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): **July 7, 2022**

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 July 7, 2022, 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 July 7, 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

July 7, 2022

Exhibit 99.1

Oramed Letter to Shareholders

- ***$169 Million in Cash and Investments***
- ***Pivotal Phase 3 Oral Insulin Data Expected January 2023***
- ***Phase 2 NASH Data Expected This Quarter***
- ***Oravax - Oral Vaccine***

NEW YORK, July 7, 2022 – 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 Chief Executive Officer, Nadav Kidron.

Dear Shareholders,

As we enter the second half of 2022, I am pleased to share with you updates regarding Oramed Pharmaceuticals and our subsidiary Oravax Medical. While we find ourselves in a tumultuous environment for the global economy, financial markets, and in particular, the biotech sector, we consider ourselves well positioned financially and clinically with multiple important milestones expected over the next six months.

Robust Balance Sheet: $169 Million in Cash and Investments

Our financial position is strong with a robust balance sheet, no debt and approximately $169 million in cash and investments as of March 31, 2022. This position gives us sufficient runway to complete our pivotal oral insulin (ORMD-0801) Phase 3 trials and advance us towards potential FDA approval. In addition, we will continue investing in our POD™ oral delivery pipeline, as well as pursuing opportunities to capitalize on strategic prospects.

Phase 3 Oral Insulin Trials: Top-Line Data Expected January 2023

In January 2023, we anticipate reaching one of the most significant milestones of this Company's history, when we report top-line efficacy data in the world's first-ever pivotal Phase 3 oral insulin trial for the treatment of type 2 diabetes, under a U.S. FDA protocol. As reported, we exceeded the number of planned participants in the first of our two oral insulin trials ORA-D-013-1, with 710 participants enrolled. Concurrently, our second Phase 3 trial, ORA-D-013-2, has enrolled nearly 50% of the planned 450 patients.

For the millions of people suffering from diabetes, we believe ORMD-0801 will offer an easier and more efficacious way of delivering insulin without the need for injections and doing so in a safer and more healthy manner. In a recent IQVIA market survey, approximately 80% of physicians said they would likely prescribe oral insulin to their patients, if approved. If you have not had a chance yet to see the webinar on the promise of oral insulin for the treatment of type 2 diabetes, I invite you to view it here: https://youtu.be/yrWtf8PSgk0

Phase 2 NASH Data Expected This Quarter

In March 2022, we completed enrollment in our Phase 2 trial of ORMD-0801 for the treatment of non-alcoholic steatohepatitis (NASH). We expect to announce top-line results later this quarter. The double-blind, multi-center trial with clinical sites in the U.S. and Israel assesses the safety and efficacy of ORMD-0801 in type 2 diabetes patients with NASH. There is currently no FDA approved treatment for NASH, which is expected to become an $84 billion market by 2029.

Oravax

The Phase 1 clinical trial of Oravax's oral virus-like particle (VLP) COVID-19 vaccine for COVID-naive participants is underway in South Africa. The trial protocol calls for two cohorts each comprised of 12 participants. The South African Health Products Regulatory Authority (SAPHRA) requires a 42-day safety waiting period once the last patient in Cohort A completes enrollment and dosing, after which Cohort B may commence enrollment and dosing.

Due to several factors, including the fact that many volunteers did not qualify during screening due to prior asymptomatic COVID-19 infection and other conditions, the rate of enrollment was slower than anticipated. We added an additional clinical site and we have since completed enrollment and dosing of Cohort A with no safety issues reported thus far and anticipate sharing top-line data this quarter. We expect Cohort B to complete dosing this quarter as well, with data expected in Q4 2022.

As we continue to develop our oral VLP COVID-19 vaccine as both a first line and booster vaccine, we are also positioning Oravax to address the broader global vaccine market and are currently exploring opportunities for additional vaccine indications. The vaccine market is projected to reach $125 billion by 2028.

To recap, Oramed is extremely well positioned in terms of cash position, Phase 3 oral insulin program, IP portfolio and platform technology-which can be used for numerous indications. We thank you for your support and look forward to keeping our shareholders updated on the exciting milestones ahead.

Sincerely,

Nadav Kidron
Chief Executive Officer

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 pace of enrollment and randomization and expected timing of results of our clinical trials, the expected timing and achievement of milestones, the potential development, benefits, safety, efficacy and timing of Oravax's oral COVID-19 vaccine, the value of potential future orders of such oral vaccine, the ability of our balance sheet to allow us to complete our Phase 3 oral insulin trials and advance Oravax's oral COVID-19 vaccine through late-stage clinical trials and begin investing in production or the potential of ORMD-0801 to be the first commercial oral insulin capsule for the treatment of diabetes, as well as its potential for the treatment of people with diabetes who also suffer from NASH. 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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