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): **January 12, 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 January 12, 2022, Oramed Pharmaceuticals Inc. (the "Company") issued a press release containing a letter to the Company's shareholders by 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 January 12, 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

January 12, 2022

Exhibit 99.1

Oramed Issues Annual Message to Shareholders

- ***Oral insulin program continues to advance with topline efficacy data expected in H2 2022***
- ***Significant value creation opportunities through oral COVID-19 vaccine program and partnerships***
- ***Well positioned to capitalize on opportunities with strong cash balance of ~$174 million as of December 3, 2021***

NEW YORK, January 12, 2022 – Oramed Pharmaceuticals Inc. (Nasdaq/TASE: ORMP), 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. To see a video message from the CEO please click here: https://www.youtube.com/watch?v=vgq1I7ylKsk

Dear Shareholders,

2021 was a defining year for Oramed as we advanced existing programs, added a new significant opportunity to address a major unmet medical need, and strategically positioned our organization to execute on anticipated 2022 milestones and beyond.

Our proprietary platform oral delivery technology has positioned the company with two potential world firsts: an oral insulin capsule and an oral triple antigen COVID-19 vaccine. Throughout 2021, the lion's share of our clinical efforts focused on the successful enrollment of subjects in the world's first pivotal Phase 3 trials for oral insulin under an FDA protocol. We anticipate topline, 6-month efficacy results, in H2, 2022. At the height of the pandemic, we along with our partner, Premas Biotech, developed a novel, proprietary oral COVID-19 vaccine via our majority-owned subsidiary, Oravax Medical. Forging ahead into 2022 with ~$174 million (unaudited) on our balance sheet as of December 3, 2021, and an expanded management team, we believe we are well positioned to complete our Phase 3 oral insulin trials and to advance Oravax's oral COVID-19 vaccine through late-stage clinical trials for potential emergency use authorization in select countries where it is most needed.

Phase 3 Oral Insulin (ORMD-0801) Trials for the Treatment of Type 2 Diabetes: Over 75% Enrollment Completed

ORA-D-013-1, the larger of two concurrent Phase 3 oral insulin trials, has enrolled over 75% of the 675 subjects planned for the U.S.-based trial. Additionally, more than a quarter of the planned 450 patients in our second Phase 3 trial, ORA-D-013-2, have been enrolled.

Upcoming Milestones:

- 6-month topline efficacy results from larger ORA-D-013-1 trial expected in 2022
- ORA-D-013-2 trial expected to complete enrollment in 2022

Oravax Medical, Inc.: Oral COVID-19 Vaccine

In March 2021, we announced the formation of Oravax, a majority owned joint venture, in partnership with Premas Biotech and others. Oravax combines Oramed's POD™ oral delivery technology with Premas' proprietary virus like particle (VLP) triple antigen vaccine. The VLP vaccine targets three structural proteins potentially creating a more robust candidate for protection across emerging mutations of the coronavirus. The oral delivery should offer a more user-friendly option potentially enabling widescale inoculation and easier distribution of the vaccine, particularly in regions of the world where cold-chain logistics pose challenges for the distribution of injectable vaccines. A Phase 1 clinical trial is underway in South Africa with endpoints including safety and efficacy by measuring the presence of an immunogenic response.

In November 2021, Oravax signed a joint venture agreement with Genomma Lab Internacional, a leading pharmaceutical and personal care products company in Latin America, to develop and commercialize Oravax's oral COVID-19 vaccine candidate in Mexico. Genomma Lab is expected to leverage their extensive presence in Latin America to support a roll-out of the vaccine throughout the region. At the end of December 2021, Oravax signed a Cooperation and Purchase Agreement with Vietnam-based Tan Thanh Holdings, to prepurchase 10 million doses of Oravax's oral COVID-19 vaccine. Tan Thanh Holdings operates one of the fastest growing pharmaceutical businesses in the ASEAN region and the Agreement grants Tan Thanh the right to sell Oravax's oral vaccine throughout the ASEAN region. The parties have agreed to negotiate follow-on orders.

Upcoming Milestones:

- Topline data from Phase 1 expected H1 2022
- Initiation of Phase 2/3 oral COVID-19 vaccine trials expected H2 2022

Phase 2 NASH Trial: 50% Enrollment Completed

Over 50% of patients have been enrolled in the U.S. and Israel in our double-blind Phase 2 trial of ORMD-0801 for the treatment of Non-Alcoholic Steatohepatitis (NASH) in subjects with type 2 diabetes.

Upcoming Milestones:

- Enrollment completion expected H1 2022
- Topline data expected in H2 2022

Oral GLP-1

We are currently conducting a bioavailability trial for ORMD-0901, our oral glucagon-like peptide-1 (GLP-1) analog capsule, in subjects with type 2 diabetes.

Upcoming Milestone:

- Bioavailability (PK and PD) expected in H1 2022

Expanded Management Team and Strong Balance Sheet

We have recently added significant core competencies to our management team with the additions of both a Chief Commercial Officer and a Chief Legal Officer rounding out the already strong team. We have grown our cash balance over 2021 to ~$174 million (unaudited) as of December 3, 2021. We believe that this strong balance sheet will 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 so we can meet the foreseeable demand for the oral COVID-19 vaccine.

We are entering 2022 with a new logo and level of excitement inspired by all the opportunities and milestones ahead of us. On behalf of all of us at Oramed, I want to thank our partners and clinical trial volunteers for helping us advance our clinical and other efforts. We look forward to a year filled with health and safety for all and we will continue to keep all of our shareholders abreast of news and developments.

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 trials 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 contribution of Tan Thanh Holdings to the clinical development and regulatory approval of such oral vaccine, the potential for Genomma Lab to develop and commercialize Oravax's oral COVID-19 vaccine candidate in Mexico and to leverage their extensive presence in Latin America to support a roll-out of the vaccine throughout the region, 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. 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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