# 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): November 3, 2014

### **ORAMED PHARMACEUTICALS INC.**

(Exact name of registrant as specified in its charter)

(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)

+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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

91390

(Zip Code)

### ITEM 7.01. REGULATION FD DISCLOSURE.

As previously announced, on November 3, 2014, Oramed Pharmaceuticals Inc., or Oramed, will host a conference call to discuss the clinical results from its Phase IIa clinical trial of ORMD-0801, Oramed's proprietary oral insulin capsules to treat type 1 diabetes. On the same day, Oramed posted to its website a presentation containing key top line results from the Phase IIa clinical trial. 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 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

- (d) Exhibits.
  - 99.1 Presentation

#### 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

November 3, 2014



# Oramed Clinical Conference Call Monday, November 3, 2014 - 10:00 a.m. Eastern Time

# Safe Harbor

Certain statements contained in this material are forward-looking statements. 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, and others, 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. which involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Please refer to the company's filings with the Securities and Exchange Commission for a comprehensive list of risk factors that could cause actual results, performance or achievements of the company to differ materially from those expressed or implied in such forward-looking statements. Oramed undertakes no obligation to update or revise any forward-looking statements.







### **Oramed ORA-D-010**

A Prospective, Randomized, Double-blind, Placebo Controlled Study to Assess the Impact of ORMD-0801 (insulin capsules) on the Exogenous Insulin Requirements of Type 1 Diabetics

25 Subject (24 Planned, 25 Enrolled)

3 Day Placebo Run-in Period (Baseline) followed by 7 Days of Treatment (Placebo or ORMD-0801)

Treatment given 3 times / day (1 hour before each meal)

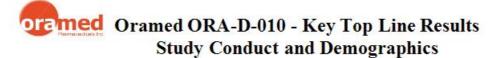
**Primary Objective:** 

To evaluate the change from baseline in exogenous insulin requirements (Basal, Bolus and Total) in Type 1 diabetes patients treated with ORMD-0801, compared to the change from baseline for patients treated with placebo.

Secondary Objectives:

To evaluate the change from baseline in mean nighttime, daytime and fasting glucose levels (by continuous glucose monitoring) in Type 1 diabetes patients treated with ORMD-0801, compared to the change from baseline for patients treated with placebo.

To evaluate the safety and tolerability of ORMD-0801 in patients with Type 1 diabetes.

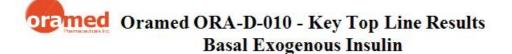


All 25 subjects completed the study.

Demographics

The active treatment group had proportionally less females (20% vs. 50%) The active treatment group had proportionally less Hispanics / Latinos (6.7% vs. 40%)Ages are similar between treatment groups (37.6 (Placebo) vs. 38.9 (Active))

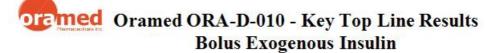
All subjects took all oral insulin doses.



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Basal Exogenous Insulin - ITT - All Subjects Placebo Run-in Period Average- 50.15 IU Day 6 and 7 Average - 49.05 IU Change → -1.10 IU

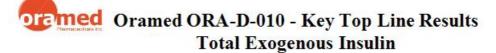
> Active Treatment Run-in Period Average - 37.67 IU Day 6 and 7 Average - 35.75 IU Change  $\rightarrow$  -1.92 IU



Bolus Exogenous Insulin - ITT - All Subjects Placebo Run-in Period Average- 37.20 IU Day 6 and 7 Average - 41.13 IU Change → 3.93 IU

### Active Treatment Run-in Period Average -30.11 IU

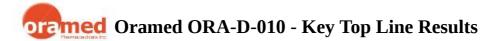
Day 6 and 7 Average - 29.93 IU Change  $\rightarrow$  -0.18 IU



Total Exogenous Insulin - ITT - All Subjects Placebo Run-in Period Average- 87.34 IU Day 6 and 7 Average - 90.17 IU Change → 2.83 IU

# Active Treatment

Run-in Period Average - 67.78 IU Day 6 and 7 Average - 65.68 IU Change  $\rightarrow$  -2.09 IU

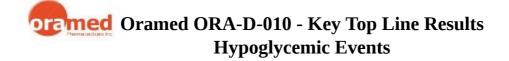


Continuous Glucose Monitoring Nighttime Glucose Placebo
Run-in Period Combined - 161.73
Last 2 Days With At Least 80% of Readings - 133.17
Change $\rightarrow$ -28.56
Active Treatment
Run-in Period Combined - 158.77
Last 2 Days With At Least 80% of Readings - 137.65
Change $\rightarrow$ -21.12
Daytime Glucose
Placebo
Run-in Period Combined - 163.29
Last 2 Days With At Least 80% of Readings - 165.73
Change $\rightarrow$ 2.44
Active Treatment
Run-in Period Combined - 153.76
Last 2 Days With At Least 80% of Readings - 145.15
Change $\rightarrow -8.61$

# oramed Oramed ORA-D-010 - Key Top Line Results Finger Stick Fasting Blood Glucose Immediately Prior to Breakfast

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Day 1 Change from Average Run-in Value Placebo  $\rightarrow$  -27.3 Delta  $\rightarrow$  -2.4 Active  $\rightarrow$  -29.7 Day 2 Change from Average Run-in Value Placebo → -31.8 Delta  $\rightarrow$  -11.7 Active  $\rightarrow$  -43.5 Day 3 Change from Average Run-in Value Placebo → -35.9 Delta  $\rightarrow$  -16.1 Active  $\rightarrow$  -52.0 Day 4 Change from Average Run-in Value Placebo  $\rightarrow$  -37.6 Delta → -21.9 Active  $\rightarrow$  -59.5 Day 5 Change from Average Run-in Value Placebo  $\rightarrow$  -31.7 Delta → -12.5 Active  $\rightarrow$  -44.2 Day 6 Change from Average Run-in Value Placebo  $\rightarrow$  -28.0 Delta → -30.9 Active  $\rightarrow$  -58.9 Day 7 Change from Average Run-in Value Placebo  $\rightarrow$  -10.2 Delta → -50.0 Active  $\rightarrow$  -60.2



### Day 6 Placebo No events - 5 (50.0%) 1 event - 3 (30.0%) 2 events - 2 (20.0%) Active No events - 1 (6.7%) 1 event - 7 (46.7%) 2 events - 2 (13.3%) 3 events - 4 (26.7%) 5 events - 1 (6.7%) Day 7 Placebo No events - 4 (40.0%) 1 event - 4 (40.0%) 2 events - 1 (10.0%) 7 events - 1 (10.0%) Active No events - 3 (20.0%) 1 event - 5 (33.3%)

2 events - 4 (26.7%) 3 events - 1 (6.7%) 4 events - 2 (13.3%)

# **THANK YOU**

