

ORAMED PHARMACEUTICALS INC.

Form 10-Q

January 13, 2010

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 November 30, 2009

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)

Nevada  
(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 91390  
(Address of principal executive offices)

+ 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

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

**APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY  
PROCEEDINGS DURING THE PRECEDING FIVE YEARS:**

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes  No

**APPLICABLE ONLY TO CORPORATE ISSUERS:**

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 57,454,707 shares issued and outstanding as of January 12, 2009.

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ORAMED PHARMACEUTICALS INC.

FORM 10-QSB

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PART I – FINANCIAL INFORMATION

ITEM 1 – FINANCIAL STATEMENTS

ORAMED PHARMACEUTICALS INC.  
(A development stage company)

INTERIM CONSOLIDATED FINANCIAL STATEMENTS

AS OF NOVEMBER 30, 2009

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ORAMED PHARMACEUTICALS INC.  
(A development stage company)

INTERIM CONSOLIDATED FINANCIAL STATEMENTS

AS OF NOVEMBER 30, 2009

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

	November 30, 2009 Unaudited	August 31, 2009 Audited
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 1,146,128	\$ 1,716,866
Short term investments	1,400,000	1,000,000
Restricted cash	16,000	16,000
Accounts receivable - other	34,154	36,939
Prepaid expenses	23,610	4,119
Grants receivable from the Office of the Chief Scientist	260,982	400,405
<b>Total current assets</b>	<b>2,880,874</b>	<b>3,174,329</b>
<b>LONG TERM DEPOSITS</b>	<b>12,222</b>	<b>12,161</b>
<b>PROPERTY AND EQUIPMENT, net</b>	<b>67,372</b>	<b>75,361</b>
<b>Total assets</b>	<b>\$ 2,960,468</b>	<b>\$ 3,261,851</b>
<b>Liabilities and stockholders' equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 364,332	\$ 321,344
Account payable with former shareholder	47,252	47,252
<b>Total current liabilities</b>	<b>411,584</b>	<b>368,596</b>
<b>PROVISION FOR UNCERTAIN TAX POSITION</b>	<b>147,063</b>	<b>147,063</b>
<b>COMMITMENTS</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock of \$ 0.001 par value - Authorized: 200,000,000 shares at November 30, 2009 and August 31, 2009; Issued and outstanding: 57,026,597 at November 30, 2009 and 56,456,710 shares at August 31, 2009, respectively	57,026	56,456
Additional paid-in capital	12,966,266	12,698,414
Deficit accumulated during the development stage	(10,621,471)	(10,008,678)
<b>Total stockholders' equity</b>	<b>2,401,821</b>	<b>2,746,192</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 2,960,468</b>	<b>\$ 3,261,851</b>

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

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

	Three months ended November 30		Period from April 12, 2002 (inception) through November 30 2009
	2009	2008 Unaudited	
RESEARCH AND DEVELOPMENT EXPENSES, net	\$ 317,545	\$ 818,680	\$ 5,462,404
IMPAIRMENT OF INVESTMENT			434,876
GENERAL AND ADMINISTRATIVE EXPENSES	299,956	383,361	4,557,507
OPERATING LOSS	617,501	1,202,041	10,454,787
FINANCIAL INCOME	(8,373)	(22,144)	(144,481)
FINANCIAL EXPENSE	3,665	8,149	151,598
LOSS BEFORE TAXES ON INCOME	612,793	1,188,046	10,461,904
TAXES ON INCOME	-	-	159,567
NET LOSS FOR THE PERIOD	\$ 612,793	\$ 1,188,046	\$ 10,621,471
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ (0.01)	\$ (0.02)	
WEIGHTED AVERAGE NUMBER OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER COMMON STOCK	57,158,865	56,363,714	

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

ORAMED PHARMACEUTICALS INC.  
(A development stage company)  
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
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, 2008 (audited):					
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 ISSUED FOR CASH- NET OF ISSUANCE EXPENSES	37,359,230	37,359	7,870,422		7,907,781
SHARES ISSUED FOR SERVICES	418,025	418	214,442		214,860
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			2,605,796		2,605,796
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS			203,982		203,982
DISCOUNT ON CONVERTIBLE NOTE RELATED TO BENEFICIAL CONVERSION FEATURE			108,000		108,000
COMPREHENSIVE LOSS				(16)	(16)
IMPUTED INTEREST			12,217		12,217
NET LOSS				(7,248,188)	(7,248,188)
BALANCE AS OF AUGUST 31, 2008 (audited)	56,252,806	56,252	11,785,012	(7,248,204)	4,593,060



SHARES ISSUED FOR SERVICES RENDERED	203,904	204	152,724		152,928
SHARES TO BE ISSUED FOR SERVICES RENDERED			203,699		203,699
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS			436,025		436,025
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS			117,174		117,174
IMPUTED INTEREST			3,780		3,780
NET LOSS				(2,760,474)	(2,760,474)
BALANCE AS OF AUGUST 31, 2009 (audited)	56,456,710	56,456	12,698,414	(10,008,678)	2,746,192
SHARES ISSUED FOR SERVICES RENDERED IN PREVIOUS PERIOD	569,887	570	(570)		-,-
SHARES TO BE ISSUED FOR SERVICES RENDERED			169,500		169,500
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO EMPLOYEES AND DIRECTORS			81,316		81,316
STOCK BASED COMPENSATION RELATED TO OPTIONS GRANTED TO CONSULTANTS			16,661		16,661
IMPUTED INTEREST			945		945
NET LOSS				(612,793)	(612,793)
BALANCE AS OF NOVEMBER 30, 2009 (unaudited)	57,026,597	\$ 57,026	\$ 12,966,266	\$ (10,621,471)	\$ 2,401,821

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

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

	Three months ended November 30		Period from April 12, 2002 (inception date) through November 30, 2009
	2009	2008 Unaudited	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (612,793)	\$ (1,188,046)	\$ (10,621,471)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation	7,989	7,497	53,931
Amortization of debt discount	-	-	108,000
Exchange differences on long term deposits	(61)	967	(1,062)
Stock based compensation	97,977	101,647	3,460,954
Common stock issued for services	-	-	367,788
Common stock to be issued for services	169,500	-	373,199
Impairment of investment	-	-	434,876
Imputed interest	945	945	16,942
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	122,717	104,880	(318,746)
Restricted cash	-	-	(16,000)
Accounts payable and accrued expenses	42,988	(100,872)	364,332
Provision for uncertain tax position	-	-	147,063
Total net cash used in operating activities	(170,738)	(1,072,982)	(5,630,194)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	-	(1,469)	(121,303)
Acquisition of short-term investments	(400,000)	-	(4,128,000)
Proceeds from sale of Short term investments	-	1,000,000	2,728,000
Lease deposits	-	(1,919)	(11,160)
Total net cash used in investing activities	(400,000)	996,612	(1,532,463)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from sales of common stocks and warrants - net of issuance expenses	-	-	7,961,481
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	-	-	8,308,785
	(570,738)	(76,370)	1,146,128



ORAMED PHARMACEUTICALS, Inc.  
(A development stage company)  
NOTES TO INTERIM 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 with Hadasit Medical Services and Development Ltd (the "First Agreement") 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 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 ASC Topic 915 (formerly FAS 7) "Development Stage Entities".

2. The accompanying unaudited interim consolidated financial statements as of November 30, 2009 and for the three 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 presentation have been included. Operating results for the three months ended November 30, 2009, are not necessarily indicative of the results that may be expected for the year ending August 31, 2010.

3. Going concern considerations

The accompanying unaudited interim 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 November 30, 2009 of \$10,621,471 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 November 30, 2009. 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 ("OCS").

These 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.



ORAMED PHARMACEUTICALS, Inc.  
(A development stage company)  
NOTES TO INTERIM FINANCIAL STATEMENTS

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

b. Newly issued and recently adopted Accounting Pronouncements

1. In April 2009, the Financial Accounting Standards Board (“FASB”) issued ASC Topic 825 “Financial Instruments” (formerly FSP No. FAS 107-1 and APB 28-1, “Interim Disclosures about Fair Value of Financial Instruments.” ASC 825 requires companies to disclose in interim financial statements the fair value of financial instruments within the scope of ASC Topic 820 “Fair Value Measurements and Disclosures” (formerly FASB Statement No. 107, Disclosures about Fair Value of Financial Instruments). However, companies are not required to provide in interim periods the disclosures about the concentration of credit risk of all financial instruments that are currently required in annual financial statements. The fair-value information disclosed in the footnotes must be presented together with the related carrying amount, making it clear whether the fair value and carrying amount represent assets or liabilities and how the carrying amount relates to what is reported in the balance sheet.

ASC 825 also requires that companies disclose the method or methods and significant assumptions used to estimate the fair value of financial instruments and a discussion of changes, if any, in the method or methods and significant assumptions during the period. The ASC shall be applied prospectively and is effective for interim and annual periods ending after June 15, 2009. To the extent relevant, the Company adopted the disclosure requirements of this pronouncement for the quarter ended November 30, 2009, in conjunction with the adoption of ASC Topic 820 (formerly FSP FAS 157-4), ASC Topic 320 (formerly FSP FAS 115-2) and ASC Topic 958 (formerly FAS 124-2). The adoption of the new disclosure requirements did not have a material impact on the Company’s financial statements.

2. In May 2009, the FASB issued ASC Topic 855 “Subsequent Events” (formerly SFAS No. 165, Subsequent Events). ASC 855 sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. ASC 855 is effective for interim or annual periods ending after June 15, 2009 and will be applied prospectively. The Company adopted the provisions of ASC 855 for the quarter ended November 30, 2009. The adoption of ASC 855 did not have a material impact on the Company’s condensed financial condition, results of operations or cash flows.

3. In June 2009, the FASB issued Accounting Standards Update (“ASU”) No. 2009-1, “Topic 105 — Generally Accepted Accounting Principles” which amended ASC 105 “The “FASB Accounting Standards Codification” and the Hierarchy of Generally Accepted Accounting Principles (formerly SFAS No. 168 “The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles – A Replacement of FASB Statement No. 162”). ASU 2009-1 establishes the FASB Accounting Standards Codification™ (Codification) as the single source of authoritative U.S. generally accepted accounting principles (U.S. GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative U.S. GAAP for SEC registrants.

ORAMED PHARMACEUTICALS, Inc.  
(A development stage company)  
NOTES TO INTERIM FINANCIAL STATEMENTS

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

ASU 2009-1 and the Codification are effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Codification supersedes all existing non-SEC accounting and reporting standards. All other nongrandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. Following ASU 2009-1, the FASB will not issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts. Instead, the FASB will issue Accounting Standards Updates, which will serve only to: (a) update the Codification; (b) provide background information about the guidance; and (c) provide the bases for conclusions on the change(s) in the Codification. The adoption of ASU 2009-1 did not have a material impact on the Company's financial statements.

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.

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 provide consulting and clinical trial services. According to the Third Agreement, Hadasit will be entitled to additional of \$200,000 to be paid by Oramed in accordance with the actual progress of the study. The total amount that was paid through November 30, 2009 was \$279,255 which refers to all three agreements.

b. During January and April 2008 the Company entered into agreements with OnQ consulting, a clinical research organization (CRO) located in Johannesburg, South Africa, to conduct Phase 1B and 2B clinical trials on its oral insulin capsules. The total cost estimated for the studies is \$229,681 of which \$107,599 was paid through November 30, 2009.

c. As to a Clinical Trial Manufacturing Agreement with Swiss Caps AG, see note 3a and 5a.

ORAMED PHARMACEUTICALS, Inc.  
(A development stage company)  
NOTES TO INTERIM FINANCIAL STATEMENTS

NOTE 2 – COMMITMENTS (continued):

d. On April 22, 2009, the subsidiary entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. (“ADRES”) 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. IND according to FDA regulations. In consideration for the services provided under the agreement, ADRES will be entitled to a total cash compensation of \$211,000, of which the amount \$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. \$80,000 of the total amount was paid through November 30, 2009.

e. Grants from the Chief Scientist Office (“OCS”)

The Subsidiary is obligated to pay royalties to the OCS on proceeds from the sale of products developed from research and development activities that were funded, partially, by grants from the OCS. In the case of failure of a project that was partly financed as described above, the Company is not obligated to pay any such royalties or repay funding received from the OCS.

Under the terms of the funding arrangements with the OCS, royalties of 3% to 3.5% are payable on the sale of products developed from projects funded by the OCS, which payments shall not exceed, in the aggregate, 100% of the amount of the grant received (dollar linked), plus interest at annual rate based on LIBOR. In addition, if the Company receives approval to manufacture the products developed with government grants outside the State of Israel, it will be required to pay an increased total amount of royalties (possibly up to 300% of the grant amounts plus interest), depending on the manufacturing volume that is performed outside the State of Israel, and, possibly, an increased royalty rate.

At November 30, 2009, the Company has not earned any revenues from the sale of products and no royalty payments have accrued.

For the three months period ended November 30, 2009 the research and development expenses are presented net of OCS Grants, in the total of \$147,590. For the year ended August 31, 2009 the OCS Grants were \$400,405.



ORAMED PHARMACEUTICALS, Inc.  
(A development stage company)  
NOTES TO INTERIM FINANCIAL STATEMENTS

NOTE 3 - STOCK BASED COMPENSATION:

The following are stocks issued for services, stock options and warrants transactions made during the three months ended November 30, 2009:

- a. On October 30, 2006 the Company entered into a Clinical Trial Manufacturing Agreement with Swiss Caps AG ("Swiss"), pursuant to which Swiss would manufacture and deliver the oral insulin capsule developed by the Company. In consideration for the services being provided to the Company by Swiss, the Company agreed to pay a certain predetermined amounts which are to be paid in common stocks of the Company, the number of stocks to be issued is based on the invoice received from Swiss, and the stock market price 10 days after the invoice was issued. The Company accounted the transaction with Swiss according to FASB ASC 480 "Distinguishing Liabilities from Equity" (formerly FAS 150).

On September 11, 2009, the Company issued 569,887 shares of its common stock to Swiss as remuneration for the services provided, for total of \$203,699.

- b. On November 23, 2009, 100,000 options were granted to a consultant, at an exercise price of \$0.76 per share (higher than the traded market price on the date of grant), the options vest in three equal annual instalments commencing November 23, 2010 and expire on November 23, 2014.
- c. On November 23, 2009, 36,000 options were granted to an employee of our Subsidiary, at an exercise price of \$0.46 per share (equivalent to the traded market price on the date of grant), the options vest in three equal annual instalments commencing November 23, 2010 and expire on November 23, 2019.

The Company recognized \$97,977 of stock based compensation expense during the three months ended November 30, 2009 related to options granted to employees and consultants, of which \$97,332 relates to options granted in prior years.

NOTE 4 - FAIR VALUE:

The fair value of the financial instruments included in the Company's working capital is usually identical or close to their carrying value due to the short-term maturities of these instruments.

ORAMED PHARMACEUTICALS, Inc.  
(A development stage company)  
NOTES TO INTERIM FINANCIAL STATEMENTS

NOTE 5 - SUBSEQUENT EVENTS:

The Company has performed an evaluation of subsequent events through January 13, 2010, which is the date the financial statements were issued.

- a) On December 29, 2009, the Company issued 328,110 shares of its common stock to Swiss as remuneration for the services provided, in the amount of \$167,310.
- b) On December 29, 2009, the Company issued 100,000 shares of its common stock to a third party as remuneration for services that will be rendered commencing December 15, 2009 for a period of six months.

## ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following information should be read in conjunction with the financial statements and notes thereto appearing elsewhere in this Quarterly Report.

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, financial condition, results of operations and prospects. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “sees,” “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 “Risks Related to Our Business” below, as well as those discussed elsewhere 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. 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.

We file reports with the Securities and Exchange Commission (the “SEC” or the “Commission”). We make available on our website under “Investor Information/SEC Filings,” free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file such materials with or furnish them to the SEC. Our website address is [www.oramed.com](http://www.oramed.com). You can also read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You can obtain additional information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an internet site ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

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

All dollar amounts refer to US dollars unless otherwise indicated.

#### Overview

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, rectal application of insulin, use of oral ingestible capsules or tablets, use of oral ingestible pills for delivery of other polypeptides and use of rectal application for delivery of other polypeptides.

Oramed was incorporated on April 12, 2002, in the State of Nevada under the name Iguana Ventures Ltd. Following the incorporation, the Company was an exploration stage company engaged in the acquisition and exploration of mineral properties. The Company was unsuccessful in implementing its business plan as a mineral exploration company. Accordingly, the Company decided to change the focus of its business by completing a share exchange with the shareholders of Integrated Security Technologies, Inc., a New Jersey private corporation ("ISTI"). On June 4, 2004, the Company changed its name to Integrated Security Technologies by filing a Certificate of Amendment with the Nevada Secretary of State. Effective June 14, 2004 the Company effected a 3.3:1 forward stock split, increasing the amount of its authorized capital to 200,000,000 shares of common stock with the par value of \$.001 per share. However, due to disappointing results of ISTI, on May 31, 2005, effective as of May 27, 2004 the Company terminated the share exchange agreement with the shareholders of ISTI.

On March 8, 2006, we executed an agreement with Hadasit Medical Services and Development Ltd. ("Hadasit") to acquire provisional patent application No. 60/718716 and related intellectual property and agreed to retain Hadasit to provide consulting and clinical trial services. The provisional patent application No. 60/718716 relates to a method of preparing insulin so that it may be taken orally to be used in the treatment of individuals with diabetes. Effective April 10, 2006, the Company changed its name from Integrated Security Technologies, Inc. to Oramed Pharmaceuticals Inc. On August 31, 2006, based on provisional patent application No. 60/718716, the Company filed a patent application under the Patent Cooperation Treaty at the Israel Patent Office for "Methods and Compositions for Oral Administration of Proteins."

## Plan of Operation

### 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 or 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 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 studies and other tests 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 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, flu vaccines, and use of rectal application for delivery of other polypeptides.

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 ensure 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. We have not yet engaged in any meaningful discussions with potential partners and 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.

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.

On November 15, 2007, we successfully completed animal studies in preparation for the Phase 1B clinical trial of our oral insulin capsule (ORMD 0801). On January 22, 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. On March 11, 2008, we successfully completed our Phase 1B clinical trials.



On April 13, 2008, we commenced a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD 0801) in type 2 diabetic volunteers at Hadassah Medical Center in Jerusalem. On August 6, 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 (ORMD 0801) on type 1 diabetic volunteers. On September 24, 2008, we announced the beginning of this trial. On July 21, 2009 we reported positive results from this trial.

On April 21, 2009, we entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. ("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.

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 (ORMD 0801) on type 2 diabetic volunteers. We are considering whether and when to conduct an additional non-FDA approved Phase 2B study in India.

**Rectal Application of Insulin and Other Polypeptides:** We filed two additional provisional patents for a suppository application to our technology portfolio. The first patent focuses on a rectal application for insulin. The second patent focuses on the usage of this rectal application to other polypeptides that at present are only available in injection.

On January 30, 2008, we entered into a master service agreement with OnQ Consulting; a clinical research organization located in Johannesburg, South Africa, to conduct non FDA approved clinical trials for the rectal application of insulin. On February 4, 2009, we announced that we had concluded a proof of concept study of the insulin suppositories.

On October 23, 2008 we commenced a non-FDA approved Phase 1A study to evaluate the safety and efficacy of our insulin suppository (ORMD 0802) on healthy volunteers, in South Africa.

As we believe that the potential commercial market for our oral insulin products are significantly greater than the potential commercial market for our rectal application products, we have determined to use our limited resources to research and develop our oral insulin capsules and tablets and have temporarily suspended our development of our rectal application products.

**GLP1 Analog:** On September 16, 2008 we announced the launch of pre-clinical trials of ORMD 0901, a GLP1-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.

On September 9, 2009, we received approval from the Institutional Review Board (IRB) 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 will be conducted on healthy volunteers at Hadassah University Medical Center in Jerusalem.

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 surprisingly 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.

**Raw Materials:** Our oral insulin capsule is currently manufactured by Swiss Caps AG, under a Clinical Trial Manufacturing Agreement. The raw materials required for the manufacturing of the capsule are purchased 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.

**Licensing:** We have recently engaged in preliminary discussions with potential partners outside of the United States regarding their management of clinical trials of our oral insulin capsules. Such agreements could involve us granting exclusive commercialization rights and profit interests in our products derived from certain geographic areas outside the United States in exchange for payment of the costs of running such clinical trials now. These discussions are in a very early stage, however, and may not result in our being able to enter into any such partnerships.

#### 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 ensure 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. 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.



## Results of Operations

### Going concern assumption

The accompanying financial statements 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 November 30, 2009 of \$10,621,471, 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 December 1, 2009, and our cash availability, we do not have sufficient cash resources to meet our liquidity requirements through November 30, 2010. The ongoing global economic and credit crisis makes it more difficult for the Company to raise financing. 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 Note 1 to our consolidated financial statements appearing at the beginning of this Quarterly Report. 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 these 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.

The following table summarizes certain statements of operations data for the Company for the three month periods ended November 30, 2009 and 2008:

Operating Data:	Three months ended	
	November 30, 2009	November 30, 2008
Research and development costs, net	\$ 317,545	\$ 818,680
General and administrative expenses	299,956	383,361