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 15, 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 July 15, 2020, Oramed Pharmaceuticals Inc. (the "Company") announced that The U.S. Food and Drug Administration (the "FDA") provided positive feedback during the Company's end of Phase II meeting for the Company's oral insulin candidate, ORMD-0801. Based on the FDA's feedback, the Company intends to initiate two Phase III clinical trials following FDA review of those Phase III protocols and nonclinical documents. The FDA outlined its expectations for design of the ORMD-0801 Phase III trials, as well as submission of the Biologics License Application ("BLA") that would follow successful trials. The Company plans to conduct the two phase III trials concurrently.

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 initiation of Phase III trials, the potential submission of a BLA, and the validation of preliminary findings in future trials. 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

July 15, 2020