

ORAMED PHARMACEUTICALS INC.

Form 10-Q

July 12, 2018

**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, 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) (Zip Code)

**10019**

**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 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 11, 2018, there were 17,362,615 shares of the issuer's common stock, \$0.012 par value per share, outstanding.



**ORAMED PHARMACEUTICALS INC.**

**FORM 10-Q**

**TABLE OF CONTENTS**

<b>PART I - FINANCIAL INFORMATION</b>	1
ITEM 1 - FINANCIAL STATEMENTS	1
ITEM 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	16
ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	24
ITEM 4 - CONTROLS AND PROCEDURES	24
<b>PART II - OTHER INFORMATION</b>	25
ITEM 2 - UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS	25
ITEM 6 - EXHIBITS	25

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, 2018, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.566 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, 2018

**TABLE OF CONTENTS**

	<b>Page</b>
<b>CONDENSED CONSOLIDATED FINANCIAL STATEMENTS:</b>	
Balance sheets	2
Statements of comprehensive loss	3
Statement of changes in stockholders' equity	4
Statements of cash flows	5
Notes to financial statements	6-15

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

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

(UNAUDITED)

	May 31, 2018	August 31, 2017
Assets		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$3,673	\$3,969
Short-term deposits	15,990	13,293
Marketable securities	3,710	2,860
Restricted cash	-	16
Prepaid expenses and other current assets	209	159
Total current assets	23,582	20,297
<b>LONG-TERM ASSETS:</b>		
Long-term deposits and investment	8,752	16,232
Marketable securities	2,293	2,151
Amounts funded in respect of employee rights upon retirement	15	14
Property and equipment, net	17	18
Total long-term assets	11,077	18,415
Total assets	\$34,659	\$38,712
Liabilities and stockholders' equity		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$3,143	\$2,716
Deferred revenues	2,449	2,449
Payable to related parties	45	-
Total current liabilities	5,637	5,165
<b>LONG-TERM LIABILITIES:</b>		
Deferred revenues	12,005	13,837
Employee rights upon retirement	19	18
Provision for uncertain tax position	11	11
Other liabilities	330	443
Total long-term liabilities	12,365	14,309
<b>COMMITMENTS</b> (note 2)		

STOCKHOLDERS' EQUITY:

Common stock, \$0.012 par value (30,000,000 authorized shares; 14,469,163 and 13,668,530 shares issued and outstanding as of May 31, 2018 and August 31, 2017, respectively)	172	163
Additional paid-in capital	82,584	75,170
Accumulated other comprehensive income	198	401
Accumulated loss	(66,297)	(56,496)
Total stockholders' equity	16,657	19,238
Total liabilities and stockholders' equity	\$34,659	\$38,712

**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, 2018	May 31, 2017	May 31, 2018	May 31, 2017
REVENUES	\$ 1,832	\$ 1,838	\$ 617	\$ 617
COST OF REVENUES (INCOME)	(86 )	187	(86 )	-
RESEARCH AND DEVELOPMENT EXPENSES	9,245	7,745	4,194	2,267
GENERAL AND ADMINISTRATIVE EXPENSES	3,050	1,824	1,043	505
OPERATING LOSS	10,377	7,918	4,534	2,155
FINANCIAL INCOME	648	599	209	210
FINANCIAL EXPENSES	72	65	29	20
LOSS BEFORE TAXES ON INCOME	9,801	7,384	4,354	1,965
TAXES ON INCOME	-	400	-	-
NET LOSS FOR THE PERIOD	9,801	7,784	4,354	1,965
UNREALIZED LOSS (INCOME) ON AVAILABLE FOR SALE SECURITIES	203	(391 )	115	(286 )
TOTAL OTHER COMPREHENSIVE LOSS (INCOME)	203	(391 )	115	(286 )
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	\$ 10,004	\$ 7,393	\$ 4,469	\$ 1,679
LOSS PER SHARE OF COMMON STOCK:				
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	\$ 0.68	\$ 0.59	\$ 0.30	\$ 0.15
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	14,401,623	13,262,310	14,518,878	13,300,937

**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

(UNAUDITED)

	Common Stock Shares	\$	Additional paid-in capital	Accumulated other comprehensive income	Accumulated loss	Total stockholders' equity
	In thousands					
BALANCE AS OF AUGUST 31, 2017	13,668	\$ 163	\$ 75,170	\$ 401	\$ (56,496 )	\$ 19,238
CHANGES DURING THE NINE-MONTH PERIOD ENDED MAY 31, 2018:						
SHARES ISSUED FOR SERVICES	8	*	60	-	-	60
ISSUANCE OF COMMON STOCK, NET	573	7	5,157	-	-	5,164
EXERCISE OF WARRANTS AND OPTIONS	189	2	995	-	-	997
STOCK-BASED COMPENSATION	32	*	1,202	-	-	1,202
NET LOSS	-	-	-	-	(9,801 )	(9,801 )
OTHER COMPREHENSIVE LOSS	-	-	-	(203 )	-	(203 )
BALANCE AS OF MAY 31, 2018	14,470	\$ 172	\$ 82,584	\$ 198	\$ (66,297 )	\$ 16,657

\*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,	
	2018	2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(9,801 )	\$(7,784 )
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	4	4
Exchange differences and interest on deposits and held to maturity bonds	48	(109 )
Stock-based compensation	1,202	642
Shares issued for services	60	51
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(50 )	71
Accounts payable, accrued expenses and related parties	472	1,128
Deferred revenues	(1,832 )	2,138
Liability for employee rights upon retirement	1	4
Other liabilities	(113 )	72
Total net cash used in operating activities	(10,009)	(3,783 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(3 )	(5 )
Purchase of short-term deposits	(4,351 )	(2,057 )
Purchase of long-term deposits	(5,540 )	(11,000)
Purchase of held to maturity securities	(2,879 )	(2,904 )
Proceeds from sale of short-term deposits	14,716	15,151
Proceeds from maturity of held to maturity securities	1,607	2,105
Funds in respect of employee rights upon retirement	(1 )	(2 )
Total net cash provided by investing activities	3,549	1,288
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net of issuance costs	5,164	-
Proceeds from exercise of warrants and options	997	320
Total net cash provided by financing activities	6,161	320
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH</b>	<b>3</b>	<b>1</b>
<b>DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(296 )</b>	<b>(2,174 )</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>3,969</b>	<b>3,907</b>

CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$3,673	\$1,733
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS - Interest received	\$592	\$564

**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 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 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.

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.

Amounts that were allocated to the License Agreement as of May 31, 2018 aggregated \$19,383, all of which were received through the balance sheet date. Through May 31, 2018, the Company recognized revenue in the amount of \$4,929, and deferred the remaining amount of \$14,454.

The following table sets forth the transactions in deferred revenues balances for the nine-month period ended May 31, 2018 and the year ended August 31, 2017:

	Nine months ended May 31, 2018	Year ended August 31, 2017
Deferred revenue at the beginning of period	\$ 16,286	\$ 14,766
Amounts received	-	4,000
Amounts due to the Company	-	(24 )
Revenue recognized	(1,832 )	(2,456 )
Deferred revenue at the end of period	14,454	16,286

Edgar Filing: ORAMED PHARMACEUTICALS INC. - Form 10-Q

Less – current deferred revenue portion	(2,449 )	(2,449 )
Non-current deferred revenue portion	\$ 12,005	\$ 13,837

7

**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 weighted average number of common stock options, warrants and RSUs excluded from the calculation of diluted net loss was 1,429,046 and 1,874,786 for the nine-month periods ended May 31, 2018 and 2017, respectively, and 1,474,042 and 1,523,869 for the three-month periods ended May 31, 2018 and 2017, respectively.



**c. 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 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, 2017 (the “2017 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 2017 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 Accounting Standards Update (“ASU”) No. 2014-09 (Topic 606) “Revenue from Contracts with Customers” that will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle of this ASU 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 in annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. The Company will implement the guidance for the annual period ending on August 31, 2019. The Company does not expect the implementation of this guidance to have an impact on its consolidated financial statements.

In January 2016, the FASB issued guidance on recognition and measurement of financial assets and financial liabilities (ASU No. 2016-01) that will supersede 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 will be effective September 1, 2018. The Company is currently evaluating the impact of the guidance on its consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07 (Topic 718) “Improvements to Nonemployee Share-Based Payment Accounting” that expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for

certain exemptions specified in the amendment. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. 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 (117,000 ordinary shares after a stock split), which is accounted for as a cost method investment (amounting to \$1). On June 28, 2018, Entera's shares began trading on **a.** the Nasdaq Capital Market and the closing price per share on such date was \$6.28; therefore, the Company will measure the investment at fair value from such date, since it now has a readily determinable fair value. 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, 2018, 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 is New Israeli Shekel (“NIS”) 119,000 (\$33) from October 2016 through September 2018 and NIS 132,000 (\$37) from October 2018 through September 2021, and is linked to the increase in the Israeli consumer price index (“CPI”) (as of May 31, 2018, the future lease payments until the expiration of the lease agreement will be \$122, based on the exchange rate as of May 31, 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 into amendments to such agreement in an amount of up to Swiss Franc (“CHF”) 1,000,000 (\$1,061), CHF 665,000 (\$675) of which was recognized through May 31, 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 through May 31, 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 (\$2,730), of which €1,375,615 (\$1,580) was recognized in research and development through May 31, 2018.

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, \$4,079 of which was recognized in research and development expenses through May 31, 2018. This agreement is part of the requirements of the License Agreement as described in note 1.

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 \$857 was recognized through May 31, 2018.

**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 May 3, 2017, the Company entered into a consulting agreement with a third party advisor for a period of one year, pursuant to which such advisor provided investor relations services and received a monthly cash fee and **h.** 10,000 shares of the Company's common stock that were issued in four equal quarterly installments commencing August 1, 2017. As of May 31, 2018, the Company had issued to such advisor 10,000 shares. The fair value of the shares at the grant date was \$81.

On April 8, 2018, the Company entered into a consulting agreement with the same 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, 2018. As of May 31, 2018, the Company had not issued to such advisor any shares in connection with this agreement.

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 **i.** Subsidiary will pay the vendor a total amount of \$958 during the term of the engagement and based on achievement of certain milestones, \$160 of which was recognized through May 31, 2018.

On December 18, 2017, the Subsidiary entered into an agreement with a vendor for the process development and **j.** 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, \$699 of which was recognized in research and development expenses through May 31, 2018.

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 **k.** 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, \$1,698 of which was recognized through May 31, 2018.

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, \$172 of which was recognized through May 31, 2018.

**m. 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.

**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):

Following an amendment to applicable regulations that was published by the IIA, the royalties rate that the Company is obligated to pay to the IIA was reduced from 3.5% to 3%, and the difference was recognized in cost of revenue.

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, 2018 was \$2,194.

As of May 31, 2018, the royalty expenses which are related to the funded project were recognized in cost of revenues in prior periods.

**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.



Edgar Filing: ORAMED PHARMACEUTICALS INC. - Form 10-Q

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, 2018, 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, 2018, the carrying amount of 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, 2018, 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.

There were no Level 3 items for the nine-month periods ended May 31, 2018 and 2017.

**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, 2018	August 31, 2017
Short-term:		
D.N.A (see b below)	\$793	\$ 996
Held to maturity bonds (see c below)	2,917	1,864
	\$3,710	\$ 2,860
Long-term:		
Held to maturity bonds (see c below)	\$2,293	\$ 2,151

**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. The fair value of those securities is measured at the quoted prices of the securities on the measurement date.

As of May 31, 2018, the Company owns approximately 6.9% of D.N.A's outstanding ordinary shares.

The cost of the securities as of May 31, 2018 and August 31, 2017 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 as of May 31, 2018, are as follows:

	May 31, 2018		
	Amortized cost	Gross unrealized losses	<b>Estimated fair value</b>
Short-term:			
Commercial bonds	\$2,879	\$ (15 )	\$ 2,864
Accrued interest	38	-	38
Long-term	2,293	(28 )	2,265
	\$5,210	\$ (43 )	\$ 5,167

As of May 31, 2018, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, \$2,293, and the yield to maturity rates vary between 1.40% to 1.90%.

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

	August 31, 2017		
	Amortized cost	Gross unrealized losses	<b>Estimated fair value</b>
Short-term:			

Edgar Filing: ORAMED PHARMACEUTICALS INC. - Form 10-Q

Commercial bonds	\$1,823	\$	(1	)	\$ 1,822
Accrued interest	41		-		41
Long-term	2,151		-		2,151
	\$4,015	\$	(1	)	\$ 4,014

As of August 31, 2017, the contractual maturities of debt securities classified as held-to-maturity are as follows: after one year through two years, \$2,151 and the yield to maturity rates vary between 1.30% to 1.87%.

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.

**ORAMED PHARMACEUTICALS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

(UNAUDITED)

**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 May 31, 2018, 575,672 shares were sold under the Sales Agreement for aggregate net proceeds of \$5,189 and an additional 1,162 shares were subsequently sold during June 2018 for aggregate net proceeds of \$9.

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

On July 1, 2008, the Subsidiary entered into two consulting agreements with KNRY Ltd. ("KNRY"), an Israeli company owned by the Chief Scientific Officer (the "CSO"), whereby the Chief Executive Officer (the "CEO") and the CSO, through KNRY, provide services to the Company (the "Consulting Agreements"). The Consulting Agreements are both terminable by either party upon 140 days prior written notice. The Consulting Agreements, as amended, provide that KNRY will be reimbursed for reasonable expenses incurred in connection with performance of the Consulting Agreements and that the monthly consulting fee paid to the CEO and the CSO is NIS 127,570 (\$36) and NIS 80,454 (\$23), respectively.

In addition to the Consulting Agreement, based on a relocation cost analysis prepared by consulting company ORI - Organizational Resources International Ltd., the Company pays for certain direct costs and expenses incurred in connection with the relocation of the CEO to New York, up to an aggregate yearly amount of \$365 in addition to any related taxation.

**NOTE 7 - TAXES ON INCOME:**

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act (the “TCJA”), which among other changes reduced the federal corporate tax rate to 21%. Deferred taxes are determined based on temporary differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The reduction of the tax rate and TCJA had no impact on the net deferred taxes of the Company.

**NOTE 8 - SUBSEQUENT EVENT:**

On July 2, 2018, the Company entered into a Securities Purchase Agreement with each of three investors (the “Purchasers”), pursuant to which the Company agreed to sell, in a registered direct offering (the “Offering”) an aggregate of 2,892,000 units (the “Units”), each Unit consisting of one share of the Company’s common stock, par value \$0.012 per share, and a warrant to purchase one share of common stock at an exercise price of \$7.25 per share (the “Warrants”), to the Purchasers for an offering price of \$6.25 per Unit. The Warrants will be exercisable commencing six months following their issuance for a period of three and one-half years from the date of issuance. The closing of the sale of the Units occurred on July 6, 2018. The net proceeds to the Company from the Offering, after deducting the placement agent’s fees and expenses and the Company’s Offering expenses were approximately \$16,500.

On July 2, 2018, the Company entered into a letter agreement with H.C. Wainwright & Co., LLC (“HCW”), pursuant to which HCW agreed to serve as exclusive placement agent for the Company in any offering of the Company occurring between July 2, 2018 and August 1, 2018. For its services in the Offering, HCW received a fee equal to 7% of the gross proceeds raised in the Offering and a management fee of 1% of the gross proceeds raised in the Offering, up to \$50,000 for non-accountable expenses as well as warrants to purchase up to 115,680 shares of common stock of the Company, exercisable for a period of three and one-half years from the date of issuance and with an exercise price of \$7.8125 per share. Upon the exercise of the Warrants, HCW will receive a fee equal to 7% of the gross proceeds raised as a result of such exercise.

## 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 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 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, 2017, or our Annual Report, as filed with the Securities and Exchange Commission, or the SEC, on November 29, 2017, 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 240 type 2 diabetic patients in multiple centers throughout the U.S. 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 (FPG), post-prandial glucose (PPG levels) during a mixed-meal tolerance test (MMTT) and weight.

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 diabetes patients dosed with ORMD-0801. 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 subjects with type 1 diabetes. Up to 48 subjects will be enrolled, including up to 24 healthy volunteers and 24 subjects with type 1 diabetes.

In August 2017, we had a call with the FDA, regarding ORMD-0801. During the call, the FDA advised that the regulatory pathway for the submission of ORMD-0801 would be a Biologics License Application, or BLA. If approved, the BLA pathway would grant us 12 years of marketing exclusivity for ORMD-0801, from the approval date, and an additional six months of exclusivity may be granted 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 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 a positive safety profile and potentially meaningful efficacy of ORMD-0801, as the efficacy data suggest ORMD-0801 improves glucose control.

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. We anticipate receiving the final report of this study in the third quarter of calendar year 2018.

In April 2016, we completed a Phase IIb clinical trial on 180 type 2 adult diabetic patients that was initiated in June 2015 and conducted in 33 sites in the United States. This double-blind, randomized, 28-day dosing clinical trial was conducted under an IND. The clinical trial, designed to assess the safety and efficacy of our 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 indicated a statistically significant lowering of blood glucose levels versus placebo across several endpoints, with no serious or severe adverse issues related to the drug. The trial successfully met all of its primary and most of its secondary and exploratory endpoints for both safety and efficacy.

Should our Phase IIb three-month dose-ranging clinical trial successfully meet its primary 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 New Drug Application with a potential FDA approval by the second half of calendar year 2023.

### ***Oral GLP-1 Analog***

In August 2015, we began a non-FDA clinical trial outside of the United States on type 2 diabetic patients for ORMD-0901, our oral GLP-1/exenatide capsule. 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 demonstrated encouraging efficacy data. We completed a three-month pre-clinical toxicology study in March 2017 and the final report will be submitted to the FDA with our IND. We expect to file an IND during the third quarter of calendar year 2018 and move directly into a small pharmacokinetics study on healthy volunteers followed by a large Phase II trial on type 2 diabetic patients which will be conducted in the United States under an IND.

### ***Other products***

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 study is projected to initiate in the fourth quarter of calendar year 2018 and be completed during calendar year 2019.

In November 2017, Israel's Ministry of Health approved us to initiate an exploratory clinical study of our oral insulin capsule, ORMD-0801, in patients with nonalcoholic steatohepatitis (NASH). The proposed three-month treatment study will assess the effectiveness of ORMD-0801 in reducing liver fat content, inflammation and fibrosis in patients with NASH. We expect to initiate the study in the third quarter of calendar year 2018 and complete it 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> Type 2 diabetes <b>oral insulin</b>				Q2 '18: Phase IIb 90-day multi-center study initiated (projected completion Q2 '19)  Q1 '20: Phase III study projected initiation (projected completion Q3 '22)
Type 1 diabetes				Q2 '18: Clamp study initiated (projected completion Q4 '18)  Q2 '18: Food effect study initiated (projected completion Q1 '19)  Q1 '20: Phase III projected initiation (projected completion Q3 '22)
<b>ORMD-0901</b> Type 2 diabetes <b>oral GLP-1</b>				Q3 '18: Pharmacokinetics clinical study projected initiation (projected completion Q1 '19)  H1 '19: Phase II projected initiation (projected completion Q4 '20)

#### *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 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 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. Through May 31, 2018, we received aggregate milestone payments of \$17.5 million.

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

**Results of Operations*****Comparison of nine and three month periods ended May 31, 2018 and 2017***

The following table summarizes certain statements of operations data of the Company for the nine and three month periods ended May 31, 2018 and 2017 (in thousands of dollars except share and per share data):

	Nine months ended		Three months ended	
	May 31, 2018	2017	May 31, 2018	2017
Revenues	\$1,832	\$1,838	\$617	\$617
Cost of revenues	(86	) 187	(86	) -
Research and development expenses	9,245	7,745	4,194	2,267
General and administrative expenses	3,050	1,824	1,043	505
Financial income, net	576	534	180	190
Taxes on income	-	400	-	-
Net loss for the period	\$9,801	\$7,784	\$4,354	\$1,965
Loss per common share - basic and diluted	\$0.68	\$0.59	\$0.30	\$0.15
Weighted average common shares outstanding	14,401,623	13,262,310	14,518,878	13,300,937

***Revenues***

Revenues consist of proceeds related to the License Agreement that are recognized over the term of the License Agreement through June 2023.

Revenues for the nine month period ended May 31, 2018 totaled \$1,832,000, consistent with \$1,838,000 for the nine month period ended May 31, 2017.

Revenues for the three month period ended May 31, 2018 totaled \$617,000, consistent with \$617,000 for the three month period ended May 31, 2017.



*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 nine month period ended May 31, 2018 decreased to income of \$86,000 compared to cost of \$187,000 for the nine month period ended May 31, 2017. The decrease is attributed to a decrease in the royalties we are obligated to pay to the Israel Innovation Authority of the Israeli Ministry of Economy & Industry from 3.5% to 3% due to the amendment of the applicable regulations, as well as due to no additional milestone payments having been received during the nine month period ended May 31, 2018.

Cost of revenues for the three month period ended May 31, 2018 decreased to income of \$86,000 compared to no cost of revenues being recognized during the three month period ended May 31, 2017. The decrease is attributed to a decrease in the royalties we are obligated to pay to the Israel Innovation Authority of the Israeli Ministry of Economy & Industry from 3.5% to 3% due to the amendment of the applicable regulations.

*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 nine month period ended May 31, 2018 increased by 19% to \$9,245,000, from \$7,745,000 for the nine month period ended May 31, 2017. The increase is mainly due to expenses related to our Phase IIb three-month treatment clinical trial 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 nine month period ended May 31, 2018 totaled \$438,000, as compared to \$456,000 during the nine month period ended May 31, 2017. 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 employees and a consultant during fiscal years 2018 and 2017.

Research and development expenses for the three month period ended May 31, 2018 increased by 85% to \$4,194,000, from \$2,267,000 for the three month period ended May 31, 2017. The increase is mainly due to expenses related to our Phase IIb three-month treatment clinical trial 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 May 31, 2018 totaled \$142,000, as compared to \$147,000 during the three month period ended May 31, 2017.

*Government grants*

In the nine month periods ended May 31, 2018 and 2017, we did not recognize any research and development grants. As of May 31, 2018, we incurred liabilities to pay royalties to the Israel Innovation Authority of the Israeli Ministry of Economy & Industry of \$406,000.

*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 nine month period ended May 31, 2018 increased by 67% to \$3,050,000 from \$1,824,000 for the nine month period ended May 31, 2017. The increase in costs related to general and administrative activities during the nine month period ended May 31, 2018 is mainly attributable to an increase in stock-based compensation costs and travel expenses related to the relocation of our Chief Executive Officer to New York, where the Company leases an office and has its principal executive office. Stock-based compensation costs for the nine month period ended May 31, 2018 totaled \$765,000, as compared to \$186,000 during the nine month period ended May 31, 2017. The increase is mainly attributable to awards granted to employees and directors during fiscal years 2018 and 2017.

General and administrative expenses for the three month period ended May 31, 2018 increased by 106% to \$1,043,000 from \$505,000 for the three month period ended May 31, 2017. The increase in costs related to general and administrative activities during the three month period ended May 31, 2018 is mainly attributable to an increase in stock-based compensation costs and travel expenses related to the relocation of our Chief Executive Officer to New York, where the Company leases an office and has its principal executive office. Stock-based compensation costs for the three month period ended May 31, 2018 totaled \$205,000, as compared to \$1,000 during the three month period ended May 31, 2017. The increase is mainly attributable to awards granted to employees and directors during fiscal years 2018 and 2017.

***Financial income, net***

Net financial income increased by 8% from net income of \$534,000 for the nine month period ended May 31, 2017 to net income of \$576,000 for the nine month period ended May 31, 2018. The increase is mainly attributable to an increase in income from bank deposits and held to maturity bonds as a result of an increase in interest rates.

Net financial income decreased by 5% from net income of \$190,000 for the three month period ended May 31, 2017 to net income of \$180,000 for the three month period ended May 31, 2018. The decrease is mainly attributable to a decrease in income from bank deposits and held to maturity bonds as a result of a decrease in cash and investments balance.

***Taxes on income***

No taxes on income were recognized for the nine month period ended May 31, 2018 as compared to \$400,000 for the nine month period ended May 31, 2017. The decrease is due to the absence of withholding taxes during the more recent period as compared to the prior period, as withholding taxes were recorded during the nine months ended May 31, 2017 related to the receipt of a milestone payment.

No taxes on income were recognized for the three month periods ended May 31, 2018 and 2017.

***Other comprehensive income***

Unrealized losses on available for sale securities for the nine month period ended May 31, 2018 of \$203,000, compared to gains of \$391,000 for the nine month period ended May 31, 2017, resulted from the decrease in fair value of the ordinary shares of D.N.A Biomedical Solutions Ltd., or D.N.A, that we hold.

Unrealized losses on available for sale securities for the three month period ended May 31, 2018 of \$115,000, compared to gains of \$286,000 for the three month period ended May 31, 2017, resulted from the decrease in fair value of the ordinary shares of D.N.A that we hold.

### *Liquidity and capital resources*

From inception through May 31, 2018, we have incurred losses in an aggregate amount of \$66,297,000. 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 \$61,243,000, 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 May 31, 2018, we had \$3,673,000 of available cash, \$24,742,000 of short-term and long-term bank deposits and \$6,003,000 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.

On July 2, 2018, we entered into a Securities Purchase Agreement with each of three investors, or the Purchasers, pursuant to which we agreed to sell, in a registered direct offering, or the Offering, an aggregate of 2,892,000 units, or the Units, each Unit consisting of one share of our common stock, par value \$0.012 per share, and a warrant to purchase one share of common stock at an exercise price of \$7.25 per share, or the Warrants, to the Purchasers for an offering price of \$6.25 per Unit. The Warrants will be exercisable commencing six months following their issuance for a period of three and one-half years from the date of issuance. The closing of the sale of the Units occurred on July 6, 2018. The net proceeds to us from the Offering, after deducting the placement agent's fees and expenses and our Offering expenses were approximately \$16,500,000.

On July 2, 2018, we entered into a letter agreement with H.C. Wainwright & Co., LLC, or HCW, pursuant to which HCW agreed to serve as exclusive placement agent in any offering by us occurring between July 2, 2018 and August 1, 2018. For its services in the Offering, HCW received a fee equal to 7% of the gross proceeds raised in the Offering and a management fee of 1% of the gross proceeds raised in the Offering, up to \$50,000 for non-accountable expenses as well as warrants to purchase up to 115,680 shares of our common stock, exercisable for a period of three and one-half years from the date of issuance and with an exercise price of \$7.8125 per share. Upon the exercise of the Warrants, HCW will receive a fee equal to 7% of the gross proceeds raised as a result of such exercise.

As of May 31, 2018, our total current assets were \$23,582,000 and our total current liabilities were \$5,637,000. On May 31, 2018, we had a working capital surplus of \$17,945,000 and an accumulated loss of \$66,297,000. As of August 31, 2017, our total current assets were \$20,297,000 and our total current liabilities were \$5,165,000. On August 31, 2017, we had a working capital surplus of \$15,132,000 and an accumulated loss of \$56,496,000. The increase in working capital from August 31, 2017 to May 31, 2018 was primarily due to investment in short-term deposits and the re-classification of long-term marketable securities to short-term.

During the nine month period ended May 31, 2018, cash and cash equivalents decreased to \$3,673,000 from the \$3,969,000 reported as of August 31, 2017, which is due to the reasons described below.

Operating activities used cash of \$10,009,000 in the nine month period ended May 31, 2018, as compared to \$3,783,000 used in the nine month period ended May 31, 2017. Cash used in operating activities in the nine month period ended May 31, 2018 primarily consisted of net loss resulting from research and development and general and

administrative expenses, as well as changes in deferred revenues due to the License Agreement and is partially offset by changes in stock-based compensation, while 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, accounts payable and accrued expenses and payable to related parties.

Investing activities provided cash of \$3,549,000 in the nine month period ended May 31, 2018, as compared to \$1,288,000 in the nine month period ended May 31, 2017. Cash provided by investing activities in the nine month periods ended May 31, 2018 and 2017 consisted primarily of the maturity of short-term deposits and held to maturity securities and is partially offset by the purchase of short-term and long-term bank deposits and marketable securities.

Financing activities provided cash of \$6,161,000 in the nine month period ended May 31, 2018, as compared to \$320,000 in the nine month period ended May 31, 2017. Financing activities in the nine month period ended May 31, 2018 consisted of aggregate net proceeds of \$5,164,000 from our issuance of 572,702 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 exercise of warrants and options while financing activities in the nine month period ended May 31, 2017 consisted of proceeds from the exercise of 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 May 31, 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.

### ***Significant Accounting Policies***

Our significant accounting policies are described in the notes to the consolidated financial statements as of August 31, 2017 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 nine month period ended May 31, 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 May 31, 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 May 31, 2018 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, 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 Stock Purchase Agreement and Letter Agreement, each dated May 3, 2017, between us and Corporate Profile.

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

### ITEM 6 - EXHIBITS

Number Exhibit

- 4.1 Form of Common Stock Purchase Warrant (incorporated by reference from the Company's Current Report on Form 8-K filed July 5, 2018).
- 10.1 Form of Securities Purchase Agreement, dated as of July 2, 2018 between the Company and each Purchaser in the Offering (incorporated by reference from the Company's Current Report on Form 8-K filed July 5, 2018).
- 10.2\* Amendment to Employment Agreement, dated April 15, 2018, between Oramed Ltd. and Joshua Hexter.
- 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, 2018, formatted in XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Comprehensive Loss, (iii) Condensed Consolidated Statement of Changes in

Edgar Filing: ORAMED PHARMACEUTICALS INC. - Form 10-Q

Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows and (v) the Notes to Condensed Consolidated Financial Statements.

\*Filed herewith

\*\*Furnished herewith

25

**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 12, 2018 By: /s/ Nadav Kidron  
Nadav Kidron  
President and Chief Executive Officer

Date: July 12, 2018 By: /s/ Hilla Eisenberg  
Hilla Eisenberg  
Chief Financial Officer  
(Principal Financial and Accounting Officer)