pay to the Subsidiary (i) royalties of 10% on net sales of the related commercialized products to be sold by HTIT in the Territory ("Royalties"), and (ii) an aggregate of $37,500, of which $3,000 was payable immediately, $8,000 will be paid subject to the Company entering into certain agreements with certain third parties, and $26,500 will be paid upon achievement of certain milestones and conditions. In the event that the Company does not meet certain conditions, the Royalties rate may be reduced to a minimum of 8%. Following the final expiration of the Company's patents covering the technology in the Territory in 2033, the Royalties rate may be reduced, under certain circumstances, to 5%.

The royalty payment obligation shall apply during the period of time beginning upon the first commercial sale of the Product in the Territory, and ending upon the later of (i) the expiration of the last-to-expire licensed patents in the Territory; and (ii) 15 years after the first commercial sale of the Product in the Territory (the "Royalty Term").

The License Agreement shall remain in effect until the expiration of the Royalty Term. The License Agreement contains customary termination provisions.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

Among others, the Company's involvement through the product submission date will include consultancy for the pre-commercialization activities in the Territory, as well as advisory services to HTIT on an ongoing basis.

As of February 29, 2020, the Company has received milestone payments in an aggregate amount of $20,500 as follows: the initial payment of $3,000 was received in January 2016. Following the achievement of certain milestones, the second and third payments of $6,500 and $4,000, respectively, were received in July 2016, the fourth milestone payment of $4,000 was received in October 2016 and the fifth milestone payment of $3,000 was received in January 2019.

In addition, on November 30, 2015, the Company entered into a Stock Purchase Agreement with HTIT (the "SPA"). According to the SPA, the Company issued 1,155,367 shares of common stock to HTIT for $12,000. The transaction closed on December 28, 2015.

In July 2015, according to the letter of intent signed between the parties or their affiliates, HTIT's affiliate paid the Subsidiary a non-refundable amount of $500 as a no-shop fee. The no-shop fee was deferred and the related revenue is recognized over the estimated term of the License Agreement.

For revenue recognition policy see note 1c.

2) Development and liquidity risks

The Company is engaged in research and development in the biotechnology field for innovative pharmaceutical solutions, including an orally ingestible insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules for delivery of other polypeptides, and has not generated significant revenues from its operations. Based on the Company's current cash resources and commitments, the Company believes it will be able to maintain its current planned development activities and the corresponding level of expenditures for at least the next 12 months, although no assurance can be given that the Company will not need additional funds prior to such time. If there are unexpected increases in its operating expenses, the Company may need to seek additional financing during the next 12 months. Successful completion of the Company's development programs and its transition to normal operations is dependent upon obtaining necessary regulatory approvals from the U.S. Food and Drug Administration prior to selling its products within the United States, obtaining foreign regulatory approvals to sell its products internationally, or entering into licensing agreements with third parties. There can be no assurance that the Company will receive regulatory approval of any of its product candidates, and a substantial amount of time may pass before the Company achieves a level of revenues adequate to support its operations, if at all. The Company also expects to incur substantial expenditures in connection with the regulatory approval process for each of its product candidates during their respective developmental periods. Obtaining marketing approval will be directly dependent on the Company's ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries. The Company cannot predict the outcome of these activities. In addition to the foregoing, based on the Company's current assessment, the Company does not expect any material impact on its long-term development timeline and its liquidity due to the worldwide spread of the COVID-19 virus. However, the Company is continuing to assess the effect on its operations by monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

b. Loss per common share

Basic and diluted net loss per common share are computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding for each period. Outstanding stock options, warrants and restricted stock units ("RSUs") have been excluded from the calculation of the diluted loss per share because all such securities are anti-dilutive for all periods presented. The weighted average number of common stock options, warrants and RSUs excluded from the calculation of diluted net loss was 4,736,787 and 4,293,395 for the six month periods ended February 29, 2020 and February 28, 2019, respectively, and 4,840,417 and 4,234,081 for the three month periods ended February 29, 2020 and February 28, 2019, respectively.

c. Revenue recognition

The License Agreement and the SPA were considered a single arrangement with multiple deliverables. The Company allocated the total consideration of $49,500 between the License Agreement and the SPA according to their fair value, as follows: $10,617 was allocated to the issuance of common stock (less issuance expenses of $23), based on the quoted price of the Company's shares on the closing date of the SPA on December 28, 2015, and $38,883 was allocated to the License Agreement.

Under Accounting Standards Codification ("ASC") 605 (which was the authoritative revenue recognition guidance applied for all periods prior to September 1, 2018) given the Company's continuing involvement through the expected product submission in June 2023, amounts received relating to the License Agreement were recognized over the period from which the Company was entitled to the respective payment, and the expected product submission date using a time-based model approach over the periods that the fees were earned.

On September 1, 2018, the Company adopted Accounting Standards Update ("ASU") 2014-09 "Revenue from Contracts with Customers (Topic 606)" ("ASC 606"), using the modified retrospective method of adoption. Under this method, the Company applied ASC 606 to the License Agreement at the adoption date and was required to make an adjustment to the September 1, 2018 opening accumulated deficit balance and all prior periods continue to be presented under ASC 605. The most significant impact from adopting ASC 606 was the impact of the timing of recognition of revenue associated with the milestone payment. Under ASC 605 (which was the authoritative revenue recognition guidance applied for all periods prior to September 1, 2018) given the Company's continuing involvement through the expected product submission in June 2023, amounts received relating to the License Agreement were recognized over the period from which the Company was entitled to the respective payment, and the expected product submission date using a time-based model approach over the periods that the fees were earned. However, under ASC 606, the Company is required to recognize the total transaction price (which includes consideration related to milestones once the criteria for recognition have been satisfied) using the input method over the period the performance obligation is fulfilled. Accordingly, once the consideration associated with a milestone is included in the transaction price, incremental revenue is recognized immediately based on the period of time that has elapsed towards complete satisfaction of the performance obligation. This method results in the recognition of revenue earlier than under ASC 605 and the resulting impact was recorded as a reduction of the opening balance of accumulated deficit at September 1, 2018 as further described below.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

Under ASC 606, the Company identified a single performance obligation in the agreement and determined that the license and services are not distinct as the license and services are highly dependent on each other. In other words, HTIT cannot benefit from the license without the related services, and vice versa.

Since the customer benefits from the services as the entity performs, revenue is recognized over time through the expected product submission date in June 2023, using the input method. The Company used the input method to measure the process for the purpose of recognizing revenue, which approximates the straight line attribution. The Company used significant judgment when it determined the product submission date.

Under ASC 606, the consideration that the Company would be entitled to upon the achievement of contractual milestones, which are contingent upon the occurrence of future events, are a form of variable consideration. When assessing the portion, if any, of such milestones-related consideration to be included in the transaction price, the Company first assesses the most likely outcome for each milestone and excludes the consideration related to milestones of which the occurrence is not considered the most likely outcome.

The Company then evaluates if any of the variable consideration determined in the first step is constrained by including in the transaction price variable consideration to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company used significant judgment when it determined the first step of variable consideration.
The potential future royalty consideration is also considered a form of variable consideration under ASC 606 as it is based on a percentage of potential future sales of the Company’s products. However, the Company applies the sales-based royalty exception and accordingly will recognize the sales-based royalty amounts when the related sale has occurred. To date, the Company has not recognized any royalty-related revenue.

Amounts that were allocated to the License Agreement as of February 29, 2020 aggregated $22,382, all of which were received through the balance sheet date. Through February 29, 2020, the Company has recognized revenue associated with this agreement in the aggregate amount of $11,370 (of which $674 was recognized in the quarter ended February 29, 2020, and deferred the remaining amount of $11,012 which is presented as deferred revenues on the condensed consolidated balance sheet.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

d. Financial instruments

In January 2016, the Financial Accounting Standards Board ("FASB") issued guidance which updates certain aspects of recognition, measurement, presentation and disclosure of financial assets and financial liabilities ("ASU 2016-01"). The guidance requires entities to recognize changes in fair value in net income rather than in accumulated other comprehensive income. The Company adopted the provisions of this update in the first quarter of fiscal year 2019. Following the adoption, as of September 1, 2018, the Company classified the available for sale securities to financial assets measured in fair value through profit or loss and no longer presents comprehensive income.

e. Condensed Consolidated Financial Statements Preparation

The condensed consolidated financial statements included herein have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and, except as described in note 1f, on the same basis as the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended August 31, 2019 (the "2019 Form 10-K"). These condensed consolidated financial statements reflect all adjustments that are of a normal recurring nature and that are considered necessary for a fair statement of the results of the periods presented. Certain information and disclosures normally included in annual consolidated financial statements have been omitted in this interim period report pursuant to the rules and regulations of the Securities and Exchange Commission. Because the condensed consolidated interim financial statements do not include all of the information and disclosures required by U.S. GAAP for annual financial statements, they should be read in conjunction with the audited consolidated financial statements and notes included in the 2019 Form 10-K. The results for interim periods are not necessarily indicative of a full fiscal year's results.

f. Recently adopted standards

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)", which supersedes the existing guidance for lease accounting, Leases (Topic 840). The new standard requires a lessee to record assets and liabilities on its balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the lessee's income statement. The Company adopted this standard as of September 1, 2019 on a modified retrospective basis and will not restate comparative periods. The Company elected the package of practical expedients permitted under the transition guidance within the new standard which, among other things, allows the Company to carryforward the historical lease classification. The Company made an accounting policy election to keep leases with an initial term of 12 months or less off of its balance sheet. The Company recognized those lease payments in its statements of operations on a straight-line basis over the lease period.

As of the adoption date, the Company recognized an operating lease asset and liability of $113 and $113, respectively, as of September 1, 2019 on its balance sheet.

NOTE 2 - COMMITMENTS AND CONTINGENCIES:

a. In March 2011, the Subsidiary sold shares of its investee company, Entera, to D.N.A, retaining 117,000 ordinary shares (after giving effect to a stock split by Entera in July 2018). In consideration for the shares sold to D.N.A, the Company received, among other payments, ordinary shares of D.N.A (see also note 4).

As part of this agreement, the Subsidiary entered into a patent transfer agreement (the "Patent Transfer Agreement") according to which the Subsidiary assigned to Entera all of its right, title and interest in and to a certain patent application related to the oral administration of proteins that it has licensed to Entera since August 2010. Under this agreement, the Subsidiary is entitled to receive from Entera royalties of 3% of Entera's net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza. As of February 29, 2020, Entera had not yet realized any revenues and had not paid any royalties to the Subsidiary. On December 11, 2018, Entera announced that it had entered into a research collaboration and license agreement (the "Amgen License") with Amgen related to research of inflammatory disease and other serious illnesses. As reported by Entera, under the terms of the Amgen License, Entera will receive a modest initial technology access fee from Amgen and will be responsible for preclinical development at Amgen's expense. Entera will be eligible to receive up to $270,000 in aggregate payments, as well as tiered royalties up to mid-single digits, upon achievement of various clinical and commercial milestones if Amgen decides to move all of these programs forward. Amgen is responsible for clinical development, manufacturing and commercialization of any of the resulting programs. To the extent the Amgen License results in net revenues as defined in the Patent Transfer Agreement, the Subsidiary will be entitled to the aforementioned royalties.

In addition, as part of a consulting agreement with a third party, dated February 15, 2011, the Subsidiary is obliged to pay this third party royalties of 8% of the net royalties received in respect of the patent that was sold to Entera in March 2011.

b. On January 3, 2017, the Subsidiary entered into a lease agreement for its office facilities in Israel. The lease agreement is for a period of 60 months commencing October 1, 2016.

The annual lease payment was New Israeli Shekel ("NIS") 119,000 ($34) from October 2016 through September 2018 and NIS 132,000 ($38) from October 2018 through September 2021, and is linked to the increase in the Israeli consumer price index ("CPI") (as of February 29, 2020, the aggregate future lease payments will be $60 until the expiration of the lease agreement, based on the exchange rate as of February 29, 2020).

As security for its obligation under this lease agreement, the Company provided a bank guarantee in an amount equal to three monthly lease payments.

NOTE 2 - COMMITMENTS AND CONTINGENCIES (continued):

c. On December 18, 2017, the Subsidiary entered into an agreement with a vendor for the process development and production of one of its oral capsule ingredients in the amount of $2,905 that will be paid over the term of the engagement and based on the achievement of certain development milestones, $1,542 of which was recognized in research and development expenses through February 29, 2020.

d. On February 14, 2018, the Subsidiary entered into a Clinical Research Organization Services Agreement with a third party, effective as of November 1, 2017, to retain it as a clinical research organization ("CRO") for the Subsidiary's three month dose-ranging clinical trial for its oral insulin capsule for type 2 diabetes patients and, on May 20, 2019, the Subsidiary entered into amendments to such agreement. As consideration for its services, the Subsidiary will pay the CRO a total amount of $10,206 during the term of the engagement and based on achievement of certain milestones, of which $8,898 was recognized in research and development expenses through February 29, 2020.

e. On May 21, 2018, the Subsidiary entered into a CRO Services Agreement with a third party to retain it as a CRO for the Subsidiary's food effect clinical trial for its oral insulin capsule. As consideration for its services, the Subsidiary will pay the CRO a total amount of $1,166 during the term of the engagement and based on achievement of certain milestones, $1,141 of which was recognized in research and development expenses through February 29, 2020.

f. On July 29, 2019, the Subsidiary entered into a CRO Services Agreement with a third party to retain it as a CRO for the Subsidiary's dose-ranging clinical trial for its oral insulin. As consideration for its services, the Subsidiary will pay the CRO a total amount of $658 during the term of the engagement and based on achievement of certain milestones, $571 of which was recognized in research and development expenses through February 29, 2020.

g. Grants from the Israel Innovation Authority ("IIA")

Under the terms of the Company's funding from the IIA, royalties of 3% are payable on sales of products developed from a project so funded, up to a maximum amount equaling 100%-150% of the grants received (dollar linked) with the addition of interest at an annual rate based on LIBOR.

At the time the grants were received, successful development of the related projects was not assured. The total amount that was received through February 29, 2020 was $2,207.

The royalty expenses which are related to the funded project were recognized in cost of revenues in the quarter ended February 29, 2020 and in prior periods.

h. Grants from the European Commission ("EC")

On November 26, 2019 the Company received an initial payment of €17.50 from the EC under the SME Instrument of the European Innovation Programme Horizon 2020.

As part of the grant terms, the Company is required to use the proceeds from the grant in Europe. The Company intends on using the grant to explore the possibility of running clinical trials in Europe.

NOTE 3 - FAIR VALUE:

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 February 29, 2020, the assets measured at fair value are comprised of equity securities (Level 1). The fair value of held to maturity bonds as presented in note 4 was based on a Level 2 measurement.

As of February 29, 2020, the carrying amounts of cash equivalents, short-term deposits and accounts payable approximate their fair values due to the short-term maturities of these instruments.

As of February 29, 2020, the carrying amounts of long-term deposits approximate their fair values due to the stated interest rates which approximate market rates.

The amounts funded in respect of employee rights are stated at cash surrender value which approximates its fair value.

There were no Level 3 items for the three and six month periods ended February 29, 2020 and February 28, 2019.

NOTE 4 - MARKETABLE SECURITIES:

The Company's marketable securities include investments in equity securities of D.N.A and Entera, and in held to maturity bonds.

a. Composition:

	February 29, 2020	August 31, 2019
Short-term:		
D.N.A (see b below)	$ 373	$ 557
Entera (see c below)	367	304
Held to maturity bonds (see d below)	1,764	2,840
Mutual funds	3,200	-
	$ 5,704	$ 3,701
Long-term:		
Held to maturity bonds (see d below)	$ 250	$ 1,295

b. D.N.A

The D.N.A ordinary shares are traded on the Tel Aviv Stock Exchange. The fair value of those securities is measured at the quoted prices of the securities on the measurement date.

As of February 29, 2020, the Company owns approximately 5.6% of D.N.A's outstanding ordinary shares.

The cost of the securities as of February 29, 2020 and August 31, 2019 is $595.

c. Entera

Entera ordinary shares have been traded on The Nasdaq Capital Market since June 28, 2018. The Company measures the investment at fair value from such date, since it has a readily determinable fair value (prior to such date the investment was accounted for as a cost method investment (amounting to $1)).

NOTE 4 - MARKETABLE SECURITIES (continued):

d. Held to maturity securities

The amortized cost and estimated fair value of held-to-maturity securities as of February 29, 2020, are as follows:

	February 29, 2020		
	Amortized cost	Gross unrealized gains	Estimated fair value
Short-term:			
Commercial bonds	$ 1,748	8	1,756
Accrued interest	16	-	16
Long-term	250	-	250
	$ 2,014	8	2,022

As of February 29, 2020, the contractual maturities of debt securities classified as held-to-maturity are as follows: before one year, $1,748, and the average yield to maturity rate is 3.28%; After one year through two years, $250, and the yield to maturity rates is 2.77%.

The amortized cost and estimated fair value of held-to-maturity securities as of August 31, 2019, are as follows:

	August 31, 2019		
	Amortized cost	Gross unrealized gains	Estimated fair value
Short-term:			
Commercial bonds	$ 2,808	$ 6	$ 2,814
Accrued interest	32	-	32
Long-term	1,295	4	1,299
	$ 4,135	$ 10	$ 4,145

As of August 31, 2019, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, $1,295 and the yield to maturity rates vary between 2.55% to 3.20%.

Held to maturity securities which will mature during the 12 months from the balance sheet date are included in short-term marketable securities. Held to maturity securities with maturity dates of more than one year are considered long-term marketable securities.

NOTE 5 - STOCKHOLDERS' EQUITY:

On September 5, 2019, the Company entered into an Equity Distribution Agreement (the "Sales Agreement"), pursuant to which the Company may, from time to time and at the Company's option, issue and sell shares of Company common stock having an aggregate offering price of up to $15,000, through a sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to the Company's effective shelf registration statement on Form S-3 including a prospectus and prospectus supplement, each dated February 10, 2020 (which superseded a prior registration statement, prospectus and prospectus supplement that related to shares sold under the Sales Agreement). The Company will pay the sales agent a cash commission of 3.0% of the gross proceeds of the sale of any shares sold through the sales agent under the Sales Agreement. As of February 29, 2020, 440,866 shares were issued under the Sales Agreement for aggregate net proceeds of $2,329.

NOTE 6 - RELATED PARTIES - TRANSACTIONS:

On July 1, 2008, the Subsidiary entered into two consulting agreements with KNRY Ltd. ("KNRY"), an Israeli company owned by the Chief Scientific Officer (the "CSO"), whereby the Chief Executive Officer (the "CEO") and the CSO, through KNRY, provide services to the Company (the "Consulting Agreements"). The Consulting Agreements, as amended, are both terminable by either party upon 140 days prior written notice. The Consulting Agreements, as amended, provide that KNRY will be reimbursed for reasonable expenses incurred in connection with performance of the Consulting Agreements and that the monthly consulting fee paid to the CEO and the CSO is NIS 127,570 ($37) and NIS 92,522 ($27), respectively. In January 2020, pursuant to an amendment to the CSO's Consulting Agreement, the monthly consulting fee paid to such executive officer was increased.

In addition to the Consulting Agreements, based on a relocation cost analysis prepared by consulting company ORI - Organizational Resources International Ltd., the Company pays for certain direct costs, related taxes and expenses incurred in connection with the relocation of the CEO to New York. During the six months ended February 29, 2020, such relocation expenses totaled $298 compared to $278 for the six months ended February 28, 2019.

NOTE 7 - SUBSEQUENT EVENT:

On February 27, 2020, the Company entered into an underwriting agreement ("Agreement") with National Securities Corporation ("Underwriter"), in connection with a public offering ("Offering") of 5,250,000 shares of the Company's common stock, at an offering price of $4.00 per share. Under the terms of the Agreement, the Company granted the Underwriter a 45-day option to purchase from the Company up to an additional 787,500 shares of common stock at the public offering price. In connection with the Offering, the Company also agreed to issue to the Underwriter, or its designees, warrants ("Underwriter's Warrants"), to purchase up to an aggregate of 7% of the shares of common stock sold in the Offering (including any additional shares sold during the 45-day option period), at an exercise price of $4.80 per share. The Underwriter's Warrants issued in the Offering will be exercisable at any time and from time to time, in whole or in part, commencing six months from issuance for a period of three years from the date of issuance. The closing of the sale of the Offering occurred on March 2, 2020. The net proceeds to the Company from the Offering, after deducting the Underwriter's fees and expenses and the Company's Offering expenses were approximately $19,292.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the related notes included elsewhere herein and in our consolidated financial statements, accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report (as defined below).

Forward-Looking Statements

The statements contained in this Quarterly Report on Form 10-Q that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Words such as "expects," "anticipates," "intends," "plans," "planned expenditures," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Quarterly Report on Form 10-Q. Additionally, statements concerning future matters are forward-looking statements. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity, or our achievements, or industry results, to be materially different from any future results, performance, levels of activity, or our achievements, or industry results, expressed or implied by such forward-looking statements. Such forward-looking statements include, among other statements, statements regarding the following:

- the expected development and potential benefits from our products in treating diabetes;
- the prospects of entering into additional license agreements, or other partnerships or forms of cooperation with other companies or medical institutions;
- future milestones, conditions and royalties under the license agreement with Hefei Tianhui Incubator of Technologies Co., Ltd., or HTIT;
- our research and development plans, including pre-clinical and clinical trials plans and the timing of enrollment, obtaining results and conclusion of trials, including without limitation, our expectation that we will initiate two six-month Phase III clinical trials, and our expectation to file a New Drug Application thereafter;
- our belief that our technology has the potential to deliver medications and vaccines orally that today can only be delivered via injection;
- the competitive ability of our technology based product efficacy, safety, patient convenience, reliability, value and patent position;
- the potential market demand for our products;
- our expectation that in the upcoming year our research and development expenses, net, will continue to be our major expenditure;
- our expectations regarding our short- and long-term capital requirements;
- our outlook for the coming months and future periods, including but not limited to our expectations regarding future revenue and expenses;
- information with respect to any other plans and strategies for our business; and
- our expectation regarding the impact of COVID-19.

Although forward-looking statements in this Quarterly Report on Form 10-Q reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading "Item 1A - Risk Factors" in this Quarterly Report on Form 10-Q and those under the same heading in our Annual Report on Form 10-K for the fiscal year ended August 31, 2019, or our Annual Report, as filed with the Securities and Exchange Commission, or the SEC, on November 27, 2019, as well as those discussed elsewhere in our Annual Report and expressed from time to time in our other filings with the SEC.

In addition, historic results of scientific research, clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not suggest different conclusions. Also, historic results referred to in this Quarterly Report on Form 10-Q could be interpreted differently in light of additional research, clinical and preclinical trials results. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. Except as required by law, we undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Quarterly Report on Form 10-Q. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this Quarterly Report on Form 10-Q which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

Overview of Operations

We are a pharmaceutical company currently engaged in the research and development of innovative pharmaceutical solutions, including an oral insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules for delivery of other polypeptides. We utilize clinical research organizations, or CROs, to conduct our clinical studies.

Recent business developments

Product Candidates

Oral insulin: We are seeking to transform the treatment of diabetes through our proprietary flagship product, an orally ingestible insulin capsule, or ORMD-0801. Our technology allows insulin to travel from the gastrointestinal tract via the portal vein to the bloodstream, revolutionizing the manner in which insulin is delivered. It enables the passage in a more physiological manner than current delivery methods of insulin. Our technology is a platform that has the potential to deliver medications and vaccines orally that today can only be delivered via injection.

FDA Guidance: In August 2017, during a call with the U.S. Food and Drug Administration, or FDA, we were advised that the regulatory pathway for the submission of ORMD-0801 would be a Biologics License Application, or BLA. If approved the BLA pathway would grant us 12 years of marketing exclusivity for ORMD-0801, from the approval date, and an additional six months of exclusivity may be granted to us if the product also receives approval for use in pediatric patients.

Phase IIb Study: In May 2018, we initiated a three-month dose-ranging Phase IIb clinical trial of ORMD-0801 (Cohort A). This placebo controlled, randomized, 90-day treatment clinical trial was conducted on 269 type 2 diabetic patients in multiple centers throughout the United States pursuant to an Investigational New Drug application, or IND, with the FDA. The primary endpoints of the trial were to assess the safety and evaluate the effect of ORMD-0801 on HbA1c levels over a 90-day treatment period. Secondary endpoints of the trial included measurements of fasting plasma glucose, or FPG, post-prandial glucose, or PPG levels, during a mixed-meal tolerance test, or MMTT, and weight. In May 2019, we began an extension of this protocol for approximately 75 type 2 diabetic patients, who were dosed using a lower dosage (Cohort B).

Cohort A:- In November 2019, we announced positive results from the initial cohort of the Phase IIb trial. Patients randomized in the trial to once-daily ORMD-0801 achieved a statistically significant (p-value 0.036) reduction from baseline in HbA1c of 0.60% (0.54% with placebo adjustment). This 0.54% reduction in HbA1c is clinically meaningful. Treatment with ORMD-0801 demonstrated an excellent safety profile, with no serious drug-related adverse events and with no increased frequency of hypoglycemic episodes when compared to placebo. In addition, during this 90-day trial, no weight gain was observed. In the initial cohort, 269 U.S.-based patients were enrolled and treated with a dose-increasing approach: 16 mg initial dose, titrated to 24 mg per dose, and then titrated to 32 mg per dose. Patients were randomized into three groups to assess dosing frequency: once-daily (32 mg per day), twice-daily (64 mg per day), thrice daily (96 mg per day). There was a corresponding placebo for each treatment arm. Two hundred nine (209) patients completed treatment to the 12-week endpoint and were included in the data analysis (24 subjects did not complete the full 12 weeks of treatment). The twice-daily arms achieved statistically significant (p-value 0.042) reductions from baseline in A1C of 0.59% (0.53% with placebo adjustment). The thrice-daily arm did not meet statistical significance (p-value 0.093). In addition, due to evidence of treatment-by-center interaction, two sites (36 patients (13.4% of enrolled subjects)) were excluded from the statistical analysis as they showed results opposite from the rest of the statistically significant results. As our internal investigation did not find a cause for such discrepancy, we have appointed an independent advisor to investigate this discrepancy.

We anticipate initiating Phase III clinical trials on both type 1 and type 2 diabetic patients in the second half of calendar year 2020. Following these trials we expect to file a BLA with potential FDA approval by the end of calendar year 2024.We also expect to have a meeting with the European Medicines Agency, or the EMA, regarding our Phase III study design, as we intend to utilize clinical sites and file for marketing approval in Europe.

Clamp Study: In June 2018, following a request from the FDA, we initiated a glucose clamp study which should quantify insulin absorption in diabetic patients treated with ORMD-0801. The glucose clamp is a method for quantifying insulin absorption in order to measure a patient's insulin sensitivity and how well a patient metabolizes glucose. This exploratory, randomized, double-blind glucose clamp study is evaluating exposure-response profiles of type 1 diabetic patients treated with ORMD-0801. Six patients with A1C levels of 10% or below, aged 18-50, are enrolled in the study. We have received the results from the study which will be used in future documentation for FDA submission.

Food Effect Study: In June 2018, we initiated a food effect trial for ORMD-0801. This single-blind, five period, randomized, placebo-controlled crossover trial is evaluating the pharmacokinetics, or PK, and pharmacodynamics, of ORMD-0801 taken at different times in relation to meals in healthy volunteers and patients with type 1 diabetes. Forty-eight (48) patients were enrolled, including 24 healthy volunteers and 24 patients with type 1 diabetes. We completed this study in April 2019 and received the study results in March 2020. According to the study results, we believe that ORMD-0801 dosed 45-minutes prior to a meal would be a reasonable dosing schedule for the future clinical studies.

NASH Study: In October 2018, we initiated an exploratory clinical study of ORMD-0801 in type 2 patients with nonalcoholic steatohepatitis, or NASH. The three-month treatment study, which was approved by Israel's Ministry of Health, will assess the effectiveness of ORMD-0801 in reducing liver fat content, inflammation and fibrosis in 30 patients with NASH. We expect to complete the study during first half of calendar year 2021.

Toxicology Study (6 Months): In March 2019, we completed a six-month dosing toxicology study of ORMD-0801, which was initiated in September 2018 following the FDA's request. We have received a draft report and we expect to receive the final report of this study in the second quarter of calendar year 2020.

Type 1 Study: In November 2019 we initiated a crossover study of type 1 diabetic patients to compare the effects of ORMD-0801 given once daily versus the effects of ORMD-0801 given three times daily. We have received a draft report and we expect to receive the final report of this study in the second quarter of calendar year 2020.

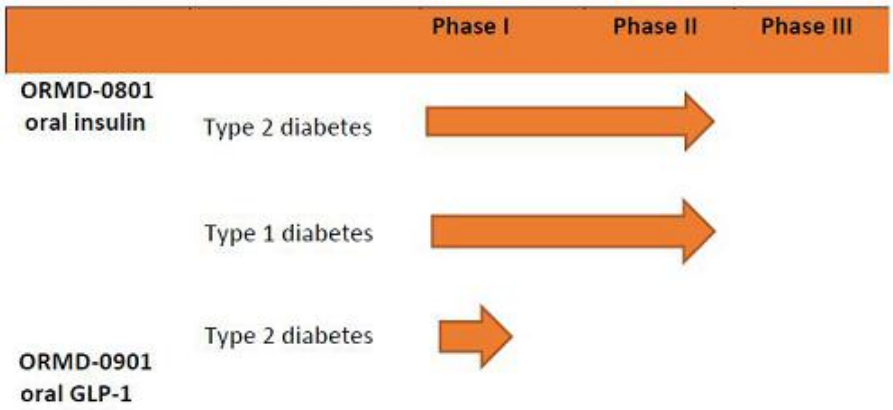
Oral Glucagon-Like Peptide-1: Glucagon-like peptide-1, or GLP-1, is an incretin hormone, which stimulates the secretion of insulin from the pancreas. In addition, GLP-1 was found to suppress glucagon release (a hormone involved in the regulation of glucose) from the pancreas, slow gastric emptying to reduce the rate of absorption of nutrients into the blood stream and increase satiety. Other important beneficial attributes of GLP-1 are its effects of increasing the number of beta cells (cells that produce and release insulin) in the pancreas and, possibly, protection of the heart. In addition to our flagship product, the ORMD-0801 insulin capsule, we are using our technology for an orally ingestible GLP-1 capsule, or ORMD-0901.

In February 2019, we completed a Phase I PK trial to evaluate the safety and the pharmacokinetics of ORMD-0901 compared to placebo. We have received a draft report and we expect to receive the final report of this study in the second quarter of calendar year 2020. This study was conducted pursuant to an IND, which we expect to be followed by further bioavailability studies (results expected in calendar year 2020) and a Phase II trial on type 2 diabetic patients which will likely be conducted in the United States under an IND.

Other products

We are developing a new drug candidate, a weight loss treatment in the form of an oral leptin capsule. We anticipate initiating a proof of concept single dose study for our oral leptin drug candidate to evaluate its pharmacokinetic and pharmacodynamics (glucagon reduction) in 10 type 1 adult diabetic patients. Due to government restrictions enacted as a result of COVID-19, we are facing delays in recruitment for this study and expect to initiate the study as soon as these restrictions have been raised.

The table below gives an overview of our primary product pipeline:



Out-Licensed Technology

On November 30, 2015, we, our Israeli subsidiary and HTIT entered into a Technology License Agreement, and on December 21, 2015 these parties entered into an Amended and Restated Technology License Agreement that was further amended by the parties on June 3, 2016 and July 24, 2016, or the License Agreement. According to the License Agreement, we granted HTIT an exclusive commercialization license in the territory of the People's Republic of China, Macau and Hong Kong, or the Territory, related to our oral insulin capsule, ORMD-0801, or the Product. Pursuant to the License Agreement, HTIT will conduct, at its own expense, certain pre-commercialization and regulatory activities with respect to our subsidiary's technology and ORMD-0801 capsule, and will pay (i) royalties of 10% on net sales of the related commercialized products to be sold by HTIT in the Territory, or Royalties, and (ii) an aggregate of $37.5 million, of which $3 million was payable immediately, $8 million will be paid subject to our entry into certain agreements with certain third parties, and $26.5 million will be paid upon achievement of certain milestones and conditions. In the event that we will not meet certain conditions, the Royalties rate may be reduced to a minimum of 8%. Following the final expiration of our patents covering the technology in the Territory in 2033, the Royalties rate may be reduced, under certain circumstances, to 5%. The royalty payment obligation shall apply during the period of time beginning upon the first commercial sale of the Product in the Territory, and ending upon the later of (i) the expiration of the last-to-expire licensed patents in the Territory; and (ii) 15 years after the first commercial sale of the Product in the Territory, or the Royalty Term. The License Agreement shall remain in effect until the expiration of the Royalty Term. The License Agreement contains customary termination provisions. Through February 29, 2020, we received aggregate milestone payments of $20.5 million out of the aggregate amount of $37.5 million.

On November 30, 2015, we also entered into a separate Securities Purchase Agreement with HTIT, or the SPA, pursuant to which, in December 2015, we issued to HTIT 1,155,367 shares of our common stock for total consideration of $12 million. In connection with the License Agreement and the SPA, we received a non-refundable payment of $500,000 as a no-shop fee.

Results of Operations

Comparison of six and three month periods ended February 29, 2020 and February 28, 2019

The following table summarizes certain statements of operations data of the Company for the six and three month periods ended February 29, 2020 and February 28, 2019 (in thousands of dollars except share and per share data):

	Six months ended		Three months ended	
	February 29, 2020	**February 28, 2019**	**February 29, 2020**	**February 28, 2019**
Revenues	$ 1,348	$ 1,340	$ 674	$ 666
Cost of revenues	-	90	-	55
Research and development expenses	5,342	7,461	3,320	3,114
General and administrative expenses	2,472	1,997	1,391	1,065
Financial income, net	235	505	349	167
Taxes on income	-	300	-	300
Net loss for the period	$ 6,231	$ 8,003	$ 3,688	$ 3,701
Loss per common share - basic and diluted	$ 0.35	$ 0.46	$ 0.21	$ 0.21
Weighted average common shares outstanding	17,645,372	17,451,411	17,818,429	17,454,109

Revenues

Revenues consist of proceeds related to the License Agreement that are recognized on a cumulative basis when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur, through the expected product submission date of June 2023 using the input method.

Revenues were $1,348,000 and $1,340,000 for the six month periods ended February 29, 2020 and February 28, 2019, respectively.

Revenues for the three month period ended February 29, 2020 were $674,000 and the revenues for the three month period ended February 28, 2019 were $666,000.

Cost of revenues

Cost of revenues consists of royalties related to the License Agreement that will be paid over the term of the License Agreement in accordance with revenue recognition accounting and the Law for the Encouragement of Industrial Research, Development and Technological Innovation, 1984, as amended, including any regulations or tracks promulgated thereunder.

Cost of revenues for the six month period ended February 29, 2020 decreased to none compared to $90,000 for the six month period ended February 28, 2019. The decrease is attributable to a milestone payment which was received during the six month period ended February 28, 2019.

There was no cost of revenues for the three month period ended February 29, 2020 compared to $55,000 for the three month period ended February 29, 2020. The decrease is attributable to a milestone payment which was received during the three month period ended February 28, 2019.

Research and development expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, employee benefits, costs of materials, supplies, the cost of services provided by outside contractors, including services related to our clinical trials, clinical trial expenses, the full cost of manufacturing drugs for use in research and preclinical development. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, or CROs, independent clinical investigators and other third-party service providers to assist us with the execution of our clinical studies.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by CROs. CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management.

Clinical trial and pre-clinical trial expenses include regulatory and scientific consultants' compensation and fees, research expenses, purchase of materials, cost of capsule manufacturing, payments for patient recruitment and treatment, as well as salaries and related expenses of research and development staff.

Research and development expenses for the six month period ended February 29, 2020 decreased by 30% to $5,342,000, from $7,641,000 for the six month period ended February 28, 2019. The decrease is primarily due to a decrease in expenses related to our Phase IIb three-month treatment clinical trial as well as a decrease in expenses related to our toxicology studies and partially offset by an increase in expenses related to materials for our future Phase III trial. Stock-based compensation costs for the six month period ended February 29, 2020 totaled $218,000, as compared to $93,000 during the six month period ended February 28, 2019. The increase is mainly attributable to awards granted to employees and a consultant during the six month period ended February 29, 2020 and during the Company's 2019 fiscal year.

Research and development expenses for the three month period ended February 29, 2020 increased by 7% to $3,320,000, from $3,114,000 for the three month period ended February 28, 2019. The increase is primarily due to an increase in expenses related to the completion of our Phase IIb three-month treatment clinical trial (including regulatory expenses) as well as an increase in expenses related to materials for our future Phase III trial. Stock-based compensation costs for the three month period ended February 29, 2020 totaled $122,000, as compared to $54,000 during the three month period ended February 28, 2019. The increase is mainly attributable to awards granted to employees and a consultant during the three month period ended February 29, 2020 and during the Company's 2019 fiscal year.

Government grants

In the six month periods ended February 29, 2020 and February 28, 2019, we did not recognize any research and development grants. As of February 29, 2020, following repayment of a portion of such grants, outstanding liabilities to pay royalties to the Israel Innovation Authority of the Israeli Ministry of Economy & Industry are equal to $315,000.

General and administrative expenses

General and administrative expenses include the salaries and related expenses of our management, consulting costs, legal and professional fees, travel expenses, business development costs, insurance expenses and other general costs.

General and administrative expenses for the six month period ended February 29, 2020 increased by 24% to $2,472,000 from $1,997,000 for the six month period ended February 28, 2019. The increase in costs related to general and administrative activities is primarily attributable to an increase in legal expenses and costs related to directors and officers. Stock-based compensation costs for the six month period ended February 29, 2020 totaled $350, as compared to $329 during the six month period ended February 28, 2019. The increase is mainly attributable to awards granted to employees and a consultant during the six month period ended February 29, 2020 and the Company's 2019 fiscal year.

General and administrative expenses for the three month period ended February 29, 2020 increased by 30% to $1,391,000 from $1,065,000 for the three month period ended February 28, 2019. The increase in costs related to general and administrative activities is primarily attributable to an increase in legal expenses, costs related to directors and officers and bonuses recorded in the first quarter in 2019 and in the second quarter in 2020. Stock-based compensation costs for the three month period ended February 29, 2020 totaled $166,000, as compared to $130,000 during the three month period ended February 28, 2019. The increase is mainly attributable to awards granted to employees and a consultant during the three month period ended February 29, 2020 and the Company's 2019 fiscal year.

Financial income, net

Net financial income decreased 53% from net financial income of $505 for the six month period ended February 29, 2020 to net financial income of $235 for the six month period ended February 28, 2019. The decrease is primarily attributable to less interest income as well as the decreases in fair value of the ordinary shares of D.N.A Biomedical Solutions Ltd. and Entera Bio Ltd.

Net financial income increased by 208% from net financial income of $167,000 for the three month period ended February 28, 2019 to net financial income of $349,000 for the three month period ended February 29, 2020. The increase is primarily attributable to the increases in fair value of the ordinary shares of D.N.A Biomedical Solutions Ltd. and Entera Bio Ltd.

Taxes on income

No taxes on income were recognized for the six month period ended February 29, 2020 as compared to $300,000 for the six month period ended February 28, 2019. The decrease is due to withholding taxes in connection with the receipt of a milestone payment pursuant to the License Agreement during 2019.

No taxes on income were recognized for the three month period ended February 29, 2020 as compared to $300,000 for the three month period ended February 28, 2019. The decrease is due to withholding taxes in connection with the receipt of a milestone payment pursuant to the License Agreement during 2019.

Liquidity and capital resources

From inception through February 29, 2020, we have incurred losses in an aggregate amount of $87,334,000. During that period and through April 6, 2020, we have financed our operations through several private placements of our common stock, as well as public offerings of our common stock, raising a total of $99,344,000, net of transaction costs. During that period, we also received cash consideration of $5,901,000 from the exercise of warrants and options. We will seek to obtain additional financing through similar sources in the future, as needed. As of February 29, 2020, we had $5,934,000 of available cash, $17,288,000 of short-term bank deposits and $5,704,000 of marketable securities.

Management continues to evaluate various financing alternatives for funding future research and development activities and general and administrative expenses through fundraising in the public or private equity markets. Although there is no assurance that we will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of future third party investments. Based on our current cash resources and commitments, we believe we will be able to maintain our current planned development activities and the corresponding level of expenditures for at least the next 12 months.

On September 5, 2019, we entered into an Equity Distribution Agreement, or the Sales Agreement, pursuant to which we may, from time to time and at our option, issue and sell shares of our common stock having an aggregate offering price of up to $15,000,000 through a sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to our effective shelf registration statement on Form S-3 including a prospectus and prospectus supplement, each dated February 10, 2020 (which superseded a prior registration statement, prospectus and prospectus supplement that related to shares sold under the Sales Agreement). We will pay the sales agent a cash commission of 3.0% of the gross proceeds of the sale of any shares sold through the sales agent under the Sales Agreement. As of February 29, 2020, 440,866 shares were issued under the Sales Agreement for aggregate net proceeds of $2,329,000. As of February 29, 2020 and April 6, 2020, 440,866 shares of common stock were sold under the Sales Agreement for aggregate net proceeds of $2,328,666.

On February 27, 2020, we entered into an underwriting agreement with National Securities Corporation, or the Underwriter, in connection with a public offering, or the Offering, of 5,250,000 shares of our common stock, at an offering price of $4.00 per share. We also granted the Underwriter a 45-day option to purchase from us up to an additional 787,500 shares of common stock at the public offering price. In connection with the Offering, we also agreed to issue to the Underwriter, or its designees, warrants, to purchase up to an aggregate of 7% of the shares of common stock sold in the Offering (including any additional shares sold during the 45-day option period), at an exercise price of $4.80 per share. The closing of the sale of the Offering occurred on March 2, 2020. The net proceeds to us from the Offering, after deducting the Underwriter’s fees and expenses and the Company’s Offering expenses were approximately $19,292.

As of February 29, 2020, our total current assets were $29,489,000 and our total current liabilities were $5,155,000. On February 29, 2020, we had a working capital surplus of $24,334,000 and an accumulated loss of $87,334,000. As of August 31, 2019, our total current assets were $33,324,000 and our total current liabilities were $5,308,000. On August 31, 2019, we had a working capital surplus of $28,016,000 and an accumulated loss of $81,103,000. The decrease in working capital from August 31, 2019 to February 29, 2020 was primarily due to the cash used in operating activities.

During the six month period ended February 29, 2020, cash and cash equivalents increased to $5,934,000 from the $3,329,000 reported as of August 31, 2019, which is due to the reasons described below.

Operating activities used cash of $6,624,000 in the six month period ended February 29, 2020, as compared to $6,015,000 used in the six month period ended February 28, 2019. Cash used in operating activities primarily consisted of net loss resulting from research and development and general and administrative expenses, as well as changes in contract liabilities due to the License Agreement and is partially offset by changes in accounts payable and accrued expenses.

Investing activities provided cash of $6,900,000 in the six month period ended February 29, 2020, as compared to $4,445,000 provided in the six month period ended February 28, 2019. Cash provided by investing activities consisted primarily of the maturity of short-term deposits and held to maturity securities and is partially offset by the purchase of short-term deposits.

Financing activities provided cash of $2,329,000 in the six month period ended February 29, 2020, as compared to no cash provided in the six month period ended February 28, 2019. Financing activities in the six month period ended February 29, 2020 consisted of aggregate net proceeds of $2,316,000 from our issuance of 440,866 shares of common stock under the Sales Agreement and proceeds from the exercise of warrants and options.

Off-balance sheet arrangements

As of February 29, 2020, we had no off-balance sheet arrangements that have had or that we expect would be reasonably likely to have a future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Critical accounting policies and estimates

Our significant accounting policies are described in the notes to the consolidated financial statements as of August 31, 2019 included in our Annual Report and in the notes to the condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

Planned Expenditures

We invest heavily in research and development, and we expect that in the upcoming years our research and development expenses will continue to be our major operating expense.

ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There has been no significant change in our exposure to market risk during the quarter ended February 29, 2020. For a discussion of our exposure to market risk, refer to Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk,” contained in our Annual Report. In addition, as described in “Item 1A. Risk Factors,” there may be implications on our business with regard to the coronavirus (COVID-19).

ITEM 4 - CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of February 29, 2020. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended February 29, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1A - RISK FACTORS

There have been no material changes from the risk factors previously disclosed in Part I, Item 1A, Risk Factors, of our Annual Report for the fiscal year ended August 31, 2019, except for the risk factors updated below:

A pandemic, epidemic or outbreak of an infectious disease in the United States, Israel or elsewhere may adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States, Israel or elsewhere, our business may be adversely affected. In December 2019, a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and, as of March 2020, has spread to over 100 countries, including the United States and Israel. The spread of COVID-19 from China to other countries has resulted in the World Health Organization declaring the outbreak of COVID-19 as a "pandemic," or a worldwide spread of a new disease, on March 11, 2020. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus. On March 10, 2020, the Government of Israel announced that effective March 12, 2020 foreign travelers arriving from any country will be required to remain in home quarantine until 14 days have passed since the date of entry into Israel; non-Israeli residents will be required to prove they have the means to self-quarantine before being allowed entry into Israel and, in addition, non-Israeli residents or citizens traveling from certain countries may be denied entry into Israel. In addition, the Ministry of Health in the State of Israel issued guidelines on March 11, 2020 recommending people avoid gatherings in one space and providing that no gathering of more than 100 people should be held under any circumstances. Employers (including us) are also required to prepare and increase as much as possible the capacity and arrangement for employees to work remotely. In addition, on March 11, 2020, the President of the United States issued a proclamation to restrict travel to the United States from foreign nationals who have recently been in certain European countries. We are still assessing the effect on our business, from the spread of COVID-19 and the actions implemented by the governments of the State of Israel, the United States and elsewhere across the globe.

The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver supplies to us on a timely basis. In addition, health professionals may reduce staffing and reduce or postpone meetings with clients in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. Although, as of the date of this Quarterly Report on Form 10-Q, we do not expect any material impact on our long-term activity, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

With respect to the COVID-19 outbreak specifically, such outbreak could also potentially affect the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to planned clinical trials and ultimately of reviews and approvals of our product candidates. The spread of COVID-19 may also slow potential enrollment of clinical trials and reduce the number of eligible patients for our clinical trials. The COVID-19 outbreak and mitigation measures also have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 outbreak impacts our business and operations will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

The recent outbreak of COVID-19 may materially and adversely affect our clinical trial operations and our financial results.

The recent outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread to multiple countries, including the United States, Israel and several European countries where we expected to initiate enrollment for a weight loss treatment in the form of an oral leptin capsule and where we expected to conduct additional clinical trials for oral insulin and Oral Glucagon-Like Peptide-1. The extent to which COVID-19 may impact our clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19, or the effectiveness of actions to contain and treat for COVID-19. The continued spread of COVID-19 globally could adversely impact our clinical trial operations in the United States, Israel and in Europe, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. In addition, if the FDA elects to delay face-to-face meetings for an extended period of time, we may have to delay the initiation of any additional clinical trials for which we require additional approval from the FDA, or, if we are seeking to commercialize our product candidates, such delay could force us to delay commercialization. Any decision by the FDA to delay meeting with us in light of COVID-19 could have a material adverse effect on our scheduled clinical trials or on our efforts to obtain commercialization approval, which could increase our operating expenses and have a material adverse effect on our financial results.

Moreover, COVID-19 may also affect employees of third-party contract research organizations located in affected geographies that we rely upon to carry out such enrollments and trials. Any negative impact COVID-19 has to patient enrollment or treatment could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

ITEM 2 - UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On February 1, 2020, we issued 2,500 shares of our common stock to Corporate Profile, LLC, or Corporate Profile, in payment of a portion of the consulting fee for investor relations services owed to Corporate Profile pursuant to a Letter Agreement, dated April 8, 2018, between us and Corporate Profile.

We issued these shares pursuant to an exemption from registration contained in Section 4(a)(2) of the Securities Act of 1933, as amended.

ITEM 6 - EXHIBITS

Number	
10.1*	Amendment to the Service Agreement, dated January 10, 2020, between KNRY Ltd. and Oramed Ltd.
10.2*	Amendment to the Equity Distribution Agreement, dated February 10, 2020, between Canaccord Genuity LLC and Oramed Pharmaceuticals Inc.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101.1*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended February 29, 2020 formatted in XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Loss, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows and (v) the Notes to Condensed Consolidated Financial Statements.

* Filed herewith
** Furnished herewith

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.

ORAMED PHARMACEUTICALS INC.

Date: April 6, 2020

By: /s/ Nadav Kidron
Nadav Kidron
President and Chief Executive Officer

Date: April 6, 2020

By: /s/ Avraham Gabay
Avraham Gabay
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

AGREEMENT AND AMENDMENT NO. 6

This AGREEMENT AND AMENDMENT NO. 6 (this "Sixth Amendment") is made this 10th day of January, 2020 by and between **ORAMED Ltd.,** a company incorporated under the laws of the State of Israel, with company registration number 513976712 and with an address at High-Tech Park 2/4, Givat Ram, Jerusalem, Israel 9370648 (the "Company"), and **KNRY**, **Ltd.,** a company incorporated under the laws of the State of Israel, with company registration number 513836502 and with an address at 2 Elza Street, Jerusalem, Israel 9370648 (the "**Consultant**").

WHEREAS:

A. The Company and the Consultant are parties to the Agreement dated as of July 1, 2008 (the "Original Agreement"), as amended on July 17, 2013 (the "First Amendment"), on November 13, 2014 (the "Second Amendment"), on July 21, 2015 (the "Third Amendment") and on June 27, 2016 (the "Fourth Amendment") and on June 30, 2017 (the "Fifth Amendment" and together with the Original Agreement, and all its amendments - the "Consulting Agreement"), for services to be provided by Dr. Miriam Kidron Israeli I.D. number 9665993 ("**Miriam**"); and

B. The Company and the Consultant wish to amend the Consulting Agreement to revise the terms of the Consultant's compensation thereunder.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements herein contained, the parties hereto covenant and agree as follows:

1. Amendment to Section 6. Section 6 of the Original Agreement is hereby amended and restated in its entirety to read as follows:

   "Compensation. Effective from January 2020 (inclusive), the Company shall pay to the Consultant in consideration for the performance of the Consulting Services, a gross monthly amount of 92,522 + VAT (approximately $26,663) (the "**Consideration**"), subject to the receipt by the Company of an invoice from the Consultant. Each of the Consultant and Miriam hereby declares that neither of them has, nor shall have in the future, any claims or demands in respect of amounts paid prior to May 2008."

2. Ratification. As amended hereby, the Consulting Agreement is ratified and confirmed and all other terms and conditions remain in full force and effect.

[Signature page follows.]

IN WITNESS WHEREOF the parties hereto have executed this Sixth Amendment effective as of the date and year first above written.

ORAMED LTD.

Per: /s/ Avraham Gabay
Name: Avraham Gabay
Title: Chief Financial Officer and Secretary

KNRY LTD.

Per: /s/ Miriam Kidron
Name: Miriam Kidron

Exhibit 10.2

AMENDMENT NO. 1 TO EQUITY DISTRIBUTION AGREEMENT

February 10, 2020

Canaccord Genuity LLC
99 High Street, Suite 1200
Boston, Massachusetts 02110

Ladies and Gentlemen:

This Amendment No. 1 to the Equity Distribution Agreement, dated as of the date first set forth above (this "Amendment"), amends that certain Equity Distribution Agreement, dated as of September 5, 2019 (the "Agreement"), by and between Canaccord Genuity LLC ("Canaccord") and Oramed Pharmaceuticals Inc., a Delaware corporation (the "Company"). Capitalized terms not otherwise defined in this Amendment shall have the respective meanings ascribed to them in the Agreement.

BACKGROUND

A. On September 5, 2019, the Company and Canaccord entered into the Agreement, which provided for the issuance and sale from time to time of up to $15,000,000 of Common Shares under the Company's registration statement on Form S-3 (Registration No. 333-215525) (the "Old Registration Statement").

B. The Old Registration Statement expired on February 2, 2020 (the third anniversary of the effective date of the Old Registration Statement). Prior to the expiration of the Old Registration Statement, the Company filed a separate registration statement on Form S-3 (Registration No. 333-236194) (the "New Registration Statement"). The Company expects that the New Registration Statement will become effective on or prior to February 10, 2020, and that a prospectus supplement will be filed covering offers and sales under the Agreement.

C. The parties now wish to amend the Agreement in order to allow the continued offer and sale of up to the remaining $12,679,003 of Common Shares under the New Registration Statement.

AGREEMENT

In consideration of the foregoing, the parties hereby agree as follows:

1. Filing of New Registration Statement. The term "Registration Statement" in the Agreement shall be deemed to mean, prior to the earlier of the effective date of the New Registration Statement and 180 days after the third anniversary of the initial effective date of the Old Registration Statement, the Old Registration Statement, and from and after the effective date of the New Registration Statement, the New Registration Statement. Sales under the New Registration Statement may commence at any time after the filing of a prospectus supplement pursuant to Rule 424(b) under the Securities Act, which shall contain substantially the same plan of distribution as contained in the prospectus supplement filed with respect to the Old Registration Statement (the "New Prospectus Supplement"). References in the Agreement, as amended, to the "Prospectus" shall, with respect to sales made under the New Registration Statement, refer to the New Prospectus Supplement and the base prospectus related to the New Registration Statement.

2. Representations and Warranties. The Company hereby represents and warrants that the representations and warranties of the Company as set forth in Section 6 of the Agreement, are true and correct in all material respects (except for those representations and warranties that are qualified by materiality, in which case such representations and warranties shall be true and correct in all respects) as of the date of this Amendment.

3. Miscellaneous. All other terms of the Agreement shall remain in full force and effect including, without limitation, all indemnification and contribution terms set forth therein.

If the foregoing accurately reflects your understanding and agreement with respect to the matters described herein please indicate your agreement by countersigning this Amendment in the space provided below.

Very truly yours,

ORAMED PHARMACEUTICALS INC.

By: /S/ Nadav Kidron, /S/ Avraham Gabay
Name: Nadav Kidron, Avraham Gabay
Title: CEO, CFO

ACCEPTED
as of the date first-above written:

CANACCORD GENUITY LLC

By: /S/ Jennifer Pardi
Name: Jennifer Pardi
Title: Sr. Managing Director

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Nadav Kidron, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Oramed Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: April 6, 2020

/s/ Nadav Kidron
Nadav Kidron
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Avraham Gabay, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Oramed Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: April 6, 2020

/s/ Avraham Gabay
Avraham Gabay
Chief Financial Officer

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the quarterly report of Oramed Pharmaceuticals Inc., or the Company, on Form 10-Q for the period ended February 29, 2020 as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Nadav Kidron, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities and Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 6, 2020

/s/ Nadav Kidron

Nadav Kidron, President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the quarterly report of Oramed Pharmaceuticals Inc., or the Company, on Form 10-Q for the period ended February 29, 2020 as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Avraham Gabay, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities and Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 6, 2020

/s/ Avraham Gabay
Avraham Gabay, Chief Financial Officer