

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 November 30, 2018

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**

(State or Other Jurisdiction of  
Incorporation or Organization)

**98-0376008**

(I.R.S. Employer  
Identification No.)

**142 W. 57th Street  
New York, New York**

(Address of Principal Executive Offices)

**10019**

(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 on its corporate Web site, if any, 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 January 11, 2019, there were 17,378,359 shares of the issuer's common stock, \$0.012 par value per share, outstanding.

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

On November 30, 2018, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.701 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 November 30, 2018

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

	<u>November 30,</u> <u>2018</u>	<u>August 31,</u> <u>2018</u>
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 3,861	\$ 4,996
Short-term deposits	19,920	20,875
Marketable securities	5,143	4,592
Prepaid expenses and other current assets	727	574
Total current assets	<u>29,651</u>	<u>31,037</u>
<b>LONG-TERM ASSETS:</b>		
Long-term deposits	11,613	13,542
Marketable securities	2,290	2,785
Amounts funded in respect of employee rights upon retirement	16	16
Property and equipment, net	23	17
Total long-term assets	<u>13,942</u>	<u>16,360</u>
Total assets	<u>\$ 43,593</u>	<u>\$ 47,397</u>
<b>Liabilities and stockholders' equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 2,982	\$ 2,058
Contract liabilities	1,131	2,449
Payable to related parties	51	46
Total current liabilities	<u>4,164</u>	<u>4,553</u>
<b>LONG-TERM LIABILITIES:</b>		
Contract liabilities	10,259	11,388
Employee rights upon retirement	20	20
Provision for uncertain tax position	11	11
Other liabilities	281	313
Total long-term liabilities	<u>10,571</u>	<u>11,732</u>
<b>COMMITMENTS (note 2)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock, \$0.012 par value (30,000,000 authorized shares; 17,378,359 and 17,369,875 shares issued and outstanding as of November 30, 2018 and August 31, 2018, respectively)	207	207
Additional paid-in capital	99,701	99,426
Accumulated other comprehensive income	-	702
Accumulated deficit	(71,050)	(69,223)
Total stockholders' equity	<u>28,858</u>	<u>31,112</u>
Total liabilities and stockholders' equity	<u>\$ 43,593</u>	<u>\$ 47,397</u>

**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)

	<b>Three months ended</b>	
	<b>November 30, 2018</b>	<b>November 30, 2017</b>
<b>REVENUES</b>	\$ 674	\$ 611
<b>COST OF REVENUES</b>	35	-
<b>RESEARCH AND DEVELOPMENT EXPENSES</b>	4,347	2,327
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b>	932	1,016
<b>OPERATING LOSS</b>	4,640	2,732
<b>FINANCIAL INCOME</b>	286	222
<b>FINANCIAL EXPENSES</b>	8	21
<b>INCOME FROM CHANGES IN FAIR VALUE OF INVESTMENTS</b>	60	-
<b>NET LOSS FOR THE PERIOD</b>	<u>\$ 4,302</u>	<u>\$ 2,531</u>
<b>UNREALIZED INCOME ON AVAILABLE FOR SALE SECURITIES</b>	-	326
<b>TOTAL OTHER COMPREHENSIVE INCOME</b>	-	326
<b>TOTAL COMPREHENSIVE LOSS FOR THE PERIOD</b>	<u>\$ 4,302</u>	<u>\$ 2,205</u>
<b>LOSS PER SHARE OF COMMON STOCK:</b>		
<b>BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK</b>	<u>\$ 0.25</u>	<u>\$ 0.18</u>
<b>WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK</b>	<u>17,448,744</u>	<u>14,239,346</u>

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					
<b>BALANCE AS OF AUGUST 31, 2018</b>	17,369	\$ 207	\$ 99,426	\$ 702	\$ (69,223)	\$ 31,112
<b>INITIAL ADOPTION OF ASC 606</b>					1,773	1,773
<b>INITIAL ADOPTION OF ASU 2016-01</b>				(702)	702	-
<b>CHANGES DURING THE THREE-MONTH PERIOD ENDED NOVEMBER 30, 2018:</b>						
<b>SHARES ISSUED FOR SERVICES</b>	8	*	36	-	-	36
<b>STOCK-BASED COMPENSATION</b>	-	*	239	-	-	239
<b>NET LOSS</b>	-	-	-	-	(4,302)	(4,302)
<b>BALANCE AS OF NOVEMBER 30, 2018</b>	<u>17,377</u>	<u>\$ 207</u>	<u>\$ 99,701</u>	<u>-</u>	<u>\$ (71,050)</u>	<u>\$ 28,858</u>
	Common Stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	\$				
	In thousands					
<b>BALANCE AS OF AUGUST 31, 2017</b>	13,668	\$ 163	\$ 75,170	\$ 401	\$ (56,496)	\$ 19,238
<b>CHANGES DURING THE THREE-MONTH PERIOD ENDED NOVEMBER 30, 2017:</b>						
<b>SHARES ISSUED FOR SERVICES</b>	3	*	24	-	-	24
<b>ISSUANCE OF COMMON STOCK, NET</b>	454	5	4,225	-	-	4,230
<b>EXERCISE OF WARRANTS AND OPTIONS</b>	178	2	928	-	-	930
<b>STOCK-BASED COMPENSATION</b>	5	*	524	-	-	524
<b>NET LOSS</b>	-	-	-	-	(2,531)	(2,531)
<b>OTHER COMPREHENSIVE INCOME</b>	-	-	-	326	-	326
<b>BALANCE AS OF NOVEMBER 30, 2017</b>	<u>14,308</u>	<u>\$ 170</u>	<u>\$ 80,871</u>	<u>\$ 727</u>	<u>\$ (59,027)</u>	<u>\$ 22,741</u>

\* 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)

	<b>Three months ended</b>	
	<b>November 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,302)	\$ (2,531)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	2	1
Exchange differences and interest on deposits and held to maturity bonds	(116)	(71)
Changes at fair value of investments	(60)	
Stock-based compensation	239	524
Shares issued for services	36	24
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(153)	(4)
Accounts payable, accrued expenses and related parties	929	(41)
Contract liabilities	(674)	(611)
Liability for employee rights upon retirement	-	1
Other liabilities	(32)	(20)
Total net cash used in operating activities	<u>(4,131)</u>	<u>(2,728)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of short-term deposits	-	(2,039)
Purchase of long-term deposits	-	(3,540)
Purchase of held to maturity securities	(397)	(2,879)
Proceeds from sale of short-term deposits	3,000	2,455
Proceeds from maturity of held to maturity securities	400	857
Purchase of property and equipment	(8)	-
Total net cash provided by (used in) investing activities	<u>2,995</u>	<u>(5,146)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net of issuance costs	-	4,230
Proceeds from exercise of warrants and options	-	930
Total net cash provided by financing activities	<u>-</u>	<u>5,160</u>
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH</b>	<u>1</u>	<u>3</u>
<b>DECREASE IN CASH AND CASH EQUIVALENTS</b>	<u>(1,135)</u>	<u>(2,711)</u>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<u>4,996</u>	<u>3,969</u>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<u>\$ 3,861</u>	<u>\$ 1,258</u>
<b>SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -</b>		
Interest received	<u>\$ 159</u>	<u>\$ 133</u>

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

**ORAMED PHARMACEUTICALS INC.**  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
U.S. Dollars in thousands (except share and per share data)  
(UNAUDITED)

**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 will be paid subject to the Company entering into certain agreements with certain third parties, and \$26,500 will be paid upon achievement of certain milestones and conditions. In the event that the Company does not meet certain conditions, the Royalties rate may be reduced to a minimum of 8%. Following the final expiration of the Company’s patents covering the technology in the Territory in 2033, the Royalties rate may be reduced, under certain circumstances, to 5%.

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

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



**ORAMED PHARMACEUTICALS INC.**  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
U.S. Dollars in thousands (except share and per share data)  
(UNAUDITED)

**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 January 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 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, although no assurance can be given that we will not need additional funds prior to such time. If there are unexpected increases in our operating expenses, we 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.

**ORAMED PHARMACEUTICALS INC.**  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
U.S. Dollars in thousands (except share and per share data)  
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**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 4,352,798 and 1,424,029 for the three-month periods ended November 30, 2018 and 2017, respectively.

**c. Revenue recognition**

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

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

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

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.

**ORAMED PHARMACEUTICALS INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
U.S. Dollars in thousands (except share and per share data)  
(UNAUDITED)

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

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 November 30, 2018 aggregated \$20,557, \$19,383 of which was received through the balance sheet date. Through November 30, 2018, the Company has recognized revenue associated with this agreement in the aggregate amount of \$7,993 (of which \$674 was recognized in the quarter ended November 30, 2018 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 \$11,390 which is presented as a contract liability on the condensed consolidated balance sheet.

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:

	<u>As reported August 31, 2018</u>	<u>Updated September 1, 2018</u>	<u>Effect of Change</u>
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 November 30, 2018 and on the condensed consolidated statement of operations for the three months ended November 30, 2018 was as follows:

	<u>As reported November 30, 2018</u>	<u>Balances without Adoption of ASC 606</u>	<u>Effect of Change</u>
Revenues	\$ 674	\$ 611	\$ 63
Cost of revenues	35	-	35
Contract liabilities (short term)	1,131	2,449	(1,318)
Contract liabilities (long term)	10,259	10,777	(518)
Accumulated deficit	71,050	72,851	(1,801)

**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.

**ORAMED PHARMACEUTICALS INC.**  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
U.S. Dollars in thousands (except share and per share data)  
(UNAUDITED)

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

**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 has 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.

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.

**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).

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**NOTE 2 - COMMITMENTS** (continued):

As part of this agreement, the Subsidiary entered into a patent transfer agreement (the "Patent Transfer Agreement") according to which the Subsidiary assigned to Entera all of its right, title and interest in and to a certain patent application related to the oral administration of proteins that it has licensed to Entera since August 2010. Under this agreement, the Subsidiary is entitled to receive from Entera royalties of 3% of Entera's net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza. As of November 30, 2018, Entera had not yet realized any revenues and had not paid any royalties to the Subsidiary. On December 11, 2018, Entera announced that it had entered into a research collaboration and license agreement (the "Amgen License") with Amgen related to research of inflammatory disease and other serious illnesses. As reported by Entera, under the terms of the Amgen License, Entera will receive a modest initial technology access fee from Amgen and will be responsible for preclinical development at Amgen's expense. Entera will be eligible to receive up to \$270,000 in aggregate payments, as well as tiered royalties up to mid-single digits, upon achievement of various clinical and commercial milestones if Amgen decides to move all of these programs forward. Amgen is responsible for clinical development, manufacturing and commercialization of any of the resulting programs. To the extent the Amgen License results in net revenues as defined in the Patent Transfer Agreement, the Subsidiary will be entitled to the aforementioned royalties.

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

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

The annual lease payment was New Israeli Shekel ("NIS") 119,000 (\$32) from October 2016 through September 2018 and NIS 132,000 (\$36) from October 2018 through September 2021, and is linked to the increase in the Israeli consumer price index ("CPI") (as of November 30, 2018, the future lease payments will be \$101 until the expiration of the lease agreement, based on the exchange rate as of November 30, 2018).

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 November 30, 2018.
- 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 November 30, 2018.
- 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 (\$2,706), of which €1,700,415 (\$1,956) was recognized in research and development expenses through November 30, 2018.

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**NOTE 2 - COMMITMENTS** (continued):

- f.** On July 24, 2016, the Subsidiary entered into a General Technical Agreement with a vendor for the scale-up process development and production of one of its oral capsule ingredients in the amount of \$4,300 that will be paid over the term of the engagement and based on the achievement of certain development milestones, \$4,087 of which was recognized in research and development expenses through November 30, 2018. This agreement is part of the requirements of the License Agreement as described in note 1.
- g.** 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 November 30, 2018.
- h.** 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 November 30, 2018, the Company had issued to such advisor 5,000 shares. The fair value of the shares at the grant date was \$25, which was recognized in general and administrative expenses.
- i.** 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 November 30, 2018.
- j.** 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, \$1,037 of which was recognized in research and development expenses through November 30, 2018.
- k.** 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, \$4,106 of which was recognized in research and development expenses through November 30, 2018.
- l.** 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 November 30, 2018.

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**NOTE 2 - COMMITMENTS** (continued):

- m.** 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 \$360 was recognized in research and development expenses through November 30, 2018.
- n.** 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. As of November 30, 2018, the Company had issued to such advisor 9,874 shares and the related expense was recognized in general and administrative expenses. The Company terminated this consulting agreement in December 2018.
- 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 November 30, 2018 was \$2,194.

The royalty expenses which are related to the funded project were recognized in cost of revenues in the quarter ended November 30, 2018 and in prior periods.

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**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 November 30, 2018, 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 November 30, 2018, 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 November 30, 2018, the carrying amounts of long-term deposits approximate their fair values due to the stated interest rates which approximate market rates.

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

There were no Level 3 items for the three-month periods ended November 30, 2018 and 2017.



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**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:**

	<b>November 30, 2018</b>	<b>August 31, 2018</b>
<b>Short-term:</b>		
D.N.A (see b below)	\$ 737	\$ 666
Entera (see c below)	621	632
Held to maturity bonds (see d below)	3,785	3,294
	<u>\$ 5,143</u>	<u>\$ 4,592</u>
<b>Long-term:</b>		
Held to maturity bonds (see d below)	\$ 2,290	\$ 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 November 30, 2018, the Company owns approximately 6.9% of D.N.A's outstanding ordinary shares.

The cost of the securities as of November 30, 2018 and August 31, 2018 is \$595.

**c. Entera**

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

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**NOTE 4 - MARKETABLE SECURITIES** (continued):

**d. Held to maturity securities**

The amortized cost and estimated fair value of held-to-maturity securities as of November 30, 2018, are as follows:

	<b>November 30, 2018</b>		
	<b>Amortized cost</b>	<b>Gross unrealized losses</b>	<b>Estimated fair value</b>
Short-term:			
Commercial bonds	\$ 3,739	\$ (26)	\$ 3,713
Accrued interest	46	-	46
Long-term	2,290	(19)	2,271
	<u>\$ 6,075</u>	<u>\$ (45)</u>	<u>\$ 6,030</u>

As of November 30, 2018, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, \$2,290, 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:

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

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.

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**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 November 30, 2018, 576,834 shares were sold under the Sales Agreement for aggregate net proceeds of \$5,198. During the three months ended November 30, 2018, the Company did not issue shares under the Sales Agreement.

**NOTE 6 - RELATED PARTIES - TRANSACTIONS:**

On July 1, 2008, the Subsidiary entered into two consulting agreements with KNRV Ltd. ("KNRV"), an Israeli company owned by the Chief Scientific Officer (the "CSO"), whereby the Chief Executive Officer (the "CEO") and the CSO, through KNRV, 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 KNRV 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 (\$34) 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 three months ended November 30, 2018, such relocation expenses totaled \$131 compared to \$88 for the three months ended November 30, 2017.

## 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 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 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. Up to 48 patients will be enrolled, including up to 24 healthy volunteers and 24 patients with type 1 diabetes.

In September 2018, we initiated a six month toxicology study of our oral insulin capsule, following the FDA’s request.

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. We initiated in the first quarter of calendar year 2019 a Phase I pharmacokinetic trial which will evaluate the safety and the pharmacokinetics of ORMD-0901 compared to placebo. This study is being 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 patients with NASH. We expect to complete the study during calendar year 2019.

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

	Phase I	Phase II	Phase III	Timeline
<b>ORMD-0801</b> <b>oral insulin</b>	Type 2 diabetes			Q2 '18: Phase IIb 90-day multi-center study initiated (projected completion Q4 '19) Q3 '20: Phase III study projected initiation (projected completion Q3 '22)
	Type 1 diabetes			Q2 '18: Clamp study initiated (projected completion Q1 '19) Q2 '18: Food effect study initiated (projected completion Q2 '19) Q3 '20: Phase III projected initiation (projected completion Q3 '22)
<b>ORMD-0901</b> <b>oral GLP-1</b>	Type 2 diabetes			Q1 '19: Pharmacokinetics clinical study initiated (projected completion Q1 '19) Q4 '19: Phase II projected initiation (projected completion Q1 '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 will be 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 November 30, 2018, we received aggregate milestone payments of \$17.5 million and an additional milestone payment of \$3 million was received in January 2019.

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

## Results of Operations

### Comparison of three month periods ended November 30, 2018 and 2017

The following table summarizes certain statements of operations data of the Company for the three month periods ended November 30, 2018 and 2017 (in thousands of dollars except share and per share data):

	Three months ended November 30,	
	2018	2017
Revenues	\$ 674	\$ 611
Cost of revenues	35	-
Research and development expenses	4,347	2,327
General and administrative expenses	932	1,016
Financial income, net	338	201
Net loss for the period	\$ 4,302	\$ 2,531
Loss per common share - basic and diluted	\$ 0.25	\$ 0.18
Weighted average common shares outstanding	17,448,744	14,239,346

### 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 three month period ended November 30, 2018 increased by 10% to \$674,000, from \$611,000 for the three month period ended November 30, 2017. The increase is primarily attributable to the effect of recognizing revenue of the variable consideration on a cumulative basis following the adoption of Accounting Standards Update 2014-09, "Revenue from Contracts with Customers (Topic 606)", or ASC 606.

### ***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 three month period ended November 30, 2018 increased to \$35,000 compared to no cost of revenues for the three month period ended November 30, 2017. The increase is attributable to the inclusion of additional milestone payments under the License Agreement in the transaction price as part of the implementation of ASC 606.

### ***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 three month period ended November 30, 2018 increased by 87% to \$4,347,000, from \$2,327,000 for the three month period ended November 30, 2017. The increase is primarily due to expenses related to our Phase IIb three-month treatment clinical trial, food effect and clamp 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. Stock-based compensation costs for the three month period ended November 30, 2018 totaled \$39,000, as compared to \$171,000 during the three month period ended November 30, 2017. The decrease is mainly attributable to the progress in amortization and the forfeiture of awards granted in prior periods.

### ***Government grants***

In the three month periods ended November 30, 2018 and 2017, we did not recognize any research and development grants. As of November 30, 2018, we incurred liabilities to pay royalties to the Israel Innovation Authority of the Israeli Ministry of Economy & Industry of \$425,000.



### ***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 three month period ended November 30, 2018 decreased by 8% to \$932,000 from \$1,016,000 for the three month period ended November 30, 2017. The decrease in costs related to general and administrative activities during the three month period ended November 30, 2018 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 three month period ended November 30, 2018 totaled \$199,000, as compared to \$352,000 during the three month period ended November 30, 2017. 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 year 2018.

### ***Financial income, net***

Net financial income increased by 68% from net income of \$201,000 for the three month period ended November 30, 2017 to net income of \$338,000 for the three month period ended November 30, 2018. The increase is primarily attributable to an increase in income from bank deposits and held to maturity bonds as a result of an increase in interest rates, as well as an increase 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 2016-01, "Recognition and Measurement of Financial Assets and Financial Liabilities."

### ***Other comprehensive income***

No unrealized gains on available for sale securities were recognized for the three month period ended November 30, 2018 as compared to gains of \$326,000 for the three month period ended November 30, 2017. The decrease is due to the implementation of Accounting Standards Update 2016-01, "Recognition and Measurement of Financial Assets and Financial Liabilities," under which changes in fair value of the ordinary shares of D.N.A and Entera that we hold are recognized as financial income.

### ***Liquidity and capital resources***

From inception through November 30, 2018, we have incurred losses in an aggregate amount of \$71,050,000. 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 November 30, 2018, we had \$3,861,000 of available cash, \$31,533,000 of short-term and long-term bank deposits and \$7,433,000 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 November 30, 2018, our total current assets were \$29,651,000 and our total current liabilities were \$4,164,000. On November 30, 2018, we had a working capital surplus of \$25,487,000 and an accumulated loss of \$71,050,000. 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 from August 31, 2018 to November 30, 2018 was primarily due to the cash used in operating activities.

During the three month period ended November 30, 2018, cash and cash equivalents decreased to \$3,861,000 from the \$4,996,000 reported as of August 31, 2018, which is due to the reasons described below.

Operating activities used cash of \$4,131,000 in the three month period ended November 30, 2018, as compared to \$2,728,000 used in the three month period ended November 30, 2017. Cash used in operating activities in the three month period ended November 30, 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 accounts payable and accrued expenses, while cash used in operating activities in the three month period ended November 30, 2017 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 \$2,995,000 in the three month period ended November 30, 2018, as compared to \$5,146,000 used in the three month period ended November 30, 2017. Cash provided by investing activities in the three month period ended November 30, 2018 consisted primarily of the maturity of short-term deposits and held to maturity securities and is partially offset by the purchase of held to maturity securities, while cash used in investing activities in the three month period ended November 30, 2017 consisted primarily of the purchase of short-term and long-term bank deposits and held to maturity securities.

Financing activities did not provide cash in the three month period ended November 30, 2018, as compared to \$5,160,000 provided in the three month period ended November 30, 2017. Financing activities in the three month period ended November 30, 2017 consisted of aggregate net proceeds of \$4,230,000 from our issuance of 453,919 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 November 30, 2018, 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 November 30, 2018. 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 November 30, 2018. 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 November 30, 2018 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 ASC 606.

## PART II – OTHER INFORMATION

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

On November 1, 2018, 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.

On October 15, 2018, we issued 5,694 shares of our common stock to Acorn Management Partners, L.L.C., or Acorn, in payment of a portion of the consulting fee for investor relations services owed to Acorn pursuant to a Consulting Agreement, dated July 15, 2018, between us and Acorn.

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

<b>Exhibit Number</b>	
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10.1*	<a href="#">Consulting Agreement, dated December 12, 2018, between Oramed Ltd. and Joshua Hexter.</a>
31.1*	<a href="#">Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.</a>
31.2*	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.</a>
32.1**	<a href="#">Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.</a>
32.2**	<a href="#">Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350.</a>
101.1*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended November 30, 2018 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.

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\* 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: January 14, 2019

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

Date: January 14, 2019

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



### Consulting Agreement

This Consulting Agreement (this “**Agreement**”) is entered into on this 12th day of December, 2018 by and between **Oramed Pharmaceuticals Inc.**, a Delaware corporation having a principal place of business at 142 W. 57th Street, 11th Floor, New York, NY 10019 (“**Oramed**”), and **Joshua Hexter**, an individual residing at 7550 Amherst Avenue, University City, MO, 63130 (“**Consultant**”).

Oramed wishes to receive certain services from Consultant as a consultant, and Consultant is willing to provide such services to Oramed as a consultant. In consideration of the foregoing and the mutual covenants and conditions hereinafter set forth, the parties hereto agree as follows:

1. **Services.** Consultant shall provide Oramed with the services specified in the attached **Schedule 1**, in accordance with Oramed’s needs and requirements, and according to a schedule and timeframe as will be agreed by Consultant and Oramed (the “**Services**”). Consultant shall perform Services faithfully, diligently and to the best of Consultant’s skill and ability. Nothing herein will prevent Oramed from dealing directly or indirectly with any third parties who provide services similar or identical to the Services.
  2. **Payment.** In consideration for the performance of the Services by Consultant, Oramed shall pay Consultant the fees set forth in **Schedule 1** hereto (the “**Fees**”). The Fees are inclusive of all taxes. Oramed will not make deductions for taxes from any amounts payable to Consultant, and any such taxes shall be the sole responsibility of Consultant. The Fees shall be payable in arrears on a current plus 30 days basis, against presentation of an invoice by Consultant. If Oramed is required by law to withhold any taxes, any amount withheld shall be deducted from the Fees. Invoices prepared by Consultant shall state the Fees in the same currency indicated in this Agreement. Oramed shall also reimburse Consultant for reasonable out-of-pocket business expenses incurred by Consultant in connection with providing the Services, provided that such expenses have been approved in writing in advance by Oramed and are evidenced by receipts.
  3. **Confidentiality.**
    - 3.1. By executing this Agreement, Consultant confirms that the provisions of the Confidential Disclosure Agreement entered into by and between Oramed and Consultant, dated November 8, 2018 (the “**CDA**”), shall continue to be in force during the term of this Agreement. A copy of the CDA is attached hereto as Exhibit A.
    - 3.2. While rendering the Services, Consultant shall not bring to Oramed, use or disclose any third party information which Consultant is prohibited from using or disclosing by another agreement to which Consultant is or becomes a party. Without the limiting the foregoing, Consultant understands that Consultant is not to breach any obligation of confidentiality that Consultant has to present or former employers or clients, and agrees to fulfill all such obligations during the term of this Agreement.
  4. **No Conflicts.** Consultant represents and warrants that Consultant’s performance of this Agreement and the Services does not and will not breach or conflict with any agreement to which Consultant is or becomes a party, nor does it require the consent of any other person or entity. Consultant shall inform Oramed, immediately after Consultant becomes aware of it, of any matter or engagement that may in any way raise a conflict of interest between Consultant and Oramed or prevent Consultant from providing the Services.
-

5. **Independent Contractor.** It is understood that Consultant is an independent contractor and not an employee of Oramed. Consultant has no authority to obligate Oramed by contract or otherwise. None of Consultant's employees will be considered an employee of Oramed or eligible for any right or benefit (including such rights and benefits that Oramed may grant to its employees). No deductions shall be made from the Fees nor any transfers made to any governmental or private entity except as set forth in this Agreement, and Consultant hereby waives any claim against Oramed based on such deductions or transfers not being made. Taxes shall be the sole responsibility of the Consultant. If, as a result of a claim or suit by Consultant or any of its employees, a competent court of law rules that the relationship between Oramed and an employee of Consultant is an employer-employee relationship and that, as a result of such relationship, such employee of Consultant is entitled to rights or compensation from Oramed, the following will apply: Consultant shall fully indemnify Oramed for any damages, liabilities or other costs and expenses incurred in connection with any such determination, and Oramed shall be entitled to offset any amount due to Consultant resulting from the determination that an employer-employee relationship exists against any amount actually paid or due under this Agreement.
6. **Code of Business Conduct and Ethics; Internal Policies.** Consultant shall at all times comply with the Code of Business Conduct and Ethics attached hereto as **Exhibit B** and the Policy regarding Securities Trades by Company Personnel attached hereto as **Exhibit C**. Without limiting the foregoing, Oramed has informed Consultant, and Consultant acknowledges that the securities of Oramed are publicly traded on the Nasdaq Capital Market in the United States and on the Tel Aviv Stock Exchange in Israel. As such, Oramed has advised Consultant of, and Consultant acknowledges the restrictions imposed by the securities laws of the United States and Israel on the purchase or sale of securities by any person who has received material, non-public information about Oramed or any of the affiliates, and on the communication of such information to any other person who may purchase or sell such securities in reliance upon such information.
7. **Term.** The term of this Agreement shall be for a period of six (6) months commencing November 16, 2018.
8. **Termination.** Either party may terminate this Agreement with or without cause upon 5 days' written notice; *provided, however*, that Sections 3.1 and 5 will survive the termination or expiration of this Agreement for any reason. Upon termination of this Agreement, Consultant shall promptly deliver to Oramed all documents and other materials of any nature pertaining to the Services.
9. **Miscellaneous.** This Agreement constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof, and supersedes all prior written or oral agreements with respect thereto. This Agreement may be assigned by Oramed without the consent of Consultant. Consultant may not assign or delegate duties under this Agreement without the prior written consent of Oramed. The provisions of this Agreement will survive the assignment of this Agreement by Oramed to any successor or other assignee. This Agreement may not be modified except by written instrument signed by a duly authorized representative of each party hereto. No failure, delay of forbearance of either party in exercising any power or right hereunder will in any way restrict or diminish such party's rights and powers under this Agreement, or operate as a waiver of any breach or nonperformance by either party of any terms of conditions hereof. If it is determined under any applicable law that a certain provision set forth in this Agreement is invalid or unenforceable, such determination will not affect the remaining provisions of this Agreement. This Agreement will be governed by the laws of the State of Delaware. Any dispute arising out of or in connection with this Agreement will be subject to the exclusive jurisdiction of the competent courts of the State of New York sitting in New York County, and of the United States District Court of the Southern District of New York, and any appellate court from any thereof.
10. **Counterparts.** For the convenience of the parties, this Agreement may be signed in counterparts, each of which will be an original instrument and all of which taken together will constitute one and the same Agreement. Delivery of a signed counterpart of this Agreement by e-mail or facsimile transmission will constitute valid and sufficient delivery thereof.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first set forth above.

**ORAMED:**

**CONSULTANT:**

**Oramed Pharmaceuticals Inc.**

**Joshua Hexter**

By: /s/ Nadav Kidron  
Nadav Kidron  
CEO

By: /s/ Joshua Hexter

## SCHEDULE 1

### Description of the Services and Fees

#### Services

- Business Development – the Consultant will act as a business development and advisor on behalf of Oramed. Consultant will seek to introduce organizations and/or individuals that will create business development opportunities for Oramed.
- Investor Relations – the Consultant will provide ongoing investor relations advice to Oramed.

Additionally, the Consultant shall advise the officers, directors and employees of Oramed on such other matters and at such times and places as may be mutually agreed upon.

Except as provided in the Agreement, the time, place and manner of performance of the Services shall be determined at the sole discretion of the Consultant.

#### Fees

For the first 10 hours of such Services, the Consultant will be paid NIS 150 per hour.

Beyond the first 10 hours of such Services, the Consultant will be paid NIS 500 per hour.

For the avoidance of doubt, these Fees shall be construed as the gross cost to Oramed and taxes shall be the sole responsibility of the Consultant.



**EXHIBIT A**

**Confidential Disclosure Agreement**

Attached

## Mutual Non Disclosure Agreement

This Mutual Non Disclosure Agreement (this “**Agreement**”) is entered by and between **Oramed Pharmaceuticals Inc.**, a Delaware Company, with an office at 142 W. 57th St., New York, NY, USA, and its Israeli subsidiary, Oramed Ltd (together - the “**Company**”) and **Joshua Hexter**, an individual residing at 7550 Amherst Avenue, University City, MO, 63130 (the “**Recipient**”). The parties wish to discuss a possible business relationship with each other, and in connection with the same each of the parties has been, and/or will be, provided with, and/or has access to certain confidential information of the other party. With respect to any and all information disclosed by either party (“**Disclosing Party**”) to the other party (“**Receiving Party**”), the parties wish to ensure due protection of such information.

Therefore, the parties hereby agree as follows:

1. Receiving Party acknowledges that it may receive information regarding the activities and business of Disclosing Party, its parent companies, subsidiaries and/or affiliates, all whether in oral, written, graphic, or machine-readable form, or in any other form, including, without limitation, concepts, techniques, processes, methods, systems, designs, drawings, photographs, models, prototypes, computer programs, research materials, formulas, development or experimental work, work in progress, mask work, inventions, cost data, marketing plans, product plans, business strategies, financial information, forecasts, personnel information and customer or supplier lists (collectively, “**Confidential Information**”). For the avoidance of doubt, nothing herein shall be deemed to impose on Disclosing Party any duty or obligation to disclose any such information to Receiving Party, and such disclosure shall be at all times at Disclosing Party’s sole and absolute discretion. Furthermore, nothing herein shall be deemed to create any representation that the Confidential Information, or any part of it, is whole, accurate or correct.
2. Notwithstanding the aforesaid, information shall not be deemed as Confidential Information, for purposes of this Agreement, if Receiving Party can show documentary evidence that: (a) such information is in the public domain at the time of disclosure, or subsequently becomes part of the public domain, through no breach of Receiving Party of its obligations hereunder; or (b) such information is received by Receiving Party from a third party exempt from confidentiality undertakings; or (c) such information was in its possession at the time of disclosure, and Receiving Party so advised Disclosing Party in writing immediately upon disclosure; or (d) Receiving Party is compelled by court or government action pursuant to applicable law to disclose such information, provided, however, that Receiving Party gives Disclosing Party prompt notice thereof so that Disclosing Party may seek a protective order or other appropriate remedy, and further provided that in the event that such protective order or other remedy is not obtained, Receiving Party shall furnish only that portion of the Confidential Information which is legally required, and shall exercise all efforts required to obtain confidential treatment for such information.
3. The Confidential Information shall be used by Receiving Party for the sole purpose of evaluating its interest in future cooperation with Disclosing Party as set forth hereinabove, and, if the parties shall engage in any relationship - solely for the limited purposes of such engagement.

4. Receiving Party hereby acknowledges that the Confidential Information is highly confidential, and undertakes that, at all times, it: (i) shall treat and maintain the Confidential Information as confidential, and hold all such Confidential Information in trust and in strict confidence, utilizing the same degree of care it uses to protect its own confidential information, but in no event less than a reasonable degree of care; (ii) shall not disclose the Confidential Information to any third party, whether or not for consideration; (iii) shall not use the Confidential Information for any purpose other than the limited purpose mentioned in Section 3 above, or exploit the Confidential Information for its own benefit or for the benefit of anyone else, without the prior written consent of Disclosing Party; and (iv) shall not make any copies of the Confidential Information without the prior written consent of Disclosing Party.

5. Receiving Party undertakes to hold all Confidential Information locked and to disclose the Confidential Information only to those of its employees and consultants (provided, with respect to such consultants, that disclosure to any consultant shall be made only after receipt of written consent of the Disclosing Party) who have to be so informed in order to ensure its proper evaluation (each, a “**Representative**”), and provided that such Representatives are bound by written confidentiality and non-use undertakings towards Receiving Party which also apply to the Confidential Information disclosed to Receiving Party under this Agreement. Receiving Party will be responsible for ensuring that the obligations of confidentiality and non-use contained herein are observed by all Representatives, and it represents that it has instituted policies and procedures which provide such adequate protection for the Confidential Information. Without derogating from the aforesaid, Receiving Party shall bear full responsibility for any harm caused to Disclosing Party by disclosure to Representatives.

6. To the extent that any portion of the Confidential Information contains proprietary and confidential notices or legends, Receiving Party shall not remove such notices or legends, and shall produce the same on each and every copy of the Confidential Information produced by it.

7. Upon Disclosing Party’s first demand, Receiving Party shall return to Disclosing Party all Confidential Information, including all records, products and samples received, and any copies thereof, as well as any notes, memoranda or other writings or documentation which contain or pertain to the Confidential Information or any portion thereof, whether in its possession or under its control, and shall erase all electronic records thereof, and shall so confirm to Disclosing Party in writing.

8. The Confidential Information and all right, title and interest therein will remain at all times the exclusive property of Disclosing Party its parent companies, subsidiaries and/or affiliates. Nothing hereunder may be construed as granting to Receiving Party any right, warranty or license by implication or otherwise under any patent, copyright, know-how or design rights, or other form of protection of industrial or intellectual property, or as creating any obligation on the part of Disclosing Party to enter into any business relationship whatsoever or to offer for sale any service or product.

9. Receiving Party recognizes, acknowledges and agrees that Disclosing Party may be irreparably harmed if Receiving Party's obligations and undertakings herein are not specifically enforced, and that Disclosing Party would not have an adequate remedy at law in the event of actual or threatened violation by Receiving Party of such obligations and undertakings. Therefore, Receiving Party agrees that Disclosing Party shall be entitled to seek and obtain an injunction, without bond, or to an appropriate decree of specific performance or any other appropriate equitable relief.

10. All of Disclosing Party's rights hereunder and all of Receiving Party's obligations and undertakings hereunder shall be in full effect for the entire term of this Agreement, and for an unlimited period of time after its termination, cancellation or expiration for any reason whatsoever, so long as any information disclosed by Disclosing Party to Receiving Party under this Agreement remains Confidential Information of Disclosing Party. Without derogating from the aforesaid, should the parties engage in any relationship, all of Disclosing Party's rights hereunder and all of Receiving Party's obligations and undertakings hereunder shall be in full effect for as long as the parties shall engage in such relationship.

11. The Recipient acknowledges that the Company is a publicly traded company. As such, the Recipient agrees not to use any Confidential Information or any other non-public information in connection with the purchase or sale of the securities of the Company in violation of United States securities laws.

12. This Agreement constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof, and supersedes all prior written or oral agreements with respect thereto. This Agreement may not be modified except by written instrument signed by a duly authorized representative of each party hereto. No failure, delay of forbearance of either party in exercising any power or right hereunder shall in any way restrict or diminish such party's rights and powers under this Agreement, or operate as a waiver of any breach or nonperformance by either party of any terms of conditions hereof. In the event that it shall be determined under any applicable law that a certain provision set forth in this Agreement is invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement unless the purpose of this Agreement is substantially frustrated thereby. This Agreement shall be governed by the laws of the State of New York and any dispute arising out of or in connection with this Agreement is hereby submitted to the sole and exclusive jurisdiction of the competent courts in New York.

/s/ Nadav Kidron

\_\_\_\_\_  
**Oramed Pharmaceuticals Inc.**

By: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

/s/ Joshua Hexter

\_\_\_\_\_  
Joshua Hexter

Date: November 8, 2018

**EXHIBIT B**

**Code of Business Conduct and Ethics**

Attached

**ORAMED PHARMACEUTICALS INC.**  
(the "Corporation")  
**CODE OF ETHICS AND BUSINESS CONDUCT**  
**FOR DIRECTORS, SENIOR OFFICERS AND EMPLOYEES OF THE CORPORATION**  
(the "Code")

This Code applies to the Chief Executive Officer, President, Chief Financial Officer, Principal Executive Officer, Principal Financial Officer, Principal Accounting Officer, Controller and persons performing similar functions (collectively, the "Senior Officers") along with all directors and employees within the Corporation (the Senior Officers, directors and employees are hereinafter collectively referred to as the "Employees"). This Code covers a wide range of business practices and procedures. It does not cover every issue that may arise, but it sets out basic principles to guide all Employees of the Corporation. All Employees should conduct themselves accordingly and seek to avoid the appearance of improper behavior in any way relating to the Corporation.

Any Employee who has any questions about the Code should consult with the Chief Executive Officer, the President, the Corporation's board of directors (the "Board") or the Corporation's audit committee (the "Audit Committee").

The Corporation has adopted the Code for the purpose of promoting:

- honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- full, fair, accurate, timely and understandable disclosure in all reports and documents that the Corporation files with, or submits to, the Securities and Exchange Commission ("SEC") and in other public communications made by the Corporation that are within the Senior Officer's area of responsibility;
- compliance with applicable governmental laws, rules and regulations;
- the prompt internal reporting of violations of the Code; and
- accountability for adherence to the Code.

**HONEST AND ETHICAL CONDUCT**

Each Senior Officer and member of the Board owes a duty to the Corporation to act with integrity. Integrity requires, among other things, being honest and candid. Employees must adhere to a high standard of business ethics and are expected to make decisions and take actions based on the best interests of the Corporation, as a whole, and not based on personal relationships or benefits. Generally, a "conflict of interest" occurs when an Employee's personal interests is, or appears to be, inconsistent with, interferes with or is opposed to the best interests of the Corporation or gives the appearance of impropriety.

Business decisions and actions must be made in the best interests of the Corporation and should not be influenced by personal considerations or relationships. Relationships with the Corporation's stakeholders for example suppliers, competitors and customers - should not in any way affect an Employee's responsibility and accountability to the Corporation. Conflicts of interest can arise when an Employee or a member of his or her family receive improper gifts, entertainment or benefits as a result of his or her position in the Corporation.

Specifically, each Employee must:

1. act with integrity, including being honest and candid while still maintaining the confidentiality of information when required or consistent with the Corporation's policies;
2. avoid violations of the Code, including actual or apparent conflicts of interest with the Corporation in personal and professional relationships;
3. disclose to the Board or the Audit Committee any material transaction or relationship that could reasonably be expected to give rise to a breach of the Code, including actual or apparent conflicts of interest with the Corporation;
4. obtain approval from the Board or Audit Committee before making any decisions or taking any action that could reasonably be expected to involve a conflict of interest or the appearance of a conflict of interest;
5. observe both the form and spirit of laws and governmental rules and regulations, accounting standards and Corporation policies;
6. maintain a high standard of accuracy and completeness in the Corporation's financial records;
7. ensure full, fair, timely, accurate and understandable disclosure in the Corporation's periodic reports;
8. report any violations of the Code to the Board or Audit Committee;
9. proactively promote ethical behavior among peers in his or her work environment; and
10. maintain the skills appropriate and necessary for the performance of his or her duties.

#### **DISCLOSURE OF CORPORATION INFORMATION**

As a result of the Corporation's status as a public company, it is required to file periodic and other reports with the SEC. The Corporation takes its public disclosure responsibility seriously to ensure that these reports furnish the marketplace with full, fair, accurate, timely and understandable disclosure regarding the financial and business condition of the Corporation. All disclosures contained in reports and documents filed with or submitted to the SEC, or other government agencies, on behalf of the Corporation or contained in other public communications made by the Corporation must be complete and correct in all material respects and understandable to the intended recipient.

The Senior Officers, in relation to his or her area of responsibility, must be committed to providing timely, consistent and accurate information, in compliance with all legal and regulatory requirements. It is imperative that this disclosure be accomplished consistently during both good times and bad and that all parties in the marketplace have equal or similar access to this information.

All of the Corporation's books, records, accounts and financial statements must be maintained in reasonable detail, must appropriately reflect the Corporation's transactions, and must conform both to applicable legal requirements and to the Corporation's system of internal controls. Unrecorded or "off the book" funds, assets or liabilities should not be maintained unless permitted by applicable law or regulation. Senior Officers involved in the preparation of the Corporation's financial statements must prepare those statements in accordance with generally accepted accounting principles, consistently applied, and any other applicable accounting standards and rules so that the financial statements materially, fairly and completely reflect the business transactions and financial statements and related condition of the Corporation. Further, it is important that financial statements and related disclosures be free of material errors.

Specifically, each Senior Officer must:

1. familiarize himself or herself with the disclosure requirements generally applicable to the Corporation;
2. not knowingly misrepresent, or cause others to misrepresent, facts about the Corporation to others, including the Corporation's independent auditors, governmental regulators, selfregulating organizations and other governmental officials;
3. to the extent that he or she participates in the creation of the Corporation's books and records, promote the accuracy, fairness and timeliness of those records; and
4. in relation to his or her area of responsibility, properly review and critically analyse proposed disclosure for accuracy and completeness.

#### **CONFIDENTIAL INFORMATION**

Employees must maintain the confidentiality of confidential information entrusted to them by the Corporation of its customers, suppliers, joint venture partners, or others with whom the Corporation is considering a business or other transaction except when disclosure is authorized by an executive officer or required or mandated by laws or regulations. Confidential information includes all non-public information that might be useful or helpful to competitors or harmful to the Corporation or its customers or suppliers, if disclosed. It also includes information that suppliers, customers and other parties have entrusted to the Corporation. The obligation to preserve confidential information continues even after employment ends.



Records containing personal data about employees or private information about customers and their employees are confidential. They are to be carefully safeguarded, kept current, relevant and accurate. They should be disclosed only to authorized personnel or as required by law.

All inquiries regarding the Corporation from non-employees, such as financial analysts and journalists, should be directed to the Board or the Audit Committee. The Corporation's policy is to cooperate with every reasonable request of government investigators for information. At the same time, the Corporation is entitled to all the safeguards provided by law for the benefit of persons under investigation or accused of wrongdoing, including legal representation. If a representative of any government or government agency seeks an interview or requests access to data or documents for the purposes of an investigation, the Employee should refer the representative to the Board or the Audit Committee. Employees also should preserve all materials, including documents and e-mails that might relate to any pending or reasonably possible investigation.

## **COMPLIANCE WITH LAWS**

The Employees must respect and obey all applicable foreign, federal, state and local laws, rules and regulations applicable to the business and operations of the Corporation.

Employees who have access to, or knowledge of, material nonpublic information from or about the Corporation are prohibited from buying, selling or otherwise trading in the Corporation's stock or other securities. "Material nonpublic" information includes any information, positive or negative, that has not yet been made available or disclosed to the public and that might be of significance to an investor, as part of the total mix of information, in deciding whether to buy or sell stock or other securities.

Employees also are prohibited from giving "tips" on material nonpublic information, that is directly or indirectly disclosing such information to any other person, including family members, other relatives and friends, so that they may trade in the Corporation's stock or other securities.

Furthermore, if, during the course of an Employee's service with the Corporation, he or she acquires material nonpublic information about another company, such as one of our customers or suppliers, or you learn that the Corporation is planning a major transaction with another company (such as an acquisition), the Employee is restricted from trading in the securities of the other company.

## REPORTING ACTUAL AND POTENTIAL VIOLATIONS OF THE CODE AND ACCOUNTABILITY FOR COMPLIANCE WITH THE CODE

The Corporation, through the Board or the Audit Committee, is responsible for applying this Code to specific situations in which questions may arise and has the authority to interpret this Code in any particular situation.

This Code is not intended to provide a comprehensive guideline for Senior Officers in relation to their business activities with the Corporation. Any Employee may seek clarification on the application of this Code from the Board or the Audit Committee.

Each Employee must:

1. notify the Corporation of any existing or potential violation of this Code, and failure to do so is itself a breach of the Code; and
2. not retaliate, directly or indirectly, or encourage others to do so, against any Employee for reports, made in good faith, of any misconduct or violations of the Code solely because that Employee raised a legitimate ethical issue.

The Board or the Audit Committee will take all action it considers appropriate to investigate any breach of the Code reported to it. All Employees are required to cooperate fully with any such investigations and to provide truthful and accurate information. If the Board or the Audit Committee determines that a breach has occurred, it will take or authorize disciplinary or preventative action as it deems appropriate, after consultation with the Corporation's counsel if warranted, up to and including termination of employment. Where appropriate, the Corporation will not limit itself to disciplinary action but may pursue legal action against the offending Employee involved. In some cases, the Corporation may have a legal or ethical obligation to call violations to the attention of appropriate enforcement authorities.

Compliance with the Code may be monitored by audits performed by the Board, Audit Committee, the Corporation's counsel and/or by the Corporation's outside auditors. All Employees are required to cooperate fully with any such audits and to provide truthful and accurate information.

Any waiver of this Code for any Employee may be made only by the Board or the Audit Committee and will be promptly disclosed to stockholders and others, as required by applicable law. The Corporation must disclose changes to and waivers of the Code in accordance with applicable law.

**ACKNOWLEDGEMENT**

Please sign below acknowledging that you have read and agreed to abide by Oramed’s Code of Ethics.

I received, reviewed and agree to be bound by Oramed’s Code of Ethics

Dated:

/s/ Josh Hexter  
Signature

Josh Hexter  
Name

COO and VP Business Development  
Title

Return this Acknowledgment to the CFO of Oramed.

**EXHIBIT C**

**Securities Trades by Company Personnel**

Attached

**ORAMED PHARMACEUTICALS INC.**

**AMENDED AND RESTATED  
INSIDER TRADING POLICY**

**(Last approved by the Board of Directors on October 2, 2014)**

This policy sets forth guidelines for all Insiders (as defined below) of Oramed Pharmaceuticals Inc. (“Oramed”) with respect to transactions in Oramed securities. This policy arises from Oramed’s responsibilities as a public company whose shares of common stock are quoted on the Nasdaq Capital Market, or Nasdaq, under the symbol “ORMP”. Failure to comply with these guidelines could result in a serious violation of the securities laws by you and/or Oramed and can involve both civil and criminal penalties. It is important that you review this policy carefully.

**I. Reason for Policy**

Oramed is subject to the insider trading laws in the United States. Under United States law, an individual may be subject to fines of up to \$5,000,000 and up to twenty years in jail for violating the securities laws by engaging in transactions in securities at a time when in possession of material non-public information. In addition, the U.S. Securities and Exchange Commission (the “SEC”) may seek the imposition of a civil penalty of up to three times the profits made or losses avoided from the trading. Insider traders must also disgorge any profits made and are often subjected to an injunction against future violations. Violators can also be barred from serving as officers or directors of public companies. Individuals also may be subjected to civil liability in private lawsuits. The foregoing penalties are subject to amendment from time to time.

Without regard to the penalties that may be imposed by others, willful violation of this policy constitutes grounds for dismissal from the Board of Directors of Oramed (the “Board”), termination of your employment or, with respect to Representatives (as defined below), termination of your engagement with Oramed.

Insider trading proscriptions are not limited to trading by the insider alone; it is also illegal to advise others to trade on the basis of undisclosed material information or to share non-public material information with others if you know or should have known that they will use such information to purchase or sell Oramed shares. Liability in such cases can extend both to the “tippee”—the person who purchased or sold Oramed shares based on this non-public information—and to the “tipper,” the Insider himself. Even if you are not in possession of material non-public information regarding Oramed, do not recommend to any other person that they buy or sell securities of Oramed because your recommendation could be imputed to Oramed and may be misleading if you do not have all of the relevant information.

Finally, the appearance of insider trading can cause a substantial loss of confidence in Oramed and its shares on the part of the public and the securities markets. This could obviously have an adverse impact on Oramed and its shareholders. Accordingly, avoiding the *appearance* of engaging in share transactions on the basis of material undisclosed information can be as important as avoiding a transaction *actually* based on such information. Furthermore, if your share transactions become the subject of scrutiny, they will be viewed after the fact with the benefit of 20/20 hindsight. Accordingly, before engaging in any transaction you should carefully consider how regulators and others might view your transaction with such hindsight and, if you have the slightest doubt, consult with Oramed’s Chief Financial Officer (“CFO”).

***In the event an Insider becomes aware of a possible violation of this policy by another Insider, he or she should contact Oramed’s CFO, without delay by telephone at 844-967-2633 (U.S.) or +972-2 566 0001 (Israel) or by email at hilla@oramed.com.***

## II. Applicability of Policy

1. *“Insiders” Defined.* This policy applies to any “Insider” of Oramed, including any (a) member of the Board and officers of Oramed or its subsidiaries, (b) employee of Oramed or its subsidiaries, including part-time or temporary employees, and (c) consultant, representative, or independent contractor (“Representative”). This policy also applies to family members and other members of an Insiders person’s household (collectively, “Family Members”), as well any entities that an Insider influences or controls, including any corporations, partnerships or trusts (collectively, “Controlled Entity”). Insiders are responsible for the compliance with this policy by such Insider’s Family Members and Controlled Entities.

2. *“Access Insiders” Defined.* This policy imposes additional restrictions upon Insiders who may have increased access to material information concerning Oramed or its subsidiaries that has not been disclosed to the public (see below for a definition of “material information”), referred to as “Access Insiders.” Access Insiders are: (a) members of the Board of Directors of Oramed, (b) the Chief Executive Officer, Chief Financial Officer, presidents, general managers, vice presidents, controllers, vice controllers, treasurers, corporate secretaries and accounting personnel of Oramed and (c) the Family Members and Controlled Entities of the foregoing persons. Access Insiders are subject to additional procedures and restrictions described in Section VI below.

3. *Inside Information Regarding Other Companies.* This policy and the guidelines described herein also apply to material non-public information relating to other companies, including Oramed’s customers, vendors or suppliers or companies with which Oramed is considering merger & acquisition transactions (“business partners”), when that information is obtained in the course of employment with, or other services performed on behalf of, Oramed. Civil and criminal penalties, and termination of employment, may result from trading on inside information regarding Oramed’s business partners. All personnel should treat material non-public information about Oramed’s business partners with the same care required with respect to information related directly to Oramed.

4. *Tail Period.* If you are aware of material, non-public information when your employment or service terminates, you may not trade in Oramed securities until that information has become public or is no longer material.

## III. Definition of Full Disclosure

Full disclosure to the public generally means that it has been widely disseminated, including released through a U.S. or international newswire service, broadcast on widely-available U.S. or international radio or television programs, published in a widely-available newspaper, magazine or news website, or disclosed in public disclosure documents filed with the SEC. A speech to an audience or an article in an obscure magazine does *not* qualify as full disclosure. In addition, full disclosure means that the securities markets have had the opportunity to fully absorb the news. Generally, information should not be considered fully absorbed until two (2) full trading days after the announcement was released.

## IV. Definition of Material Information

It is not possible to define all categories of material information. In general, information should be regarded as material if there is a likelihood that it would be considered important by a reasonable investor in making a decision regarding the purchase or sale of Oramed securities. Both positive and negative information can be **material**, as well as information that forecasts whether an event may or may not occur.

Although it may be difficult under this standard to determine whether certain information is material, there are various categories of information that would almost always be regarded as material. Examples of such information are: earnings information and quarterly or annual results; guidance on earnings estimates; clinical results; product and research developments; marketing plans; major licensing transactions; government inspections, approvals or other regulatory actions; status of patent applications; changes in senior management; proposed payment of a dividend or change in dividend policy; planned share splits or repurchases; new equity or debt offerings; other events regarding Oramed securities (e.g., defaults on debt, changes to the rights of security holders); major changes in accounting policies; collaborations, mergers, acquisitions or divestitures, and significant litigation matters. Moreover, material information does not have to be related to a company’s business. For example, advance knowledge of the contents of a forthcoming article that is expected to affect the market price of a security can be material. If any Insider has questions as to the materiality of information, he or she should contact the CFO of Oramed for clarification.

## V. Confidentiality, Prohibited Transactions and Pre-clearance

1. *Confidentiality of Non-public Information.* Non-public information relating to Oramed is the property of Oramed and the unauthorized disclosure of such information is forbidden. Keep all memoranda, correspondence and other documents that reflect non-public information in a secure place, such as a locked office or a locked file cabinet, so that they cannot be seen by third persons. Do not discuss non-public information where it can be overheard, such as in restaurants, elevators, restrooms and other public places.

2. *Trading while in Possession.* Insiders may not engage in a transaction (purchase or sale) in Oramed shares at any time between the date on which any non-public material information becomes known to the individual and the close of business on the second (2<sup>nd</sup>) full Nasdaq trading day *after* such information is publicly disclosed. Nasdaq is generally open for trading Monday through Friday. If, for example, Oramed publicly disclosed information on a Monday, then you may not trade in Oramed securities until Thursday.

3. *Speculative Trading.* No Insider may engage in transactions of a speculative nature at any time. All Insiders are prohibited from short-selling Oramed common stock or engaging in transactions involving Oramed-based derivative securities. "Derivative Securities" are options, warrants, stock appreciation rights or similar rights whose value is derived from the value of an equity security, such as Oramed common stock. This prohibition includes, but is not limited to, trading in Oramed-based put and call option contracts, transacting in straddles, and the like. However, as indicated below, holding and exercising options or other derivative securities granted under Oramed's employee stock option or equity incentive plans is not prohibited by this policy.

4. *Short-Term Trading.* Short-term trading of Oramed securities may be distracting to the person and may unduly focus the person on Oramed's short-term stock market performance instead of Oramed's long-term business objectives. For these reasons, any Insider of Oramed who purchases Oramed securities in the open market may not sell any Oramed securities of the same class during the six months following the purchase (or vice versa).

5. *Short Sales.* Short sales of Oramed securities (i.e., the sale of a security that the seller does not own) may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in Oramed's prospects. In addition, short sales may reduce a seller's incentive to seek to improve Oramed's performance. For these reasons, short sales of Oramed securities are prohibited. In addition, Section 16(c) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), prohibits officers and directors from engaging in short sales. (Short sales arising from certain types of hedging transactions are governed by the paragraph below captioned "Hedging Transactions.")

6. *Hedging Transactions.* Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit a director, officer or employee to continue to own Oramed securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the director, officer or employee may no longer have the same objectives as Oramed's other shareholders. Therefore, directors, officers and employees are permitted to engaging in any such transactions, subject to in writing pre-clearance by the CFO or the Chief Executive Officer.

7. *Margin Accounts and Pledged Securities.* Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material non-public information or otherwise is not permitted to trade in Oramed securities, directors, officers and other employees are prohibited from holding Oramed securities in a margin account or otherwise pledging Oramed securities as collateral for a loan. (Pledges of Oramed securities arising from certain types of hedging transactions are governed by the paragraph above captioned "Hedging Transactions.")

8. *Ad hoc Restrictions.* From time to time, an event may occur that is material to Oramed and is known by only a few Insiders. So long as the event remains material and non-public, Oramed may impose restrictions on trading in Oramed securities by appropriate individuals. In addition, Oramed's financial results may be sufficiently material in a particular fiscal quarter that, in the judgment of the CFO, Access Insiders should refrain from trading in Oramed securities even sooner than the typical Blackout Period described below. In such event, the CFO or her designee will notify the affected individuals, either personally, by email or by voicemail, to inform them of the restrictions, but may do so without disclosing the reason for the restriction. The existence of an event-specific trading restriction period or extension of a Blackout Period will not be announced to Oramed as a whole, and should not be communicated to any other person. Even if the CFO has not designated you as a person who should not trade due to an event-specific restriction, you should not trade while aware of material non-public information. Exceptions will not be granted during an event-specific trading restriction period.

9. *Open Orders.* Any Insider who has placed a limit order or open instruction to buy or sell Oramed securities shall bear responsibility for canceling such instructions immediately in the event restrictions are imposed on their ability to trade in accordance with the paragraph above captioned "Ad hoc Restrictions".

## VI. Additional Procedures for Access Insiders

*Pre-clearance.* All Access Insiders must inform Oramed's CFO whenever they intend to execute a trade in Oramed securities, including the placing of limit orders. At the time of executing a trade in Oramed securities, such individuals will be responsible for verifying that Oramed has not imposed any restrictions on their ability to engage in trades. If the individual has not completed the trade within five (5) trading days of notification of the intention to trade, then the individual must re-confirm with Oramed's CFO that they intend to execute a trade and the individual must re-verify the nonexistence of any restrictions on such trade. Before each transaction in Oramed securities, each such officer and director should contact the CFO regarding (a) compliance with Rule 144 under the Securities Act of 1933, as amended, which contains guidelines for the sale of privately issued shares and sales by affiliates of Oramed, if such sales are not covered by an effective registration statement, to the extent applicable, and (b) the reporting of purchases and sales of shares through the filing of Forms 4 with the SEC.

## VI. Exceptions

***The only exceptions to the policy are set forth below.*** It does not matter that the Insider may have decided to engage in a transaction before learning of the undisclosed material information or that delaying the transaction might result in economic loss. It is also irrelevant that publicly disclosed information about Oramed might, even aside from the undisclosed material information, provide a substantial basis for engaging in the transaction. Additionally, there are no limits on the size of a transaction that will trigger insider trading liability; relatively small trades have in the past occasioned investigations and law suits. You simply cannot trade in Oramed shares while in possession of undisclosed material information about Oramed. The only exceptions to the policy are as follows:

1. Exercise of an option under Oramed's share option plan. Note that this exception does not include (a) any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option or (b) a subsequent sale of the shares acquired pursuant to the exercise of the option under the Oramed share option plan.

2. Bona fide gifts of securities are not deemed to be transactions for the purposes of this policy. Whether a gift is truly bona fide will depend on the circumstances surrounding each gift. The more unrelated the donee is to the donor, the more likely the gift would be considered "bona fide" and not a "transaction". For example, gifts to charities, religious institutions and service organizations would clearly not be "transactions". On the other hand, gifts to dependent children followed by a sale of the "gift" securities in close proximity to the time of the gift may imply some economic benefit to the donor and, therefore, make the gift non-bona fide.

3. Any transaction specifically approved in writing and in advance by at least two of the following individuals (excluding the individual whose prospective trade is the subject to the approval): the Chairman of the Board, Chief Executive Officer, CFO, or any member of the Audit Committee of the Board.



4. The restrictions set forth in the preceding paragraphs shall not apply to sales made pursuant to a Qualified Selling Plan. For purposes of this exception, a “Qualified Selling Plan” is a written plan for selling Oramed’s shares which meets each of the following requirements: (a) the plan is adopted by the Insider or temporary Insider during a period when the Insider or temporary Insider is not in possession of material non-public information; (b) the plan is adhered to strictly by the Insider or temporary Insider; (c) the plan either (i) specifies the amount of securities to be sold and the date on which the securities are to be sold, (ii) includes a written formula or algorithm, or computer program, for determining the amount of securities to be sold and the price at which and the date on which the securities are to be purchased or sold, or (iii) does not permit the Insider or temporary Insider to exercise any subsequent influence over how, when, or whether to effect sales; provided, in addition, that any other person who, pursuant to the plan, does exercise such influence must not have been aware of the material non-public information when doing so; and (iv) at the time it is adopted the plan conforms to all other requirements of Rule 10b5-1(c)(1)(C) under the Exchange Act as then in effect.

**VI. Acknowledgement**

Please sign the attachment acknowledging that you have read and agree to abide by this policy and return it to Hilla Eisenberg, Oramed’s CFO, by facsimile to +972 (0)72 274 0406 or by email at [hilla@oramed.com](mailto:hilla@oramed.com). If you have any questions, please contact Ms. Eisenberg.

**ACKNOWLEDGEMENT**

Please sign below acknowledging that you have read and agreed to abide by Oramed’s Insider Trading Policy.

I received, reviewed and agree to be bound by Oramed’s Insider Trading Policy.

Dated: August 8, 2018

/s/ Joshua Hexter  
\_\_\_\_\_  
Signature

Joshua Hexter  
\_\_\_\_\_  
Name

Chief Operating Officer  
\_\_\_\_\_  
Title

Return this Acknowledgment to the CFO of Oramed.

*Insider Trading Policy Acknowledgment*

**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: January 14, 2019

/s/ Nadav Kidron

Nadav Kidron

President and Chief Executive Officer

**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: January 14, 2019

/s/ Hilla Eisenberg

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Hilla Eisenberg  
Chief Financial Officer

**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 November 30, 2018 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: January 14, 2019

/s/ Nadav Kidron

Nadav Kidron,  
President and Chief Executive Officer

**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 November 30, 2018 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: January 14, 2019

/s/ Hilla Eisenberg  
Hilla Eisenberg,  
Chief Financial Officer