

**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 26, 2015

ORAMED PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or Other Jurisdiction
of Incorporation)

001-35813

(Commission
File Number)

98-0376008

(IRS Employer
Identification No.)

Hi-Tech Park 2/4 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))
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Item 8.01. Other Events.

On May 26, 2015, Oramed Pharmaceuticals Inc. issued the press release filed as Exhibit 99.1 to this Current Report on Form 8-K, which press release is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release dated May 26, 2015.

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

May 27, 2015

**Oramed Submits Protocol to U.S. FDA for its Phase IIb Oral Insulin Study**

Company's largest study to date with over 30 clinical sites in the U.S. to participate

JERUSALEM May 26, 2015 — Oramed Pharmaceuticals Inc. (NASDAQ: ORMP) (www.oramed.com), a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, announced today that it has submitted the study protocol for the company's Phase IIb trial of ORMD-0801, its oral insulin capsule, to the U.S. Food and Drug Administration (FDA). The submission was made under the company's existing Investigational New Drug (IND) application.

The Phase IIb study of ORMD-0801 for type 2 diabetics is designed to generate ample data for both efficacy and safety endpoints. The double-blind, randomized study will recruit approximately 180 patients and has a 28-day treatment period. The study has already received Institutional Review Board (IRB) approval and patient enrollment is expected to start in the short term.

About Oramed Pharmaceuticals

Oramed Pharmaceuticals is a technology pioneer in the field of oral delivery solutions for drugs currently delivered via injection. Established in 2006, Oramed's Protein Oral Delivery (PODTM) technology is based on over 30 years of research by top scientists at Jerusalem's Hadassah Medical Center. Oramed is seeking to revolutionize the treatment of diabetes through its proprietary flagship product, an orally ingestible insulin capsule ([ORMD-0801](#)). Having completed separate Phase IIa clinical trials, the company anticipates the initiation of separate Phase IIb clinical trials, in patients with both type 1 and type 2 diabetes under an Investigational New Drug application with the U.S. Food and Drug Administration. In addition the company is developing an oral GLP-1 analog capsule ([ORMD-0901](#)).

For more information, the content of which is not part of this press release, please visit www.oramed.com

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Forward-looking statements: This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates” and similar expressions or variations of such words are intended to identify forward-looking statements. For example, we are using forward-looking statements when we discuss our clinical trials and revolutionizing the treatment of diabetes with our products. These forward-looking statements are based on the current expectations of the management of Oramed 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 our product candidates; competition from other pharmaceutical or biotechnology companies; and our ability to obtain additional funding required to conduct our 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 our clinical trials; changes in legislation; inability to timely develop and introduce new technologies, products and applications; lack of validation of our technology as we progress further and lack of acceptance of our methods by the scientific community; inability to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties that may develop with our 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; our patents may not be sufficient; and finally that products may harm recipients, all of which could cause the actual results or performance of Oramed to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Oramed 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 Oramed, reference is made to Oramed's reports filed from time to time with the Securities and Exchange Commission.

Company Contact

Oramed Pharmaceuticals

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