

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **November 10, 2022**

ORAMED PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

DELAWARE

(State or Other Jurisdiction
of Incorporation)

001-35813

(Commission File Number)

98-0376008

(IRS Employer
Identification No.)

1185 Avenue of the Americas, Third Floor, New York, New York

(Address of Principal Executive Offices)

10036

(Zip Code)

844-967-2633

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, par value \$0.012	ORMP	The Nasdaq Capital Market, Tel Aviv Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On November 10, 2022, Oramed Pharmaceuticals Inc. issued a press release announcing its financial results for the period ended September 30, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description of Document
99.1	Press release dated November 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 hereunto duly authorized.

ORAMED PHARMACEUTICALS INC.

By: /s/ Nadav Kidron

Name: Nadav Kidron

Title: President and CEO

November 10, 2022

Oramed Reports Third Quarter 2022 Financial Results

NEW YORK, November 10, 2022 – Oramed Pharmaceuticals Inc. (“Oramed” or the “Company”) (Nasdaq/TASE: ORMP) (www.oramed.com), a clinical-stage pharmaceutical company focused on the development of oral drug delivery platforms, today reported its financial results for the quarter ended September 30, 2022.

"We are pleased to share our quarterly report for the third quarter of 2022. We had a strong quarter filled with important milestones, including positive Phase 2 NASH data and initial positive results from our Phase 1 oral Covid-19 vaccine trial. Over the next few months, we look forward to sharing multiple milestones, most notably topline data from our first Phase 3 oral insulin trial expected in January," said Oramed Chief Executive Officer, Nadav Kidron. "Oramed remains in a strong financial position with approximately \$160 million in cash and investments as of September 30, 2022, allowing us to continue advancing all aspects of our pipeline and giving us sufficient runway to complete our pivotal oral insulin (ORMD-0801) Phase 3 trials and advance us towards potential FDA approval."

Financial Results for the Three Month Period Ended September 30, 2022

- As of September 30, 2022, we had approximately \$160 million in **cash and investments**, comprised of \$33,196,000 of available **cash**, \$121,119,000 of short-term **bank deposits** and \$5,234,000 of **marketable securities**.
 - **Research and development expenses** for the three month period ended September 30, 2022 decreased by 12% to \$5,347,000, compared to \$6,086,000 for the three month period ended September 30, 2021. The decrease was mainly due to lower research and development expenses in our subsidiary Oravax Inc. (“Oravax”) in the third quarter of 2022. Stock-based compensation expenses for the three month period ended September 30, 2022 were \$771,000, compared to \$495,000 during the three month period ended September 30, 2021. This increase was mainly due to equity awards granted to employees in 2022, and equity awards granted by Oravax to employees and board members of Oravax and to other service providers in September 2022.
 - **Sales and marketing expenses** for the three month period ended September 30, 2022 increased by 169% to \$463,000, compared to \$172,000 for the three month period ended September 30, 2021. The increase was primarily due to stock-based compensation expenses and consulting expenses. Stock-based compensation costs for the three month period ended September 30, 2022 were \$303,000, compared to \$142,000 for the three month period ended September 30, 2021. This increase was mainly due to equity awards granted to an employee during fiscal years 2021 and 2022.
 - **General and administrative expenses** for the three month period ended September 30, 2022 increased by 60% to \$3,061,000 compared to \$1,909,000 for the three month period ended September 30, 2021. The increase was mainly due to higher stock-based compensation expenses and salary expenses. Stock-based compensation costs for the three month period ended September 30, 2022 were \$1,977,000, compared to \$644,000 for the three month period ended September 30, 2021. This increase was mainly due to equity awards granted to directors, officers and other employees in 2022, and equity awards granted by Oravax to employees and board members of Oravax and to other service providers in September 2022.
 - **Basic and diluted loss per share** of common stock for the three month period ended September 30, 2022 decreased by 14% to \$0.18, compared to \$0.21 for the three month period ended September 30, 2021. The decrease in loss was mainly due to a higher number of weighted average shares of common stock in the three month period ended September 30, 2022 compared to the three month period ended September 30, 2021.
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Full financial tables are included below.

About Oramed Pharmaceuticals

Oramed Pharmaceuticals (Nasdaq/TASE: ORMP) is a platform technology pioneer in the field of oral delivery solutions for drugs currently delivered via injection. Established in 2006, with offices in the United States and Israel, Oramed has developed a novel Protein Oral Delivery (POD™) technology. Oramed is seeking to transform the treatment of diabetes through its proprietary lead candidate, ORMD-0801, which is being evaluated in two pivotal Phase 3 studies and has the potential to be the first commercial oral insulin capsule for the treatment of diabetes. In addition, Oramed is developing an oral GLP-1 (Glucagon-like peptide-1) analog capsule (ORMD-0901).

For more information, please visit www.oramed.com.

Forward-looking statements: This press release contains forward-looking statements. For example, we are using forward-looking statements when we discuss the potential development and timing of an oral COVID-19 vaccine, what our financial position is expected to allow us to achieve, our expectations to share multiple milestones, including topline data from our first Phase 3 oral insulin trial, the expected timing of results of our clinical trials, the expected timing and achievement of milestones and other anticipated future results. In addition, historic results of scientific research and clinical trials do not guarantee that the conclusions of future research or trials will suggest identical or even similar conclusions. These forward-looking statements are based on the current expectations of the management of Oramed only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements, including the risks and uncertainties related to the progress, timing, cost, and results of clinical trials and product development programs; difficulties or delays in obtaining regulatory approval or patent protection for our product candidates; competition from other pharmaceutical or biotechnology companies; and our ability to obtain additional funding required to conduct our research, development and commercialization activities. In addition, the following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; delays or obstacles in launching our clinical trials; changes in legislation; inability to timely develop and introduce new technologies, products and applications; lack of validation of our technology as we progress further and lack of acceptance of our methods by the scientific community; inability to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties that may develop with our process; greater cost of final product than anticipated; loss of market share and pressure on pricing resulting from competition; laboratory results that do not translate to equally good results in real settings; our patents may not be sufficient; and finally that products may harm recipients, all of which could cause the actual results or performance of Oramed to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Oramed undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Oramed, reference is made to Oramed's reports filed from time to time with the Securities and Exchange Commission.

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FINANCIAL TABLES

ORAMED PHARMACEUTICALS INC.
INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. Dollars in thousands (except share and per share data)
(UNAUDITED)

	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 33,196	\$ 27,456
Short-term deposits	121,119	111,077
Marketable securities	5,234	7,747
Prepaid expenses and other current assets	623	1,657
Total current assets	<u>160,172</u>	<u>147,937</u>
LONG-TERM ASSETS:		
Long-term deposits	2	25,094
Long-term investments	2,700	-
Marketable securities	-	3,875
Amounts funded in respect of employee rights upon retirement	23	26
Property and equipment, net	535	388
Operating lease right-of-use assets	1,005	500
Total long-term assets	<u>4,265</u>	<u>29,883</u>
Total assets	<u>\$ 164,437</u>	<u>\$ 177,820</u>
Liabilities and stockholders' equity		
CURRENT LIABILITIES:		
Accounts payable, accrued expenses and other liabilities	\$ 4,205	\$ 4,535
Deferred revenues	2,022	2,703
Payable to related parties	70	-
Operating lease liabilities	228	130
Total current liabilities	<u>6,525</u>	<u>7,368</u>
LONG-TERM LIABILITIES:		
Long-term deferred revenues	4,000	3,340
Employee rights upon retirement	21	22
Provision for uncertain tax position	11	11
Operating lease liabilities	672	370
Other liabilities	61	99
Total long-term liabilities	<u>4,765</u>	<u>3,842</u>
COMMITMENTS (note 2)		
Equity		
EQUITY ATTRIBUTABLE TO COMPANY'S STOCKHOLDERS:		
Common stock, \$0.012 par value (60,000,000 authorized shares; 39,113,236 and 38,158,792 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively)	470	459
Additional paid-in capital	307,876	292,514
Accumulated deficit	(154,538)	(126,520)
Total stockholders' equity	<u>153,808</u>	<u>166,453</u>
Non-controlling interests	(661)	157
Total equity	<u>153,147</u>	<u>166,610</u>
Total liabilities and equity	<u>\$ 164,437</u>	<u>\$ 177,820</u>

ORAMED PHARMACEUTICALS INC.
INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
U.S. Dollars in thousands (except share and per share data)
(UNAUDITED)

	Nine months ended		Three months ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
REVENUES	\$ 2,022	2,022	\$ 682	682
RESEARCH AND DEVELOPMENT EXPENSES	20,362	15,452	5,347	6,086
SALES AND MARKETING EXPENSES	1,433	172	463	172
GENERAL AND ADMINISTRATIVE EXPENSES	11,085	4,937	3,061	1,909
OPERATING LOSS	<u>30,858</u>	<u>18,539</u>	<u>8,189</u>	<u>7,485</u>
FINANCIAL INCOME (EXPENSE), NET	1,930	1,031	1,036	(51)
LOSS BEFORE TAX EXPENSES	28,928	17,508	7,153	7,536
TAX EXPENSES	100	-	100	-
NET LOSS FOR THE PERIOD	\$ 29,028	17,508	\$ 7,253	7,536
NET LOSS ATTRIBUTABLE TO NON-CONTROLLING INTERESTS	1,010	764	193	279
NET LOSS ATTRIBUTABLE TO STOCKHOLDERS	<u>28,018</u>	<u>16,744</u>	<u>7,060</u>	<u>7,257</u>
LOSS PER SHARE				
BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	\$ 0.72	\$ 0.54	\$ 0.18	\$ 0.21
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING BASIC AND DILUTED LOSS PER SHARE OF COMMON STOCK	<u>38,856,514</u>	<u>31,097,270</u>	<u>39,100,231</u>	<u>34,539,487</u>

ORAMED PHARMACEUTICALS INC.
INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars in thousands
(UNAUDITED)

	Nine months ended September 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (29,028)	\$ (17,508)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	41	69
Non-cash expense for acquired in-process research and development	-	1,040
Exchange differences and interest on deposits and held to maturity bonds	(933)	429
Changes in fair value of investments	494	(732)
Stock-based compensation	8,961	2,896
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,034	128
Accounts payable, accrued expenses and related parties	(330)	1,875
Net changes in operating lease	(105)	-
Deferred revenues	(21)	(2,022)
Liability for employee rights upon retirement	(1)	-
Other liabilities	32	(74)
Total net cash used in operating activities	<u>(19,856)</u>	<u>(13,899)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of held to maturity securities	-	(8,593)
Purchase of short-term deposits	(111,500)	(6,000)
Investment in long-term deposits	-	(25,000)
Proceeds from short-term deposits	128,000	9,500
Proceeds from maturity of held to maturity securities	5,336	6,065
Long-term investments	(2,700)	-
Proceeds from sale of mutual funds	-	3,029
Funds in respect of employee rights upon retirement	3	-
Purchase of property and equipment	(188)	(55)
Total net cash provided by (used in) investing activities	<u>18,951</u>	<u>(21,054)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	7,345	74,743
Proceeds from exercise of warrants and options	42	21,496
Transaction with non-controlling interests	-	1,500
Tax withholdings related to stock-based compensation settlements	(783)	-
Total net cash provided by financing activities	<u>6,604</u>	<u>97,739</u>
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	<u>41</u>	<u>(3)</u>
INCREASE IN CASH AND CASH EQUIVALENTS	5,740	62,783
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	<u>27,456</u>	<u>21,630</u>
CASH AND CASH EQUIVALENTS AT END OF PERIOD	<u>\$ 33,196</u>	<u>\$ 84,413</u>
(A) SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -		
Interest received	<u>\$ 906</u>	<u>\$ 505</u>
(B) SUPPLEMENTARY DISCLOSURE ON CASH FLOWS -		
Recognition of operating lease right of use assets and liabilities	\$ 678	\$ -
(C) ASSET ACQUISITION TRANSACTION (see note 8) -		
In-process research and development	-	1,040
Transaction with non-controlling interests	-	1,500
Additional paid in capital	-	(1,045)
Non-controlling interests	<u>\$ -</u>	<u>\$ (1,495)</u>