ORAMED PHARMACEUTICALS INC. Form 10-Q July 13, 2009

### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### FORM 10-Q

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

For the Quarterly Period Ended May 31, 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 98-0376008
(State or other jurisdiction of incorporation or organization) No.)

Hi-Tech Park 2/5 Givat Ram
PO Box 39098
Jerusalem, Israel 91390
(Address of principal executive offices)

+ 972 2 5660001 (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 x 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 x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes "No x

# 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: 56,456,710 shares issued and outstanding as of July 10, 2009.

## 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 MAY 31, 2009

### ORAMED PHARMACEUTICALS INC.

(A development stage company)

## INTERIM CONSOLIDATED FINANCIAL STATEMENTS

## AS OF MAY 31, 2009

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# ORAMED PHARMACEUTICALS INC. (A development stage company)

# CONDENSED CONSOLIDATED BALANCE SHEETS U.S. dollars

	May 31, 2009 Unaudited	August 31, 2008 Audited
Assets	Unaudited	Audited
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 3,217,986	\$ 2,267,320
Short term investments	-	2,728,000
Prepaid expenses and other current assets	35,048	402,574
Total current assets	3,253,034	5,397,894
LONG TERM DEPOSITS	14,382	10,824
PROPERTY AND EQUIPMENT, net	79,646	98,296
Total assets	\$ 3,347,062	\$ 5,507,014
Liabilities and stockholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 427,776	\$ 866,702
Account payable with former shareholder	47,252	47,252
Total current liabilities	475,028	913,954
COMMITMENTS		
OTTO CIVILOI DEDGI FOLUTIV		
STOCKHOLDERS' EQUITY:		
Common stock of \$ 0.001 par value - Authorized: 200,000,000 shares at May 31, 2009		
and August 31, 2008; Issued and outstanding: 56,456,710 at May 31, 2009	# C 1 # C	7.070
and 56,252,806 shares at August 31, 2008, respectively	56,456	56,252
Additional paid-in capital	12,423,370	11,785,012
Deficit accumulated during the development stage	(9,607,792)	
Total stockholders' equity	2,872,034	4,593,060
Total liabilities and stockholders' equity	\$ 3,347,062	\$ 5,507,014
	• • • • •	

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

	1	Nine mon May 31, 2009		ended May 31, 2008		Three mon May 31, 2009 naudited		ended May 31, 2008	Period from April 12, 2002 (inception) through May 31, 2009
RESEARCH AND DEVELOPMENT									
EXPENSES	\$	1,448,466	\$	655,934	\$	374,097	\$	464,119	\$ 5,036,300
IMPAIRMENT OF INVESTMENT									434,876
GENERAL AND ADMINISTRATIVE									
EXPENSES		931,861		913,950		157,711		381,697	3,962,319
OPERATING LOSS		2,380,327		1,569,884		531,808		845,816	9,433,495
INTEREST INCOME		(38,950)		(67,040)		(18,518)		(25,346)	(146,724)
INTEREST EXPENSE		18,211		6,034				1,051	158,857
LOSS BEFORE TAXES ON INCOME		2,359,588		1,508,878		513,290		821,521	9,445,628
TAXES ON INCOME		-		-		-		-	162,164
NET LOSS FOR THE PERIOD	\$	2,359,588	\$	1,508,878	\$	513,290	\$	821,521	\$ 9,607,792
BASIC AND DILUTED LOSS PER									
COMMON SHARE	\$	0.04	\$	0.03	\$	0.01	\$	0.02	
WEIGHTED AVERAGE NUMBER OF									
COMMON STOCK USED IN									
COMPUTING BASIC AND DILUTED									
LOSS PER COMMON STOCK	5	6,546,323	2	47,041,387	5	6,802,562	4	17,059,078	

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 Shares	Stock	\$	Additional paid-in capital	Deficit accumulated during the development stage		Total ckholders' equity
BALANCE AS OF APRIL 12, 2002	24.020.200	Ф 24.0	<b>3</b> 0	Φ 10.072		ф	52.700
(inception) CHANGES DURING THE PERIOD	34,828,200	\$ 34,8	28	\$ 18,872		\$	53,700
FROM APRIL 12, 2002 THROUGH							
AUGUST 31, 2007 (audited): SHARES CANCELLED	(10,900,000)	(10.9)	00)	10.900			
	(19,800,000)	(19,8)	00)	19,800			-
SHARES ISSUED FOR INVESTMENT	1 144 410	1.1	4.4	422 722			124.076
IN ISTI-NJ	1,144,410	1,1	44	433,732			434,876
SHARES ISSUED FOR OFFERING	1.752.041	1.7	50	(1.752)			
COSTS	1,752,941	1,7.		(1,753)			2 122 001
SHARES ISSUED FOR CASH	27,181,228	27,1		2,095,800			2,122,981
SHARES ISSUED FOR SERVICES	125,000	1.	25	98,625			98,750
CONTRIBUTIONS TO PAID IN				10.001			10.001
CAPITAL STOCK BASED COMPENSATION				18,991			18,991
RELATED TO OPTIONS GRANTED							
TO EMPLOYEES AND DIRECTORS				1,968,547			1 060 547
STOCK BASED COMPENSATION				1,908,347			1,968,547
RELATED TO OPTIONS GRANTED							
TO CONSULTANTS				177,782			177 792
DISCOUNT ON CONVERTIBLE NOTE				1//,/62			177,782
RELATED TO BENEFICIAL							
CONVERSION FEATURE				108,000			108,000
COMPREHENSIVE LOSS				100,000	(16)		(16)
IMPUTED INTEREST				8,437	(10)		8,437
NET LOSS				0,437	(4,478,917)	(	4,478,917)
BALANCE AS OF AUGUST 31, 2007					(4,470,717)	(	7,770,717)
(audited)	45,231,779	45,2	31	4,946,833	(4,478,933)		513,131
RECEIPTS ON ACCOUNT OF SHARES	73,231,777	73,2	<i>J</i> 1	7,770,033	(4,470,733)		313,131
AND WARRANTS				6,061			6,061
SHARES ISSUED FOR CONVERSION				0,001			0,001
OF CONVERTIBLE NOTE	550,000	5	50	274,450			275,000
SHARES AND WARRANTS ISSUED	330,000	<i>J</i> .	50	274,430			273,000
FOR CASH – NET OF ISSUANCE							
EXPENSES	10,178,002	10,1	78	5,774,622			5,784,800
SHARES ISSUED FOR SERVICES	293,025		93	115,817			116,110
STOCK BASED COMPENSATION	275,025			113,017			110,110
RELATED TO OPTIONS GRANTED							
TO EMPLOYEES AND DIRECTORS				459,467			459,467
				203,982			203,982
				200,702			_00,,002

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STOCK BASED COMPENSATION					
RELATED TO OPTIONS GRANTED					
TO CONSULTANTS					
IMPUTED INTEREST			3,780		3,780
NET LOSS				(2,769,271)	(2,769,271)
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	203,904	204	152,724		152,928
SHARES TO BE ISSUED FOR					
SERVICES RENDERED			109,590		109,590
STOCK BASED COMPENSATION					
RELATED TO OPTIONS GRANTED					
TO EMPLOYEES AND DIRECTORS			295,230		295,230
STOCK BASED COMPENSATION					
RELATED TO OPTIONS GRANTED					
TO CONSULTANTS			77,980		77,980
IMPUTED INTEREST			2,834		2,834
NET LOSS				(2,359,588)	(2,359,588)
BALANCE AS OF MAY 31, 2009					
(unaudited)	56,456,710	\$ 56,456	\$12,423,370	\$ (9,607,792)	\$ 2,872,034

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

			Period from April
			12, 2002
			(inception date)
		nths ended	through
	May 31,	May 31,	May 31,
	2009	2008	2009
		Unaudited	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (2,359,588) \$	(1,508,878) \$	(9,607,792)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation	22,760	7,078	38,214
Amortization of debt discount	-		108,000
Exchange differences on long term deposits	1,110	707	(532)
Stock based compensation	373,210	246,679	3,182,988
Common stock issued for services	-	172,101	214,860
Impairment of investment	-	-	434,876
Imputed interest	2,834	2,835	15,051
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	367,526	(50,033)	(35,048)
Accounts payable and accrued expenses	(176,408)	(74,414)	690,294
Total net cash used in operating activities	(1,768,556)	(1,203,925)	(4,959,089)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(4,110)	(98,415)	(117,860)
Acquisition of short-term investments	-	-	(2,728,000)
Proceeds from sale of Short term investments	2,728,000	-	2,728,000
Lease deposits	(4,668)	(1,558)	(13,850)
Total net cash provided by (used in) investing activities	2,719,222	(99,973)	(131,710)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from sales of common stocks and warrants -			
net of issuance expenses		2,044,986	7 067 542
Proceeds from convertible notes	-	2,044,960	7,967,542 275,000
Proceeds from short term note payable	-		120,000
Payments of short term note payable	-	<u>-</u>	(120,000)
Shareholder advances	-		66,243
Net cash provided by financing activities	-	2,044,986	8,308,785
ivet easii provided by imaneing activities	-	2,044,900	0,300,703
INCREASE IN CASH AND CASH EQUIVALENTS	950,666	741,088	3,217,986
CASH AND CASH EQUIVALENTS AT			
BEGINNING OF PERIOD	2,267,320	1,918,229	
CASH AND CASH EQUIVALENTS AT END OF			
PERIOD	\$ 3,217,986 \$	2,659,317 \$	3,217,986

Non cash investing and financing activities:			
Shares issued for offering costs			\$ 1,753
Contribution to paid in capital			\$ 18,991
Stock issued for receipts on account of shares issuance		\$ 1,036,060	
Shares issued for services rendered	\$ 152,928	\$ 172,101	
Shares to be issued for services rendered	\$ 109,590		\$ 109,590
Receipts on account of shares issuance - reclassified			
from liability to shareholder's equity		\$ 4,000	

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

# ORAMED PHARMACEUTICULS 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 March 8, 2006, the Company entered into an agreement with Hadasit Medical Services and Development Ltd ("Hadasit") (the "First Agreement") to acquire the provisional patent related to orally ingestible insulin pill to be used for the treatment of individuals with diabetes, see also note 5.

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. ("the Subsidiary"), which is engaged in research and development.

2. The accompanying unaudited interim consolidated financial statements as of May 31, 2009 and for the nine and 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 nine and three months ended May 31, 2009, are not necessarily indicative of the results that may be expected for the year ending August 31, 2009.

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 May 31, 2009 of \$9,607,792, 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 June 1, 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.

# ORAMED PHARMACEUTICULS INC. (A development stage company) NOTES TO INTERIM FINANCIAL STATEMENTS

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

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.

b. Share-based payment:

The Company implements Statement of Financial Accounting Standards No. 123 (revised 2004) "Share-based Payment" ("FAS 123(R)"). FAS 123(R) 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 expense over the requisite service period, net of estimated forfeitures. The Company recognizes compensation cost for an award with only service conditions that has a graded vesting schedule using the accelerated method of amortization under FAS 123(R) over the requisite service period for the entire awards.

In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 ("SAB 107"). SAB 107 provides supplemental implementation guidance on FAS 123(R), including guidance on valuation methods, inventory capitalization of share-based compensation cost, income statement effects, disclosures and other issues. SAB 107 requires share-based payment to be classified in the same expense line items as cash compensation. The company has applied the provisions of SAB 107 in its adoption of FAS 123(R).

The Company accounts for equity instruments issued to third party service providers (non-employees) in accordance with the fair value based on an option-pricing model, pursuant to the guidance in EITF 96-18 "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services". The fair value of the options granted is revalued over the related service periods and recognized over the vesting period.

c. Recently Issued Accounting Pronouncements

1. In November 2007, the FASB ratified EITF Issue No. 07-01, "Accounting for Collaborative Arrangements" ("EITF 07-01"). EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-01 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-01 is effective for fiscal years beginning after December 15, 2008 (September 1, 2009, for the Company). EITF 07-01 shall be applied using a modified version of retrospective transition for those arrangements in place at the effective date. An entity should report the effects of applying EITF 07-01 as a change in accounting principle through retrospective application to all prior periods presented for all arrangements existing as of the effective date, unless it is impracticable to apply the effects of the change retrospectively. The Company is currently assessing the impact that EITF 07-01 may have on its results of operations and financial position.

# ORAMED PHARMACEUTICULS INC. (A development stage company) NOTES TO INTERIM FINANCIAL STATEMENTS

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

2. In April 2008, the FASB issued Staff Position No. FAS 142-3, "Determination of the Useful Life of Intangible Assets ("FSP FAS 142-3"). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "Goodwill and Other Intangible Assets." The intent of FSP FAS 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under FAS 141(R), and other U.S. generally accepted accounting principles. The provisions of FSP FAS 142-3 are effective for the fiscal year beginning September 1, 2009; early adoption is prohibited. The Company is currently evaluating the impact of the provisions of FSP FAS 142-3.

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

- a. On September 8, 2008, the Company entered into Clinical Research agreement with ETI Karle Clinical Pvt. Ltd. ("ETI"), pursuant to the agreement ETI will be conducting clinical trials for the Company in India. In consideration for the services provided under the agreement, ETI will be entitled to estimated cash compensation of \$227,000.
- b.On April 22, 2009, our 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.

#### NOTE 3 - STOCK BASED COMPENSATION:

The following are stock issued for services, stock options and warrants transactions made during the nine months ended May 31, 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 certain predetermined amounts which are to be paid in common stock of the Company. The number of shares 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 for the transaction with Swiss according to FAS 150 "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity".

# ORAMED PHARMACEUTICULS INC. (A development stage company) NOTES TO INTERIM FINANCIAL STATEMENTS

#### NOTE 3 - STOCK BASED COMPENSATION (continued):

On October 17, 2008, the Company issued 203,904 shares of its common stock to Swiss as remuneration for the services provided, in the amount of \$152,928.

As of May 31, 2009 Swiss was entitled to receive 365,300 shares of the Company for services provided, in the amount of \$109,590.

- b. On October 12, 2008, 828,000 options were granted to an employee of our Subsidiary, at an exercise price of \$0.47 per share (equivalent to the traded market price on the date of grant). The options vest in three equal annual instalments commencing on November 1, 2009 and expire on October 11, 2018. The fair value of these options on the date of grant was \$330,699, 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%; risk-free interest rates of 3.27%; and the remaining contractual life of 6.00 years. On March 31, 2009 the employee ended his services with the Company and the options were forfeited before they had vested. The Company recognized an expense of \$71,406 during the six months ended February 28, 2009 and reverse that expense in the three months ended May 31, 2009.
- c.On October 12, 2008, 56,000 options were granted to an employee of our Subsidiary, at an exercise price of \$0.47 per share (equivalent to the traded market price on the date of grant). The options vest in two equal annual instalments commencing on May 1, 2009 and expire on October 11, 2018. The fair value of these options on the date of grant was \$21,988, 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%; risk-free interest rates of 2.77%; and the remaining contractual life of 5.67 years.
- d. On January 11, 2009, an aggregate of 600,000 options were granted to two Board of Directors members and 150,000 options were granted to an employee of our Subsidiary. All 750,000 options were granted at an exercise price of \$0.43 per share (equivalent to the traded market price on the date of grant). The options vest in three equal annual instalments commencing on January 1, 2010 and expire on January 10, 2019. The fair value of these options on the date of grant was \$285,028, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 126%; risk-free interest rates of 1.51%; and the remaining contractual life of 6.00 years. On May 31, 2009 such employee left the Company and the options were forfeited before they had vested. The Company recognized an expense of \$4,354 during the six months ended February 28, 2009 and reverse that expense in the three months ended May 31, 2009.
- e. On January 11, 2009, an aggregate of 300,000 options were granted to three Scientific Advisory Board members, at an exercise price of \$0.76 per share (higher than the traded market price on the date of grant). The options vest in four equal quarterly instalments commencing on April 1, 2009 and expire on January 10, 2019. The fair value of the vested options was \$21,090 and the fair value of the unvested options as of May 31, 2009 was \$91,684, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 128%; risk-free interest rates of 3.47%; and the remaining contractual life of 9.62 years.

# ORAMED PHARMACEUTICULS INC. (A development stage company) NOTES TO INTERIM FINANCIAL STATEMENTS

#### NOTE 4 - FAIR VALUE

On September 1, 2008, the Company adopted the methods of fair value as described in SFAS No. 157 ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value in accordance with GAAP and expands disclosure about fair value measurements to value its financial assets and liabilities. As defined in SFAS No. 157, fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, SFAS No. 157 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 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 Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

The adoption of SFAS 157 did not have a material impact on the Company's results of operations and financial condition as the Company does not have any financial assets and liabilities measured at fair value on a recurring basis subject to the requirements of SFAS 157.

#### NOTE 5 - RELATED PARTIES TRANSACTIONS

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, of which \$199,255 was paid through May 31, 2009. 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 amount 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") to provide for the closing referenced in the First Agreement. In the Second Agreement, Hadasit confirms that it has conveyed, transferred and assigned all of its ownership rights in the patents acquired under the First Agreement and certain other patents filed by the Company after the First Agreement as a result of the collaboration between the Company and Hadasit.

See also note 6(b) for information regarding a third agreement with Hadasit.

# ORAMED PHARMACEUTICULS INC. (A development stage company) NOTES TO INTERIM FINANCIAL STATEMENTS

#### NOTE 6 - SUBSEQUENT EVENTS:

- a. On June 3, 2009, 400,000 options were granted to an employee of our Subsidiary, at an exercise price of \$0.47 per share (equivalent to the traded market price on the date of grant). The options vest in three annual installments of 133,333, 133,333 and 133,334 on October 19, 2010, October 19, 2011 and October 19, 2012, respectively, and expire on October 19, 2019. The fair value of these options on the date of grant was \$170,193, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 130%; risk-free interest rates of 3.16%; and the remaining contractual life of 6.19 years.
- b.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 a total consideration of \$400,000 to be paid by Oramed. \$200,000 of this amount was agreed in the terms of the First Agreement, see note 5, and the remaining of \$200,725 will be paid in ten equal quarterly instalments commencing May 2009, in accordance with the actual progress of the study.

# 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.

We have included in this Quarterly Report certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 concerning our business, operations and financial condition. "Forward-looking statements" consist of all non-historical information, and the analysis of historical information, including the references in this Quarterly Report to future revenues, collaborative agreements, future expense growth, future credit exposure, earnings before interest, taxes, depreciation and amortization, future profitability, anticipated cash resources, anticipated capital expenditures, capital requirements, and the Company's plans for future periods. In addition, the words "could", "expects", "anticipates", "objective", "plan", "may affect", "may depend", "believes", "estimate and similar words and phrases are also intended to identify such forward-looking statements.

Actual results could differ materially from those projected in our forward-looking statements due to numerous known and unknown risks and uncertainties, including, among other things, unanticipated technological difficulties, the length, scope and outcome of our clinical trials, difficulties or delays in obtaining regulatory approval for our product candidates, competition from other pharmaceutical or biotechnology companies, costs related to intellectual property, cost of manufacturing and higher consulting costs, product demand, changes in domestic and foreign economic, market and regulatory conditions, the inherent uncertainty of financial estimates and projections, the uncertainties involved in certain legal proceedings, instabilities arising from terrorist actions and responses thereto, our ability to obtain additional funding required to conduct our research, development and commercialization activities and other considerations described as "Risk Factors" in other filings by the Company with the SEC. Such factors may also cause substantial volatility in the market price of our common stock. All such forward-looking statements are current only as of the date on which such statements were made. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

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 U.S. dollars in thousands unless otherwise indicated.

#### Overview

We are a pharmaceutical company engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin pill to be used for the treatment of individuals with diabetes, rectal application of insulin, flu vaccines, 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" as 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 private New Jersey corporation ("ISTI"), and changed its name to Integrated Security Technologies. 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, the Company executed an agreement (the "First 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." 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" on August 31, 2006.

On January 7, 2009, the Company entered into an agreement with Hadasit (the "Second Agreement") to provide for the closing referenced in the First Agreement. In the Second Agreement, Hadasit confirms that it has conveyed, transferred and assigned all of its ownership rights in the patents acquired under the First Agreement and certain other patents filed by the Company after the First Agreement as a result of the collaboration between the Company and Hadasit (the "Patents"). Hadasit further acknowledges that the 4,141,532 shares of common stock issued to Hadasit by the Company in connection with the First Agreement constitute complete compensation for the Patents.

For information regarding the third agreement with Hadasit see "Related Party Transactions" below.

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 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 Application ("IND") with the U.S. Food and Drug Administration ("FDA"). Additional clinical trials are planned in other countries such as Israel, South Africa and India, 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, including an insulin suppository and use of rectal application for delivery of other polypeptides.

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 II diabetic volunteers at Hadassah Medical Center in Jerusalem. On August 6, 2008, we announced the successful results of this trial.

During 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 I diabetic volunteers. On September 24, 2008, we announced the beginning of this trail. The results of the trial have not yet been published.

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 II diabetic volunteers. We also consider 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 available only via 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. The trials are expected to begin during the coming months.

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. On February 4, 2009, we announced the completion of this study.

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 a dog trial which suggests that the GLP-1analog 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 surprisingly that glucose ingested by mouth (oral) stimulated two to three times more insulin release than the same amount of glucose administered intravenously. GLP-1 was found in addition to stimulate the release of insulin, to suppress the release of glucagon (a hormone involved in the regulation of glucose) from the pancreas, to slow gastric emptying, to reduce the rate of absorption of nutrients into the blood stream, and to increases 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 to protect the heart.

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 May 31, 2009 of \$9,607,792, as well as negative cash flow from operating activities. Based upon our existing spending commitments, estimated at \$4.7 million for the twelve months following June 1, 2009, and our cash availability, we do not have sufficient cash resources to meet our liquidity requirements through May 31 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

Valuation of options and warrants: We have granted options to purchase shares of our common stock to employees and consultants and issued warrants in connection with fundraising.

Effective March 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-based Payment" ("FAS 123(R)"). FAS 123(R) requires that 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 expense over the requisite service period, net of estimated forfeitures. The Company estimated forfeitures based on historical experience and anticipated future conditions.

In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 ("SAB 107"). SAB 107 provides supplemental implementation guidance on FAS 123(R), including guidance on valuation methods, inventory capitalization of share-based compensation cost, income statement effects, disclosures and other issues. SAB 107 requires share-based payment to be classified in the same expense line items as cash compensation. The Company has applied the provisions of SAB 107 in its adoption of FAS 123(R).

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

The Company elected to adopt the modified prospective application transition method, as permitted by FAS 123(R). Under such transition method, upon the adoption of FAS 123(R), the Company's financial statements for periods prior to the effective date of the Statement are not restated.

In December 2007, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 110 ("SAB 110") relating to the use of a "simplified" method in developing an estimate of the expected term of "plain vanilla" share options. SAB 107 previously allowed the use of the simplified method until December 31, 2007. SAB 110 allows, under certain circumstances, to continue to accept the use of the simplified method beyond December 31, 2007. The Company has applied the provisions of SAB 110 in its financial statements.

The Company accounts for equity instruments issued to third party service providers (non-employees) in accordance with the fair value based on an option-pricing model or, when more reliability is based on the fair value of the services received, pursuant to the guidance in EITF 96-18 "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services". The fair value of the options granted is revalued over the related service periods and recognized using the accelerated 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. The Company has provided a full valuation allowance with respect to its deferred tax assets.

Regarding Oramed, Ltd., paragraph 9(f) of FAS 109, "Accounting for Income Taxes", 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.

As of September 1, 2007, the Company adopted FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109" ("FIN 48"). FIN 48 specifies how tax benefits for uncertain tax positions are to be recognized, measured and derecognized in financial statements, requires certain disclosures of uncertain tax positions, specifies how reserves for uncertain tax positions should be classified on the balance sheet, and provides transition and interim-period guidance, among other provisions. On May 2, 2007, the FASB issued FASB Staff Position No. FIN 48-1, "Definition of Settlement in FASB Interpretation No. 48-1" ("FSP FIN 48-1"). FSP FIN 48-1 provides guidance regarding how an entity should determine whether a tax position is effectively settled for the purpose of recognizing previously unrecognized tax benefits.

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 the Company's clinical trials, clinical trial expenses, the full cost of manufacturing drugs 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. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company's clinical trials are performed primarily by contract research organizations ("CROs"). CROs typically perform most of the start-up activities for the Company's trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management.

The following table summarizes certain statements of operations data for the Company for the nine month periods ended May 31, 2009 and May 31, 2008:

		Nine months ended			Three months en			ended
Operating Data:		May 31, 2009		May 31, 2008	]	May 31, 2009	]	May 31, 2008
Research and development costs	\$	1,448,466	\$	655,934	\$	374,097	\$	464,119
General and administrative expenses		931,861		913,950		157,711		381,697
Financial (income) expense, net		(20,739)		(61,006)		(18,518)		(24,295)
Loss before taxes on income		2,359,588		1,508,878		513,290		821,521
Loss per common share – basic and diluted	\$	0.04	\$	0.03	\$	0.01	\$	0.02
Weighted average common shares outstanding	4	56,546,323	2	46,041,387	5	56,802,562	4	7,059,078

#### Research and development costs

Research and development expenses are the costs incurred in the process of our pre-clinical and our clinical trials. Clinical trial and pre-clinical 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.

During the nine months ended May 31, 2009, research and development expenses totaled \$1,448,466, compared to \$655,934 for the nine months ended May 31, 2008. The increase is mainly attributable to increased purchase of materials, clinical trials activities and patent related costs. The research and development costs include stock based compensation costs, which during the nine months ended May 31, 2009 totaled \$192,076, as compared to \$80,183 during the nine months ended May 31, 2008.

The decrease in research and development expenses during the three months ended May 31, 2009 as compared to the three months ended May 31, 2008 is attributable to a charge related to consulting expenses of \$170,000 with a regulatory consultant that was incurred in April 2008.

#### General and administrative expenses

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

For the nine months ended May 31, 2009, general and administrative expenses totaled \$931,861, compared to \$913,950 for the nine months ended May 31, 2008. Costs incurred related to general and administrative activities during the nine months ended May 31, 2009 reflect an increase of payroll and related expenses, professional, legal and consulting expenses and an increase in general expenses such as office and maintenance expenses. During the nine months ended May 31, 2009, as part of our general and administrative expenses, we incurred \$181,134 related to stock options granted to employees and consultants, as compared to \$166,556 during the nine months May 31, 2008.

The decrease in general and administrative expenses during the three months ended May 31, 2009 as compared to the three months ended May 31, 2008 is mainly attributable to extraordinary legal and accounting expenses, that were incurred during the three months ended May 31, 2008 and related to replacing both legal and accounting services providers. Another cause to the said decrease is derived from a decrease in stock based compensation costs.

#### Financial income/expense, net

During the nine months ended May 31, 2009 and May 31, 2008, we generated interest income on available cash and cash equivalents balance, which were offset by bank charges as well as a devaluation of assets denominated in New Israeli Shekel (NIS), due to the devaluation of the NIS as compared to the US\$.

The decrease in the interest income for the nine and three months period ending May 31, 2009 as compared with the corresponding periods in the preceding year is attributable to the decrease in interest rates in both the United States and the state of Israel, due to the current global financial crises.

#### Liquidity and Capital Resources

From inception through May 31, 2009, we incurred losses in an aggregate amount of \$9,607,792. We have financed our operations through the private placements of equity and debt financing. Since inception through May 31, 2009, we raised a total of \$8,308,785, net of transaction costs, through private placements of equity and debt financing. We anticipate that we will obtain additional financing through similar sources. As of May 31, 2009, we had \$3,217,986 of available cash. The Company anticipates it will require approximately \$4.7 million to finance its activities during the twelve months following June 1, 2009.

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 or though arrangements to out license our technology. 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.

Our financing activities during the nine months ended May 31, 2009 include the following:

•On October 17, 2008, Oramed issued 203,904 shares of common stock valued at \$152,928 to a third party, for services rendered in the prior year.

Employee's and Consultant's Stock Options and Warrants

Employee and consultant stock options grants and warrant issuance activities for the nine months ending May 31, 2009 include the following:

- •On October 12, 2008, we granted options under the 2008 Stock Incentive Plan to purchase up to 828,000 shares of our common stock at an exercise price of \$0.47 to Chaime Orlev our Chief Financial Officer. On March 31, 2009 Mr. Orlev ended his services with the Company and the options were forfeited before they had vested.
- •On October 12, 2008, we granted options under the 2008 Stock Incentive Plan to purchase up to 56,000 shares of our common stock at an exercise price of \$0.47 to an employee of our subsidiary.
- •On January 11, 2009, we granted options under the 2008 Stock Incentive Plan to purchase up to 100,000 shares of our common stock at an exercise price of \$0.76 to each of Dr. Nir Barzilai, Prof. Ele Ferrannini and Dr. Derek LeRoith, three members of our Scientific Advisory Board.
- •On January 11, 2009, we granted options under the 2008 Stock Incentive Plan to purchase up to 150,000 shares of our common stock at an exercise price of \$0.43 to an employee of our subsidiary. In May 2009 such employee left the Company and the options were forfeited before they had vested
- •On January 11, 2009, we granted options under the 2008 Stock Incentive Plan to purchase up to 300,000 shares of our common stock at an exercise price of \$0.43 to each of Leonard Sank and Dr. Harold Jacob, two members of our Board of Directors.

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 June 1, 2008 are as follows:

Operating Data:	Amount		
Research and development costs	\$ 3,500,000		
General and administrative expenses	1,200,000		
Financial income, net	(11,000)		
Total	\$ 4.692.000		

As previously indicated, we are planning to conduct further clinical studies as well as file an IND with the FDA for our orally ingested insulin. 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.

#### **Employment and Consulting Agreements**

On May 1, 2008, we entered into a consulting agreement with a Dr. Ehud Arbit for a period of twelve months, pursuant to which Dr. Arbit will assist our efforts to complete the FDA approval process for its oral insulin capsule. Dr. Arbit is entitled to a fixed monthly fee of \$8,333 effective from May 1, 2008, and reimbursement of pre-approved out-of-pocket expenses. On October 3, 2008, we amended the consulting agreement with Dr. Arbit. Pursuant to the amendment, Dr. Arbit will perform his work under the contract on a full-time basis and his compensation will be \$16,666 per month, effective as of July 1, 2008. On June 18, 2009, the Company and Dr. Arbit agreed on a second amendment to the agreement, according to which, Dr. Arbit will be entitled to a monthly fee of \$7,000 for a period of three months commencing May 1, 2009.

On April 19, 2009 we entered into an employment agreement with Yifat Zommer (the "Employment Agreement"), pursuant to which Ms. Zommer was appointed as Chief Financial Officer ("CFO"), Treasurer and Secretary of Oramed. Ms. Zommer's responsibilities include oversight of Oramed's financial reporting and controls and she will be employed on a part-time basis of 80%. The employment agreement provides that for the period through October 19, 2009, Ms. Zommer will be compensated a gross monthly amount of NIS 17,600. Beginning on October 20, 2009 and continuing until the employment agreement is terminated by either party pursuant to the employment agreement, Ms. Zommer's monthly gross salary compensation will be increased by 10%. Ms. Zommer has also agreed that during the term of her employment with Oramed and for a 12 month period thereafter, she will not compete with Oramed nor solicit employees of Oramed. On April 19, 2009, Oramed and Ms. Zommer also entered into an indemnification agreement, pursuant to which Oramed agrees to indemnify Ms. Zommer for any liability she may incur by reason of the fact that she serves as Oramed's CFO, to the maximum extent permitted by law. On June 3, 2009, we granted options under the 2008 Stock Incentive Plan to purchase up to 400,000 shares of our common stock at an exercise price of \$0.47 to Ms. Zommer.

On April 22, 2009, the Company 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 Company 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. A part of \$110,000 will be paid as a monthly fixed fee of \$10,000 for 11 months commencing May 2009, and rest will be paid based on achievement of certain milestones.

#### **Related Party Transactions**

Under the terms of the First Agreement with Hadasit, 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, of which \$199,255 was paid through May 31, 2009. 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 amount of 10% of all the funds deposited into this research fund.

On July 8, 2009 the Company entered into an 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 a 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 \$200,725 will be paid in ten equal quarterly instalments commencing May 2009, in accordance with the actual progress of the study.

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

Not applicable.

#### ITEM 4T - CONTROLS AND PROCEDURES

Our management, including our chief executive officer and chief financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of May 31, 2009. Based on such review, our chief executive officer and chief financial officer have determined that in light of their conclusion with respect to the effectiveness of our internal control over our financial reporting as of such date, the weaknesses in controls and procedures described in our Form 10-KSB filed on November 26, 2008 continued this quarter and 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.

Our management, under the supervision of our chief executive officer and chief financial officer, is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Securities Exchange Act of 1934, as amended. The Company's internal control over financial reporting is defined as a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and asset dispositions;
- •provide reasonable assurance that transactions are recorded as necessary to permit the preparation of our financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we evaluated the effectiveness of our internal control over financial reporting as of May 31, 2009 based on the framework for Internal Control-Integrated Framework set forth by The Committee of Sponsoring Organizations of the Treadway Commission. Due to the inherent limitations of our company, derived from our small size and the limited number of employees, management evaluation concluded that there is a material weakness with respect to segregation of duties that may not provide reasonable assurance regarding the reliability of internal control over financial reporting and may not prevent or detect misstatements. 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. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on this evaluation, our management concluded that there is no reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and that the Company's internal controls over financial reporting were not effective as of May 31, 2009.

As previously reported in our Form 10-KSB filed on November 26, 2008, during the nine month ended May 31, 2009, management, including our principal executive officer and principal financial officer, has started an extensive process of documenting all major procedures related to the financial reporting, in order to strengthen our internal controls over financial reporting in order to reasonably ensure that reliability of financial reporting and the preparation of financial statements.

This management report on internal control over financial reporting shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended or otherwise subject to the liabilities of that Section.

There were no changes in our internal controls over financial reporting identified in connection with the evaluation thereof that occurred during the quarter ended May 31, 2009 that have materially affected, or are reasonable likely to materially affect our internal control over financial reporting.

#### PART II – OTHER INFORMATION

#### ITEM 1 - LEGAL PROCEEDINGS

Except as previously disclosed, we know of no material, active or pending legal proceedings against us, nor are we involved as a plaintiff in any material proceedings or pending litigation.

#### **ITEM 6 - EXHIBITS**

#### Number Exhibit

- (3) Articles of Incorporation and By-laws
- 3.1 Articles of Incorporation (incorporated by reference from our Registration Statement on Form SB-2, filed on November 29, 2002).
- 3.2 Bylaws (incorporated by reference from our Current Report on Form 8-K filed on April 10, 2006).
- 3.3 Articles of Merger filed with the Nevada Secretary of State on March 29, 2006 (incorporated by reference to our Current Report on Form 8-K filed on April 10, 2006).
- (4) Instruments defining rights of security holders, including indentures
- 4.1 Specimen Stock Certificate (incorporated by reference from our Registration Statement on Form SB-2, filed on November 29, 2002).
- Form of warrant certificate (incorporated by reference from our current report on Form 8-K filed on June 18, 2007)
- (10) Material Contracts
- 10.1 Agreement between our company and Hadasit Medical Services and Development Ltd. dated February 17, 2006 (incorporated by reference from our current report on Form 8-K filed February 17, 2006).
- 10.2 Agreement between our company and Hadasit Medical Services and Development Ltd. dated January 7, 2008 (incorporated by reference from our current report on Form 8-K filed January 7, 2008).
- 10.3 Consulting Agreement, dated May 1, 2008, between Oramed Pharmaceuticals Inc. and Dr. Ehud Arbit (incorporated by reference from our annual report on Form 10-KSB filed November 26, 2008)
- 10.4 Amended and Restated Consulting Agreement, dated as of May 1, 2008, between Oramed Pharmaceuticals Inc. and Dr. Ehud Arbit (incorporated by reference from our annual report on Form 10-KSB filed November 26, 2008)
- 10.5 Amended to Consulting Agreement, dated as of October 3, 2008, between Oramed Pharmaceuticals Inc. and Dr. Ehud Arbit (incorporated by reference from our annual report on Form 10-KSB filed November 26, 2008)
- 10.6 Amended and Restated to Consulting Agreement, dated as of June 18, 2009, between Oramed Pharmaceuticals Inc. and Dr. Ehud Arbit.
- 10.7 Employment Agreement, dated as of April 19, 2009, by and between Oramed Ltd. and Yifat Zommer (incorporated by reference from our current report on Form 8-K filed on

- April 22, 2009).
- 10.8 Indemnification Agreement, dated as of April 19, 2009, by and between Oramed Ltd. and Yifat Zommer (incorporated by reference from our current report on Form 8-K filed on April 22, 2009).
- 10.9 Agreement dated April 22, 2009, between Oramed Ltd. and ADRES Advanced Regulatory Services Ltd. (incorporated by reference from our current report on Form 8-K filed April 22, 2009).
- 10.10 Agreement dated July 8, 2009, between our company and Hadasit Medical Services and Development Ltd. (incorporated by reference from our current report on Form 8-K filed July 9, 2009).
- (31) Section 302 Certification
- 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 Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- (32) Section 906 Certification
- 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 Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act Of 2002

\* Filed 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: July 13, 2009 By: /s/ Nadav Kidron

Nadav Kidron

President, Chief Executive Officer and Director

Date: July 13, 2009 By: /s/ Yifat Zommer

Yifat Zommer

Chief Financial Officer