ORAMED PHARMACEUTICALS INC.
Form 8-K
July 28, 2016

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 28, 2016**

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))

Item 7.01. Regulation FD Disclosure.

On July 28, 2016, Oramed Pharmaceuticals Inc., or Oramed, posted to its website a presentation containing key results from its Phase 2b clinical trial described below. A copy of this presentation is furnished with this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Item 8.01. Other Events.

On July 28, 2016, Oramed announced additional results from its Phase 2b clinical trial for its oral insulin capsule ORMD-0801 in patients with type 2 diabetes. The double blind randomized trial of 180 adults was conducted at 33 sites in the United States under an Investigational New Drug application with the U.S.Food and Drug Administration. The Phase 2b trial indicated a statistically significant lowering of glucose relative to placebo across several endpoints. The trial's positive topline data showed that the study successfully met its primary efficacy and safety endpoint. The trial primarily evaluated the nighttime glucose lowering effect and safety of ORMD-0801 compared to a placebo. The results of the mean nighttime glucose showed a significant difference in mean change from run-in. ORMD-0801 oral insulin was safe and well-tolerated for the dosing regimen in this trial. The trial further evaluated the effect of ORMD-0801 on mean 24-hour glucose, fasting glucose, and daytime glucose and the results showed a statistically significant difference in mean change from run-in. No significant difference was shown in change in morning fasting serum insulin, C-Peptide, or triglycerides.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Presentation (furnished herewith)

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.

July 28, 2016 By: /s/ Nadav Kidron
Name: Nadav Kidron
Title: President and CEO