

ORAMED PHARMACEUTICALS INC.  
Form 10-Q  
April 04, 2012

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended February 29, 2012

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

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  
(IRS Employer Identification  
No.)

Hi-Tech Park 2/5 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)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

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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

Accelerated filer

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

Smaller reporting company

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 April 3, 2012 there were 70,320,583 shares of the issuer's Common Stock, \$.001 par value, outstanding.

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ORAMED PHARMACEUTICALS INC.

FORM 10-Q

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PART I – FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

ORAMED PHARMACEUTICALS INC.  
(A development stage company)

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF FEBRUARY 29, 2012

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ORAMED PHARMACEUTICALS INC.  
(A development stage company)

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AS OF FEBRUARY 29, 2012

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ORAMED PHARMACEUTICALS INC.  
(A development stage company)  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(UNAUDITED)  
U.S. dollars

	February 29, 2012	August 31, 2011
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 1,824,141	\$ 1,513,365
Short term deposits	838,738	1,801,400
Marketable securities	341,454	384,565
Restricted cash	16,000	16,000
Accounts receivable - other	46,668	542,891
Prepaid expenses	12,805	1,670
Related parties	432	-
Grants receivable from the Chief Scientist	28,045	24,191
<b>T o t a l current assets</b>	<b>3,108,283</b>	<b>4,284,082</b>
<b>LONG TERM DEPOSITS AND INVESTMENT AMOUNTS FUNDED IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT</b>	<b>9,412</b>	<b>10,186</b>
<b>PROPERTY AND EQUIPMENT, net</b>	<b>17,101</b>	<b>14,293</b>
<b>T o t a l assets</b>	<b>\$ 3,142,588</b>	<b>\$ 4,325,937</b>
<b>Liabilities and stockholders' equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 534,907	\$ 375,538
Related parties	-	18,502
Account payable with former shareholder	47,252	47,252
<b>T o t a l current liabilities</b>	<b>582,159</b>	<b>441,292</b>
<b>LONG TERM LIABILITIES:</b>		
Employee rights upon retirement	23,982	22,675
Provision for uncertain tax position	138,054	138,054
	162,036	160,729
<b>COMMITMENTS (note 2)</b>		
<b>T o t a l liabilities</b>	<b>744,195</b>	<b>602,021</b>
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock of \$ 0.001 par value - authorized: 200,000,000 shares at February 29, 2012 and August 31, 2011; issued and outstanding: 70,187,583 shares at February 29, 2012 and 70,104,583 at August 31, 2011	70,187	70,104
Additional paid-in capital	18,339,399	18,201,111
Deficit accumulated during the development stage	(16,011,193)	(14,547,299)
<b>T o t a l stockholders' equity</b>	<b>2,398,393</b>	<b>3,723,916</b>
<b>T o t a l liabilities and stockholders' equity</b>	<b>\$ 3,142,588</b>	<b>\$ 4,325,937</b>

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

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ORAMED PHARMACEUTICALS INC.  
(A development stage company)  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(UNAUDITED)  
U.S. dollars

	Six months ended		Three months ended		Period from April 12, 2002 (inception) through February 29, 2012
	February 29, 2012	February 28, 2011	February 29, 2012	February 28, 2011	
RESEARCH AND DEVELOPMENT EXPENSES	\$ 894,663	\$ 627,816	\$ 710,647	\$ 341,328	\$ 8,746,512
IMPAIRMENT OF INVESTMENT	-	-	-	-	434,876
GENERAL AND ADMINISTRATIVE EXPENSES	511,605	621,016	229,704	305,887	7,469,988
OPERATING LOSS	1,406,268	1,248,832	940,351	647,215	16,651,376
FINANCIAL INCOME	(14,528 )	(10,045 )	(7,574 )	(7,856 )	(208,560 )
FINANCIAL EXPENSES	29,043	6,788	9,487	3,432	210,300
GAIN ON SALE OF INVESTMENT	-	-	-	-	(1,033,004 )
IMPAIRMENT OF AVAILABLE- FOR-SALE SECURITIES	43,111	-	43,111	-	240,523
LOSS BEFORE TAXES ON INCOME	1,463,894	1,245,575	985,375	642,791	15,860,635
TAXES ON INCOME	-	-	-	-	150,558
NET LOSS FOR THE PERIOD	\$ 1,463,894	\$ 1,245,575	\$ 985,375	\$ 642,791	\$ 16,011,193
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ 0.02	\$ 0.02	\$ 0.01	\$ 0.01	
WEIGHTED AVERAGE NUMBER OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER COMMON STOCK	70,140,610	60,344,880	70,176,638	62,804,799	

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



ORAMED PHARMACEUTICALS INC.  
(A development stage company)  
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
(UNAUDITED)  
U.S. dollars

	Common Stock Shares	\$	Additional paid-in capital	Deficit accumulated during the development stage	Total stockholders' equity
BALANCE AS OF APRIL 12, 2002 (inception)	34,828,200	\$ 34,828	\$ 18,872		\$ 53,700
CHANGES DURING THE PERIOD FROM APRIL 12, 2002 THROUGH AUGUST 31, 2010 :					
SHARES CANCELLED	(19,800,000)	(19,800 )	19,800		-
SHARES ISSUED FOR INVESTMENT IN ISTI-NJ	1,144,410	1,144	433,732		434,876
SHARES ISSUED FOR OFFERING COSTS	1,752,941	1,753	(1,753 )		-
SHARES AND WARRANTS ISSUED FOR CASH- NET OF ISSUANCE EXPENSES	37,359,230	37,359	7,870,422		7,907,781
SHARES ISSUED FOR SERVICES	1,730,540	1,731	819,606		821,337
CONTRIBUTIONS TO PAID IN CAPITAL			18,991		18,991
RECEIPTS ON ACCOUNT OF SHARES AND WARRANTS			6,061		6,061
SHARES ISSUED FOR CONVERSION OF CONVERTIBLE NOTE	550,000	550	274,450		275,000
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS			3,554,921		3,554,921
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS			615,882		615,882
DISCOUNT ON CONVERTIBLE NOTE RELATED TO BENEFICIAL CONVERSION FEATURE			108,000		108,000
				(16 )	(16 )

OTHER COMPREHENSIVE  
LOSS

IMPUTED INTEREST			19,777		19,777
NET LOSS				(12,986,038)	(12,986,038)
BALANCE AS OF AUGUST 31, 2010	57,565,321	57,565	13,758,761	(12,986,054)	830,272
SHARES ISSUED FOR SERVICES RENDERED	730,636	731	226,838		227,569
SHARES AND WARRANTS ISSUED FOR CASH	11,808,626	11,808	3,682,404		3,694,212
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS			502,593		502,593
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS			26,733		26,733
IMPUTED INTEREST			3,782		3,782
NET LOSS				(1,561,245 )	(1,561,245 )
BALANCE AS OF AUGUST 31, 2011	70,104,583	70,104	18,201,111	(14,547,299)	3,723,916
SHARES ISSUED FOR SERVICES	83,000	83	24,817		24,900
SHARES TO BE ISSUED FOR SERVICES RENDERED			30,435		30,435
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS			66,136		66,136
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS			16,900		16,900
NET LOSS				(1,463,894 )	(1,463,894 )
BALANCE AS OF FEBRUARY 29, 2012	70,187,583	\$ 70,187	\$ 18,339,399	\$ (16,011,193)	\$ 2,398,393

## ORAMED PHARMACEUTICALS INC.

(A development stage company)

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

U.S. dollars

	Six months ended		Period from
	February	February	April 12,
	29,	28,	2002
	2012	2011	(inception
			date) through
			February 29,
			2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$(1,463,894)	\$(1,245,575)	\$(16,011,193)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation	11,713	15,122	117,820
Amortization of debt discount	-	-	108,000
Exchange differences	2,963	(570 )	295
Stock based compensation	83,036	335,797	4,783,165
Common stock issued for services	24,900	119,800	1,072,996
Common stock to be issued for services	30,435	-	30,435
Gain on sale of investment	-	-	(1,033,004 )
Impairment of investment	-	-	434,876
Impairment of available for sales securities	43,111	-	240,523
Imputed interest	-	1,891	23,559
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	30,802	(29,124 )	(87,140 )
Restricted cash	-	8	(16,000 )
Accounts payable and accrued expenses	140,867	107,249	534,907
Liability of employee rights upon retirement	1,307	-	23,982
Provision for uncertain tax position	-	-	138,054
Total net cash used in operating activities	(1,094,760)	(695,402 )	(9,638,725 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	(2,129 )	(1,475 )	(125,612 )
Acquisition of short-term investments, net	961,262	(1,677,000)	(4,467,120 )
Funds in respect of employee rights upon retirement	(3,597 )	-	(17,890 )
Proceeds from sale of investment in Entera	450,000	-	450,000
Proceeds from sale of Short term investments	-	-	3,628,000
Lease deposits	-	-	(7,509 )
Total net cash derived from (used in) investing activities	1,405,536	(1,678,475)	(540,131 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock and warrants - net of issuance expenses	-	3,106,000	11,655,693

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Receipts on account of shares issuances	-	-	6,061
Proceeds from convertible notes	-	-	275,000
Proceeds from short term note payable	-	-	120,000
Payments of short term note payable	-	-	(120,000 )
Shareholder advances	-	-	66,243
Net cash provided by financing activities	-	3,106,000	12,002,997
<b>INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>310,776</b>	<b>732,123</b>	<b>1,824,141</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>1,513,365</b>	<b>1,199,638</b>	<b>-</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$1,824,141</b>	<b>\$1,931,761</b>	<b>\$1,824,141</b>
<b>Non cash investing and financing activities:</b>			
Shares issued for offering costs			\$1,753
Contribution to paid in capital			\$18,991
Discount on convertible note related to beneficial conversion feature			\$108,000

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

ORAMED PHARMACEUTICALS, Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:

a.

General:

1. 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 (the "First Agreement") with Hadasit Medical Services and Development Ltd ("Hadasit") to acquire the provisional patent related to orally ingestible insulin pill to be used for the treatment of individuals with diabetes. The Company has been in the development stage since its formation and has not yet realized any revenues from its planned operations. On March 11, 2011, Oramed 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").

The Group is engaged in research and development in the biotechnology field and is considered a development stage company in accordance with Accounting Standard Codification ("ASC") No. 915, "Development Stage Entities".

2. The accompanying unaudited condensed consolidated financial statements as of February 29, 2012 and for the six months then ended, have been prepared in accordance with accounting principles generally accepted in the United States relating to the preparation of financial statements for interim periods. Accordingly, they do not include all the information and footnotes required for annual financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair statement have been included. The accounting principles applied in the preparation of the condensed statements are consistent with those applied in the preparation of the annual financial statements, however the condensed statements do not include all the information and explanations required for the annual financial statements. Operating results for the six months ended February 29, 2012, are not necessarily indicative of the results that may be expected for the year ending August 31, 2012.

ORAMED PHARMACEUTICALS, Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

3. Going concern considerations

The accompanying unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has net losses for the period from inception (April 12, 2002) through February 29, 2012 of \$16,011,193 as well as negative cash flow from operating activities. Presently, the Company does not have sufficient cash resources to meet its requirements in the twelve months following February 29, 2012. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is in the process of evaluating various financing alternatives as the Company will need to finance 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 the Company 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 shareholders, as well as on going funding from the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor of Israel ("OCS").

These condensed consolidated financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent on its ability to obtain additional financing as may be required and ultimately to attain profitability.

b. Newly issued and recently adopted Accounting Pronouncements

1. In May 2011, the Financial Accounting Standard Board ("FASB") issued an accounting update that amends ASC No. 820, "Fair Value Measurement" regarding fair value measurements and disclosure requirements. The amendments are effective during interim and annual periods beginning after December 15, 2011 and are to be applied prospectively. The accounting update will be applicable to the Company beginning in the third quarter of fiscal year 2012. As applicable to the Company, the adoption of the new guidance is not expected to have a material impact on the consolidated financial statements.

2. In June 2011, the FASB issued an update to ASC No. 220, "Presentation of Comprehensive Income," which eliminates the option to present other comprehensive income and its components in the statement of shareholders' equity. The Company can elect to present the items of net income and other comprehensive income in a single continuous statement of comprehensive income or in two separate, but consecutive, statements. Under either method the statement would need to be presented with equal prominence as the other primary financial statements. The amended guidance, which must be applied retroactively, is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, with earlier adoption permitted. In December 2011, the FASB issued another update on the topic, which deferred the effective date pertaining only to the presentation of reclassification adjustments on the face of the financial statements. The accounting update will be applicable to the Company beginning on September 1, 2012. The adoption of the new guidance is not expected to have a material impact on the consolidated financial statements.



ORAMED PHARMACEUTICALS, Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 2 - COMMITMENTS:

a. Under the terms of the First Agreement with Hadasit (note 1a(1) above), the Company retained Hadasit to provide consulting and clinical trial services. As remuneration for the services provided under the agreement, Hadasit is entitled to \$200,000. The primary researcher for Hadasit is Dr. Miriam Kidron, a director and officer of the Company. The funds paid to Hadasit under the agreement are deposited by Hadasit into a research fund managed by Dr. Kidron. Pursuant to the general policy of Hadasit with respect to its research funds, Dr. Kidron receives from Hadasit a management fee in the rate of 10% of all the funds deposited into this research fund. The total amount paid to Dr. Kidron out of this fund was \$10,214.

On January 7, 2009, the Company entered into a second agreement with Hadasit (the "Second Agreement") which confirms that Hadasit has conveyed, transferred and assigned all of its ownership rights in the patents acquired under the First Agreement to the Company, and certain other patents filed by the Company after the First Agreement as a result of the collaboration between the Company and Hadasit.

On July 8, 2009 the Company entered into a third agreement with Hadasit, Prof. Itamar Raz and Dr. Miriam Kidron ("the Third Agreement"), to retain consulting and clinical trial services from Hadasit. According to the Third Agreement, Hadasit will be entitled to total consideration of \$400,000 to be paid by Oramed. \$200,000 of this amount was agreed in the terms of the First Agreement, and the remaining of \$200,000 will be paid in accordance with the actual progress of the study. The total amount that was paid through February 29, 2012 was \$400,000.

On September 11, 2011, the Company entered into a fourth agreement with Hadasit, Dr. Miriam Kidron and Dr. Daniel Schurr ("the Fourth Agreement"), to retain consulting and clinical trial services. According to the Fourth Agreement, Hadasit will be entitled to consideration of \$200,000 to be paid by the Company, none of which was recognized or paid through February 29, 2012.

b. On March 18, 2012, the Subsidiary entered into a lease agreement for its office facilities in Israel. The lease agreement is for a period of 57 months commencing January 1, 2012. The monthly lease payment will be NIS 3,400 in 2012, NIS 4,225 in 2013 and NIS 5,610 from 2014 onwards, and will be linked to the increase in the Israeli consumer price index (as of February 29, 2012, the monthly payment in the Company's functional currency is \$903, the future annual lease payments under the agreement will be \$10,836 - \$17,878).

As security for its obligation under the lease agreements the Subsidiary provided a bank guarantee in an amount equal to three monthly lease payments. valid until November 30, 2016.

ORAMED PHARMACEUTICALS, Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 2 - COMMITMENTS (continued):

c. On April 21, 2009, the Subsidiary entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. ("ADRES") (the "Original Agreement") pursuant to which ADRES will provide consulting services relating to quality assurance and regulatory processes and procedures in order to assist the Subsidiary in submission of a U.S. Investigational New Drug ("IND") according to the U.S. Food and Drug Administration (the "FDA") regulations. In consideration for the services provided under the agreement, ADRES will be entitled to total cash compensation of \$211,000, of which the amount of \$110,000 will be paid as a monthly fixed fee of \$10,000 each month for 11 months commencing May 2009, and the remaining \$101,000 will be paid based on achievement of certain milestones. \$160,000 of the total amount was paid through November 30, 2011, \$50,000 of which was paid for completing the first three milestones.

On February 26, 2012, the parties entered into an amendment agreement, according to which the Subsidiary will pay the remaining \$51,000 of the Original Agreement upon issuance the amendment agreement. In addition, beginning March 1, 2012 and until submission of the IND, the Subsidiary will pay ADRES a monthly fee of approximately \$3,600. The Company recognized the \$51,000 as an expense through February 29, 2012.

d. On February 10, 2010, the Subsidiary entered into an agreement with Vetgenerics Research G. Ziv Ltd, a clinical research organization, to conduct a toxicology trial on its oral insulin capsules. The total cost estimated for the studies is €107,100 (\$143,831) of which €89,293 (\$120,029) was paid through February 29, 2012.

e. 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 on February 22, 2011 and an option to purchase up to 250,000 shares of common stock, par value \$0.001 per share, of the Company at an exercise price of \$0.50 per share. The option vest in five annual installments commencing February 16, 2012 and expire on February 16, 2021. The initial fair value of the option on the date of grant was \$71,495, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 113.80%; risk-free interest rates of 3.42%; and the remaining contractual life of 10 years. The fair value of the options granted is measured on a final basis at each balance sheet reporting date and is recognized over the related service period using the straight-line method.

ORAMED PHARMACEUTICALS, Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 2 - COMMITMENTS (continued):

- f. On May 13, 2011, the Company entered into a consulting agreement with a third party (the "Consultant") for a period of 12 months, pursuant to which the Consultant will provide investor relations services and will be entitled to a cash monthly fee of \$4,000, that may be increased up to \$10,000 upon the completion of a \$5,000,000 capital raise by the Company. In addition, the Consultant received a warrant to purchase up to 32,000 shares of the Company. The warrant has a term of five years and an exercise price of \$0.50 per Share and will vest in 12 installments in the period from October 2011 to May 2016. The Company records expenses in respect of this warrant during the term of the services.
- g. On June 22, 2011, the Subsidiary issued a purchase order to SAFC Pharma for producing one of its oral capsule ingredients in the amount of \$600,000, \$170,000 of which was recognized through February 29, 2012.
- h. On August 15, 2011, the Company entered into an advisory agreement with a third party (the "Advisor") for a period of nine months, pursuant to which the Advisor will provide investors relations services and will be entitled to a cash monthly fee of \$4,000, and an additional \$3,000 in the first month. In addition, the Advisor will be issued 249,000 shares of the Company's common stock in three equal installments over the engagement period, commencing November 2011. See also notes 4 and 5.
- i. On December 12, 2011, the Subsidiary entered into a Supply Agreement with Swiss Caps AG ("Swiss Caps"), according to which, Swiss Caps will manufacture insulin capsules for a total consideration of CHF 395,000 (approximately \$440,600) of which CHF 180,000 (approximately \$195,600) was paid through February 29, 2012.
- j. On February 15, 2012, the Company entered into an advisory agreement with a third party for a period of one year, pursuant to which such third party will provide investors relations services and will be entitled to a share based compensation as follows: 300,000 shares of common stock of the Company will be issued in six installments over the engagement period, commencing February 15, 2012, and a warrant to purchase 750,000 shares of common stock of the Company. The warrant has a term of five years and an exercise price of \$0.50 per share and will vest in 12 monthly installments over the term of the agreement. The Company records expenses in respect of this warrant during the term of the services. See also note 5.

k.

Grants from Bio-Jerusalem

The Subsidiary is committed to pay royalties to 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 \$52,733. As of February 29, 2012, the Subsidiary had not yet realized any revenues and did not incur any royalty liability.

For the six month period ended February 29, 2012, there were no grants received from the Bio-Jerusalem fund.

ORAMED PHARMACEUTICALS, Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 2 - COMMITMENTS (continued):

1. Grants from the Office of the Chief Scientist ("OCS")

The Subsidiary is committed to pay royalties to the Government of Israel on proceeds from sales of products in the research and development of which the Government participates by way of grants.

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

Under the terms of the Subsidiary'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 Subsidiary (dollar linked) with the addition of annual interest at a rate based on LIBOR.

As of February 29, 2012, the Subsidiary had not yet realized any revenues from such product and did not incur any royalty liability. The total amount received through February 29, 2012 was \$1,078,545.

For the six month period ended February 29, 2012, the research and development expenses are presented net of OCS grants, in the total amount of \$57,038.

NOTE 3 - FAIR VALUE:

The Company measures fair value and discloses fair value measurements for financial assets. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

- 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 not quoted on active markets, but corroborated by market data.
- 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.

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.

## ORAMED PHARMACEUTICALS, Inc.

(A development stage company)

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)

## NOTE 3 - FAIR VALUE (continued):

Marketable securities consist wholly of equity securities of D.N.A Biomedical Solutions Ltd. which were received in March 2011 as part of the consideration for selling the Company's equity method investee Entera. Those securities are classified as available-for-sale and are recorded at fair value. The D.N.A Shares are listed on the Tel Aviv Stock Exchange ("TASE") and their tradability was restricted for a period of 6 months from the closing date of the transaction according to TASE policy with regards to private placements. Until September 30, 2011, the fair value of the restricted securities was measured based on the quoted prices of the otherwise identical unrestricted securities, adjusted for the effect of the restriction by applying a proper discount. The discount was determined with reference to other similar restricted instruments. Similar securities, with no restriction on tradability, are quoted on an active market. As of October 1, 2011, the securities are not restricted and the fair value of the securities is measured based on the quoted prices of the securities on an active market.

Transfers in and/or out of Level 3 are recognized in the beginning of the reporting period.

Financial items carried at fair value as of February 29, 2012 and August 31, 2011 are classified in the tables below in one of the three categories described above:

	Fair value measurements at reporting date using			Total
	Level 1	Level 2	Level 3	
Marketable securities:				
February 29, 2012	\$ 341,454	-	-	\$ 341,454
August 31, 2011	-	-	\$ 384,565	\$ 384,565

The following table summarizes the activity for those financial assets where fair value measurements are estimated utilizing Level 3 inputs:

	Six months ended February 29, 2012 Unaudited
Carrying value at the beginning of the period	\$ 384,565
Reclassification to level 1	(384,565 )
Carrying value at the end of the period	-

ORAMED PHARMACEUTICALS, Inc.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 4 - STOCK HOLDERS' EQUITY:

On December 12, 2011, the Company issued 83,000 shares of its common stock to the Advisor as remuneration for services provided. The fair value of the shares at the date of grant was \$24,900. See also note 2h.

NOTE 5 - SUBSEQUENT EVENTS:

On March 14, 2012, the Company issued 83,000 and 50,000 shares of its common stock, respectively, to two advisory companies as remuneration for services provided. The fair values of the shares at the date of grant were \$24,070 and \$14,500 respectively. See also notes 2h and 2j.

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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 together with the financial statements and the related notes included elsewhere herein and in our condensed consolidated financial statements, accompanying notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the fiscal year ended August 31, 2011.

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 regarding our business, clinical trials, financial condition, expenditures, results of operations and prospects. Words such as "expects," "anticipates," "intends," "plans," "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 "Item 1A – Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended August 31, 2011, and filed with the Securities and Exchange Commission (the "SEC" or the "Commission") on November 29, 2011, 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.

As used in this Quarterly Report on Form 10-Q, the terms "we", "us", "our", the "Company", and "Oramed" mean Oramed Pharmaceuticals Inc. and our subsidiary, Oramed Ltd., unless otherwise indicated.

All dollar amounts refer to U.S. dollars unless otherwise indicated.

### Overview of Operations

We are a pharmaceutical company engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin capsule or tablet to be used for the treatment of individuals with diabetes, use of orally ingestible capsules, tablets or pills for delivery of other polypeptides.

### Recent Business Developments

On September 11, 2011, we entered into a fourth agreement with Hadasit Medical Services and Development Ltd. ("Hadasit"), Dr. Miriam Kidron and Dr. Daniel Schurr (the "Fourth Agreement"), to facilitate clinical trials and provide other services. According to the Fourth Agreement, Hadasit will be entitled to a consideration of \$200,000. The terms and conditions of the Fourth Agreement are substantially similar to those of the previous Hadasit agreements, which are described in our Annual Report on Form 10-K for the fiscal year ended August 31, 2011.

On January 10, 2012, we announced the filing of a provisional patent application with the United States Patent and Trademark Office for a combination therapy of our lead compound, ORMD0801 in combination with our oral exenatide formulation, ORMD0901.

On January 24, 2012, we announced the issuance of a patent by the Australian Patent Office that covers a part of our technology which allows for the oral delivery of peptides.

On December 12, 2011, we entered into a Supply Agreement (the "Supply Agreement") with Swiss Caps AG ("Swiss Caps"), according to the which, Swiss Caps will manufacture insulin capsules for total consideration of CHF 395,000 (approximately \$440,600).

On February 26, 2012, we entered into an amendment agreement with ADRES Advanced Regulatory Services Ltd. ("ADRES"), according to which we will pay the remaining \$51,000 of the original agreement with ADRES upon issuance the amendment agreement. In addition, beginning March 1, 2012 and until submission of the IND, we will pay ADRES a monthly fee of approximately \$3,600.

### Short Term Business Strategy

We plan to conduct further research and development on the technology covered by the patent application "Methods and Composition for Oral Administration of Proteins", which we acquired from Hadasit, as well as the other patents we have filed since. Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach and intestines and will be effective in delivering active insulin for the treatment of diabetes. The enzymes and vehicles that are added to the insulin in the formulation process must not modify the insulin chemically or biologically, and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct the clinical trials necessary to file an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration (the "FDA"). Additional clinical trials are planned in other countries such as Israel, India and South Africa, in order to substantiate our results as well as for purposes of making future filings for drug approval in these countries. We also plan to conduct further research and development by deploying our proprietary drug delivery technology for the delivery of other polypeptides in addition to insulin, and to develop other innovative pharmaceutical products.



## Long Term Business Strategy

If our oral insulin capsule or other drug delivery solutions show significant promise in clinical trials, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) to increase the likelihood of obtaining regulatory approvals and registrations in the appropriate markets in a timely manner. We further anticipate that such partner, or partners, would also be responsible for sales and marketing of our oral insulin capsule in these markets. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would enable the partnership to develop new oral dosage form for other polypeptides. While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. Under certain circumstances, we may determine to develop one or more of our oral dosage form on our own, either world-wide or in select territories.

## Other Planned Strategic Activities

In addition to developing our own oral dosage form drug portfolio, we are, on an on-going basis, considering in-licensing and other means of obtaining additional technologies to complement and/or expand our current product portfolio. Our goal is to create a well-balanced product portfolio that will enhance and complement our existing drug portfolio.

## Product Development

### Orally Ingestible Insulin

During fiscal year 2007 we conducted several clinical studies of our orally ingestible insulin. The studies were intended to assess both the safety/tolerability and absorption properties of our proprietary oral insulin. Based on the pharmacokinetic and pharmacologic outcomes of these trials, we decided to continue the development of our oral insulin product.

In November 2007, we successfully completed animal studies in preparation for the Phase 1B clinical trial of our oral insulin capsule (ORMD0801). In January 2008, we commenced the non-FDA approved Phase 1B clinical trials with our oral insulin capsule, in healthy human volunteers with the intent of dose optimization. In March 2008, we successfully completed our Phase 1B clinical trials.

In April 2008, we commenced a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD0801) in type 2 diabetic volunteers at Hadassah Medical Center in Jerusalem. In August 2008, we announced the successful results of this trial.

In July 2008 we were granted approval by the Institutional Review Board Committee of Hadassah Medical Center in Jerusalem to conduct a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD0801) on type 1 diabetic volunteers. In September 2008, we announced the beginning of this trial. In July 2009, we reported positive results from this trial.

In April 2009, we entered into a consulting service agreement with ADRES, pursuant to which ADRES will provide services for the purpose of filing an IND application with the FDA for a Phase 2 study according to the FDA

requirements. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

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In May 2009, we commenced a non-FDA approved Phase 2B study in South Africa to evaluate the safety, tolerability and efficacy of our oral insulin capsule (ORMD0801) on type 2 diabetic volunteers. In May 2010, we reported that the capsule was found to be well tolerated and exhibited a positive safety profile. No cumulative adverse effects were reported throughout this first study of extended exposure to the capsule.

In February 2010, we entered into agreements with Vetgenerics Research G. Ziv Ltd., a clinical research organization, to conduct a toxicology trial on our oral insulin capsules. In March 2011, we reported that we successfully completed the resulting comprehensive toxicity study for our oral insulin capsule (ORMD0801). The study was completed under conditions prescribed by the FDA Good Laboratory Practices regulations.

In September 2010, we reported the successful results of an exploratory clinical trial testing the effectiveness of our oral insulin capsule (ORMD0801) in type 1 diabetes patients suffering from uncontrolled diabetes. Unstable or labile diabetes is characterized by recurrent, unpredictable and dramatic blood glucose swings often linked with irregular hyperglycemia and sometimes serious hypoglycemia affecting type 1 diabetes patients. This exploratory study was a proof of concept study for defining a novel indication for ORMD0801. We believe the encouraging results justify further clinical development of ORMD0801 capsule application toward management of uncontrolled diabetes.

We intend to file an IND application with the FDA for Phase 2 clinical studies of our orally ingested insulin during the fourth calendar quarter of 2012. If we do not receive comments from the FDA on our IND application within 30 days from submission, we intend to immediately commence an FDA approved Phase 2 study to evaluate the safety, tolerability and efficacy of our oral insulin capsule (ORMD0801) on type 2 diabetic volunteers.

#### GLP-1 Analog

In September 2008 we announced the launch of pre-clinical trials of ORMD0901, a GLP-1-analog. The pre-clinical trials include animal studies which suggest that the GLP-1 analog (exenatide-4) when combined with Oramed's absorption promoters is absorbed through the gastrointestinal tract and retains its biological activity.

Glucagon-like peptide-1 (GLP-1) is an incretin hormone - a type of gastrointestinal hormone that stimulates the secretion of insulin from the pancreas. The incretin concept was hypothesized when it was noted that glucose ingested by mouth (oral) stimulated two to three times more insulin release than the same amount of glucose administered intravenously. In addition to stimulating insulin release, GLP-1 was found to suppress glucagon release (hormone involved in regulation of glucose) from the pancreas, slow gastric emptying to reduce the rate of absorption of nutrients into the blood stream, and increase satiety. Other important beneficial attributes of GLP-1 are its effects of increasing the number of beta cells (cells that manufacture and release insulin) in the pancreas and, possibly, protection of the heart.

In September 2009, we received approval from the Institutional Review Board in Israel to commence human clinical trials of an oral GLP-1 analog. The approval was granted after successful pre-clinical results were reported. The trials are being conducted on healthy volunteers at Hadassah University Medical Center in Jerusalem. Oramed's first-in-humans clinical trial is testing the safety and efficacy of ORMD0901, an encapsulated oral GLP-1 analog formulation. The study monitored the responses of healthy males to a single dose delivered 60 minutes before a glucose load. ORMD0901 was well tolerated by all subjects and demonstrated physiological activity, as extrapolated from ensuing subject insulin levels when compared to those observed after treatment with placebo.

## Raw Materials

Our oral insulin capsule is currently manufactured by Swiss Caps, under the Supply Agreement.

In July 2010, our subsidiary, Oramed Ltd., entered into a Manufacturing Supply Agreement ("MSA") with Sanofi-Aventis Deutschland GMBH ("Sanofi-Aventis"). According to the MSA, Sanofi-Aventis will supply our subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the United States.

We purchase the raw materials required for the manufacturing of the capsule from third parties, under separate agreements. We generally depend upon a limited number of suppliers for the raw materials. Although alternative sources of supply for these materials are generally available, we could incur significant costs and disruptions in changing suppliers. The termination of our relationships with our suppliers or the failure of these suppliers to meet our requirements for raw materials on a timely and cost-effective basis could materially adversely affect our business, prospects, financial condition and results of operations.

## Patents and Licenses

We maintain a proactive intellectual property strategy which includes patent filings in multiple jurisdictions, including the United States and other commercially significant markets. We hold 36 patent applications currently pending, with respect to various compositions, methods of production and oral administration of proteins and exenatide. Expiration dates for pending patents will fall between 2026 and 2032. We also hold one patent issued by the Australian Patent Office that covers a part of our technology which allows for the oral delivery of peptides.

Consistent with our strategy to seek protection in key markets worldwide, we have been and will continue to pursue the patent applications and corresponding foreign counterparts of such applications. We believe that our success will depend on our ability to obtain patent protection for our intellectual property.

Our patent strategy is as follows:

- Aggressively protect all current and future technological developments to assure strong and broad protection by filing patents and/or continuations in part as appropriate;
- Protect technological developments at various levels, in a complementary manner, including the base technology, as well as specific applications of the technology; and
- Establish comprehensive coverage in the United States and in all relevant foreign markets in anticipation of future commercialization opportunities.

The validity, enforceability, written supports, and breadth of claims in our patent applications involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that any patents based on pending patent applications or any future patent applications filed by us will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of the patents that have been or may be issued to us will be held valid or enforceable if subsequently challenged, or that others will not claim rights in or ownership of the patents and other proprietary rights held or licensed by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or design around any patents that have been or may be issued to us. Since patent applications in the United States are maintained in secrecy for the initial period of time following filing, we also cannot be certain that others did not first file applications for inventions covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. Our policy is to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, board of directors, technical review board and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as the exclusive property of our company. There can be no assurance, however, that all persons who we desire to sign such agreements will sign, or if they do, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.

Our success will also depend in part on our ability to commercialize our technology without infringing the proprietary rights of others. No assurance can be given that patents do not exist or could not be filed which would have an adverse effect on our ability to market our technology or maintain our competitive position with respect to our technology. If our technology components, products, processes or other subject matter are claimed under other existing United States or foreign patents or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our technology. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed technology or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse effect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease the development and commercialization of our technology.

#### Partnerships and Collaborative Arrangements

We believe that working together with strategic partners will expedite product formulation, production and approval.

In February 2006, we entered into an agreement with Hadasit to facilitate clinical trials and provide other services.

In October 2006, we entered into a Clinical Trial Manufacturing Agreement with Swiss Caps, pursuant to which Swiss Caps currently manufactures the oral insulin capsule developed by us.

During April 2008, we entered into a five year master services agreement with SAFC Pharma, an operating division of Sigma-Aldrich, Inc., a leading developer, manufacturer and distributor of chemicals and biochemicals, pursuant to which SAFC is providing services for individual projects, which may include strategic planning, expert consultation, clinical trial services, statistical programming and analysis, data processing, data management, regulatory, clerical, project management, central laboratory services, pre-clinical services, pharmaceutical sciences services, and other research and development services.

In April 2009, we entered into a consulting service agreement with ADRES pursuant to which ADRES will provide services for the purpose of filing an IND application with the FDA for a Phase 2 study in accordance with FDA requirements.

In July 2009 we entered into an additional agreement with Hadasit, to facilitate additional clinical trials to be performed at Hadassah Medical Center in Jerusalem.

In February 2010, we entered into agreements with Vetgenerics Research G. Ziv Ltd., a clinical research organization, to conduct a toxicology trial on our oral insulin capsules.

In May 2010, we entered into an additional agreement with SAFC Pharma, to develop a process to produce one of our oral capsule ingredients.

In July 2010, our subsidiary, Oramed Ltd., entered into an MSA with Sanofi-Aventis. Pursuant to the MSA, Sanofi-Aventis will supply our subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the United States.

In May 2011, we entered into a consulting agreement with a third party for a period of 12 months, pursuant to which such consultant will provide investor relations services and will be entitled to a cash monthly fee of \$4,000, that may be increased up to \$10,000 upon the completion of a \$5,000,000 capital raise by us. In addition, the consultant received a warrant to purchase up to 32,000 shares of our common stock. The warrant has a term of five years and an exercise price of \$0.50 per share and will vest in 12 installments during the period from October 2011 to May 2016.

In August 2011, we entered into a consulting agreement with a third party for a period of nine months, pursuant to which such consultant will provide investor relations services and will be entitled to a cash monthly fee of \$4,000, and an additional \$3,000 in the first month. In addition, the consultant will be issued 249,000 shares of our common stock in three installments over the engagement period, commencing November 2011.

In September 2011, we entered into a fourth agreement with Hadasit, Dr. Miriam Kidron and Dr. Daniel Schurr (the "Fourth Agreement"), to facilitate clinical trials and provide other services. According to the Fourth Agreement, Hadasit will be entitled to a consideration of \$200,000. The terms and conditions of the Fourth Agreement are substantially similar to those of the previous Hadasit agreements.

In December 2011, we entered into a Supply Agreement with Swiss Caps, according to the which, Swiss Caps will manufacture insulin capsules for total consideration of CHF 395,000 (approximately \$440,600).

In February 2012, we entered into an advisory agreement with a third party (the "Advisor") for a period of one year, pursuant to which the Advisor will provide investors relations services and will be entitled to a share based compensation as follows: 300,000 shares of common stock of the Company will be issued in six installments over the engagement period, commencing as of February 15, 2012, and a warrant to purchase 750,000 shares of common stock of the Company. The warrant has a term of five years and an exercise price of \$0.50 per share and will vest in 12 monthly installments over the term of the agreement.

#### Out-Licensed Technology

In June 2010, our subsidiary, Oramed Ltd., entered into a joint venture agreement with D.N.A Biomedical Solutions Ltd. (formerly Laser Detect Systems Ltd), an Israeli company listed on the Tel Aviv Stock Exchange ("D.N.A"), for the establishment of a new company to be called Entera Bio Ltd. ("Entera").

Under the terms of a license agreement that was entered into between Oramed and Entera in August 2010, we out-licensed technology to Entera, on an exclusive basis, for the development of oral delivery drugs for certain indications to be agreed upon between the parties. The out-licensed technology differs from our main delivery technology that is used for oral insulin and GLP-1 analog and is subject to different patent applications. Entera's initial development effort is for an oral formulation for the treatment of osteoporosis. The license was royalty-free unless our ownership interest in Entera decreased to 30% or less of its outstanding share capital, in which case royalties would have been payable with respect to revenues derived from certain indications. Under certain circumstances, Entera may have received ownership of the licensed technology, in which case we would have received a license back on the same terms.

D.N.A initially invested \$600,000 in Entera, and Entera was initially owned in equal parts by Oramed and D.N.A. Entera's Chief Executive Officer, Dr. Phillip Schwartz, was granted options to purchase ordinary shares of Entera, reflecting 9.9% of Entera's share capital, upon full exercise.

On March 31, 2011, we consummated a transaction with D.N.A, whereby we sold to D.N.A 47% of Entera's outstanding share capital on an undiluted basis. As consideration for the Entera shares, we received a promissory note issued by D.N.A in the principal amount of \$450,000, with an annual interest rate of 0.45%, to be paid within four months after closing, and 8,404,667 ordinary shares of D.N.A, having an aggregate market value of approximately \$581,977 as of March 31, 2011. The promissory note was secured by a personal guarantee of the D.N.A majority shareholders and its term was extended by an Addendum to the Share Purchase agreement dated August 11, 2011. D.N.A paid off the promissory note in November 2011. The ordinary shares of D.N.A were restricted for six months from the closing. In addition, D.N.A invested \$250,000 in our private placement investment round, which closed in February 2011, for which it received 781,250 shares of our common stock and five-year warrants to purchase 273,438 shares of common stock at an exercise price of \$0.50 per share.

As part of the transaction with D.N.A, we entered into a patent transfer agreement (to replace the original license agreement upon closing) pursuant to which Oramed assigned to Entera all of its right, title and interest in and to the patent application that it had licensed to Entera in August 2010. Under this agreement, our subsidiary, Oramed Ltd., is entitled to receive from Entera royalties of 3% of Entera's net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza.

On March 31, 2011, Oramed, Entera and D.N.A terminated the joint venture agreement entered into in June 2010 in connection with the formation of Entera.

In September 2011, Entera reported successful Phase 1 clinical trial results. We believe the Phase 1 data supports the continued development of Entera's oral osteoporosis drug. The Phase 1 clinical trial consisted of twelve healthy patients and was conducted at the Hadassah Medical Center in Jerusalem. No adverse events were reported.

## Results of Operations

### Going concern assumption

The financial statements appearing elsewhere in this quarterly report have been prepared assuming that we will continue as a going concern. We have net losses for the period from inception (April 12, 2002) through February 29, 2012 of \$16,011,193, as well as negative cash flow from operating activities. Based upon our existing spending commitments, estimated at \$5.7 million for the twelve months following February 29, 2012, and our cash availability, we do not have sufficient cash resources to meet our liquidity requirements through February 28, 2013. Accordingly, these factors raise substantial doubt about our ability to continue as a going concern. Management is in the process of evaluating various financing alternatives, as we will need to finance 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 shareholders.

The financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. Our continuation as a going concern is dependent on our ability to obtain additional financing as may be required and ultimately to attain profitability.

### Critical accounting policies

Our significant accounting policies are more fully described in the notes to our condensed consolidated financial statements included in our annual report on Form 10-K for the fiscal year ended August 31, 2011. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.





The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Marketable securities: Consist mainly of equity securities classified as available-for-sale and are recorded at fair value. Until September 30, 2011, the fair value of the restricted securities was measured based on the quoted prices of the otherwise identical unrestricted securities, adjusted for the effect of the restriction by applying a proper discount. The discount was determined with reference to other similar restricted instruments. Similar securities, with no restriction on tradability, are quoted on an active market. As of October 1, 2011, the securities are not restricted and the fair value of the securities is measured based on the quoted prices of the securities on an active market. Changes in fair value, net of taxes, are reflected in other comprehensive income (loss).

Factors considered in determining whether a loss is temporary include the extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee based on our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. The loss is recorded as a charge to earnings.

Valuation of options and warrants: We granted options to purchase shares of our common stock to employees and consultants and issued warrants in connection with some of our financings and to other certain consultants.

We account for share-based payments in accordance with the guidance that requires awards classified as equity awards be accounted for using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, net of estimated forfeitures. We estimated forfeitures based on historical experience and anticipated future conditions.

We elected to recognize compensation cost for an award with only service conditions that has a graded vesting schedule using the accelerated method based on the multiple-option award approach.

When stock options are granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock options issued, whichever is more reliably measurable, pursuant to the guidance. The fair value of the options granted is measured on each reporting date, and the gains (losses) are recorded to earnings over the related service period using the straight-line method.

Taxes on income: Deferred taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have provided a full valuation allowance with respect to its deferred tax assets.



Regarding our subsidiary, Oramed Ltd., the guidance prohibits the recognition of deferred tax liabilities or assets that arise from differences between the financial reporting and tax bases of assets and liabilities that are measured from the local currency into dollars using historical exchange rates, and that result from changes in exchange rates or indexing for tax purposes. Consequently, the abovementioned differences were not reflected in the computation of deferred tax assets and liabilities.

Comparison of six and three month periods ended February 29, 2012 and February 28, 2011

The following table summarizes certain statements of operations data for the Company for the six month and three month periods ended February 29, 2012 and February 28, 2011:

Operating Data:	Six months ended		Three months ended	
	February 29, 2012	February 28, 2011	February 29, 2012	February 28, 2011
Research and development costs	\$894,663	\$627,816	\$710,647	\$341,328
General and administrative expenses	511,605	621,016	229,704	305,887
Impairment of available for sale securities	43,111		43,111	
Financial (income) expense, net	14,515	(3,257 )	1,913	(4,424 )
Net loss for the period	\$1,463,894	\$1,245,575	\$985,375	\$642,791
Loss per common share – basic and diluted	\$0.02	\$0.02	\$0.01	\$0.01
Weighted average common shares outstanding	70,140,610	60,344,880	70,176,638	62,804,799

#### 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 registered patents 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, 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 contract research organizations ("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, costs related to the maintenance of our registered patents, costs related to the filings of patent applications, as well as salaries and related expenses of research and development staff.

In August 2009, Oramed Ltd., our wholly owned Israeli subsidiary, was awarded a government grant amounting to a total net amount of New Israeli Shekels ("NIS") 3.1 million (approximately \$813,000), from the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor of Israel (the "OCS"). This grant was used for research and development expenses for the period of February 2009 to June 2010. The funds were used by us to support further research and development and clinical study of our oral insulin capsule and oral GLP-1-analog. In December 2010, Oramed Ltd., was awarded another grant amounting to a total net amount of NIS 2.9 million (approximately \$807,000) from the OCS, which was designated for research and development expenses for the period of July 2010 to November 2011. We used the funds to support further research and development and clinical study of our oral insulin capsule and oral GLP-1-analog. The two grants are subject to repayment according to the terms determined by the OCS and applicable law. See "--Government Grants" below. In December 2011, Oramed Ltd. applied for a third grant. The application is currently being assessed by the OCS committees.

During the six months ended February 29, 2012, research and development expenses totaled \$894,663, compared to \$627,816 for the six months ended February 28, 2011. The increase is a result of two main factors – the preparation for the FDA approved Phase 2 study that will follow the expected IND filing in the fourth calendar quarter of 2012, that caused an increase of \$234,000, and the end of the OCS support on November 30, 2011 that resulted in an increase of \$152,000. The increase in development expenses was partially offset by a decrease in stock based compensation costs due to amortization of options granted in the prior period. The research and development costs include stock based compensation costs, which during the six months ended February 29, 2012 totaled \$36,820 as compared to \$162,896 during the six months ended February 28, 2011.

The increase in research and development expenses during the three months ended February 29, 2012, as compared to the three months ended February 28, 2011 is attributable to the same reasons mentioned above.

#### Government Grants

In the six and three months ended February 29, 2012, we recognized research and development grants in an amount of \$57,038 and \$15,781, respectively and in the six and three months ended February 28, 2011, we recognized research and development grants in an amount of \$208,674 and \$56,698, respectively. As of February 29, 2012, we had no contingent liabilities to the OCS.

#### Grants from Bio-Jerusalem

We are committed to pay royalties to 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) in the total amount of \$52,733. As of February 29, 2012, we had not yet realized any revenues and did not incur any royalty liability.

For the six months period ended February 29, 2012, there were no grants received from the Bio-Jerusalem fund and in the six months period ended February 28, 2011, we received \$20,950 from said fund.

#### 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 six months ended February 29, 2012, general and administrative expenses totaled \$511,605 compared to \$621,016 for the six months ended February 28, 2011. Costs incurred related to general and administrative activities during the six months ended February 29, 2012, reflect a decrease in professional fee expenses of net \$81,000 as well as stock options granted to employees and consultants. The decrease in general and administrative expenses was partially offset by an increase in investor relations costs, some of which were paid with share based compensation. During the six months ended February 29, 2012, as part of our general and administrative expenses, we incurred \$46,216 related to stock options granted to employees and consultants, as compared to \$172,901 during the six months ended February 28, 2011.

The increase in general and administrative expenses during the three months ended February 29, 2012 as compared to the three months ended February 28, 2011, is attributable to the same reasons mentioned above.

#### Financial income/expense, net

During the six months ended February 29, 2012 and 2011, we generated interest income on available cash and cash equivalents which was offset by bank charges and imputed interest.

#### Liquidity and Capital Resources

From inception through February 29, 2012, we incurred losses in an aggregate amount of \$16,011,193. We have financed our operations through the private placements of equity and debt financing, raising a total of \$11,655,693, net of transaction costs. We will seek to obtain additional financing through similar sources. As of February 29, 2012, we had \$1,824,141 of available cash as well as \$838,738 in short term interest bearing investments. We anticipate that we will require approximately \$5.7 million to finance our activities during the twelve months following February 29, 2012.

Management is in the process of evaluating various financing alternatives as we will need to finance 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 shareholders as well as through additional funding from the OCS.

During the six month period ended February 29, 2012, cash and cash equivalents increased by \$310,776 from the \$1,513,365 reported as of August 31, 2011, which is due, mainly, to proceeds from short-term bank deposits and proceeds from sale of investment in Entera, as further detailed below. Cash balances increased in the three months ended February 29, 2012 for the reasons presented below.

Operating activities used cash of \$1,094,760 in the six months ended February 29, 2012. Cash used for operating activities in the six months ended February 29, 2012 primarily consisted of net loss partially offset by stock based compensation adjustments.

Investing activities provided cash of \$1,405,536 in the six months ended February 29, 2012. Cash used in investing activities consisted primarily of proceeds from short-term bank deposits and proceeds from sale of investment in Entera.

There were no financing activities during the six months ended February 29, 2012.

During the six months ended February 29, 2012 we received approximately \$52,155 from the OCS towards our research and development expenses. The OCS has supported our activity in the past two years. In December 2011, we filed an application for a third year program for the period December 2011 until November 2012. There is no assurance that the OCS will approve a grant for the third year's R&D activity. The amount of such requested grant is also not certain.

In the six month period ended February 29, 2012, we issued a total of 83,000 shares of common stock to a third party for services rendered. The value of those shares of common stock was \$24,900.

During fiscal years 2010 and 2011 we issued a total of 927,387 shares of common stock to various third party vendors for services rendered. The aggregate value of those shares was approximately \$290,529. We also consummated a private placement by selling 937,500 "units" at a purchase price of \$0.32 per unit for a total consideration of \$300,000. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 of a share of common stock at an exercise price of \$0.50 per share.

#### Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

## 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 March 1, 2012 are as follows:

Category:	Amount
Research and development costs	\$ 4,570,000
General and administrative expenses	1,118,000
Financial income, net	(1,000 )
Taxes on income	-
Total	\$ 5,687,000

As previously indicated, we are planning to conduct further clinical studies as well as file an IND application with the FDA for our orally ingested insulin during the fourth calendar quarter of 2012. We expect to have a significant increase in research and development expenses as a result of preparation for the FDA approved Phase 2 study that will follow the IND filing, and during the term of the study. Our ability to proceed with these activities is dependent on several major factors including the ability to attract sufficient financing on terms acceptable to us and receiving additional grant from the OCS.

## Employment and Consulting Agreements

In February 2012, we entered into an advisory agreement with a third party (the "Advisor") for a period of one year, pursuant to which the Advisor will provide investors relations services and will be entitled to a share based compensation as follows: of 300,000 shares of common stock of the Company will be issued in six installments over the engagement period, commencing as of February 15, 2012, and a warrant to purchase 750,000 shares of common stock of the Company. The warrant has a term of five years and an exercise price of \$0.50 per share and will vest in 12 monthly installments over the term of the agreement.

## 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 February 29, 2012. Due to the inherent limitations of our company, derived from our small size and the limited number of employees, the management evaluation concluded that there is a material weakness with respect to segregation of duties. Specifically, our CFO serves as our only qualified internal accounting and financial reporting personnel and as such performs all accounting and financial reporting functions without the benefit of independent checks, confirmations or backup other than bookkeeping functions performed by an outside accounting firm. Based on such review, our chief executive officer and chief financial officer have determined that the Company did not have in place effective controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding



required disclosure, and is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms.

#### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended February 29, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1 - LEGAL PROCEEDINGS

From time to time we may become subject to litigation incidental to our business. We are not currently a party to any material legal proceedings.

ITEM 2 – UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

- (a) On December 12, 2011, we issued 83,000 shares of our common stock, valued at \$24,900, in the aggregate, to a third party for services rendered.
- (b) On March 14, 2012, we issued 133,000 shares of our common stock, valued at \$38,570, in the aggregate, to two third parties for services rendered and to be rendered.

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

ITEM 6 - EXHIBITS

Number Exhibit

- 31.1 \* Certification Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 \* Certification Statement of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 \*\* Certification Statement of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act Of 2002.
- 32.2 \*\* Certification Statement of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act Of 2002.
- 101 \*\* The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended February 29, 2012, filed on April 4, 2012, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Changes in Stockholders' Equity, (iv) Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements.

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Filed herewith  
Furnished herewith

SIGNATURES

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

ORAMED  
PHARMACEUTICALS  
INC.  
Registrant

Date: April 4, 2012

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

Date: April 4, 2012

By: /s/ Yifat Zommer  
Yifat Zommer  
Chief Financial Officer