

ORAMED PHARMACEUTICALS INC.

Form 10-Q

July 06, 2017

**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 May 31, 2017**

**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.)

**Hi-Tech Park 2/4 Givat Ram**

**91390**

**PO Box 39098**

**Jerusalem, Israel**

(Address of Principal Executive Offices) (Zip Code)

**+ 972-2-566-0001**

(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

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 July 4, 2017, there were 13,320,962 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 May 31, 2017, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.561 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 MAY 31, 2017

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**ORAMED PHARMACEUTICALS INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

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

(UNAUDITED)

	May 31, 2017	August 31, 2016
Assets		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 1,733	\$ 3,907
Short-term deposits	21,400	24,254
Marketable securities	3,072	2,855
Restricted cash	16	16
Prepaid expenses and other current assets	127	198
Total current assets	26,348	31,230
<b>LONG-TERM ASSETS:</b>		
Long-term deposits and investment	12,005	11,043
Marketable securities	1,409	530
Amounts funded in respect of employee rights upon retirement	13	11
Property and equipment, net	17	16
Total long-term assets	13,444	11,600
Total assets	\$ 39,792	\$ 42,830
Liabilities and stockholders' equity		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 2,526	\$ 1,411
Deferred revenues	2,449	2,162
Related parties	61	48
Total current liabilities	5,036	3,621
<b>LONG-TERM LIABILITIES:</b>		
Deferred revenues	14,455	12,604
Employee rights upon retirement	18	14
Provision for uncertain tax position	11	11
Other liabilities	462	390
Total long-term liabilities	14,946	13,019
<b>COMMITMENTS</b> (note 2)		
<b>STOCKHOLDERS' EQUITY:</b>		

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Common stock, \$0.012 par value (30,000,000 authorized shares; 13,319,172 and 13,183,425 shares issued and outstanding as of May 31, 2017 and August 31, 2016, respectively)	159	157
Additional paid-in capital	72,954	71,943
Accumulated other comprehensive income	497	106
Accumulated loss	(53,800)	(46,016 )
Total stockholders' equity	19,810	26,190
Total liabilities and stockholders' equity	\$39,792	\$ 42,830

**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)

	Nine months ended		Three months ended	
	May 31, 2017	May 31, 2016	May 31, 2017	May 31, 2016
REVENUES	\$ (1,838	) \$ (288	) \$ (617	) \$ (163
COST OF REVENUES	187	12	-	8
RESEARCH AND DEVELOPMENT EXPENSES	7,745	4,914	2,267	1,710
GENERAL AND ADMINISTRATIVE EXPENSES	1,824	1,833	505	555
OPERATING LOSS	7,918	6,471	2,155	2,110
FINANCIAL INCOME	(599	) (330	) (210	) (137
FINANCIAL EXPENSES	65	63	20	23
LOSS BEFORE TAXES ON INCOME	7,384	6,204	1,965	1,996
TAXES ON INCOME	400	-	-	-
NET LOSS FOR THE PERIOD	7,784	6,204	1,965	1,996
UNREALIZED LOSS (GAIN) ON AVAILABLE FOR SALE SECURITIES	(391	) 244	(286	) (84
TOTAL OTHER COMPREHENSIVE LOSS (INCOME)	(391	) 244	(286	) (84
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	\$ 7,393	\$ 6,448	\$ 1,679	\$ 1,912
LOSS PER SHARE OF COMMON STOCK:				
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	\$0.59	\$0.50	\$0.15	\$0.15
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	13,262,310	12,450,497	13,300,937	13,118,611

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



**ORAMED PHARMACEUTICALS INC.****CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

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

(UNAUDITED)

	Common Stock Shares	\$	Additional paid-in capital	Accumulated other comprehensive income	Accumulated loss	Total stockholders' equity
BALANCE AS OF AUGUST 31, 2016	13,183	\$ 157	\$ 71,943	\$ 106	\$ (46,016 )	\$ 26,190
CHANGES DURING THE NINE-MONTH PERIOD ENDED MAY 31, 2017:						
SHARES ISSUED FOR SERVICES	8	*	51	-	-	51
EXERCISE OF OPTIONS	64	1	319	-	-	320
STOCK-BASED COMPENSATION	64	1	641	-	-	642
NET LOSS	-	-	-	-	(7,784 )	(7,784 )
OTHER COMPREHENSIVE INCOME	-	-	-	391	-	391
BALANCE AS OF MAY 31, 2017	13,319	\$ 159	\$ 72,954	\$ 497	\$ (53,800 )	\$ 19,810

\* 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)

	Nine months ended	
	May 31,	May 31,
	2017	2016
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(7,784 )	\$(6,204 )
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	4	3
Exchange differences and interest on deposits and held to maturity bonds	(109 )	(120 )
Stock-based compensation	642	590
Shares issued for services	51	81
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	71	(294 )
Accounts payable, accrued expenses and related parties	1,128	(301 )
Deferred revenues	2,138	4,095
Liability for employee rights upon retirement	4	2
Other liabilities	72	-
Total net cash used in operating activities	(3,783 )	(2,148 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(5 )	(9 )
Purchase of short-term deposits	(2,057 )	(6,511 )
Purchase of long-term deposits	(11,000)	(10,874)
Purchase of held to maturity securities	(2,904 )	(1,775 )
Proceeds from sale of short-term deposits	15,151	8,870
Proceeds from maturity of held to maturity securities	2,105	600
Funds in respect of employee rights upon retirement	(2 )	(1 )
Total net cash provided by (used in) investing activities	1,288	(9,700 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock and vested restricted stock units net of issuance expenses	-	10,594
Proceeds from exercise of warrants and options	320	1,338
Total net cash provided by financing activities	320	11,932
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS</b>	<b>1</b>	<b>5</b>
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>(2,174 )</b>	<b>89</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>3,907</b>	<b>3,213</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$1,733</b>	<b>\$3,302</b>

SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -

Interest received	\$564	\$187
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**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. (“Hadasit”) to acquire the provisional patent related to 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 and its Israeli subsidiary entered into a Technology License Agreement with Hefei Tianhui Incubation 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 closing of the License Agreement was conditioned upon the approval of the Israel Innovation Authority of the Israeli Ministry of Economy & Industry ("IIA"), which was received on December 21, 2015.

The initial payment of \$3,000 was received in January 2016 and the second and third payments of \$6,500 and \$4,000, respectively, were received in July 2016 following the achievement of certain milestones and the fourth milestone payment of \$4,000 was received in October 2016.

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.

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. Given the Company's continuing involvement through the expected product submission (June 2023), amounts received relating to the License Agreement are recognized over the period from which the Company is entitled to the respective payment, and the expected product submission date using a time-based model approach over the periods that the fees are earned.

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.

Amounts that were allocated to the License Agreement as of May 31, 2017 aggregated \$19,383, all of which were received through the balance sheet date. Through May 31, 2017, the Company recognized revenue in the amount of \$2,479, and deferred the remaining amount of \$16,904.

**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):

**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. Continued operation of the Company is contingent upon obtaining sufficient funding until it becomes profitable. 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.

**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 total number of common stock options, warrants and RSUs excluded from the calculation of diluted net loss was 1,874,786 and 2,740,656 for the nine month periods ended May 31, 2017 and 2016, respectively, and 1,523,869 and 2,584,518 for the three month periods ended May 31, 2017 and 2016, respectively, because the effect would be anti-dilutive.



**c. Condensed Consolidated Financial Statements Preparation**

The condensed consolidated financial statements included herein have been prepared in accordance with U.S. GAAP and 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, 2016 (the "2016 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 2016 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):

**d. Newly issued and recently adopted Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (“FASB”) issued guidance on revenue from contracts with customers that will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle is that an entity will recognize revenue upon the transfer of goods or services to customers in an amount that the entity expects to be entitled to in exchange for those goods or services. 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 for the interim and annual periods beginning on or after December 15, 2017 (early adoption is permitted for the interim and annual periods beginning on or after December 15, 2016). The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

**NOTE 2 - COMMITMENTS:**

In March 2011, the Subsidiary sold shares of its investee company, Entera Bio Ltd. (“Entera”) to D.N.A Biomedical Solutions Ltd. (“D.N.A”), retaining a 3% interest as of March 2011, which is accounted for as a cost method investment (amounting to \$1). In consideration for the shares sold to D.N.A, the Company received, among other payments, 4,202,334 ordinary shares of D.N.A (see also note 4).

As part of this agreement, the Subsidiary entered into a patent transfer agreement according to which, the Subsidiary assigned to Entera all of its right, title and interest in and to the patent application 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 May 31, 2017, Entera had not yet realized any revenues and had not paid any royalties to the

Subsidiary.

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.

**ORAMED PHARMACEUTICALS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

(UNAUDITED)

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

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

The annual lease payment will be New Israeli Shekel (“NIS”) 119,000 (\$33) from October 2016 through September 2018 and NIS 132,000 (\$36) from October 2018 through September 2021, and will be linked to the increase in the Israeli consumer price index (“CPI”) (as of May 31, 2017, the future lease payments until the expiration of the lease agreement will be \$156, based on the exchange rate as of May 31, 2017).

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 for process development and production of its capsules and on November 24, 2016 and April 3, 2017 into amendments to such agreement with a vendor in an amount of up to Swiss Franc (“CHF”) 880,000 (\$879), CHF 485,000 (\$501) of which was recognized through May 31, 2017.

**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 \$1,200 during the term of the engagement and based on achievement of certain milestones, of which \$1,163 was recognized through May 31, 2017.

**e.** On May 31, 2016, the Company entered into a consulting agreement with a third party advisor for a period of one year, pursuant to which such advisor will provide investor relations services and will be entitled to receive a monthly cash fee and 10,000 shares of the Company’s common stock that will be issued in four equal quarterly installments commencing August 1, 2016. As of May 31, 2017, the Company had issued to such advisor 10,000 shares. The fair value of the shares at the grant date was \$72.

On May 3, 2017, the Company entered into a consulting agreement with the same third party advisor for a period of additional year, pursuant to which such advisor will provide investor relations services and will be entitled to receive a monthly cash fee and 10,000 shares of the Company's common stock that will be issued in four equal quarterly installments commencing August 1, 2017. As of May 31, 2017, the Company had not issued to such advisor any shares in connection with this agreement.

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 (\$2,630), of which €800,000 (\$892) is a non-refundable fee to be paid within 12 months from the effective date, and €550,000 (\$597) of which was recognized in research and development through May 31, 2017. The remaining fee will be paid over the term of the engagement and will be based on achievement of certain milestones.

**ORAMED PHARMACEUTICALS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

(UNAUDITED)

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

On March 3, 2014, the Subsidiary entered into a Master Service Agreement with a vendor for the process development and production of one of its oral capsule ingredients in the amount of \$311, \$175 of which was **g.** recognized through May 31, 2017, and bonus payments of up to \$600 that will be paid upon achieving certain milestones, as described in the agreement, none of which was recognized through May 31, 2017.

On July 24, 2016, the Subsidiary entered into a General Technical Agreement with the same vendor, for the scale-up process development and production of the same 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, \$3,263 of which were recognized in research and development through May 31, 2017. This agreement is part of the requirements of the License Agreement as described in note 1.

**h.** On September 21, 2016, the Subsidiary entered into a Clinical Research Organization Service Agreement with a third party to retain it as a Clinical Research Organization (“CRO”) for its Phase 2a dose finding clinical trial for an oral insulin capsule for type 2 diabetes patients, which began in the fourth quarter of calendar year 2016. As consideration for its services, the Subsidiary will pay the CRO a total amount of approximately \$819 during the term of the engagement and based on achievement of certain milestones, all of which was recognized through May 31, 2017.

**i.** 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 for type 2 and type 1 diabetes patients. 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 \$426 was recognized through May 31, 2017.

**ORAMED PHARMACEUTICALS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

(UNAUDITED)

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

**j.** Grants from the Bio-Jerusalem Fund  
("Bio-Jerusalem")

The Subsidiary is committed to pay royalties to Bio-Jerusalem on proceeds from future sales at a rate of 4% and up to 100% of the amount of the grant received (Israeli CPI linked) at the total amount of \$65. The Company received no grants from Bio-Jerusalem since fiscal year 2013.

Royalty expenses for the nine month period ended May 31, 2017 of \$47 are included in cost of revenues. As of May 31, 2017, the Subsidiary had realized revenues from its related project in the amount of \$2,097.

**k.** Grants from the IIA

Under the terms of the Company's funding from the IIA, royalties of 3.5% 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 May 31, 2017 was \$2,194.

Royalty expenses for the nine month period ended May 31, 2017 of \$140 are included in cost of revenues and will be paid over the term of the License Agreement in accordance with the revenue recognized from the related project. As of May 31, 2017, the Subsidiary had realized revenues from its project in the amount of \$2,097.



**ORAMED PHARMACEUTICALS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

(UNAUDITED)

**NOTE 3 - FAIR VALUE:**

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability 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 May 31, 2017, the assets or liabilities measured at fair value are comprised of available for sale equity securities (Level 1).

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible.

As of May 31, 2017, the carrying amount of cash and cash equivalents, short-term deposits and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term maturities of these instruments.

As of May 31, 2017, the carrying amount of long-term deposits approximates their fair values due to the stated interest rates which approximate market rates.

The fair value of held to maturity bonds as presented in note 4 was based on a Level 1 measurement.

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

**ORAMED PHARMACEUTICALS INC.**

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(UNAUDITED)

**NOTE 4 - MARKETABLE SECURITIES:**

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

**a. Composition:**

	May 31, 2017	August 31, 2016
Short-term:		
D.N.A (see b below)	\$1,092	\$ 701
Held to maturity bonds (see c below)	1,980	2,154
	\$3,072	\$ 2,855
Long-term:		
Held to maturity bonds (see c below)	\$1,409	\$ 530

**b. D.N.A**

The investment in D.N.A is reported at fair value, with unrealized gains and losses, recorded as a separate component of other comprehensive income in equity until realized. Unrealized losses that are considered to be other-than-temporary are charged to statement of operations as an impairment charge and are included in the consolidated statement of operations under impairment of available-for-sale securities.

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

As of May 31, 2017, the Company owns approximately 8.7% of D.N.A's outstanding ordinary shares.

The cost of the securities as of each of May 31, 2017 and August 31, 2016 is \$595.

**ORAMED PHARMACEUTICALS INC.**

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(UNAUDITED)

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

**c. Held to maturity securities**

The amortized cost and estimated fair value of held-to-maturity securities at May 31, 2017, are as follows:

	May 31, 2017		
	Amortized cost	Gross unrealized losses	<b>Estimated fair value</b>
Short-term:			
Commercial bonds	\$ 1,951	\$ (1 )	\$ 1,950
Accrued interest	29	-	29
Long-term	1,409	-	1,409
	\$ 3,389	\$ (1 )	\$ 3,388

As of May 31, 2017, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, \$1,409, and the yield to maturity rates vary between 1.40% to 2.05%.

The amortized cost and estimated fair value of held-to-maturity securities at August 31, 2016, are as follows:

	August 31, 2016	
	Amortized cost	Gross unrealized gains

			<b>Estimated fair value</b>
Short-term:			
Commercial bonds	\$2,118	\$ -	\$ 2,118
Accrued interest	36	-	36
Long-term	530	1	531
	\$2,684	\$ 1	\$ 2,685

As of August 31, 2016, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, \$530 and the yield to maturity rates vary between 0.96% to 1.8%.

**ORAMED PHARMACEUTICALS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

(UNAUDITED)

**NOTE 5 - STOCK-BASED COMPENSATION**

On November 1, 2016, the Company granted a total of 70,000 RSUs representing a right to receive 70,000 shares of the Company's common stock to an employee of the Subsidiary. The RSUs vest in 19 installments, consisting of one installment of 9,000 shares on November 1, 2016, 18 equal monthly installments of 1,500 shares each, commencing a. November 30, 2016 and 17,000 shares on each of April 30, 2017 and 2018. The total fair value of these RSUs on the date of grant was \$463, using the quoted closing market share price of \$6.62 on the Nasdaq Capital Market on the date of grant. The Company elected to recognize compensation cost for this award using the accelerated method based on the multiple-option award approach.

On February 9, 2017, options to purchase an aggregate of 27,731 shares of the Company were granted to four members of the Company's Board of Directors as follows: 16,337 options at an exercise price of \$1 per share (lower than the traded market price on the date of grant) and 11,394 options at an exercise price of \$6.23 per share b. (equivalent to the traded market price on the date of grant). The options vested immediately and expire on February 9, 2027. The fair value of all these options on the date of grant was \$135, using the Black Scholes option-pricing model and was based on the following assumptions: Stock price of \$6.23 dividend yield of 0% for all years; expected volatility of 77.29%; risk-free interest rates of 1.88%; and expected term of 5 years.

On March 20, 2017, options to purchase an aggregate of 37,152 of the Company's shares of common stock were granted to a consultant at an exercise price of \$6.00 per share (higher than the traded market price on the date of grant). The options expire on March 20, 2027. The options vest in 24 consecutive equal installments of 1,548 shares c. of common stock each, commencing March 31, 2017. The fair value of these options as of May 31, 2017 was \$248, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 75.52%; risk-free interest rates of 2.21%; and expected term of 9.8 years.

d. On April 2, 2015, the Company entered into an At The Market Issuance Sales Agreement and on April 5, 2017 into an amendment to such agreement (as amended, the "Sales Agreement") with FBR Capital Markets & Co. ("FBR") 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. To date, no shares have been sold under the Sales Agreement.



**ORAMED PHARMACEUTICALS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

(UNAUDITED)

**NOTE 6 - RELATED PARTIES - TRANSACTIONS**

On July 1, 2008, the Subsidiary entered into a consulting agreement with KNR Y Ltd. (“KNRY”), an Israeli company owned by the Company’s Chief Executive Officer (“CEO”), whereby the CEO, through KNR Y, provides services to the Company (the “Consulting Agreement”). The Consulting Agreement is terminable by either party upon 60 days written notice. The Consulting Agreement provides that KNR Y (i) will be paid a gross amount of NIS 50,400 (\$13) per month for the CEO and (ii) will be reimbursed for reasonable expenses incurred in connection with the performance of the Consulting Agreement.

The Consulting Agreement has been amended several times. According to the latest amendment on November 28, 2016, the CEO’s monthly payment was set at NIS 127,570 (\$33) effective January 2017, and an additional cost of \$10 per year was approved for the use and maintenance of the CEO’s car effective November 2016.

**NOTE 7 - SUBSEQUENT EVENT**

On June 30, 2017, the Company granted options to purchase shares of the Company and RSU’s to its related parties as follows:

to the CEO, options to purchase an aggregate of 147,000 shares of the Company, at an exercise price of \$7.77 per share (equivalent to the traded market price on the date of grant). The options shall vest in three equal annual installments of 49,000 each, on each of December 31, 2017, 2018 and 2019, subject to the Company share price reaching the target of \$8.00 per share, \$9.50 per share and \$12.50 per share, respectively. These options expire on June 30, 2027.

b. To the Chief Scientific Officer, 75,000 RSUs representing a right to receive shares of the Company’s common stock which vested immediately, and options to purchase an aggregate of 69,999 shares of the Company, at an exercise

price of \$7.77 per share (equivalent to the traded market price on the date of grant). The options shall vest in three equal annual installments of 23,333 each, on each of December 31, 2017, 2018 and 2019. These options expire on June 30, 2027.

c. To four members of the Company's Board of Directors, options to purchase an aggregate of 67,092 shares of the Company (16,773 options to each director), at an exercise price of \$7.77 per share (equivalent to the traded market price on the date of grant). The options shall vest in three equal annual installments, on each of December 31, 2017, 2018 and 2019. These options expire on June 30, 2027.

d. To a member of the Company's Board of Directors, options to purchase an aggregate of 56,773 shares of the Company at an exercise price of \$7.77 per share (equivalent to the traded market price on the date of grant). The options shall vest in four annual installments, 15,591 shall vest on each of December 31, 2017, 2018 and 2019, and 10,000 shall vest on December 31, 2020. These options expire on June 30, 2027.

## 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 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;

future milestones, conditions and royalties under the license agreement with Hefei Tianhui Incubation of Technologies Co. Ltd., or HTIT;

our research and development plans, including pre-clinical and clinical trials plans, the timing of conclusion of trials and trials' results;

our expectation that in the upcoming years 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, 2016, or our Annual Report, as filed with the Securities and Exchange Commission, or the SEC, on November 25, 2016, as well as those discussed elsewhere in our Annual Report and in this Quarterly Report on Form 10-Q. 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 attempts 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***

We completed a Phase IIb clinical trial on 180 type 2 adult diabetic patients that was conducted in 33 sites in the United States. This double-blind, randomized, 28-day dosing clinical trial was conducted under an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA. The clinical trial, designed to assess the safety and efficacy of our oral insulin capsule, or ORMD-0801, investigated ORMD-0801 over a 28 day treatment period and had statistical power to give us greater insight into the drug's efficacy. The trial was initiated in June 2015, was completed during April 2016 and indicated a statistically significant lowering of blood glucose levels versus placebo across several endpoints, with no adverse health issues related to the drug. The trial successfully met its primary and most of its secondary and exploratory endpoints for safety and efficacy.

In February 2017, we completed a Phase IIa dose finding clinical trial which was initiated in October 2016. This randomized, double-blind trial was conducted on 32 type 2 adult diabetic patients in order to better define the optimal dosing of ORMD-0801 moving forward. The results of the trial indicated an excellent safety profile and potentially meaningful efficacy of ORMD-0801, as the efficacy data suggest ORMD-0801 improves glucose control, and that dosing two or three times per day provides additional benefit.

In March 2017, we initiated a six month toxicology study to allow for the use of our oral insulin capsule for a longer period than previously performed, in preparation for our future Phase III clinical trial for type 2 and type 1 diabetes. We anticipate receiving the final report of this study in the fourth quarter of calendar year 2017.

Following our successfully completed Phase IIb trial of our oral insulin capsule ORMD-0801 in the treatment of type 2 diabetes, an End-of-Phase II meeting with the FDA is expected to take place on August 31, 2017, in order to review the Phase IIb results with the FDA and seek guidance from the regulatory agency on the clinical design and protocol of our upcoming Phase III trial, in preparation for filing a New Drug Application.

In September 2013, we submitted a pre-IND package to the FDA for ORMD-0901, our oral exenatide capsule, for a Phase II clinical trial on healthy volunteers and type 2 diabetic patients. In August 2015, we began an ex-US non-FDA clinical trial on type 2 diabetic patients. The trial was completed during the second quarter of calendar year 2016 and indicated positive results as it showed ORMD-0901 to be safe and well tolerated and also demonstrated encouraging efficacy data. We completed a toxicology study in March 2017 and anticipate receiving the final report during the third quarter of calendar year 2017 and expect to file an IND and move directly into a pharmacokinetics study followed by a large Phase II trial in the United States.

During the first quarter of calendar 2017, we began developing a new drug candidate, a weight loss treatment in the form of an oral leptin capsule, and 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 table below gives an overview of our product pipeline (calendar quarters):

	<b>Phase I</b>	<b>Phase II</b>	<b>Phase III</b>	<b>Timeline</b>
<b>ORMD-0801</b> oral insulin				Q1 '14: Phase IIa completed
				Q2 '16: Phase IIb multi-center study completed
	Type 2 diabetes			Q1 '17: Phase IIa - dose finding study completed
				Q4 '17: Phase III multi-center study projected initiation
				Q3 '14: Phase IIa study completed
	Type 1 diabetes			Q1 '18: Phase III study projected initiation
<b>ORMD-0901</b> oral GLP-1				Q2 '16: Phase Ib ex-US study completed
	Type 2 diabetes			Q1 '17: Toxicology study completed
				Q4 '17: Clinical study projected initiation

*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 these 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 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 approximately \$37.5 million, of which \$3 million is payable immediately, \$8 million will be 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 final expiration of the last-to-expire licensed patent 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. The initial payment of \$3 million was received in January 2016. Following achievement of certain milestones, the second and third milestone payments of \$6.5 million and \$4 million, respectively, were received in July 2016, and the fourth milestone payment of \$4 million was received in October 2016.



On November 30, 2015, we also entered into a separate Stock 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 nine and three month periods ended May 31, 2017 and 2016*

The following table summarizes certain statements of operations data of the Company for the nine and three month periods ended May 31, 2017 and 2016 (in thousands of dollars except share and per share data):

	Nine months ended		Three months ended	
	May 31, 2017	2016	May 31, 2017	2016
Revenues	\$(1,838	) \$(288	) \$(617	) \$(163
Cost of revenues	187	12	-	8
Research and development expenses	7,745	4,914	2,267	1,710
General and administrative expenses	1,824	1,833	505	555
Financial income, net	(534	) (267	) (190	) (114
Taxes on income	400	-	-	-
Net loss for the period	\$7,784	\$6,204	\$1,965	\$1,996
Loss per common share - basic and diluted	\$(0.59	) \$(0.50	) \$(0.15	) \$(0.15
Weighted average common shares outstanding	13,262,310	12,450,497	13,300,937	13,118,611

### *Revenues*

Revenues consist of proceeds related to the License Agreement that are recognized over the period from which we are entitled to each milestone payment through June 2023.

During 2016 and the first quarter of 2017, we received milestone payments in the amount of \$17,500,000, resulting in an increase in the reported revenues as follows:

Revenues for the nine month period ended May 31, 2017 increased by 538% to \$1,838,000 from \$288,000 for the nine month period ended May 31, 2016.

Revenues for the three month period ended May 31, 2017 increased by 279% to \$617,000 from \$163,000 for the three month period ended May 31, 2016.

***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 the revenue recognition accounting policy and the Israeli Law for the Encouragement of Industrial Research and Development, 1984, as amended.

Cost of revenues for the nine month period ended May 31, 2017 increased to \$187,000 from \$12,000 for the nine month period ended May 31, 2016. The increase is attributable to additional milestone payments received during the period in connection with the License Agreement.

No cost of revenues was recognized during the three month period ended May 31, 2017 compared to cost of revenues of \$8,000 for the three month period ended May 31, 2016. The decrease is due to no additional milestone payments having been received during the three month period ended May 31, 2017.

***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, payroll taxes, 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 nine month period ended May 31, 2017 increased by 58% to \$7,745,000, from \$4,914,000 for the nine month period ended May 31, 2016. The increase is mainly attributable to expenses related to process development and production of our capsules and the required ingredients, as well as progress in toxicology studies, and is partially offset by a decrease in clinical trials due to completion of our Phase IIb clinical trial. Stock-based compensation costs for the nine month period ended May 31, 2017 totaled \$456,000, as compared to \$288,000 during the nine month period ended May 31, 2016. The increase is mainly attributable to awards granted to employees and a consultant during fiscal year 2017 and is partially offset by a decrease due to the progress in amortization of awards granted in prior periods.

Research and development expenses for the three month period ended May 31, 2017 increased by 33% to \$2,267,000, from \$1,710,000 for the three month period ended May 31, 2016. The increase is mainly attributable to expenses related to process development and production of our capsules and the required ingredients as well as to progress in toxicology studies and preparations for our Phase III clinical trial, and is partially offset by a decrease in clinical trials due to completion of our Phase IIb clinical trial. Stock-based compensation costs for the three month period ended May 31, 2017 totaled \$147,000, as compared to \$38,000 during the three month period ended May 31, 2016. The increase is mainly attributable to awards granted to employees and a consultant during fiscal year 2017 and is partially offset by a decrease due to the progress in amortization of awards granted in prior periods.

*Government grants*

In the nine month periods ended May 31, 2017 and 2016, we did not recognize any research and development grants. As of May 31, 2017, we incurred liabilities to pay royalties to the Israel Innovation Authority of the Israeli Ministry of Economy & Industry of \$571,000.

*General and administrative expenses*

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

General and administrative expenses for the nine month period ended May 31, 2017 decreased by 0.5% to \$1,824,000 from \$1,833,000 for the nine month period ended May 31, 2016. The decrease in costs related to general and administrative activities during the nine month period ended May 31, 2017 is mainly due to a decrease in stock-based compensation costs and is partially offset by an increase in salaries and consulting expenses. Stock-based compensation costs for the nine month period ended May 31, 2017 totaled \$186,000, as compared to \$302,000 during the nine month period ended May 31, 2016. The decrease is mainly attributable to the progress in amortization of awards granted in prior periods and is partially offset by an increase due to awards granted to directors and employees during the period.

General and administrative expenses for the three month period ended May 31, 2017 decreased by 9% to \$505,000 from \$555,000 for the three month period ended May 31, 2016. The decrease in costs related to general and administrative activities during the three month period ended May 31, 2017 is mainly attributable to a decrease in stock-based compensation costs. Stock-based compensation costs for the three month period ended May 31, 2017 totaled \$1,000, as compared to \$67,000 during the three month period ended May 31, 2016. The decrease is mainly attributable to the progress in amortization of awards granted in prior periods.

*Financial income, net*

Net financial income increased by 100% from net income of \$267,000 for the nine month period ended May 31, 2016 to net income of \$534,000 for the nine month period ended May 31, 2017. The increase is mainly attributable to an increase in income from bank deposits and held to maturity bonds as a result of the increase in interest rates and cash

and investment balances.

During the three month period ended May 31, 2017, net financial income increased by 67% to \$190,000 from \$114,000 for the three month period ended May 31, 2016. This increase is mainly attributable to an increase in income from bank deposits and held to maturity bonds as a result of the increase in interest rates and cash and investment balances.

***Taxes on income***

We had taxes on income of \$400,000 for the nine month period ended May 31, 2017 as compared to no taxes on income for the nine month period ended May 31, 2016. The increase is due to withholding tax deducted from revenues received from the License Agreement, since according to the Company's estimations, the withholding tax is not expected to be utilized in the next five years. No taxes on income were recognized for the three month periods ended May 31, 2017 and 2016.

*Other comprehensive income*

Unrealized gains on available for sale securities for the nine month period ended May 31, 2017 of \$391,000, compared to losses of \$244,000 for the nine month period ended May 31, 2016, resulted from the increase in fair value of the ordinary shares of D.N.A Biomedical Solutions Ltd., or D.N.A, that we hold.

Unrealized gains on available for sale securities for the three month periods ended May 31, 2017 and 2016 of \$286,000 and \$84,000, respectively, resulted from the increase in fair value of the ordinary shares of D.N.A that we hold.

*Liquidity and capital resources*

From inception through May 31, 2017, we have incurred losses in an aggregate amount of \$53,800,000. 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 \$56,054,000, net of transaction costs. During that period, we also received cash consideration of \$3,639,000 from the exercise of warrants and options. We will seek to obtain additional financing through similar sources in the future, as needed. As of May 31, 2017, we had \$1,733,000 of available cash, \$33,405,000 of short-term and long-term bank deposits and \$4,481,000 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, including the investment and milestone payments by HTIT, 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 May 31, 2017, our total current assets were \$26,348,000 and our total current liabilities were \$5,036,000. On May 31, 2017, we had a working capital surplus of \$21,312,000 and an accumulated loss of \$53,800,000. As of August 31, 2016, our total current assets were \$31,230,000 and our total current liabilities were \$3,621,000. On August 31, 2016, we had a working capital surplus of \$27,609,000 and an accumulated loss of \$46,016,000. The decrease in working capital from August 31, 2016 to May 31, 2017 was primarily due to the cash used in operating activities and the investment of a portion of the milestone payments received in accordance with the License Agreement in long-term deposits and marketable securities.

During the nine month period ended May 31, 2017, cash and cash equivalents decreased to \$1,733,000 from the \$3,907,000 reported as of August 31, 2016, which is due to the reasons described below.

Operating activities used cash of \$3,783,000 in the nine month period ended May 31, 2017, as compared to \$2,148,000 used in the nine month period ended May 31, 2016. Cash used in operating activities in the nine month period ended May 31, 2017 primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by changes in deferred revenues due to the License Agreement and changes in accounts payable, accrued expenses and related parties, while cash used in operating activities in the nine month period ended May 31, 2016 primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by deferred revenues and stock-based compensation amounts.

Investing activities provided cash of \$1,288,000 in the nine month period ended May 31, 2017, as compared to \$9,700,000 used in the nine month period ended May 31, 2016. Cash provided by investing activities in the nine month period ended May 31, 2017 consisted primarily of proceeds from sale of short-term deposits, while cash used in investing activities in the nine month period ended May 31, 2016 consisted primarily of the purchase of short-term and long-term bank deposits, as well as the purchase of marketable securities.



Financing activities provided cash of \$320,000 in the nine month period ended May 31, 2017, as compared to \$11,932,000 that were provided in the nine month period ended May 31, 2016. Financing activities in the nine month period ended May 31, 2017 consisted of proceeds from the exercise of options while financing activities in the nine month period ended May 31, 2016 consisted of proceeds from our issuance of common stock and proceeds from exercise of warrants and options.

#### *Off-balance sheet arrangements*

As of May 31, 2017, 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.

#### *Significant Accounting Policies*

Our significant accounting policies are described in the notes to the consolidated financial statements as of August 31, 2016 included in our Annual Report.

#### **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 three month period ended May 31, 2017. 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 May 31, 2017. 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 May 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

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

On May 1, 2017, 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 and a Stock Purchase Agreement, dated May 18, 2016 between us and Corporate Profile. We issued these shares pursuant to an exemption from registration contained in Section 4(a)(2) of the Securities Act of 1933, as amended.

### ITEM 5 - OTHER INFORMATION

In July 2017, we received approval from the Israel Securities Authority and the Tel-Aviv Stock Exchange, or the TASE, to begin trading our common stock on the TASE. We expect that our common stock will begin trading on the TASE on July 12, 2017 under the symbol “ORMP”. Our common stock will continue to trade on The NASDAQ Stock Market LLC under the symbol “ORMP”.

### ITEM 6 - EXHIBITS

Number Exhibit

- 31.1\* Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 31.2\* Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
- 32.1\*\* Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
- 32.2\*\* Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
- 101.1\* The following financial statements from the Company’s Quarterly Report on Form 10-Q for the quarter ended May 31, 2017, 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: July 5, 2017 By: /s/ Nadav Kidron  
Nadav Kidron  
President and Chief Executive Officer

Date: July 5, 2017 By: /s/ Yifat Zommer  
Yifat Zommer  
Chief Financial Officer  
(Principal Financial and Accounting Officer)