

**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))
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### 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

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Name: Nadav Kidron

Title: President and CEO

Date: May 24, 2013

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## **Oramed Receives FDA Clearance to Initiate Oral Insulin Trials in the U.S.**

JERUSALEM May 17, 2013—Oramed Pharmaceuticals Inc. (NASDAQCM: ORMP) ([www.oramed.com](http://www.oramed.com)), a developer of oral drug delivery systems, announced today that the United States Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug application (IND) for ORMD-0801, its oral insulin capsule.

"We are very pleased to have the FDA clearance to proceed," stated Nadav Kidron, CEO of Oramed. "The upcoming trial is a major milestone for Oramed and we look forward to continuing to progress ORMD-0801's clinical development in the US."

### **About ORMD-0801 Oral Insulin**

Oramed's ORMD-0801 is an orally ingestible insulin capsule indicated for the early stages of type 2 diabetes, when it can still slow the rate of degeneration of the disease by providing additional insulin to the body and allowing pancreatic respite. Moreover, orally administered insulin has the potential benefit of enhanced patient compliance at this crucial stage as well as the advantage of mimicking insulin's natural location and gradients in the body by first passing through the liver before entering the bloodstream.

For more information on ORMD-0801, the content of which is not part of this press release, please visit <http://oramed.com/index.php?page=14>

### **About Oramed Pharmaceuticals**

Oramed Pharmaceuticals is a technology pioneer in the field of oral delivery solutions for drugs and vaccines currently delivered via injection. Established in 2006, Oramed's technology is based on over 30 years of research by top research 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) currently initiating Phase 2 clinical trials under an Investigational New Drug application with the U.S. Food and Drug Administration, and with its oral exenatide capsule (ORMD-0901; a GLP-1 analog), currently approaching Phase 2a trials. The company's corporate and R&D headquarters are based in Jerusalem

**For more information, the content of which is not part of this press release, please visit [www.oramed.com](http://www.oramed.com)**

**Forward-looking statements:** This press release contains forward-looking statements. For example, we are using forward-looking statements when we discuss ORMD-0801 slowing the rate of diabetes, increasing patient compliance, and our products approaching Phase 2 trials. 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 final 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.

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