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): **February 20, 2024**

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

DELAWARE	**001-35813**	**98-0376008**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1185 Avenue of the Americas, Third Floor, New York, New York	**10036**
(Address of Principal Executive Offices)	(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 8.01. Other Events.

On February 20, 2024, Oramed Pharmaceuticals Inc. (the "Company") issued a press release containing a letter to the Company's shareholders from its Chief Executive Officer, Nadav Kidron. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press release dated February 20, 2024
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

February 20, 2024

Exhibit 99.1

Oramed Letter to Shareholders

- ***Initiating Phase 3 oral insulin trial in the United States under a new protocol***
- ***JV with Chinese Partner, HTIT***
- ***Scilex Senior Secured Note***
- ***PeriTech Asset Purchase & Strategic Out-licensing***

NEW YORK, February 20, 2024 – Oramed Pharmaceuticals Inc. (Nasdaq/TASE: ORMP) (www.oramed.com), a clinical-stage pharmaceutical company focused on the development of oral drug delivery platforms, today issued a Letter to Shareholders from its President and Chief Executive Officer, Nadav Kidron.

Dear Shareholders,

I am pleased to share with you an update regarding Oramed. Despite the unexpected negative results we received for our U.S. based Phase 3 trial at the outset of last year, I am happy to report that we stand today on solid ground with many opportunities through which we seek to increase shareholder value.

Oramed's Chinese Partner, HTIT, Successfully Completed Phase 3 Trial and Advances Production Facilities:
Hefei Tianhui Biotechnology Co. Ltd. ("HTIT"), a strategic partner of Oramed, achieved a noteworthy milestone by successfully completing its Phase 3 trials of oral insulin for type 2 diabetes in China, currently in the final stages of regulatory approval.

In addition, HTIT has made substantial investments in facilities to enable commercial-scale production of the oral insulin capsule. This development underscores our belief in HTIT's commitment to advancing the accessibility of innovative oral insulin solutions for patients in China and potentially beyond, as evidenced by the proposed Joint Venture described below.

Phase 3 Oral Insulin Program:
In January 2023, Oramed announced that its U.S.-based, Phase 3 oral insulin trial for the treatment of type 2 diabetes did not meet its primary or secondary endpoints. Oramed has since completed an in-depth review of the trial data and the analysis found that subpopulations of patients with specific parameters, such as body mass index (BMI), baseline HbA1c, and age responded well to oral insulin. These subsets exhibited an over 1% placebo adjusted, statistically significant, reduction in HbA1c and closely approximate the patient population in the HTIT trials.

We are encouraged by the results of our analysis and have begun discussions with the FDA. We intend to initiate a Phase 3 oral insulin trial in the U.S. under a differentiated protocol that aligns with this positive data later this year.

Oramed and HTIT Joint Venture:
In January 2024, Oramed entered into a definitive agreement with HTIT, marking a milestone in the creation of a joint venture ("JV"), centered around Oramed's cutting-edge oral drug delivery technology. The JV is poised to be a dynamic force, focusing on the development, marketing, and global commercialization of innovative products derived from Oramed's oral insulin and POD™ (Protein Oral Delivery) pipeline. This strategic partnership will harness HTIT's advanced manufacturing capabilities and technologies.

The joint venture will receive a significant capital infusion, with HTIT committing a notable $70 million investment, supplemented by a $20 million investment from Oramed (comprised of $10 million in cash and $10 million in shares of Oramed common stock). This robust financial foundation is intended to help with the completion of clinical trials in the United States and to support various clinical and business activities crucial to the venture's overall success. Additionally, we are exploring further strategies with HTIT to leverage their top-of-the-line production capabilities and capitalize on the expected launch of oral insulin sales in China. While there are evident synergies and logical collaborations on many levels, the proposed transactions contemplated by the JV are intricate and are still in process. There is no certainty that we will be able to close some or all of these transactions. We will keep you informed as we make progress in this regard.

Scilex Senior Secured Note:
In September 2023, Scilex Holding Company ("Scilex") issued an 18-month Senior Secured Promissory Note to Oramed (the "Note"), carrying an initial principal balance of $101,875,000 and an interest rate of SOFR plus 8.5% (currently ~13.8%). Oramed secured a senior lien on nearly all assets of Scilex and its subsidiaries as collateral for the Note. Concurrently, Scilex granted Oramed new warrants for up to 13 million shares of Scilex common stock at an exercise price of $0.01 per share, subject to vesting as well as certain ownership and other restrictions. Repayment of the principal balance began on December 21, 2023, with fixed increments due every three months thereafter. In addition, a failure to fully repay the Note by March 21, 2024, triggers an exit fee of $3,056,250 upon full repayment.

Peritech Asset Acquisition and Strategic Out-Licensing:
In December 2023, Oramed executed and completed an agreement with PeriTech Pharma Ltd. ("PeriTech"), acquiring the rights to their cutting-edge film-forming technology tailored for the delivery of topical/dermatology agents. This includes a once-daily over-the-counter treatment for hemorrhoids, surpassing existing market alternatives. The PeriTech pipeline extends its potential applications to include indications such as pruritus ani, anal warts, anal fissures and herpes labialis.

In emphasizing the potential benefits of this acquisition, Oramed has entered into an exclusive Licensing Agreement with an international consumer product and pharmaceutical group, pursuant to which Oramed granted the development and commercialization rights to the PeriTech pipeline in exchange for a royalty based on net sales. Oramed's shareholders stand to benefit from the worldwide potential inherent in this transaction.

In summary, Oramed is well positioned in terms of its balance sheet and is currently taking active steps to continue the development of its oral insulin program as well as continuing to take advantage of strategic opportunities in order to increase shareholder value. We thank you for your support and look forward to keeping our shareholders updated on the important milestones ahead.

Sincerely,

Nadav Kidron
Chief Executive Officer

About Oramed Pharmaceuticals

Oramed Pharmaceuticals Inc. (Nasdaq/TASE: ORMP) is a platform technology pioneer in the field of oral delivery solutions for drugs currently delivered via injection. Oramed's novel Protein Oral Delivery (POD™) technology is designed to protect drug integrity and increase absorption. Oramed has offices in Israel. For more information, please visit www.oramed.com.

Forward-looking statements: This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements. For example, we are using forward-looking statements when we discuss Oramed's opportunities and ability to increase shareholder value, the anticipated regulatory approval of HTIT's clinical trial data and the timing of such approval, the expected timing and achievement of milestones, the potential development, benefits, safety, efficacy and timing of our oral insulin program, our intention to begin a Phase 3 oral insulin trial in the U.S. and the timing of such trial, the potential benefits, capabilities and overall success of our JV with HTIT, the closing of the transactions contemplated by the JV including receipt of expected capital contributions, the completion of clinical trials related to the JV and the expected launch of oral insulin sales in China, the potential benefits in connection with our Licensing Agreement, and the ability of our balance sheet to allow us to continue to the development of our oral insulin program and take advantage of strategic opportunities. 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 close the transactions contemplated by our JV with HTIT in a timely manner or at all; inability of Scilex to repay the Note or our inability to realize the value of the Scilex warrants issued or transferred to us; 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.

Company Contact:

+1-844-9-ORAMED

ir@oramed.com