#### UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

## **FORM 10-Q**

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

For the quarterly period ended May 31, 2014

o 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 x No o

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 x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 o

Accelerated filer o

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

Smaller reporting company x

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

Yes o No x

As of July 11, 2014, there were 9,955,991 shares of the issuer's common stock, \$0.012 par value per share, outstanding.

## ORAMED PHARMACEUTICALS INC. FORM 10-Q TABLE OF CONTENTS

PART I – FINANCIAL INFORMATION	2
ITEM 1 - FINANCIAL STATEMENTS	2
ITEM 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	3
ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	9
ITEM 4 - CONTROLS AND PROCEDURES	9
PART II - OTHER INFORMATION	9
ITEM 2 - UNREGISTERED SALES OF SECURITIES AND USE OF PROCEEDS	9

10

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.

**ITEM 6 - EXHIBITS** 

On May 31, 2014, the exchange rate between the NIS and the dollar, as quoted by the Bank of Israel, was NIS 3.475 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

# PART I – FINANCIAL INFORMATION

# ITEM 1 - FINANCIAL STATEMENTS

# ORAMED PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF MAY 31, 2014

# CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

# AS OF MAY 31, 2014

# TABLE OF CONTENTS

	Page
CONDENSED CONSOLIDATED FINANCIAL STATEMENTS:	
Balance sheets	F - 2
Statements of comprehensive loss	F - 3
Statements of changes in stockholders' equity	F - 4
Statements of cash flows	F - 5
Notes to financial statements	F - 6 - F - 13

# CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED) U.S. dollars

		May 31, 2014		August 31, 2013
Assets				_
CURRENT ASSETS:				
Cash and cash equivalents	\$	2,474,839	\$	2,272,228
Short term deposits		12,005,172		5,246,627
Marketable securities		1,063,409		956,376
Restricted cash		61,000		16,000
Prepaid expenses and other current assets		97,525		90,103
Related parties		523		4,530
Grants receivable from the chief scientist	<u> </u>	267,131		58,412
T o t a l current assets	_	15,969,599	_	8,644,276
LONG TERM DEPOSITS AND INVESTMENT		6,508,269		4,593
AMOUNTS FUNDED IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT		6,688		5,545
PROPERTY AND EQUIPMENT, NET		13,547		5,768
Total assets	\$	22,498,103	\$	8,660,182
Liabilities and stockholders' equity				
CURRENT LIABILITIES:				
Accounts payable and accrued expenses	\$	447,792	\$	450,941
Account payable with former shareholder	Ψ	47,252	Ψ	47,252
Total current liabilities		495,044	_	498,193
1 of a 1 current nationales		433,044		450,155
LONG TERM LIABILITIES:				
Employee rights upon retirement		8,732		8,004
Provision for uncertain tax position		23,210		23,210
		31,942		31,214
COMMITMENTS (note 2)				
STOCKHOLDERS' EQUITY:				
Common stock, \$ 0.012 par value (16,666,667 authorized shares;				
9,955,991 and 7,937,872 shares issued and outstanding as of May				
31, 2014 and August 31, 2013, respectively)		119,456		95,238
Additional paid-in capital		47,574,340		29,855,723
Accumulated other comprehensive income		467,974		303,403
Accumulated deficit		(26,190,653)		(22,123,589)
Total stockholders' equity		21,971,117		8,130,775
Total liabilities and stockholders' equity	\$	22,498,103	\$	8,660,182

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

# CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED) U.S. dollars

	Nine months ended			Three months ended				
		May 31, 2014		May 31, 2013		May 31, 2014		May 31, 2013
RESEARCH AND DEVELOPMENT EXPENSES, net	\$	2,513,142	\$	1,977,258	\$	1,089,298	\$	835,636
GENERAL AND ADMINISTRATIVE EXPENSES		1,743,902		1,349,081		813,923		499,034
OPERATING LOSS		4,257,044		3,326,339		1,903,221		1,334,670
FINANCIAL INCOME		(199,566)		(223,638)		(79,486)		(84,594)
FINANCIAL EXPENSES		9,586		338,267		4,167		6,265
NET LOSS FOR THE PERIOD	\$	4,067,064	\$	3,440,968	\$	1,827,902	\$	1,256,341
SUBSEQUENT (INCREASE) DECREASE IN THE FAIR VALUE OF AVAILABLE								
FOR SALE SECURITIES PREVIOUSLY WRITTEN DOWN AS IMPAIRED		(34,156)		(84,010)		19,664		38,967
RECLASSIFICATION ADJUSTMENT TO FINANCIAL INCOME OF GAINS ON								
AVAILABLE-FOR-SALE SECURITIES		80,017		69,178		35,626		18,491
UNREALIZED (GAIN) LOSS ON AVAILABLE FOR SALE SECURITIES		(210,432)		(117,092)		323,721		55,126
TOTAL OTHER COMPREHENSIVE (INCOME) LOSS		(164,571)		(131,924)		379,011		112,584
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	\$	3,902,493	\$	3,309,044	\$	2,206,913	\$	1,368,925
LOSS PER COMMON SHARE:								
BASIC AND DILUTED LOSS PER COMMON SHARE	\$	0.45	\$	0. 49	\$	0.18	\$	0.17
WEIGHTED AVERAGE NUMBER OF COMMON STOCK USED IN								
COMPUTING BASIC AND DILUTED LOSS PER COMMON STOCK	_	8,988,446	_	7,087,831	_	9,888,126	_	7,223,377

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

# CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (UNAUDITED) U.S. dollars

	Commo	on Stocl	k	Additional paid-in	Accumulated other omprehensive	Accumulated	Total stockholders'
	Shares		\$	capital	 income	deficit	equity
BALANCE AS OF AUGUST 31, 2013	7,937,872	\$	95,238	\$ 29,855,723	\$ 303,403	\$ (22,123,589)	\$ 8,130,775
SHARES ISSUED FOR CASH, NET *	1,580,000		18,960	14,868,125	-	`	14,887,085
SHARES ISSUED FOR SERVICES **	10,000		120	64,280	-	-	64,400
SHARES ISSUED ***	2,252		27	(27)	-	-	-
EXERCISE OF WARRANTS AND OPTIONS	425,867		5,111	1,746,077	-	-	1,751,188
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS	_		_	1,003,735	_	_	1,003,735
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS	_		_	36,427	-	-	36,427
NET LOSS	-		-	-	-	(4,067,064)	(4,067,064)
OTHER COMPREHENSIVE INCOME			-		164,571		164,571
BALANCE AS OF MAY 31, 2014	9,955,991	\$	119,456	\$ 47,574,340	\$ 467,974	\$ (26,190,653)	\$ 21,971,117

- \* See note 5b.
- \*\* See note 5a.
- \*\*\* See note 5e.

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

### 

	Nine mon	ths ended
	May 31, 2014	May 31, 2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (4,067,064)	\$ (3,440,968)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	4,079	3,697
Exchange differences and interest on deposits	(13,140)	10,880
Stock based compensation	1,040,162	627,511
Shares issued for services rendered	64,400	93,713
Gain on sale of investment	(80,017)	(69,178)
Exchange of warrants	-	296,982
Changes in fair value of warrant liabilities	-	(44,699)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(212,134)	(400,523)
Accounts payable and accrued expenses	(3,149)	(198,401)
Liability of employee rights upon retirement	728	5,821
Total net cash used in operating activities	(3,266,135)	(3,115,165)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(11,858)	(4,659)
Acquisition of short term investments and short term deposits	(41,745,000)	(2,317,198)
Acquisition of long term deposits	(6,500,000)	(2,317,130)
Funds related to employee rights upon retirement	(884)	(3,023)
Proceeds from sale of investment and marketable securities	137,555	226,671
Proceeds from sale of short term deposits	34,940,776	454,381
Total net cash used in investing activities	(13,179,411)	(1,643,828)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sales of common stock and		
warrants - net of issuance expenses	14,887,085	1,450,936
Proceeds from exercise of warrants and options	1,751,188	
Net cash derived from financing activities	16,638,273	1,450,936
EFFECT OF EXCHANGE RATE CHANGES ON CASH	9,884	(17,786)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	202,611	(3,325,843)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	2,272,228	4,430,740
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 2,474,839	\$ 1,104,897
Non-such investing and financing activities		
Non cash investing and financing activities:		¢ 047.000
Exchange of warrants	<del>-</del>	\$ 917,809
Shares and warrants issued for marketable securities	-	\$ 628,630

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

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

#### 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. 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. In subsequent periods, the Company entered into additional development agreements with Hadasit, the most recent of which was signed on September 11, 2011. See also note 2a.

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., which is engaged in research and development. Unless the context indicates otherwise, the term "Group" refers to Oramed Pharmaceuticals Inc. and its Israeli subsidiary, Oramed Ltd. (the "Subsidiary").

## 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.

Successful completion of the Company's development programs and its transition to normal operations is dependent upon obtaining necessary regulatory approvals from the 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.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

#### b. Newly issued and recently adopted Accounting Pronouncements

- 1) In June 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation ("ASU 2014-10"). This update removes the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from accounting principles generally accepted in the United States of America ("U.S. GAAP"). In addition, ASU 2014-10 eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The amendments also clarify that the guidance in Topic 275, Risks and Uncertainties, is applicable to entities that have not commenced planned principal operations. The amendments in ASU 2014-10 will be effective retrospectively except for the clarification to Topic 275, which shall be applied prospectively for annual reporting periods beginning after December 15, 2014, and interim periods therein. Early application of each of the amendments 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 2014-10 in the third quarter of fiscal year 2014.
- 2) In February 2013, the FASB issued ASU 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income ("ASU 2013-02"). This update requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, ASU 2013-02 requires presentation, either on the face of the income statement or in the notes, of significant amounts reclassified out of accumulated other comprehensive income by respective line items of net income, but only if the amounts reclassified are required to be reclassified in their entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about these amounts. The amendments in ASU 2013-02 will be effective prospectively for annual reporting periods beginning after December 15, 2012, and interim periods within those annual periods. The Company adopted ASU 2013-02 in the first quarter of fiscal year 2014. The adoption of ASU 2013-02 did not have any material effect on the consolidated financial statement presentation.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

# c. Condensed Consolidated Financial Statements Preparation

The condensed consolidated financial statements included herein have been prepared in accordance with U.S. GAAP and on the same basis as the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended August 31, 2013 (the "2013 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 2013 Form 10-K. The results for interim periods are not necessarily indicative of a full fiscal year's results.

#### **NOTE 2 - COMMITMENTS:**

- a. On September 11, 2011, the Subsidiary entered into an agreement with Hadasit, Dr. Miriam Kidron and Dr. Daniel Schurr (the "Agreement") to retain consulting and clinical trial services. According to the Agreement, Hadasit will be entitled to a consideration of \$200,000 to be paid by the Company in accordance with the actual progress of the studies, \$95,000 of which were paid and recognized through May 31, 2014. See also note 1a(1).
- b. On July 5, 2010, the Subsidiary of the Company entered into a Manufacturing Supply Agreement ("MSA") with Sanofi-Aventis Deutschland GMBH ("Sanofi"). According to the MSA, Sanofi will supply the Subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the United States
- c. 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 \$8,000, 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 initial fair value of the option on the date of grant was \$62,185, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 78.65%; risk-free interest rates of 3.62%; and the remaining expected term of 10 years. The fair value of the option as of May 31, 2014 was \$100,441, using the following assumptions: dividend yield of 0% and expected term of 6.72 years; expected volatility of 82.19%; and risk-free interest rate of 2.24%. 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.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

d. On March 18, 2012, the Subsidiary entered into a lease agreement for its facilities in Israel. The lease agreement was for a period of 57 months commencing January 1, 2012.

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 will be NIS 89,052 from 2014 through 2016, and will be linked to the increase in the Israeli consumer price index ("CPI") (as of May 31, 2014, the future annual lease payments under the new agreement will be \$25,626, based on the exchange rate as of May 31, 2014).

The lease expenses for the nine and three month periods ended May 31, 2014 were approximately \$16,081 and \$6,478, respectively.

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

e. On April 15, 2013, the Company entered into a consulting agreement with a third party advisor for a period of twelve months, pursuant to which such 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 issued in three equal installments, on each of May 1, 2013, August 1, 2013 and November 15, 2013. On July 11 and November 4, 2013 the Company issued to such advisor 5,000 and 10,000 shares, respectively. The fair value of the shares at these dates was \$34,900 and \$64,400, respectively. See also note 5a.

On May 13, 2014, the Company entered into an additional consulting agreement with the same third party advisor for a period of an additional twelve months, pursuant to which such 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.

f. On April 29, 2013, the Subsidiary entered into a Clinical Research Organization Service Agreement with a third party, to retain it as a Clinical Research Organization ("CRO"), for its Phase 2a clinical trial for an oral insulin capsule for type 2 diabetes patients. As consideration for its services, the Subsidiary will pay the CRO a total amount of approximately \$332,702 that will be paid during the term of the engagement and based on achievement of certain milestones, \$282,807 of which were paid and recognized through May 31, 2014.

On February 6, 2014, the Subsidiary entered into an additional agreement with the same CRO, to retain it as a CRO, for its Phase 2a clinical trial for an oral insulin capsule for type 1 diabetes patients, which is expected to be completed in approximately nine months. As consideration for its services, the Subsidiary will pay the CRO a total amount of approximately \$280,008 that will be paid during the term of the engagement and based on achievement of certain milestones, \$140,000 of which were paid and recognized through May 31, 2014.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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

g. On July 23, 2013, the Subsidiary entered into a Master Service Agreement with a vendor for the process development and production of one of its oral capsule ingredients in the amount of \$102,280, of which \$68,187 were paid and recognized through May 31, 2014.

On March 3, 2014, the Subsidiary entered into an additional agreement with the same vendor, for the process development and production of one of its oral capsule ingredients in a different technology in the amount of \$310,500, and bonus payments of up to \$600,000 that will be paid upon achieving certain milestones, as described in the agreement. The Subsidiary paid and recognized \$15,000 of said amount through May 31, 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 \$214,000, of which \$103,370 were paid and recognized through May 31, 2014.

- h. On May 26, 2014, the Subsidiary entered into a supply agreement with a vendor, according to which, the vendor will manufacture insulin capsules for total consideration of \$214,100, none of which was paid or recognized through May 31, 2014.
- i. 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 \$65,053. As of May 31, 2014, the Subsidiary had not yet realized any revenues and did not incur any royalty liability.

During the nine and three month periods ended May 31, 2014, the Company received no grants from the Bio-Jerusalem fund.

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 Israeli Government, 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.

On May 31, 2014, the Subsidiary had not yet realized any revenues from the said project and did not incur any royalty liability. The total amount that was actually received through May 31, 2014 is \$1,783,994.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

# NOTE 2 - COMMITMENTS (continued):

For the nine and three month periods ended May 31, 2014, the research and development expenses are presented net of OCS and Bio-Jerusalem fund grants, in the total amount of \$333,522 and \$194,081, 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 May 31, 2014 and August 31, 2013, the assets or liabilities measured at fair value were comprised of available for sale securities (level 1). See also note 4.

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

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.

In order to secure the fulfillment of the Company's obligations under credit cards, the Company has placed a restricted deposit with the bank in an amount of \$61,000.

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.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

#### **NOTE 4 - MARKETABLE SECURITIES:**

As of May 31, 2014, marketable securities consisted wholly of equity securities of D.N.A Biomedical Solutions Ltd ("D.N.A").

During the nine months ended May 31, 2014, the Subsidiary sold in aggregate 2,625,989 of the D.N.A shares for a total of \$137,555.

As of May 31, 2014, the Group owns approximately 9.8% of D.N.A's outstanding ordinary shares.

The cost of the securities sold and the amount reclassified out of accumulated other comprehensive income into financial income (amounting to \$80,017 during the nine month period ended May 31, 2014), were determined by specific identification.

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

As of May 31, 2014 and August 31, 2013, the available for sale securities are classified as level 1 as described in the table below:

	Level 1
Marketable securities:	
May 31, 2014	\$1,063,409
August 31, 2013	\$ 956,376

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.

### NOTE 5 - STOCK HOLDERS' EQUITY:

- a. As described in note 2e, onNovember 4, 2013, the Company issued 10,000 shares of its common stock to an advisor as remuneration for services rendered. The total fair value of the shares at the date of grant was \$64,400.
- b. On December 24, 2013, the Company entered into a Placement Agency Agreement with Aegis Capital Corp. (the "Placement Agent"), pursuant to which the Placement Agent agreed to use its reasonable best efforts to arrange for the sale of up to 1,580,000 shares of the Company's common stock. In connection therewith, on December 24, 2013, the Company entered into a Securities Purchase Agreement, pursuant to which the Company agreed to sell an aggregate of 1,580,000 shares of common stock, at a price of \$10.00 per share, to two institutional investors in a registered direct offering (the "Offering"). The Company received all funds and issued all shares of common stock in connection with the Offering as of December 30, 2013. The net proceeds to the Company from the Offering were approximately \$14,887,085, after deducting Placement Agent's commissions of \$815,500 and other offering expenses of the Company.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

# NOTE 5 - STOCK HOLDERS' EQUITY (continued):

- c. During January and April 2014, 398,965 warrants were exercised for cash and resulted in the issuance of 398,965 shares of common stock. The cash consideration received for the exercise of the warrants was \$1,571,638.
- d. During January through April 2014, 26,902 options were exercised as part of the Company's stock based compensation plan for cash and resulted in the issuance of 26,902 shares of common stock. The cash consideration received for exercise of the options was \$179,550.
- e. In May 2014, the Company issued 2,252 shares of its common stock as payment of liquidated damages related to certain registration rights contained in a 2012 securities purchase agreement.

#### NOTE 6 - STOCK BASED COMPENSATION:

- a. On April 9, 2014, options to purchase an aggregate of 94,268 shares of the Company were granted to Nadav Kidron, the Company's President, Chief Executive Officer and a director, and Miriam Kidron, the Company's Chief Medical and Technology Officer and a director, both related parties, at an exercise price of \$12.45 per share (equivalent to the traded market price on the date of grant). The options vested with respect to 31,420 shares of common stock on April 30, 2014, and the remaining shares of common stock will vest in eight equal monthly installments of 7,586 each. These options expire on April 9, 2024. The fair value of these options on the date of grant was \$781,391, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 82.06%; risk-free interest rates of 1.65%; and expected term of 5.21 years.
- b. On April 9, 2014, options to purchase an aggregate of 52,376 shares of the Company were granted to four Board of Directors members at an exercise price of \$12.45 per share (equivalent to the traded market price on the date of grant). The options vest in two equal installments, on July 1, 2014 and January 1, 2015, and expire on April 9, 2024. The fair value of these options on the date of grant was \$217,711, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 82.06%; risk-free interest rates of 1.65%; and expected term of 5.25 years.
- c. On April 9, 2014, options to purchase 2,556 shares of the Company were granted to an employee of the Subsidiary, at an exercise price of \$12.45 per share (equivalent to the traded market price on the date of grant). The options vest in four equal quarterly installments, commencing May 1, 2014, and expire on April 9, 2024. The fair value of these options on the date of grant was \$21,220, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 82.06%; risk-free interest rates of 1.65%; and expected term of 5.23 years.

#### 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," "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, 2013, or our Annual Report, as filed with the Securities and Exchange Commission, or the SEC, on November 27, 2013, 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 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 expect to begin non-U.S. based Phase 1a and 1b trials and IND-enabling studies in the third quarter of calendar year 2014.

We originally filed an Investigational New Drug application, or IND, with the FDA in December 2012 for clearance to begin a Phase 2 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 2 trial. As a result, we withdrew the original IND and, in April 2013, we submitted a new IND for the Phase 2a sub-study. Following the FDA's clearance to proceed in May 2013, we began the Phase 2a sub-study in July 2013. As we announced in January 2014, the Phase 2a sub-study met all primary and secondary endpoints. Specifically, the Phase 2a study evaluated the pharmacodynamic effects of ORMD 0801 on mean nighttime glucose (determined using a continuous glucose monitor). The results show that the ORMD-0801, has exhibited a sound safety profile, led to reduced mean daytime and nighttime glucose readings, when compared to placebo and lowered fasting blood glucose concentrations, when compared to placebo. In addition, no serious adverse events occurred during the Phase 2a study, and the only adverse events that occurred during the study were not drug related. In light of these results, we believed that we should move forward with the Phase 2b clinical trial on approximately 180 type 2 diabetic patients, which we are preparing to initiate in the fourth quarter of calendar year 2014. This clinical trial will be designed to assess the safety and efficacy of ORMD-0801 and its structure is still under design by us.

In February 2014, we submitted a protocol to the FDA to initiate a Phase 2a 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 will be carried out at an inpatient setting on twenty-four type 1 diabetic patients. We began this study in March 2014. Results are anticipated in the fourth quarter of calendar year 2014.

The table below gives an overview of our product pipeline:

		Phase I	Phase II	Phase III	Timeline
ORMD-0801	Type 2 diabetes		$\Rightarrow$		Q4, '13: Phase 2a completed Q4, '14: Phase 2b multi-center study projected initiation
orar msumi	Type 1 diabetes		$\Rightarrow$		Q1, '14: Phase 2a initiated Q1, '15: Phase 2b multi-center study projected initiation
ORMD-0901 oral GLP-1	Type 2 diabetes	<b>\</b>			Q3, '14: Preclinical/IND studies projected initiation Q3, '14: Phase 1b ex-US study projected initiation Q2, '15: Phase 2 multi-center study projected initiation

## Intellectual Property

During the months September 2013 through January 2014, we received allowances for a patent entitled "Methods and Compositions for Oral Administrations of Proteins," which was filed under the Patent Cooperation Treaty in 2006, from the Australian, Canadian, Japanese and European Patent Offices. The Australian Patent Office issued this patent in October 2013, and this patent was granted by the Hong Kong patent office in April 2014.

During the months September 2013 through January 2014, we received allowances for a patent entitled "Methods and Compositions for Oral Administrations of Proteins," which was filed under the Patent Cooperation Treaty in 2009, from the Australian, Chinese, Israeli, Russian and Japanese Patent Offices. The Japanese Patent Office issued this patent in October 2013.

In December 2013 and February 2014, we received allowances for a patent entitled "Methods and Compositions for Oral Administration of Exenatide," from the Israeli and Australian Patent Offices, respectively. The Israeli Patent was granted in May 2014.

# **Results of Operations**

### Comparison of nine and three month periods ended May, 2014 and 2013

The following table summarizes certain statements of operations data for the Company for the nine and three month periods ended May 31, 2014 and 2013:

	Nine months ended				Three months ended				
	May 31,				May 31,				
	2014 2013		2014 2013 2014		2014	2013			
Research and development expenses, net	\$	2,513,142	\$	1,977,258	\$	1,089,298	\$	835,636	
General and administrative expenses		1,743,902		1,349,081		813,923		499,034	
Financial (income) expense, net		(189,980)		114,629		(75,319)		(78,329)	
Net loss for the period	\$	4,067,064	\$	3,440,968	\$	1,827,902	\$	1,256,341	
Loss per common share – basic and diluted	\$	(0.45)	\$	(0.49)	\$	(0.18)	\$	(0.17)	
Weighted average common shares outstanding		8,988,446		7,087,831		9,888,126		7,223,377	

#### 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.

During the nine months ended May 31, 2014, research and development expenses totaled \$2,513,142, compared to \$1,977,258 for the nine months ended May 31, 2013. The increase is attributed to expenses related to the increase in clinical trials and preparation for the Phase 2b clinical trial, as well as to the increase in research and development staff and to cash bonuses to research and development staff for the Company's 2013 achievements, as well as to the increase in stock based compensation costs, which is attributed to awards granted to officers and directors in April 2014. During the nine months ended May 31, 2014, stock based compensation costs totaled \$665,321, as compared to \$301,804 during the nine months ended May 31, 2013.

During the three months ended May 31, 2014, research and development expenses totaled \$1,089,298, compared to \$835,636 for the three months ended May 31, 2013. The increase in research and development expenses during the three months ended May 31, 2014, as compared to the three months ended May 31, 2013, is mainly attributable to the increase in stock based compensation costs, which is attributed to awards granted to officers and directors during the three months ended May 31, 2014.

#### Government grants

In May 2013, Oramed Ltd., or the Subsidiary, was granted a fourth grant amounting to a total amount of NIS 975,000 (approximately \$265,000) 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 January 2013 to December 2013. In March 2014, the OCS accepted the Subsidiary's application to shorten that period to ten months, ending October 31, 2013. In March 2014, the Subsidiary was also granted a fifth grant amounting to a total amount of NIS 1,206,990 (approximately \$345,000) from the OCS, which was designated for research and development expenses for the period of November 2013 to October 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 nine months ended May 31, 2014, we recognized research and development grants in an amount of \$333,522, and in the nine months ended May 31, 2013, we recognized research and development grants in an amount of \$101,639. As of May 31, 2014, we had not yet realized any revenues from the said project and did not incur any royalty liability 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.

For the nine months ended May 31, 2014, general and administrative expenses totaled \$1,743,902 compared to \$1,349,081 for the nine months ended May 31, 2013. The increase in costs incurred related to general and administrative activities during the nine months ended May 31, 2014, reflects an increase in salaries and related expenses resulting from cash bonuses to employees for the Company's 2013 achievements, that was partially offset by a decrease in professional expenses. During the nine months ended May 31, 2014, as part of our general and administrative expenses, we incurred \$374,841 related to stock options granted to employees and consultants, as compared to \$325,707 during the nine months ended May 31, 2013.

For the three months ended May 31, 2014, general and administrative expenses totaled \$813,923 compared to \$499,034 for the three months ended May 31, 2013. The increase in general and administrative expenses during the three months ended May 31, 2014, as compared to the three months ended May 31, 2013, is attributable to the increase in stock based compensation costs, which is attributed to awards granted to officers and directors during the three months ended May 31, 2014.

#### Financial (income) expense, net

Net financial expense decreased from net expense of \$114,629 for the nine months ended May 31, 2013 to net income of \$189,980 for the May 31, 2014 period. The decrease is mainly due to the decrease of warrant liabilities attributable to warrants held by Regals Fund LP and corresponding increase in stockholders' equity on November 29, 2012, as a result of the removal of the anti-dilution provisions of the warrants, which resulted in a net cost of \$296,982, and from an increase in interest income on available cash and cash equivalents primarily due to the increase in cash and cash equivalents balance that resulted from public offerings completed in July and December 2013.

During the three months ended May 31, 2014, net financial income totaled \$75,319, compared to \$78,329 for the three months ended May 31, 2013. The decrease in net financial income during the three months ended May 31, 2014, as compared to the three months ended May 31, 2013, is attributable to decrease in exchange rate differences expenses.

#### Other comprehensive income

Subsequent increase in the fair value of available for sale securities previously written down as impaired for the nine months ended May 31, 2014 of \$34,156 resulted from the increase in fair value of the ordinary shares of D.N.A Biomedical Solutions Ltd, or D.N.A, that we hold. Reclassification adjustments for gains included in net loss for the nine months ended May 31, 2014 of \$80,017, resulted from the sale of 2,625,989 of our D.N.A ordinary shares in October and November 2013 and January and March 2014. Unrealized gains on available for sale securities for the nine months ended May 31, 2014 of \$210,432, resulted from the increase in fair value of our D.N.A ordinary shares.

#### Liquidity and capital resources

From inception through May 31, 2014, we have incurred losses in an aggregate amount of \$26,190,653. 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 in July and December 2013, raising a total of \$35,746,638, net of transaction costs. During that period we also received cash consideration of \$1,860,763 from exercise of warrants and options. We will seek to obtain additional financing through similar sources in the future as needed. As of May 31, 2014, we had \$2,474,839 of available cash, \$12,005,172 of short term bank deposits, \$6,508,269 of long term bank deposits and \$1,063,409 of marketable securities. Marketable securities are presented at fair value and their realization is subject to certain limitations if sold through the market, and we are therefore exposed to market risk. There is no assurance that at the time of sale of the marketable securities the price per share will be the same or higher, nor that we will be able to sell all of the securities at once given the volume of securities we hold. We anticipate that we will require approximately \$11 million to finance our activities during the 12 months following May 31, 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 and existing stockholders, future public offerings, and additional funding from the OCS. Based on our current cash resources and commitments, including cash received in public offerings in the period ended May 31, 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.

During the nine month period ended May 31, 2014, cash and cash equivalents increased to \$2,474,839 from the \$2,272,228 reported as of August 31, 2013, which is due to the reasons described below.

Operating activities used cash of \$3,266,135 in the nine month period ended May 31, 2014, as compared to \$3,115,165 used in the nine months May 31, 2013. Cash used for operating activities in the nine months ended May 31, 2014 primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by stock based compensation adjustments, while cash used by operating activities in the nine months May 31, 2013, primarily consisted of net loss resulting from research and development and general and administrative expenses, partially offset by stock based compensation adjustments and exchange of warrants.

During the nine month period ended May 31, 2014, we received \$124,784 in OCS grants towards our research and development expenses, while we recognized the amount of \$333,522 during such period and \$58,237 was recognized in the year ended August 31, 2013. Most of the amounts that were recognized but not received during the nine month period ended May 31, 2014, were received from the OCS in June 2014. The amounts that were recognized but not received during the nine month period ended May 31, 2013, were received from the OCS during fiscal year 2013. The OCS has supported our activity in the past three years.

Investing activities used cash of \$13,179,411 in the nine month period ended May 31, 2014, as compared to \$1,643,828 that was used in the nine month period ended May 31, 2013. Cash used in investing activities in the nine months ended May 31, 2014 consisted primarily of the acquisition of short-term and long term bank deposits, while cash used in investing activities in the nine months ended May 31, 2013 consisted primarily of the acquisition of short-term bank deposits.

Financing activities provided cash of \$16,638,273 in the nine month period ended May 31, 2014, as compared to \$1,450,936 of cash provided by financing activities during the nine months ended May 31, 2013, which consisted of proceeds from our issuance of common stock and proceeds from exercise of warrants and options in the nine months ended May 31, 2014 and of proceeds from our issuance of common stock and warrants in the nine months ended May 31, 2013.

#### Off-balance sheet arrangements

As of May 31, 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 June 1, 2014 are as follows:

Category	<del>_</del>	Amount
Research and development, net of OCS funds	\$	8,291,000
General and administrative expenses		2,772,000
Financial income, net		(67,000)
Total	\$	10,996,000

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 the combination therapy, respectively, 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 and receiving additional grants from the OCS.

# ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this Item.

#### 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, 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 May 31, 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 April 1, 2014, the Company issued 137,300 shares of its common stock upon exercise of a warrant previously issued in a private placement for an aggregate exercise price of \$1,648.

On April 30, 2014, the Company issued 2,816 shares of its common stock upon exercise of a warrant previously issued in a private placement for an aggregate exercise price of \$16,896.

On June 6, 2014, the Company issued 2,252 shares of its common stock as payment of liquidated damages related to certain registration rights contained in a 2012 securities purchase agreement.

The issuances described above were exempt under Section 4(a)(2) of the Securities Act of 1933, as amended.

### **ITEM 6 - EXHIBITS**

### Num**b**æhibit

- 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 May 31, 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.
- \* Filed herewith
- \*\* Furnished herewith

# **SIGNATURES**

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

### ORAMED PHARMACEUTICALS INC.

Date: July 14, 2014 By: \(\s/\)s/ Nadav Kidron

Nadav Kidron

President and Chief Executive Officer

Date: July 14, 2014 By: /s/ Yifat Zommer

Yifat Zommer

Chief Financial Officer

(principal financial and accounting officer)

# CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

- I, Nadav Kidron, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Oramed Pharmaceuticals Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: July 14, 2014

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

# CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

- I, Yifat Zommer, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Oramed Pharmaceuticals Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: July 14, 2014

<u>/s/ Yifat Zommer</u> Yifat Zommer Chief Financial Officer

# CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the quarterly report of Oramed Pharmaceuticals Inc., or the Company, on Form 10-Q for the period ended May 31, 2014, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Nadav Kidron, President, Chief Executive Officer and a Director of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities and Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: July 14, 2014

/s/ Nadav Kidron

Nadav Kidron, President and Chief Executive Officer

# CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the quarterly report of Oramed Pharmaceuticals Inc., or the Company, on Form 10-Q for the period ended May 31, 2014, as filed with the Securities and Exchange Commission on the date hereof, or the Report, I, Yifat Zommer, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities and Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: July 14, 2014

<u>/s/ Yifat Zommer</u> Yifat Zommer, Chief Financial Officer