

ORAMED PHARMACEUTICALS INC.

Form 10-Q

January 08, 2015

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

FORM 10-Q

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

For the quarterly period ended November 30, 2014

☐ 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  
PO Box 39098  
Jerusalem, Israel  
(Address of Principal Executive Offices)

91390  
(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,

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or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="radio"/>	Accelerated filer	<input checked="" type="radio"/>
Non-accelerated filer (Do not check if a smaller reporting company)	<input type="radio"/>	Smaller reporting company	<input type="radio"/>

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

Yes ☐ No ☒

As of January 6, 2015, there were 10,833,131 shares of the issuer’s common stock, \$0.012 par value per share, outstanding.

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

On November 30, 2014, the exchange rate between the New Israeli Shekel, or NIS, and the dollar, as quoted by the Bank of Israel, was NIS 3.889 to \$1.00. Unless indicated otherwise by the context, statements in this Quarterly Report on Form 10-Q that provide the dollar equivalent of NIS amounts or provide the NIS equivalent of dollar amounts are based on such exchange rate.

PART I – FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

ORAMED PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF NOVEMBER 30, 2014

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ORAMED PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF NOVEMBER 30, 2014

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ORAMED PHARMACEUTICALS INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(UNAUDITED)

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

	November 30, 2014	August 31, 2014
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 6,656	\$ 1,762
Short term deposits	17,026	18,481
Marketable securities	688	1,047
Restricted cash	16	16
Prepaid expenses and other current assets	120	64
Related parties	-	330
Grants receivable from the chief scientist	27	78
T o t a l current assets	24,533	21,778
<b>LONG TERM DEPOSITS AND INVESTMENT</b>		
	5	3
<b>AMOUNTS FUNDED IN RESPECT OF</b>		
<b>EMPLOYEE RIGHTS UPON RETIREMENT</b>	7	7
<b>PROPERTY AND EQUIPMENT, NET</b>	15	14
T o t a l assets	\$ 24,560	\$ 21,802
<b>Liabilities and stockholders' equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 795	\$ 926
Related Parties	32	47
T o t a l current liabilities	827	973
<b>LONG TERM LIABILITIES:</b>		
Employee rights upon retirement	9	9
Provision for uncertain tax position	27	27
	36	36
<b>COMMITMENTS (note 2)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock, \$ 0.012 par value (30,000,000 authorized shares; 10,812,471 and 10,102,555 shares issued and outstanding as of November 30, 2014 and August 31, 2014, respectively)	129	121
Additional paid-in capital	53,191	48,040
Accumulated other comprehensive income	93	452
Accumulated loss	(29,716 )	(27,820 )
T o t a l stockholders' equity	23,697	20,793
T o t a l liabilities and stockholders' equity	\$ 24,560	\$ 21,802

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

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ORAMED PHARMACEUTICALS INC.  
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS  
(UNAUDITED)

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

	Three months ended	
	November 30, 2014	November 30, 2013
RESEARCH AND DEVELOPMENT EXPENSES, NET	\$ 1,302	\$ 750
GENERAL AND ADMINISTRATIVE EXPENSES	600	418
OPERATING LOSS	1,902	1,168
FINANCIAL INCOME	(27 )	(46 )
FINANCIAL EXPENSES	21	2
NET LOSS FOR THE PERIOD	\$ 1,896	\$ 1,124
SUBSEQUENT DECREASE (INCREASE) IN THE FAIR VALUE OF AVAILABLE FOR SALE SECURITIES PREVIOUSLY WRITTEN DOWN AS IMPAIRED	9	(5 )
RECLASSIFICATION ADJUSTMENT TO FINANCIAL INCOME OF GAINS ON AVAILABLE-FOR-SALE SECURITIES	-	18
UNREALIZED LOSS (GAIN) ON AVAILABLE FOR SALE SECURITIES	350	(44 )
TOTAL OTHER COMPREHENSIVE LOSS (INCOME)	359	(31 )
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	\$ 2,255	\$ 1,093
LOSS PER COMMON SHARE:		
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ 0.19	\$ 0.14
WEIGHTED AVERAGE NUMBER OF COMMON SHARES USED IN COMPUTING BASIC AND DILUTED LOSS PER COMMON STOCK	10,142,013	7,941,059

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



ORAMED PHARMACEUTICALS INC.  
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
(UNAUDITED)

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

	Common Stock Shares In thousands	\$	Additional paid-in capital	Accumulated other comprehensive income	Accumulated loss	Total stockholders' equity
BALANCE AS OF AUGUST 31, 2014	10,103	\$ 121	\$ 48,040	\$ 452	\$ (27,820 )	\$ 20,793
SHARES ISSUED FOR CASH, NET	696	8	4,825	-	-	4,833
SHARES ISSUED FOR SERVICES	4	*	26	-	-	26
STOCK BASED COMPENSATION	9	*	300	-	-	300
NET LOSS	-	-	-	-	(1,896 )	(1,896 )
OTHER COMPREHENSIVE LOSS	-	-	-	(359 )	-	(359 )
BALANCE AS OF NOVEMBER 30, 2014	10,812	\$ 129	\$ 53,191	\$ 93	\$ (29,716 )	\$ 23,697

\* 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  
(UNAUDITED)  
U.S. dollars in thousands

	Three months ended November 30,	
	2014	2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(1,896 )	\$(1,124 )
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1	2
Exchange differences and interest on deposits	(9 )	(22 )
Stock based compensation	300	204
Common stock issued for services	26	64
Gain on sale of investment	-	(18 )
Changes in operating assets and liabilities:		
Prepaid expenses, other current assets and related parties	325	(25 )
Accounts payable, accrued expenses and related parties	(146 )	170
Liability for employee rights upon retirement	-	1
Total net cash used in operating activities	(1,399 )	(748 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(2 )	(5 )
Purchase of short term deposits	(820 )	(4,300 )
Proceeds from sale of short term deposits	2,300	4,100
Proceeds from sale of marketable securities	-	43
Funds in respect of employee rights upon retirement	*	*
Other	(2 )	-
Total net cash derived from (used in) investing activities	1,476	(162 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock - net of issuance expenses**	4,833	-
Net cash derived from financing activities	4,833	-
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH</b>	(16 )	9
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	4,894	(901 )
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	1,762	2,272
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	\$6,656	\$1,371

\* Represents an amount of less than \$1.

\*\* See note 5.

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

ORAMED PHARMACEUTICALS Inc.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:

a.

General:

1) Incorporation and operations

Oramed Pharmaceuticals Inc. (the “Company”) was incorporated on April 12, 2002, under the laws of the State of Nevada. 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 March 11, 2011, the Company was reincorporated from the State of Nevada to the State of Delaware.

On May 14, 2007, the Company incorporated a wholly-owned subsidiary in Israel, Oramed Ltd. (the “Subsidiary”), which is engaged in research and development. Unless the context indicates otherwise, the term “Group” refers to Oramed Pharmaceuticals Inc. and the Subsidiary.

Following the adoption of Accounting Standards Update (“ASU”) 2014-10, Development Stage Entities (Topic 915), the Company removed the inception to date information and all reference to development.

2) Development and liquidity risks

The Group 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 any revenues from its operations. Continued operation of the Company is contingent upon obtaining sufficient funding until it becomes profitable.

ORAMED PHARMACEUTICALS Inc.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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 ("FDA") prior to selling its products within the United States, and foreign regulatory approvals must be obtained to sell its products internationally. 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.

Based on its current cash resources and commitments, and cash received in private and public offerings in the three month period ended November 30, 2014 and in the year ended August 31, 2014, the Company believes it will be able to maintain its current planned development activities and the corresponding level of expenditures for at least the next 12 months and beyond the date that the financial statements are issued, although no assurance can be given that it will not need additional funds prior to such time. If there are unexpected increases in general and administrative expenses or research and development expenses, the Company may need to seek additional financing during the next 12 months.

ORAMED PHARMACEUTICALS Inc.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

b. Newly issued and recently adopted Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15"). This new standard requires management to assess the entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 will be effective prospectively for annual reporting periods ending after the first annual period ending after December 15, 2016 and interim periods therein. Early application of the standard is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued. The Company has elected to early adopt the provisions of ASU 2014-15 in fiscal year 2014. The adoption of ASU 2014-15 did not have any material effect on the consolidated financial statement presentation.

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, 2014 (the "2014 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 2014 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  
(UNAUDITED)

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

NOTE 2 - COMMITMENTS:

- a. On September 11, 2011, the Subsidiary entered into an agreement with Hadasit, the Company's Medical and Chief Technology Officer (the "CTO") and Dr. Daniel Schurr (the "Hadasit Agreement") to retain consulting and clinical trial services. According to the Hadasit Agreement, Hadasit will be entitled to a consideration of \$200 to be paid by the Company in accordance with the actual progress of the studies, \$95 of which were recognized through November 30, 2014. See also note 1a(1).
- b. On February 15, 2011, the Subsidiary entered into a consulting agreement with a third party (the "Consultant") for a period of five years, pursuant to which the Consultant will provide consultation on scientific and clinical matters. The Consultant is entitled to a fixed monthly fee of \$8, royalties of 8% of the net royalties actually received by the Subsidiary in respect of the patent that was sold to Entera Bio Ltd. ("Entera") on March 31, 2011 and an option to purchase up to 20,834 shares of the Company at an exercise price of \$6.00 per share. The option vests in five annual installments commencing February 16, 2012 and expires on February 16, 2021. The fair value of the option as of November 30, 2014 was \$107, using the following assumptions: dividend yield of 0% and expected term of 6.21 years; expected volatility of 80.45%; and risk-free interest rate of 1.89%. The fair value of the unvested options is remeasured at each balance sheet reporting date and is recognized over the related service period using the straight-line method.
- c. On April 28, 2013, the Subsidiary entered into a new lease agreement for its office facilities in Israel, which replaced the lease agreement from 2012. The new lease agreement is for a period of 36 months commencing November 4, 2013. The annual lease payment is NIS 89,000 from 2014 through 2016, and will be linked to the increase in the Israeli consumer price index ("CPI") (as of November 30, 2014, the future annual lease payments under the new agreement will be \$22, based on the exchange rate as of November 30, 2014).
- As security for its obligation under this lease agreement the Company provided a bank guarantee in an amount equal to three monthly lease payments.
- d. On May 13, 2014, the Company entered into a consulting agreement with a third party advisor for a period of twelve months, pursuant to which the advisor will provide investor relations services and will be entitled to receive a monthly cash fee and 15,000 shares of the Company's common stock that will be issued in four equal installments, on each of August 1, 2014, November 1, 2014, February 1, 2015 and May 1, 2015. As of November 30, 2014, the Company issued to such advisor 7,500 shares. The aggregate fair value of the shares at the dates of the grant was \$64.

ORAMED PHARMACEUTICALS Inc.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

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

NOTE 2 - COMMITMENTS (continued):

e. On February 6, 2014, the Subsidiary entered into a second agreement with a clinical research organization ("CRO"), for its Phase IIa clinical trial for an oral insulin capsule for type 1 diabetes patients, which was completed in October 2014. As consideration for its services, the Subsidiary paid the CRO a total amount of approximately \$280 during the term of the engagement and based on achievement of certain milestones, all of which were recognized through November 30, 2014.

On July 22, 2014, the Subsidiary entered into a third agreement with the same CRO, for its Phase IIb clinical trial for an oral insulin capsule for type 2 diabetes patients, which is expected to begin in the first quarter of calendar year 2015. As consideration for its services, the Subsidiary will pay the CRO a total amount of approximately \$3,290 that will be paid during the term of the engagement and based on achievement of certain milestones, \$595 of which were recognized through November 30, 2014.

f. On March 3, 2014, the Subsidiary entered into an additional agreement with a vendor, for the process development and production of one of its oral capsule ingredients in the amount of \$311, \$40 of which were recognized through November 30, 2014, and bonus payments of up to \$600 that will be paid upon achieving certain milestones, as described in the agreement, none of which were recognized through November 30, 2014.

On May 15, 2014, the Subsidiary entered into an additional agreement with the same vendor, for the process development and production of the same capsule ingredients in the amount of \$217, \$174 of which was recognized through November 30, 2014.

g. On May 26, 2014, the Subsidiary entered into a supply agreement with another vendor, according to which the vendor will manufacture insulin capsules for total consideration of \$214, \$134 of which were recognized through November 30, 2014.

h. Grants from Bio-Jerusalem

The Subsidiary is committed to pay royalties to the Bio-Jerusalem fund on proceeds from future sales at a rate of 4% and up to 100% of the amount of the grant received by the Company (Israeli CPI linked) at the total amount of \$65. As of November 30, 2014, the Subsidiary had not yet realized any revenues and did not incur any royalty liability.

During the three month period ended November 30, 2014, the Company received no grants from the Bio-Jerusalem fund.

ORAMED PHARMACEUTICALS Inc.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

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

NOTE 2 - COMMITMENTS (continued):

- i. Grants from the Office of the Chief Scientist of the Ministry of Economy (formerly the Ministry of Industry, Trade and Labor) of Israel ("OCS").

Under the terms of the Company's funding from the OCS, royalties of 3%-3.5% are payable on sales of products developed from a project so funded, up to 100% of the amount of the grant received by the Company (dollar linked) with the addition of annual interest at a rate based on LIBOR.

At the time the grants were received, successful development of the related projects was not assured. In case of failure of a project that was partly financed as above, the Company is not obligated to pay any such royalties.

As of November 30, 2014, the Subsidiary had not yet realized any revenues from said projects and did not incur any royalty liability. The total amount that was actually received through November 30, 2014 was \$2,134.

- j. For the three month periods ended November 30, 2014 and 2013, the research and development expenses are presented net of OCS and Bio-Jerusalem fund grants, in the total amount of \$16 and \$67, respectively.

NOTE 3 - FAIR VALUE:

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 November 30, 2014, the assets or liabilities measured at fair value were comprised of available for sale securities (Level 1). See also note 4.

As of November 30, 2014, the carrying amount of cash and cash equivalents, short term deposits, other current assets, accounts payables and accrued expenses approximates their fair values due to the short-term maturities of these instruments.



ORAMED PHARMACEUTICALS Inc.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

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

NOTE 3 - FAIR VALUE (continued):

The fair value of long-term deposits also approximates their carrying value, since they bear interest at rates close to the prevailing market rates. The amounts funded in respect of employee rights are stated at cash surrender value which approximates its fair value.

NOTE 4 - MARKETABLE SECURITIES:

Available-for-sale securities are 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 Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost, and the Company's ability and intent to hold the investment. Realized gains and losses on sales of the securities are included in the consolidated statement of operations as financial income or expenses.

As of November 30, 2014, marketable securities consisted wholly of equity securities of D.N.A Biomedical Solutions Ltd ("D.N.A"). D.N.A's 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.

During the three month period ended November 30, 2013, the Subsidiary sold in aggregate 1,025,989 of the D.N.A ordinary shares for a total of \$43. During the three month period ended November 30, 2014, the Group did not sell any of the D.N.A ordinary shares.

As of November 30, 2014, the Group owns approximately 9.8% of D.N.A's outstanding ordinary shares.

The cost of the securities as of November 30 and August 31, 2014 is \$595.

The cost of the securities sold and the amount reclassified out of accumulated other comprehensive income into financial income (amounting to \$0 and \$18 during the three month periods ended November 30, 2014 and 2013, respectively) were determined by specific identification.

As of November 30 and August 31, 2014, the available-for-sale securities are classified as Level 1.

ORAMED PHARMACEUTICALS Inc.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

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

**NOTE 5 - STOCK HOLDERS' EQUITY:**

On November 3, 2014, the Company entered into a Stock Purchase Agreement with Guangxi Wuzhou Pharmaceutical (Group) Co., Ltd. (the "Investor"), pursuant to which the Investor agreed to buy and the Company agreed to sell an aggregate of 696,378 shares of common stock, or the Shares, at a price of \$7.18 per Share, which was equal to the closing price of the Company's common stock on the Nasdaq Capital Market on October 31, 2014, for aggregate gross proceeds of approximately \$5,000. The net proceeds to the Company from the offering were approximately \$4,833, after deducting a finder's fee of \$150 and other offering expenses of the Company. The offering closed on November 28, 2014.

**NOTE 6 - STOCK BASED COMPENSATION:**

- a. On November 13, 2014, the Company granted a total of 19,576 restricted stock units ("RSUs") representing a right to receive shares of the Company's common stock to the Company's Chief Executive Officer and director (the "CEO"), and the CTO, both related parties. The RSUs vest in two equal installments, each of 9,788 shares, on November 30 and December 31, 2014. The total fair value of these RSUs on the date of grant was \$135, using the quoted closing market share price of \$6.90 on the Nasdaq Capital Market on the date of grant.
- b. On November 13, 2014, the Company granted a total of 10,872 RSUs representing a right to receive shares of the Company's common stock to four members of the Company's Board of Directors. The RSUs vest on January 1, 2015. The total fair value of these RSUs on the date of grant was \$75, using the quoted closing market share price of \$6.90 on the Nasdaq Capital Market on the date of grant.

**NOTE 7 - RELATED PARTIES - TRANSACTIONS**

On July 1, 2008, the Subsidiary entered into two consulting agreements with KNRY Ltd. ("KNRY"), an Israeli company owned by the CEO, whereby the CEO and the CTO, through KNRY, provide services to the Group (the "Consulting Agreements"). The Consulting Agreements are both terminable by either party upon 60 days prior written notice. The Consulting Agreements provide that KNRY (i) will be paid a gross amount of NIS 50,400 per month for each of the CEO and CTO (\$14) and (ii) will be reimbursed for reasonable expenses incurred in connection with performance of the Consulting Agreements.

On July 17, 2013, the Subsidiary entered into amendments to the Consulting Agreements with KNRY, according to which, the CEO's and CTO's annual payment was set at \$250 and \$200, respectively, calculated at an exchange rate of NIS 3.6 per U.S. dollar, and in addition to such payment they were granted the use of a company car and certain cash bonus payments, effective July 1, 2013.

On November 13, 2014, the Subsidiary entered into an amendment to the Consulting Agreements (the "Amendment Agreement"), according to which, the CEO and the CTO made some representations with regards to their relationship with KNRY and agreed to indemnify the Subsidiary in certain circumstances as defined in the amendment, among other revisions.



ORAMED PHARMACEUTICALS Inc.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

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

NOTE 8 - SUBSEQUENT EVENT

In December 2014, the Subsidiary entered into an agreement with the same vendor as mentioned in note 2f, for the process development and production of the same capsule ingredient in the amount of \$550 that will be paid upon achieving certain milestones, as described in the agreement.

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## 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

This Quarterly Report on Form 10-Q (including the section regarding Management's Discussion and Analysis of Financial Condition and Results of Operations) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, regarding our business, clinical trials, financial condition, expenditures, results of operations and prospects. Words such as "expects," "anticipates," "intends," "plans," "planned expenditures," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Quarterly Report on Form 10-Q. Additionally, statements concerning future matters are forward-looking statements.

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, 2014, or our Annual Report, as filed with the Securities and Exchange Commission, or the SEC, on November 14, 2014, 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 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

In September 2013, we submitted a pre-Investigational New Drug, or pre-IND, package to the U.S. Food and Drug Administration, or FDA, for ORMD-0901, our oral exenatide capsule, for a Phase 2 clinical trial on healthy volunteers and type 2 diabetic patients. We began pre-clinical studies in November 2014 and expect to begin non-U.S. based Phase Ib trials and IND-enabling studies in the second quarter of calendar year 2015. We then intend to then file an IND and move immediately and directly into a large Phase II multi-center trial in the U.S.



We originally filed an IND with the FDA in December 2012 for clearance to begin a Phase II clinical trial of ORMD-0801, in order to evaluate the safety, tolerability and efficacy of our oral insulin capsule on type 2 diabetic volunteers. Because the identical formulation of ORMD-0801 had not yet been studied in humans at bedtime, in February 2013 the FDA noted concerns about mitigating potential risks of severe hypoglycemia and requested that we perform a sub-study in a controlled in-patient setting for a one-week period prior to beginning the larger multi-centered Phase II trial. As a result, we withdrew the original IND and, in April 2013, we submitted a new IND for the Phase IIa sub-study. Following the FDA's clearance to proceed in May 2013, we began the Phase IIa sub-study in July 2013. As we announced in January 2014, the Phase IIa sub-study met all primary and secondary endpoints. Specifically, the Phase IIa study evaluated the pharmacodynamic effects of ORMD-0801 on mean nighttime glucose (determined using a continuous glucose monitor). The results showed that ORMD-0801 exhibited a sound safety profile, led to reduced mean daytime and nighttime glucose readings and lowered fasting blood glucose concentrations, when compared to placebo. In addition, no serious adverse events occurred during this study, and the only adverse events that occurred were not drug related. In light of these results, we believe that we should move forward with the Phase IIb clinical trial on approximately 180 type 2 diabetic patients and will be conducted in approximately 30 sites in the United States, which we are preparing to initiate in the first quarter of calendar year 2015. This double-blind, randomized, 28-day study clinical trial will be designed to assess the safety and efficacy of ORMD-0801 and will investigate ORMD-0801 over a longer treatment period and which will have statistical power to give us greater insight into the drug's efficacy. We anticipate the data read out from this trial before the end of 2015.

In February 2014, we submitted a protocol to the FDA to initiate a Phase IIa trial of our oral insulin capsule for type 1 diabetes volunteers. The protocol was submitted under our existing IND to include both type 1 and type 2 diabetes indications. The double-blind, randomized, placebo controlled, seven-day study design was carried out at an inpatient setting on 25 type 1 diabetic patients. We began this study in March 2014. As we announced in October 2014, the results showed that ORMD-0801 oral insulin given before meals appeared to be safe and well-tolerated for the dosing regimen in this study. Although the study was not powered to show statistical significance, there were internally consistent trends observed. Consistent with the timing of administration, the data showed a decrease in rapid acting insulin, a decrease in post-prandial glucose, a decrease in daytime glucose by continual glucose monitoring and an increase in post-prandial hypoglycemia in the active group.

The table below gives an overview of our product pipeline:

## Results of Operations

Comparison of three month periods ended November 30, 2014 and 2013

The following table summarizes certain statements of operations data for the Company for the three month periods ended November 30, 2014 and 2013 (in thousands of dollars except share and per share data):

	Three months ended November 30,	
	2014	2013
Research and development expenses, net	\$ 1,302	\$ 750
General and administrative expenses	600	418
Financial income, net	(6)	(44)
Net loss for the period	\$ 1,896	\$ 1,124
Loss per common share – basic and diluted	\$ (0.19)	\$ (0.14)
Weighted average common shares outstanding	10,142,013	7,941,059

## 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 drug for use in research, 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 capsules, payments for patient recruitment and treatment, as well as salaries and related expenses of research and development staff.

Research and development expenses, for the three months ended November 30, 2014 increased by 74% to \$1,302,000, from \$750,000 for the three months ended November 30, 2013. The increase is mainly attributable to preparing for the initiation of our Phase IIb clinical trial. Stock based compensation costs for the three months ended November 30, 2014 totaled \$164,000, as compared to \$178,000 during the three months ended November 30, 2013.



#### Government grants

In March 2014, the Subsidiary was granted a fifth grant amounting to a total amount of NIS 1,206,990 (approximately \$345,000) from the Office of the Chief Scientist of the Ministry of Economy (formerly the Ministry of Industry, Trade and Labor) of Israel, or OCS, which was designated for research and development expenses for the period of November 2013 to October 2014. In September 2014, the OCS extended the period of this fifth year until December 2014. We used the funds to support further research and development and clinical studies of our oral insulin capsule and oral GLP-1 analog.

In the three months ended November 30, 2014, we recognized research and development grants in an amount of \$16,000, and in the three months ended November 30, 2013, we recognized research and development grants in an amount of \$67,000. As of November 30, 2014, we had no contingent liabilities to the OCS.

#### General and administrative expenses

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

General and administrative expenses for the three months ended November 30, 2014, increased by 44% to \$600,000 from \$418,000 for the three months ended November 30, 2013. The increase in costs incurred related to general and administrative activities during the three months ended November 30, 2014 is mainly due to the increase in stock-based compensation expenses, which increased from \$26,000 during the three months ended November 30, 2013 to \$137,000 in the three months ended November 30, 2014, which is attributed to awards granted to officers and directors during the three months ended November 30, 2014.

#### Financial income, net

Net financial income decreased by 86% from net income of \$44,000 for the three months ended November 30, 2013 to net income of \$6,000 for the November 30, 2014 period. The decrease is mainly due to the increase in exchange rate differences expenses.

#### Other comprehensive income

Subsequent decrease in the fair value of available for sale securities previously written down as impaired for the three months ended November 30, 2014 of \$9,000 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 months ended November 30, 2014 of \$350,000, resulted from the decrease in fair value of our D.N.A ordinary shares.

#### Liquidity and capital resources

From inception through November 30, 2014, we have incurred losses in an aggregate amount of \$29,716,000. 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 \$40,580,000, net of transaction costs. During that period we also received cash consideration of \$1,862,000 from the exercise of warrants and options. We will seek to obtain additional financing through similar sources in the future as needed. As of November 30, 2014, we had \$6,656,000 of available cash, \$17,026,000 of short term bank deposits and \$688,000 of marketable securities. We anticipate that we will require approximately \$9.9 million to finance our activities during the 12 months following November 30, 2014.



Management continues to evaluate various financing alternatives for funding future research and development activities and general and administrative expenses through fund raising 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 ongoing financing discussions with third party investors, including the investor in connection with the private placement entered into in November 2014, and existing stockholders, future public offerings, and additional funding from the OCS. Based on our current cash resources and commitments, including cash received in a private placement in the period ended November 30, 2014, we believe we will be able to maintain our current planned development activities and the corresponding level of expenditures for at least the next 12 months and beyond.

As of November 30, 2014, our total current assets were \$24,533,000 and our total current liabilities were \$827,000. On November 30, 2014, we had a working capital surplus of \$23,706,000 and an accumulated loss of \$29,716,000. As of August 31, 2014, our total current assets were \$21,778,000 and our total current liabilities were \$973,000. On August 31, 2014, we had a working capital surplus of \$20,805,000 and an accumulated loss of \$27,820,000. The increase from August 31, 2014 to November 30, 2014 was primarily due to proceeds from our private placement completed in November 2014.

During the three month period ended November 30, 2014, cash and cash equivalents increased to \$6,656,000 from the \$1,762,000 reported as of August 31, 2014, which is due to the reasons described below.

Operating activities used cash of \$1,399,000 in the three month period ended November 30, 2014, as compared to \$748,000 used in the three months ended November 30, 2013. Cash used for operating activities in the three months ended November 30, 2014 and 2013 primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by stock based compensation amounts.

During the three month period ended November 30, 2014, we received \$68,000 in OCS grants towards our research and development expenses, while we recognized the amount of \$16,000 during such period and \$67,000 was recognized in the three month period ended November 30, 2013. During the three month period ended November 30, 2013, we received \$125,000 in OCS grants. The amounts that were recognized but not received during the three month period ended November 30, 2014, should be received from the OCS during calendar year 2015. The OCS has supported our activity in the past four years.

Investing activities provided cash of \$1,476,000 in the three month period ended November 30, 2014, as compared to \$162,000 that was used in the three month period ended November 30, 2013. Cash provided in investing activities in the three months ended November 30, 2014 consisted primarily of the proceeds from sale of short-term bank deposits, while cash used in investing activities in the three months ended November 30, 2013 consisted primarily of the acquisition of short-term bank deposits.

Financing activities provided cash of \$4,833,000 in the three month period ended November 30, 2014, as compared to no financing activities during the three months ended November 30, 2013. Financing activities in the three month period ended November 30, 2014 consisted of proceeds from our issuance of common stock in the three months ended November 30, 2014.

#### Off-balance sheet arrangements

As of November 30, 2014, 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.



## Planned Expenditures

The estimated expenses referenced herein are in accordance with our business plan. Since our technology is still in the development stage, it can be expected that there will be changes in some budgetary items. Our planned expenditures for the twelve months beginning December 1, 2014 are as follows (in thousands):

Category	Amount
Research and development, net of OCS funds	\$ 7,525
General and administrative expenses	2,328
<b>Total</b>	<b>\$ 9,853</b>

In December 2012 and April 2013, we filed IND applications with the FDA for our orally ingested insulin and we are conducting, or planning to conduct, further clinical studies with our oral exenatide capsule, and others. Our ability to complete these expected activities is dependent on several major factors including the ability to attract sufficient financing on terms acceptable to us.

## ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There has been no significant change in our exposure to market risk during the three months ended November 30, 2014. 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 on Form 10-K for the year ended August 31, 2014.

## ITEM 4 - CONTROLS AND PROCEDURES

### Disclosure Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of November 30, 2014. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective.

### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended November 30, 2014 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 SECURITIES AND USE OF PROCEEDS.

On November 6, 2014, we issued 3,750 shares of our common stock to an advisor as remuneration for services rendered. Such issuance and sale was exempt under Section 4(a)(2) of the Securities Act of 1933, as amended.

ITEM 6 - EXHIBITS

Number	Exhibit
31.1*	Certification Statement 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 Statement 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 Statement of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2**	Certification Statement 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 November 30, 2014, formatted in XBRL: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Comprehensive Loss, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows and (v) the Notes to Condensed Consolidated Financial Statements, tagged as blocks of text and in detail.

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\* Filed herewith

\*\* Furnished herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ORAMED PHARMACEUTICALS INC.

Date: January 7, 2015

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

Date: January 7, 2015

By: /s/ Yifat Zommer  
Yifat Zommer  
Chief Financial Officer  
(principal financial and  
accounting officer)