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 12, 2019**

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 November 12, 2019, Oramed Pharmaceuticals Inc. (the "Company") announced positive results from the initial cohort of the Phase IIb trial evaluating the efficacy and safety of its lead oral insulin candidate, ORMD-0801, which has the potential to be the first commercial oral insulin capsule for the treatment of diabetes. The placebo-controlled, double-blind, 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 a dose range.

Patients randomized in the trial to once-daily ORMD-0801 achieved a reduction in mean A1C of 0.60% from baseline, or a reduction of 0.54% adjusted for placebo (p value = 0.036). This 0.54% reduction in A1C is considered clinically meaningful, reflecting an improved glucose control that would result in reduced risk of developing diabetes-related complications.

Treatment with ORMD-0801 demonstrated an excellent safety profile, with no serious drug-related adverse events and with no increased frequency of hypoglycemic episodes. In addition, during this 90-day trial, no weight gain was observed.

The primary efficacy endpoint was a reduction in Hemoglobin A1c (A1C, also known as HbA1c, is a key clinical measure of blood glucose control) at Week 12.

In the initial cohort, 269 U.S.-based patients were enrolled and treated with a dose-increasing approach: 16 mg initial dose, titrated to 24 mg per dose, and then titrated to 32 mg per dose. Patients were randomized into three groups to assess dosing frequency: once-daily (32 mg per day), twice-daily (64 mg per day), thrice-daily (96 mg per day). There was a corresponding placebo for each treatment arm. Two hundred nine (209) patients completed treatment to the 12-week endpoint and were included in the data analysis (24 subjects did not complete the full 12 weeks of treatment). In addition, due to evidence of treatment-by-center interaction, two sites (36 patients (13.4% of enrolled subjects)) were excluded from the statistical analysis.

The once-daily and twice-daily arms achieved statistically significant (p-value 0.036 and 0.042, respectively) reductions from baseline in A1C of 0.60% (0.54% with placebo adjustment) and 0.59% (0.53% with placebo adjustment), respectively. The thrice-daily arm did not meet statistical significance (p-value 0.093). ORMD-0801 demonstrated an excellent safety profile with no serious drug-related adverse events.

The ongoing second cohort is designed with a sample size of 15 subjects per treatment group to identify the optimal dose of ORMD-0801 for the Phase III trial. In the low-dose second cohort, 75 patients have been 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 twice-daily. Oramed expects to announce the results from the second cohort in the first quarter of 2020.

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 A1c, timing of expected clinical development programs and clinical trials, including patient enrollment, release of results, recruitment of additional cohorts or revolutionizing the treatment of diabetes with its products. 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

November 12, 2019