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 28, 2019

☐ 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.)
142 W. 57th Street New York, New York	**10019**
(Address of Principal Executive Offices)	(Zip Code)

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

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 9, 2019, there were 17,380,859 shares of the issuer's common stock, $0.012 par value per share, outstanding.

ORAMED PHARMACEUTICALS INC.
FORM 10-Q
TABLE OF CONTENTS

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 Israeli subsidiary, Oramed Ltd., unless otherwise indicated. All dollar amounts refer to U.S. Dollars unless otherwise indicated.

On February 28, 2019, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.604 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 28, 2019

TABLE OF CONTENTS

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

	February 28, 2019	August 31, 2018
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,429	$ 4,996
Short-term deposits	19,748	20,875
Marketable securities	5,474	4,592
Prepaid expenses and other current assets	950	574
Total current assets	29,601	31,037
LONG-TERM ASSETS:		
Long-term deposits	11,120	13,542
Marketable securities	1,051	2,785
Amounts funded in respect of employee rights upon retirement	17	16
Property and equipment, net	21	17
Total long-term assets	12,209	16,360
Total assets	$ 41,810	$ 47,397
Liabilities and stockholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 2,346	$ 2,058
Contract liabilities	2,703	2,449
Payable to related parties	55	46
Total current liabilities	5,104	4,553
LONG-TERM LIABILITIES:		
Contract liabilities	11,020	11,388
Employee rights upon retirement	21	20
Provision for uncertain tax position	11	11
Other liabilities	306	313
Total long-term liabilities	11,358	11,732
COMMITMENTS (note 2)		
STOCKHOLDERS' EQUITY:		
Common stock, $0.012 par value (30,000,000 authorized shares; 17,380,859 and 17,369,875 shares issued and outstanding as of February 28, 2019 and August 31, 2018, respectively)	207	207
Additional paid-in capital	99,892	99,426
Accumulated other comprehensive income	-	702
Accumulated deficit	(74,751)	(69,223)
Total stockholders' equity	25,348	31,112
Total liabilities and stockholders' equity	$ 41,810	$ 47,397

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

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

	Six months ended		Three months ended	
	February 28, 2019	February 28, 2018	February 28, 2019	February 28, 2018
REVENUES	$ 1,340	$ 1,215	$ 666	$ 604
COST OF REVENUES	90	-	55	-
RESEARCH AND DEVELOPMENT EXPENSES	7,461	5,051	3,114	2,724
GENERAL AND ADMINISTRATIVE EXPENSES	1,997	2,007	1,065	991
OPERATING LOSS	8,208	5,843	3,568	3,111
FINANCIAL INCOME	559	439	273	217
FINANCIAL EXPENSES	27	43	19	22
LOSS FROM CHANGES IN FAIR VALUE OF INVESTMENT	27	-	87	-
LOSS BEFORE TAXES ON INCOME	7,703	5,447	3,401	2,916
TAXES ON INCOME	300	-	300	-
NET LOSS FOR THE PERIOD	8,003	5,447	3,701	2,916
UNREALIZED LOSS ON AVAILABLE FOR SALE SECURITIES	-	88	-	414
TOTAL OTHER COMPREHENSIVE LOSS	-	88	-	414
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	$ 8,003	$ 5,535	$ 3,701	$ 3,330
LOSS PER SHARE OF COMMON STOCK:				
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	$ 0.46	$ 0.38	$ 0.21	$ 0.20
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	17,451,411	14,342,024	17,454,109	14,445,844

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 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

	Common Stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated loss	Total stockholders' equity
	Shares	$				
	In thousands					
BALANCE AS OF AUGUST 31, 2017	13,668	$ 163	$ 75,170	$ 401	$ (56,496)	$ 19,238
CHANGES DURING THE SIX-MONTH PERIOD ENDED FEBRUARY 28, 2018:						
SHARES ISSUED FOR SERVICES	5	*	43	-	-	43
ISSUANCE OF COMMON STOCK, NET	533	6	4,875	-	-	4,881
EXERCISE OF WARRANTS AND OPTIONS	189	2	995	-	-	997
STOCK-BASED COMPENSATION	11	*	856	-	-	856
NET LOSS	-	-	-	-	(5,447)	(5,447)
OTHER COMPREHENSIVE LOSS	-	-	-	(88)	-	(88)
BALANCE AS OF FEBRUARY 28, 2018	14,406	$ 171	$ 81,939	$ 313	$ (61,943)	$ 20,480

* 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 28,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (8,003)	$ (5,447)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	4	3
Exchange differences and interest on deposits and held to maturity bonds	(83)	106
Changes at fair value of investments	27	
Stock-based compensation	422	856
Shares issued for services	44	43
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(376)	(65)
Accounts payable, accrued expenses and related parties	297	(447)
Contract liabilities	1,659	(1,215)
Liability for employee rights upon retirement	1	1
Other liabilities	(7)	(39)
Total net cash used in operating activities	(6,015)	(6,204)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of short-term deposits	(2,650)	(4,351)
Purchase of long-term deposits	(2,750)	(5,540)
Purchase of held to maturity securities	(397)	(2,879)
Proceeds from sale of short-term deposits	9,051	11,216
Proceeds from maturity of held to maturity securities	1,200	1,207
Purchase of property and equipment	(8)	(3)
Funds in respect of employee rights upon retirement	(1)	(1)
Total net cash provided by (used in) investing activities	4,445	(351)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	-	4,881
Proceeds from exercise of warrants and options	-	997
Total net cash provided by financing activities	-	5,878
EFFECT OF EXCHANGE RATE CHANGES ON CASH	3	3
DECREASE IN CASH AND CASH EQUIVALENTS	(1,567)	(674)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,996	3,969
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 3,429	$ 3,295
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -		
Interest received	$ 461	$ 457

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 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 was paid subject to the Company entering into certain agreements with certain third parties, and $26,500 is payable 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.

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. Milestone payments received as of February 28, 2019 totaled $20,500.

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 and beyond, although no assurance can be given that the Company will not need additional funds prior to such time. If there are unexpected increases in the Company's operating expenses, it 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.

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 4,293,395 and 1,406,175 for the six-month periods ended February 28, 2019 and 2018, respectively, and 4,234,081 and 1,388,122 for the three-month periods ended February 28, 2019 and 2018, 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. 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 at the earlier of the time (a) when the related sale has occurred and (b) the Company has fulfilled the related performance obligation. To date, the Company has not recognized any royalty-related revenue.

As of the adoption date, the Company adjusted its accumulated deficit by $1,773 against contract liabilities due to the effect of variable consideration.

Amounts that were allocated to the License Agreement as of February 28, 2019 aggregated $22,382, all of which was received through the balance sheet date. Through February 28, 2019, the Company recognized revenue associated with this agreement in the aggregate amount of $8,659 (of which $1,340 was recognized in the six-month period ended February 28, 2019 and $1,773 was recognized as an increase to the September 1, 2018 opening balance of stockholders' equity associated with the impact of the adoption of ASC 606 under the modified retrospective method of adoption), and deferred the remaining amount of $13,723, which is presented as a contract liability on the condensed consolidated balance sheet. During the six-month and three-month periods ended February 28, 2019, the Company recognized revenue in the amount of $1,143 and $568, respectively, that was included in the contract liabilities balance at the beginning of the period.

U.S. Dollars in thousands (except share and per share data)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

In accordance with ASC 606, the disclosure of the impact of adoption to the Company's consolidated balance sheet as of August 31, 2018 was as follows:

	As reported August 31, 2018	Updated September 1, 2018	Effect of Change
Contract liabilities (short term)	$ 2,449	$ 1,230	$ (1,219)
Contract liabilities (long term)	11,388	10,834	(554)
Accumulated deficit	69,223	67,450	(1,773)

The impact of adoption of ASC 606 on the condensed consolidated balance sheet as of February 28, 2019 and on the condensed consolidated statement of operations for the six months ended February 28, 2019 was as follows:

	As reported February 28, 2019	Balances without Adoption of ASC 606	Effect of Change
Revenues	$ 1,340	$ 1,342	$ (2)
Cost of revenues	90	90	-
Contract liabilities (short term)	2,703	3,110	(407)
Contract liabilities (long term)	11,020	12,384	(1,364)
Accumulated deficit	74,751	76,522	(1,771)

The impact of adoption of ASC 606 on the condensed consolidated statement of operations for the three months ended February 28, 2019 was as follows:

	As reported February 28, 2019	Balances without Adoption of ASC 606	Effect of Change
Revenues	$ 666	$ 731	$ (65)
Cost of revenues	55	90	(35)

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 (investments in equity securities of D.N.A Biomedical Solutions Ltd. ("D.N.A") and Entera Bio Ltd. ("Entera")) to financial assets measured in fair value through profit or loss. The Company adopted the standard using the modified retrospective method and, accordingly, reclassified the cumulative unrealized gain from accumulated other comprehensive income to a reduction of its accumulated deficit in an amount of $702.

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, 2018 (the "2018 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 2018 Form 10-K. The results for interim periods are not necessarily indicative of a full fiscal year's results.

f. Newly issued and recently adopted Accounting Pronouncements

In May 2014, the FASB issued ASC 606 which supersedes existing revenue recognition guidance, including industry-specific guidance. Under the new standard, a good or service is transferred to the customer when (or as) the customer obtains control of the good or service, which differs from the risk and rewards approach under current guidance. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. The guidance is effective in annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. The Company implemented the guidance for its annual period ending on August 31, 2019 and interim periods within such annual period. The Company adopted the standard using the modified retrospective method. See additional information regarding the adoption in note 1c.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

In January 2016, the FASB issued guidance on recognition and measurement of financial assets and financial liabilities (ASU 2016-01) that supersedes most current guidance. Changes to the U.S. GAAP model primarily affect the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting for other financial instruments, such as loans, investments in debt securities, and financial liabilities, is largely unchanged. The classification and measurement guidance under ASU 2016-01 became effective as of September 1, 2018. See additional information regarding the adoption in note 1d.

In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)" ("ASU 2016-02"), which supersedes the existing guidance for lease accounting, "Leases (Topic 840)". ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in ASU 2016-02 are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

NOTE 2 - COMMITMENTS:

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. 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.

NOTE 2 - COMMITMENTS (continued):

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 ($33) from October 2016 through September 2018 and NIS 132,000 ($37) from October 2018 through September 2021, and is linked to the increase in the Israeli consumer price index ("CPI") (as of February 28, 2019, the future lease payments will be $95 until the expiration of the lease agreement, based on the exchange rate as of February 28, 2019).

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

c. On March 3, 2016, the Subsidiary entered into an agreement with a vendor for process development and production of its capsules and on November 24, 2016, April 3, 2017 and July 10, 2017 the Subsidiary entered into amendments to such agreement in an amount of up to Swiss Franc ("CHF") 1,000,000 ($1,003), CHF 665,000 ($675) of which was recognized in research and development expenses through February 28, 2019.

d. On May 11, 2016, the Subsidiary entered into a Master Service Agreement with a vendor to retain its services for a pre-clinical toxicology trial for an oral GLP-1 analog capsule for type 2 diabetes patients. As consideration for its services, the Subsidiary will pay the vendor a total amount of $1,283 during the term of the engagement and based on achievement of certain milestones, of which $1,275 was recognized in research and development expenses through February 28, 2019.

e. On June 13, 2016, the Subsidiary entered into a four-year service agreement with a third party and on December 19, 2016, this agreement and all of the third party rights and obligations thereunder were assigned to another third party. This agreement is required by the License Agreement as described in note 1 and will support the Company's research and development. The Subsidiary is obligated to pay the third party a total amount of up to €2,360,000 ($2,694), of which €1,878,215 ($2,144) was recognized in research and development expenses through February 28, 2019.

f. On February 21, 2017, the Subsidiary entered into an agreement with a vendor to retain its services for a pre-clinical toxicology trial for an oral insulin capsule. As consideration for its services, the Subsidiary will pay the vendor a total of up to $952 during the term of the engagement and based on achievement of certain milestones, of which $857 was recognized in research and development expenses through February 28, 2019.

g. On April 8, 2018, the Company entered into a consulting agreement with a third party advisor for a period of one year, pursuant to which such advisor provides investor relations services and is entitled to receive a monthly cash fee and 10,000 shares of the Company's common stock issued in four equal quarterly installments commencing August 1, 2018. As of February 28, 2019, the Company had issued to such advisor 7,500 shares. The fair value of the shares at the grant date was $33, which was recognized in general and administrative expenses.

NOTE 2 - COMMITMENTS (continued):

h. On June 5, 2017, the Subsidiary entered into a clinical research agreement with a vendor, for the conduct of its clamp clinical trial for an oral insulin capsule for type 1 diabetes patients. As consideration for its services, the Subsidiary will pay the vendor a total amount of $958 during the term of the engagement and based on achievement of certain milestones, $578 of which was recognized in research and development expenses through February 28, 2019.

i. 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, $1,361 of which was recognized in research and development expenses through February 28, 2019.

j. 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. As consideration for its services, the Subsidiary will pay the CRO a total amount of $7,030 during the term of the engagement and based on achievement of certain milestones, $5,219 of which was recognized in research and development expenses through February 28, 2019.

k. 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, $758 of which was recognized in research and development expenses through February 28, 2019.

l. On July 4, 2018, the Subsidiary entered into an agreement with a vendor to retain its services for a pre-clinical six months toxicology trial for its oral insulin capsule. As consideration for its services, the Subsidiary will pay the vendor a total of up to $971 during the term of the engagement and based on achievement of certain milestones, of which $551 was recognized in research and development expenses through February 28, 2019.

m. On July 15, 2018, the Company entered into a consulting agreement with a third party advisor for a period of one year, pursuant to which such advisor provides investor relations services and is entitled to receive a monthly cash fee and shares of the Company's common stock issued in four quarterly installments in an amount equal to $25 per quarter, pursuant to and in accordance with the terms of the agreement, commencing July 15, 2018. The Company terminated this consulting agreement in December 2018. As of the date of termination, the Company had issued to such advisor 9,874 shares and the related expense was recognized in general and administrative expenses.

n. In December 2018, the Company entered into an agreement with HTIT and its affiliate, under which if HTIT does not have an agreement with the relevant subcontractors, Oramed agreed that specific activities under the work plan may be conducted under the existing agreements of Oramed and the subcontractors and HTIT will pay the required payment directly to the subcontractor. In addition, under certain terms and conditions, and upon the Company's decision, the Company will assist HTIT to coordinate payments and may pay certain contractors on behalf of HTIT. Amounts due to the subcontractors and the corresponding amounts from HTIT, are recorded as current assets and current liabilities in the balance sheet.

NOTE 2 - COMMITMENTS (continued):

o. 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 28, 2019 was $2,194.

The royalty expenses which are related to the funded project were recognized in cost of revenues in the quarter ended February 28, 2019 and in prior periods.

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 28, 2019, 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 1 measurement.

As of February 28, 2019, 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 28, 2019, 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 six-month periods ended February 28, 2019 and 2018.

U.S. Dollars in thousands (except share and per share data)

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 28, 2019	August 31, 2018
Short-term:		
D.N.A (see b below)	$ 762	$ 666
Entera (see c below)	509	632
Held to maturity bonds (see d below)	4,203	3,294
	$ 5,474	$ 4,592
Long-term:		
Held to maturity bonds (see d below)	$ 1,051	$ 2,785

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 28, 2019, the Company owns approximately 6.9% of D.N.A's outstanding ordinary shares.

The cost of the securities as of February 28, 2019 and August 31, 2018 was $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)).

U.S. Dollars in thousands (except share and per share data)

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 28, 2019, are as follows:

	February 28, 2019		
	Amortized cost	Gross unrealized losses	Estimated fair value
Short-term:			
Commercial bonds	$ 4,169	$ (13)	$ 4,156
Accrued interest	34	-	34
Long-term	1,051	(1)	1,050
	$ 5,254	$ (14)	$ 5,240

As of February 28, 2019, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, $1,051, and the yield to maturity rates vary between 1.65% to 3.20%.

The amortized cost and estimated fair value of held-to-maturity securities as of August 31, 2018, are as follows:

	August 31, 2018		
	Amortized cost	Gross unrealized losses	Estimated fair value
Short-term:			
Commercial bonds	$ 3,259	$ (17)	$ 3,242
Accrued interest	35	-	35
Long-term	2,785	(17)	2,768
	$ 6,079	$ (34)	$ 6,045

As of August 31, 2018, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, $2,785 and the yield to maturity rates vary between 1.45% to 3.13%.

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 April 2, 2015, the Company entered into an At The Market Issuance Sales Agreement (the "Sales Agreement") with B. Riley FBR, Inc., as successor to FBR Capital Markets & Co. ("FBR"), as amended, pursuant to which the Company may, from time to time and at its option, issue and sell shares of its common stock having an aggregate offering price of up to $25,000 through FBR as its 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 dated February 2, 2017, as supplemented by a prospectus supplement dated April 5, 2017. The Company will pay FBR a commission of 3.0% of the gross proceeds of the sale of any shares sold through FBR. Through February 28, 2019, 576,834 shares were sold under the Sales Agreement for aggregate net proceeds of $5,198. During the six months ended February 28, 2019, the Company did not issue shares under the Sales Agreement.

NOTE 6 - STOCK-BASED COMPENSATION:

On February 26, 2019, the Company granted options to purchase an aggregate of 360,000 shares of common stock of the Company at an exercise price of $3.16 per share (equivalent to the closing price of the Company's common stock on the date of grant) as follows: 196,500 to the CEO; 104,000 to the CSO; and 59,500 to employees of the Subsidiary. The options will vest in four equal annual installments, on each of December 31, 2019, 2020, 2021 and 2022. These options expire on February 26, 2029. The fair value of all these options on the date of grant was $731, using the Black Scholes option-pricing model and was based on the following assumptions: stock price of $3.16; dividend yield of 0% for all years; expected volatility of 69.05%; risk-free interest rates of 2.54%; and expected term of 6.25 years.

NOTE 7 - 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 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 ($35) and NIS 80,454 ($22), respectively.

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 28, 2019, such relocation expenses totaled $278 compared to $214 for the six months ended February 28, 2018.

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 if our Phase IIb three-month dose-ranging clinical trial is successful, and our expectation to file a New Drug Application, or NDA, 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; and
- information with respect to any other plans and strategies for our business.

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 our Annual Report on Form 10-K for the fiscal year ended August 31, 2018, or our Annual Report, as filed with the Securities and Exchange Commission, or the SEC, on November 28, 2018, as well as those discussed elsewhere in our Annual Report and this Quarterly Report on Form 10-Q 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 or pills for delivery of other polypeptides.

Recent business developments

Product Candidates

Oral Insulin

In April 2018, we initiated a three-month dose-ranging Phase IIb clinical trial of our proprietary flagship product, an orally ingestible insulin capsule, or ORMD-0801. This placebo controlled, randomized, 90 day treatment clinical trial is being conducted on approximately 285 type 2 diabetic patients in multiple centers throughout the United States pursuant to an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA. The primary endpoints of the trial are 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 include measurements of fasting plasma glucose, or FPG, post-prandial glucose, or PPG levels, during a mixed-meal tolerance test, or MMTT, and weight. We intend to submit an extension of this protocol for approximately 75 type 2 diabetic patients, to be dosed using a lower dosage. The first part of the trial, which included the initial approximately 285 patients, is projected to be completed in the fourth quarter of calendar year 2019. Subsequently, we will perform an interim analysis on this part of the trial.

We had a call with the FDA in August 2017 regarding ORMD-0801 after the completion of a Phase IIb clinical trial on 180 diabetic patients, which indicated a statistically significant blood glucose lowering effect of ORMD-0801 versus placebo across several endpoints. During the call, the FDA advised that the regulatory pathway for the submission of ORMD-0801 would be a Biologics License Application, or BLA. 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. The FDA confirmed that the approach to nonclinical toxicology, chemistry manufacturing controls and qualification of excipients would be driven by their published guidance documents.

In June 2018, we initiated a glucose clamp study which will quantify insulin absorption in type 1 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 HbA1c levels of 10% or below, aged 18-50, are enrolled in the study.

In June 2018, we also initiated a food effect trial in the United States for ORMD-0801. This single-blind, five period, randomized, placebo-controlled crossover trial is evaluating the pharmacokinetics and pharmacodynamics of ORMD-0801 taken at different times in relation to meals in healthy volunteers and patients with type 1 diabetes. 48 patients are enrolled, including 24 healthy volunteers and 24 patients with type 1 diabetes.

In March 2019, we completed a six month dosing toxicology study of our oral insulin formulation, which was initiated in September 2018 following the FDA's request. We expect to get the results of this study in the first quarter of calendar year 2020.

Should our Phase IIb three-month dose-ranging clinical trial successfully meet its primary or secondary endpoints, we anticipate initiating two six-month Phase III clinical trials on both type 1 and type 2 diabetic patients, following which we expect to file a NDA with potential FDA approval by the second half of calendar year 2023.

Oral GLP-1 Analog

In addition to our flagship product, the ORMD-0801 insulin capsule, we are using our technology for an orally ingestible GLP-1/exenatide capsule, or ORMD-0901. In September 2018, the FDA cleared our IND application for human trials of ORMD-0901. In February 2019, we completed a Phase I pharmacokinetic trial which was initiated in January 2019 to evaluate the safety and the pharmacokinetics of ORMD-0901 compared to placebo. We expect to get the results of this study in the second quarter of calendar year 2019. This study was conducted pursuant to the IND and will be followed by a Phase II trial on type 2 diabetic patients which will be conducted in the United States under an IND.

Other products

In April 2017, Israel's Ministry of Health approved our commencement of 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. The study is projected to be initiated in calendar year 2019 and be completed during calendar year 2019.

In October 2018, we initiated an exploratory clinical study of ORMD-0801 in 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. As requested by Israel's Ministry of Health, the first part of the study will be conducted on 10 participants and is expected to be completed during calendar year 2019.

The table below gives an overview of our primary product pipeline (calendar quarters):

		Phase I	Phase II	Phase III	Timeline
ORMD-0801 oral insulin	Type 2 diabetes				Q2 '18: Phase IIb 90-day multi-center study initiated (projected completion of the first part of the study Q4 '19) Q3 '20: Phase III study projected initiation (projected completion Q3 '22)
	Type 1 diabetes				Q2 '18: Clamp study initiated (projected completion Q2 '19) Q2 '18: Food effect study initiated (projected completion Q2 '19) Q3 '20: Phase III projected initiation (projected completion Q3 '22)
ORMD-0901 oral GLP-1	Type 2 diabetes				Q1 '19: Pharmacokinetics clinical study completed (projected results Q2 '19) Q1 '20: Phase II projected initiation (projected completion Q4 '21)

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 was paid subject to our entry into certain agreements with certain third parties, and $26.5 million is payable 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 28, 2019, we received aggregate milestone payments of $20.5 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.

In March 2019, we were formally informed by HTIT that the Center for Drug Evaluation of the China National Medical Products Administration approved HTIT's IND for two doses of ORMD-0801 and the initiation of clinical trials in China for ORMD-0801, which are expected by HTIT to begin in the second quarter of calendar year 2019.

Results of Operations

Comparison of six and three-month periods ended February 28, 2019 and 2018

The following table summarizes certain statements of operations data of the Company for the six and three-month periods ended February 28, 2019 and 2018 (in thousands of dollars except share and per share data):

	Six months ended February 28,		Three months ended February 28,	
	2019	2018	2019	2018
Revenues	$ 1,340	$ 1,215	$ 666	$ 604
Cost of revenues	90	-	55	-
Research and development expenses	7,461	5,051	3,114	2,724
General and administrative expenses	1,997	2,007	1,065	991
Financial income, net	505	396	167	195
Taxes on income	300	-	300	-
Net loss for the period	$ 8,003	$ 5,447	$ 3,701	$ 2,916
Loss per common share - basic and diluted	$ 0.46	$ 0.38	$ 0.21	$ 0.20
Weighted average common shares outstanding	17,451,411	14,342,024	17,454,109	14,445,844

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 for the six-month period ended February 28, 2019 increased by 10% to $1,340,000, from $1,215,000 for the six-month period ended February 28, 2018. The increase is primarily attributable to the additional milestone payments received under the License Agreement during the six-month period ended February 28, 2019.

Revenues for the three-month period ended February 28, 2019 increased by 10% to $666,000, from $604,000 for the three-month period ended February 28, 2018. The increase is primarily attributable to the additional milestone payments received under the License Agreement during the three-month period ended February 28, 2019.

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 28, 2019 increased to $90,000 compared to no cost of revenues for the six-month period ended February 28, 2018. The increase is attributable to additional milestone payments received under the License Agreement during the six-month period ended February 28, 2019.

Cost of revenues for the three-month period ended February 28, 2019 increased to $55,000 compared to no cost of revenues for the three-month period ended February 28, 2018. The increase is attributable to additional milestone payments received under the License Agreement 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 manufacturing of the oral insulin and exenatide capsules, 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 28, 2019 increased by 48% to $7,461,000, from $5,051,000 for the six-month period ended February 28, 2018. The increase is primarily due to expenses related to our Phase IIb three-month treatment clinical trial, food effect, clamp and GLP-1 pharmacokinetics clinical trials and is partially offset by a decrease in expenses related to the scale-up process development and production of our oral capsule ingredients and stock-based compensation expenses. Stock-based compensation costs for the six-month period ended February 28, 2019 totaled $93,000, as compared to $296,000 during the six-month period ended February 28, 2018. The decrease is primarily attributable to the progress in amortization and the forfeiture of awards granted in prior periods.

Research and development expenses for the three-month period ended February 28, 2019 increased by 14% to $3,114,000, from $2,724,000 for the three-month period ended February 28, 2018. The increase is primarily due to expenses related to our Phase IIb three-month treatment clinical trial, GLP-1 pharmacokinetics clinical trial and toxicology expenses and is partially offset by a decrease in expenses related to the scale-up process development and production of our oral capsule ingredients. Stock-based compensation costs for the three-month period ended February 28, 2019 totaled $54,000, as compared to $125,000 during the three-month period ended February 28, 2018. The decrease is primarily attributable to the progress in amortization and the forfeiture of awards granted in prior periods.

Government grants

In the six-month periods ended February 28, 2019 and 2018, we did not recognize any research and development grants. As of February 28, 2019, we incurred liabilities to pay royalties to the Israel Innovation Authority of the Israeli Ministry of Economy & Industry of $391,000.

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 28, 2019 decreased by 0.5% to $1,997,000 from $2,007,000 for the six-month period ended February 28, 2018. The decrease in costs related to general and administrative activities during the six-month period ended February 28, 2019 is primarily attributable to a decrease in stock-based compensation costs and is partially offset by an increase in salaries and related expenses. Stock-based compensation costs for the six-month period ended February 28, 2019 totaled $329,000, as compared to $560,000 during the six-month period ended February 28, 2018. The decrease is primarily attributable to the progress in amortization of awards granted to employees and directors during fiscal year 2017 and is partially offset by an increase due to awards granted during fiscal years 2018 and 2019.

General and administrative expenses for the three-month period ended February 28, 2019 increased by 7% to $1,065,000 from $991,000 for the three-month period ended February 28, 2018. The increase in costs related to general and administrative activities during the three-month period ended February 28, 2019 is primarily attributable to an increase in salaries and related expenses and is partially offset by a decrease in stock-based compensation costs. Stock-based compensation costs for the three-month period ended February 28, 2019 totaled $130,000, as compared to $208,000 during the three-month period ended February 28, 2018. The decrease is primarily attributable to the progress in amortization of awards granted to employees and directors during fiscal year 2017 and is partially offset by an increase due to awards granted during fiscal years 2018 and 2019.

Taxes on income

Taxes on income of $300,000 were recognized for the six-month period ended February 28, 2019 as compared to no taxes on income for the six-month period ended February 28, 2018. The increase is due to withholding taxes in connection with the receipt of a milestone payment pursuant to the License Agreement during the more recent period.

Taxes on income of $300,000 were recognized for the three-month period ended February 28, 2019 as compared to no taxes on income for the three-month period ended February 28, 2018. The increase is due to withholding taxes in connection with the receipt of a milestone payment pursuant to the License Agreement during the more recent period.

Financial income, net

Net financial income increased by 28% from net income of $396,000 for the six-month period ended February 28, 2018 to net income of $505,000 for the six-month period ended February 28, 2019. The increase is primarily attributable to an increase in income from bank deposits as a result of an increase in interest rates, partially offset by a decrease in fair value of the ordinary shares of D.N.A Biomedical Solutions Ltd., or D.N.A, and Entera Bio Ltd., or Entera, which was classified in other comprehensive income in fiscal year 2018, prior to the implementation of Accounting Standards Update, or ASU, 2016-01, “Recognition and Measurement of Financial Assets and Financial Liabilities," or ASU 2016-01.

Net financial income decreased by 14% from net income of $195,000 for the three-month period ended February 28, 2018 to net income of $167,000 for the three-month period ended February 28, 2019. The decrease is primarily attributable to a decrease in fair value of the ordinary shares of D.N.A and Entera, which were classified in other comprehensive income in fiscal year 2018, prior to the implementation of ASU 2016-01, partially offset by an increase in income from bank deposits and held to maturity bonds as a result of an increase in interest rates.

Other comprehensive income

No unrealized losses on available for sale securities were recognized for the six-month period ended February 28, 2019 as compared to losses of $88,000 for the six-month period ended February 28, 2018. The decrease is due to the implementation of ASU 2016-01, under which changes in fair value of the ordinary shares of D.N.A and Entera that we hold are recognized as financial income or expenses.

No unrealized losses on available for sale securities were recognized for the three-month period ended February 28, 2019 as compared to losses of $414,000 for the three-month period ended February 28, 2018. The decrease is due to the implementation of ASU 2016-01, under which changes in fair value of the ordinary shares of D.N.A and Entera that we hold are recognized as financial income or expenses.

Liquidity and capital resources

From inception through February 28, 2019, we have incurred losses in an aggregate amount of $74,751,000. During that period 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 $77,736,000, net of transaction costs. During that period, we also received cash consideration of $5,877,000 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 28, 2019, we had $3,429,000 of available cash, $30,868,000 of short-term and long-term bank deposits and $6,525,000 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 and beyond.

As of February 28, 2019, our total current assets were $29,601,000 and our total current liabilities were $5,104,000. On February 28, 2019, we had a working capital surplus of $24,497,000 and an accumulated loss of $74,751,000. As of August 31, 2018, our total current assets were $31,037,000 and our total current liabilities were $4,553,000. On August 31, 2018, we had a working capital surplus of $26,484,000 and an accumulated loss of $69,223,000. The decrease in working capital surplus from August 31, 2018 to February 28, 2019 was primarily due to the cash used in operating activities.

During the six-month period ended February 28, 2019, cash and cash equivalents decreased to $3,429,000 from the $4,996,000 reported as of August 31, 2018, which is due to the reasons described below.

Operating activities used cash of $6,015,000 in the six-month period ended February 28, 2019, as compared to $6,204,000 used in the six-month period ended February 28, 2018. Cash used in operating activities in the six-month period ended February 28, 2019 primarily consisted of net loss resulting from research and development and general and administrative expenses and is partially offset by changes in contract liabilities primarily due to a milestone payment received during the period in the amount of $3,000,000 under the License Agreement, while cash used in operating activities in the six-month period ended February 28, 2018 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 stock-based compensation.

Investing activities provided cash of $4,445,000 in the six-month period ended February 28, 2019, as compared to $351,000 used in the six-month period ended February 28, 2018. Cash provided by investing activities in the six-month period ended February 28, 2019 consisted primarily of the maturity of short-term deposits and held to maturity securities and is partially offset by the purchase of short-term and long-term deposits and held to maturity securities, while cash used in investing activities in the six-month period ended February 28, 2018 consisted primarily of the purchase of short-term and long-term bank deposits and held to maturity securities and is partially offset by the maturity of short-term deposits and held to maturity securities.

Financing activities did not provide cash in the six-month period ended February 28, 2019, as compared to $5,878,000 provided in the six-month period ended February 28, 2018. Financing activities in the six-month period ended February 28, 2018 consisted of aggregate net proceeds of $4,881,000 from our issuance of 532,801 shares of common stock under an At The Market Issuance Sales Agreement, dated April 2, 2015, or the Sales Agreement, with B. Riley FBR, Inc., as successor to FBR Capital Markets & Co., or FBR, as amended, and proceeds from the exercise of warrants and options. Pursuant to the Sales Agreement, 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 $25,000,000 through FBR as 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 dated February 2, 2017, as supplemented by a prospectus supplement dated April 5, 2017. We will pay FBR a commission of 3.0% of the gross proceeds of the sale of any shares sold through FBR.

Off-balance sheet arrangements

As of February 28, 2019, 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, 2018 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 28, 2019. 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.

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 28, 2019. 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 28, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except for new controls with regard to the implementation of ASU 2014-09, "Revenue from Contracts with Customers (Topic 606).

PART II – OTHER INFORMATION

ITEM 1A - RISK FACTORS

An investment in our securities involves a high degree of risk, a number of which risks are described under the caption "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended August 31, 2018, or our Annual Report. You should consider carefully the information about these risks in our Annual Report and below, together with the other information contained in our Annual Report and the information contained under the heading "Forward-Looking Statements" and elsewhere in this Quarterly Report on Form 10-Q before making an investment decision. Our business, prospects, financial condition and results of operations may be materially and adversely affected as a result of any of the risks described in our Annual Report or below. The value of our securities could decline as a result of any of these risks. You could lose all or part of your investment in our securities. Some of the statements in "Item 1A. Risk Factors" are forward-looking statements. The following risk factors are not the only risk factors facing us. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Clinical trials of our products conducted by third parties may encounter delays, suspensions or other problems and are outside of our control.

Third parties who conduct clinical trials of our products may encounter problems that may cause delays, suspensions or other problems at any phase. These problems could include the possibility that they may not be able to conduct clinical trials at their preferred sites, enroll a sufficient number of patients for their clinical trials at one or more sites or begin or successfully complete clinical trials in a timely fashion, if at all. In addition, these third parties are not controlled by us and may conduct these trials in a manner in which we disagree or which may prove to be unsuccessful. Furthermore, domestic or foreign regulatory agencies may suspend clinical trials at any time if they believe the subjects participating in the trials are being exposed to unacceptable health risks or if they find deficiencies in the clinical trial process or conduct of the investigation. If such clinical trials conducted by third parties fail, it could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

On February 1, 2019, 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	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.
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 28, 2019 formatted in XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Comprehensive 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 10, 2019

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

Date: April 10, 2019

By: /s/ Hilla Eisenberg
Hilla Eisenberg
Chief Financial Officer
(Principal Financial and Accounting Officer)

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 10, 2019

/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, Hilla Eisenberg, 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 10, 2019

/s/ Hilla Eisenberg
Hilla Eisenberg
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 28, 2019 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 10, 2019

/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 28, 2019 as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Hilla Eisenberg, 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 10, 2019

/s/ Hilla Eisenberg
Hilla Eisenberg
Chief Financial Officer