ORAMED PHARMACEUTICALS INC.
Form 8-K
September 17, 2018

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): **September 17, 2018**

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.)

142 W. 57th Street, New York, New York	**10018**
(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))

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 September 17, 2018, Oramed Pharmaceuticals Inc. (the "Company") announced that the U.S. Food and Drug Administration has cleared its Investigational New Drug ("IND") application for human trials of its oral GLP-1 analog capsule ORMD-0901.

The Company plans to initiate a Phase 1 pharmacokinetic (PK) trial which will evaluate the safety and the pharmacokinetics of ORMD-0901 compared to placebo. This fully-randomized, single-blind, placebo-controlled 4-way crossover study will be conducted on up to 15 healthy subjects pursuant to the IND.

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 planned initiation and parameters of its Phase I trial. 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 the Company's product candidates; competition from other pharmaceutical or biotechnology companies; and the Company's 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 the Company's clinical trials; changes in legislation; inability to timely develop and introduce new technologies, products and applications; lack of validation of the Company's technology as it progresses further and lack of acceptance of the Company's methods by the scientific community; inability to retain or attract key employees whose knowledge is essential to the development of the Company's products; unforeseen scientific difficulties that may develop with the Company's 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; the Company's patents may not be sufficient; and final 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

September 17, 2018

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