ORAMED PHARMACEUTICALS INC.
Form 8-K
September 05, 2017

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): **August 31, 2017**

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.)

Hi-Tech Park 2/4 Givat Ram, PO Box 39098, Jerusalem, Israel	**91390**
(Address of Principal Executive Offices)	(Zip Code)

+972-2-566-0001

(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 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 August 31, 2017, Oramed Pharmaceuticals Inc. (the "Company") had a meeting with the U.S. Food and Drug Administration (the "FDA") regarding its oral insulin capsule, ORMD-0801.

At the meeting, the FDA gave guidance that the regulatory pathway for submission of ORMD-0801 would be a Biologics License Application (BLA). Such a pathway would grant a full 12 years of marketing exclusivity for ORMD-0801 if approved. On top of this, an additional six months of exclusivity can be granted if the product also receives approval for use in pediatric patients.

The FDA confirmed that the approach to nonclinical toxicology, chemistry manufacturing controls and qualification of excipients would be driven by their published guidance documents. They also made specific recommendations for clinical trials designed to provide pivotal data prior to registration. At the suggestion of the FDA, the Company plans to initiate a three-month trial in patients with type 2 diabetes to evaluate the effect of ORMD-0801 on HbA1c, the main FDA registrational endpoint, later this year. In addition, the FDA confirmed the Company's ability to use insulin from different suppliers in the Phase 3 study.

Warning Concerning Forward Looking Statements

This Current Report on Form 8-K (the "Report") contains statements which constitute forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other securities laws. These forward looking statements are based upon the Company's present intent, beliefs or expectations, but forward looking statements are not guaranteed to occur and may not occur for various reasons, including some reasons which are beyond the Company's control. For example, the Report discusses the expected pathway for ORMP-0801 and related timing and potential benefits of that pathway and related trials and studies. In fact, the pathway and related timing and potential benefits of that pathway and related trials and studies could change due to various factors. For this reason, among others, you should not place undue reliance upon the Company's forward looking statements. Except as required by law, the Company undertakes no obligation to revise or update any forward looking statements in order to reflect any event or circumstance that may arise after the date of the Report.

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
September 5, 2017 Title: President and CEO