

ORAMED PHARMACEUTICALS INC.
Form 8-K
May 24, 2013

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): May 17, 2013

ORAMED PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

DELAWARE
(State or Other Jurisdiction
of Incorporation)

000-50298
(Commission
File Number)

98-0376008
(IRS Employer
Identification No.)

Hi-Tech Park 2/5 Givat Ram, PO Box 39098, Jerusalem, Israel
(Address of Principal Executive Offices)

91390
(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 8.01. Other Events.

On May 17, 2013, the registrant announced that “Oramed Receives FDA Clearance to Initiate Oral Insulin Trials in the U.S.”, indicating that the U.S. Food and Drug Administration cleared an Investigational New Drug application (“IND”) for ORMD-0801, its oral insulin. The described IND relates to a sub-study/Phase 2a trial that will be a one-week, in-patient study with 30 individuals.

A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

This Current Report on Form 8-K contains forward-looking statements within the meaning of the federal securities laws. Statements preceded by, followed by, or that otherwise include the words “expects,” “anticipates,” “intends,” “plans,” “planned expenditures,” “believes,” “seeks,” “estimates” and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements. Additionally, statements concerning future matters are forward-looking statements. For example, statements related to the sub-study/Phase 2a trial are forward-looking statements. Because such statements deal with future events, they are subject to various risks and uncertainties and these uncertainties may cause actual future results or outcomes to differ materially from those expressed in the registrant’s forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the registrant 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 hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting the registrant, reference is made to the registrant’s reports filed from time to time with the Securities and Exchange Commission.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by the registrant on May 17, 2013.

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

Date: May 24, 2013