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 26, 2020**

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, Suite 228, 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 26, 2020, Oramed Pharmaceuticals Inc. (the "Company") announced positive topline data from the second and final cohort of the Phase IIb trial evaluating the efficacy and safety of its lead oral insulin candidate, ORMD-0801, at lower dose regimes, which has the potential to be the first commercially available oral insulin capsule for the treatment of diabetes. The placebo-controlled, double-blinded, randomized, 90-day dose-ranging phase IIb trial in type 2 diabetes patients with inadequate glycemic control on oral antihyperglycemic agents, assessed the change in A1C, the primary efficacy endpoint, from baseline to week 12, as well as safety endpoints, when ORMD-0801 was given in different regimens across three daily dose ranges (8 mg, 16 mg,32 mg). Following this trial, the Company expects to discuss with The U.S. Food and Drug Administration ("FDA") its planned Phase III trial.

Patients randomized in the trial treated with 8 mg of ORMD-0801 once-daily achieved an observed mean reduction of 1.29% from baseline and a least square mean reduction of 0.95% from baseline, or 0.81% adjusted for placebo (p value = 0.028). Patients who had A1C readings above 9% at baseline and received 8 mg of oral insulin once-daily experienced a 1.26% reduction in A1C by week 12.

Treatment with ORMD-0801 at all doses demonstrated an excellent safety profile, with no serious drug-related adverse events and with no increased frequency of hypoglycemic episodes or weight gain compared to placebo.

The primary efficacy endpoint was a reduction in Hemoglobin A1C (A1C, also known as HbA1C, a key clinical measure of blood glucose control) at week 12.

In the second cohort, 78 U.S.-based patients were enrolled, treated, and randomized into five groups: 8 mg dosed once-daily; 8 mg dosed twice-daily; 16 mg dosed once-daily; 16 mg dosed twice-daily; and placebo dosed once-daily. The same two sites which were excluded from the statistical analysis in the primary cohort due to evidence of treatment-by-center interaction and a statistically significant placebo effect, were excluded in the second cohort, representing a patient population of 13 patients. Of the 65 patients included in the analysis, 57 completed through week 12.

The once-daily and twice-daily arms of patients dosed at 8 mg achieved statistically significant (p-value 0.028 and 0.029, respectively) reductions from baseline in A1C of 0.95% (0.81% with placebo adjustment) and 0.95% (0.82% with placebo adjustment), respectively. Patients dosed once-daily at 16 mg and twice-daily at 16 mg did not show statistically significant reductions in A1C.

Forward-looking Statements

This Current Report on Form 8-K contains forward-looking statements. For example, the Company is using forward-looking statements when it discusses the potential of ORMD-0801 to be the first commercial oral insulin capsule for the treatment of diabetes, the safety and efficacy of ORMD-0801, the ability of ORMD-0801 to reduce HbA1C, the timing of expected clinical development programs and discussions with the FDA. 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 the Company 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 its product candidates; competition from other pharmaceutical or biotechnology companies; and its ability to obtain additional funding required to conduct its 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 its clinical trials; changes in legislation; inability to timely develop and introduce new technologies, products and applications; lack of validation of its technology as the Company progress further and lack of acceptance of its methods by the scientific community; inability to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties that may develop with its 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; its patents may not be sufficient; and finally that products may harm recipients, all of which could cause the actual results or performance of the Company to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, the Company 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 the Company, reference is made to the Company’s reports filed from time to time with the U.S. Securities and Exchange Commission.

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 26, 2020