

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

(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))

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

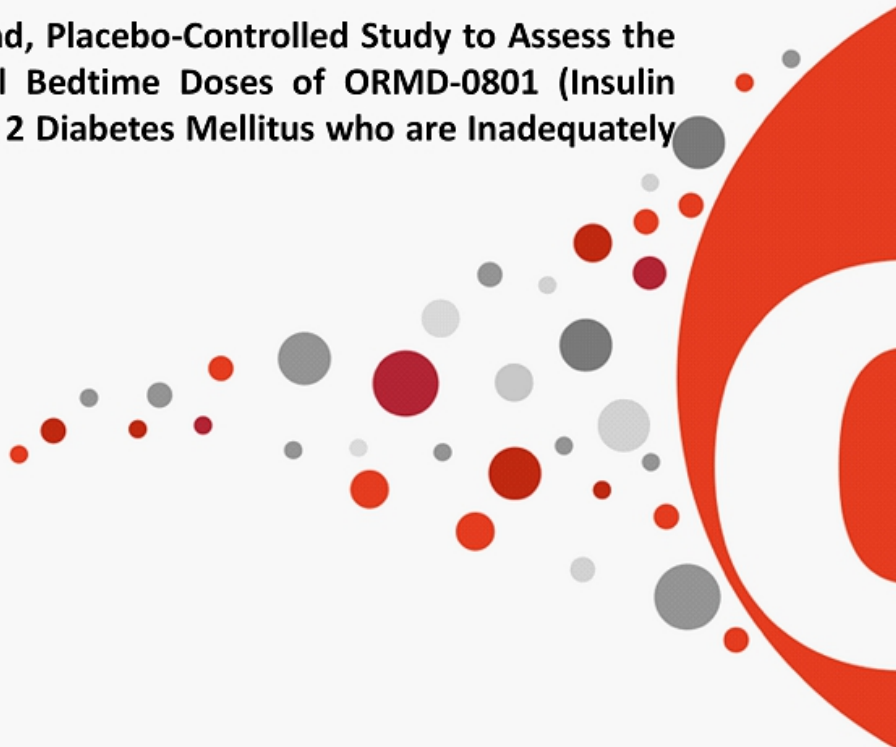
By: /s/ Nadav Kidron
Name: Nadav Kidron
Title: President and CEO



ORA-D-007: Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Multiple Oral Bedtime Doses of ORMD-0801 (Insulin Capsules) in Adult Patients with Type 2 Diabetes Mellitus who are Inadequately Controlled with Diet and Metformin

Presentation of Results

July 28, 2016



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.

Study Objectives

Primary Objectives

- To evaluate the pharmacodynamics effects of ORMD-0801 on mean nighttime glucose (determined using continuous glucose monitoring (CGM)).
- To evaluate the safety of ORMD-0801, including incidence of hypoglycemia.

Secondary Objectives

- To evaluate changes from baseline in fasting blood glucose (FBG), morning fasting serum insulin, c-peptide, and triglycerides.

Exploratory Objectives

- To evaluate the immunogenicity of ORMD-0801 through quantitation of anti-insulin antibodies.
- To evaluate changes from baseline in HbA1c, 24-hour, fasting and daytime glucose levels on CGM, weight, and C-Reactive Protein (CRP).

Study Disposition Summary

Number of Subjects in Safety Population (Received Treatment)

Placebo – 64 Subjects

ORMD-0801 460IU – 61 Subjects

ORMD-0801 690IU – 63 Subjects

Overall – 188 Subjects

Number of Subjects Discontinuing Study

Placebo – 2 Subjects (3.1%)

ORMD-0801 460IU – 4 Subjects (6.6%)

ORMD-0801 690IU – 2 Subjects (3.2%)

Overall – 8 Subjects (4.3%)

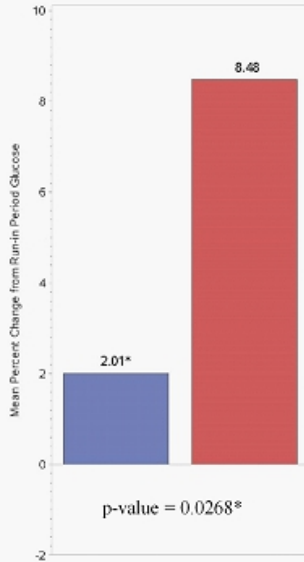
Summary of Demographics

	Placebo (N=64)	ORMD-0801 460IU (N=61)	ORMD-0801 690IU (N=63)
Sex - n (%)			
Male	29 (45.3)	39 (63.9)	34 (54.0)
Female	35 (54.7)	22 (36.1)	29 (46.0)
Race - n (%)			
White	53 (82.8)	50 (82.0)	55 (87.3)
Black or African American	7 (10.9)	8 (13.1)	4 (6.3)
Asian	2 (3.1)	2 (3.3)	2 (3.2)
American Indian or Alaskan Native	0	0	0
Native Hawaiian or Other Pacific Islander	2 (3.1)	1 (1.6)	0
Other	0	0	2 (3.2)
Ethnicity - n (%)			
Hispanic or Latino	31 (48.4)	32 (52.5)	36 (57.1)
Not Hispanic or Latino	33 (51.6)	29 (47.5)	27 (42.9)
Not Reported	0	0	0
Age (years)			
Sample Size	64	61	63
Mean	58.61	57.89	57.25
Standard Deviation	9.203	8.021	8.786
Median	58.80	58.45	58.07
Min, Max	37.3, 75.9	36.5, 75.7	31.0, 71.0
Coefficient of Variation	15.701	13.855	15.347



Primary Efficacy Objective

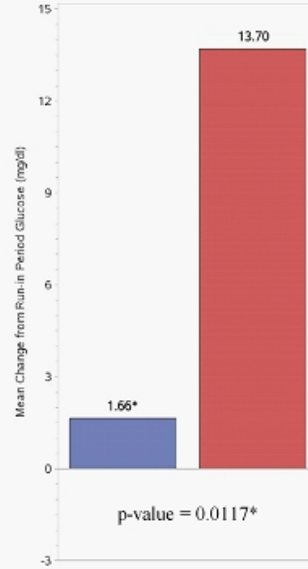
Oramed ORA-D-007 - Nighttime Glucose
Percent Change from Run-in



Treatment ALL ORMD-0801 Placebo

Nighttime=6 Hours Post-Dose
* Indicates statistically significant difference from Placebo (p-Value<0.05)

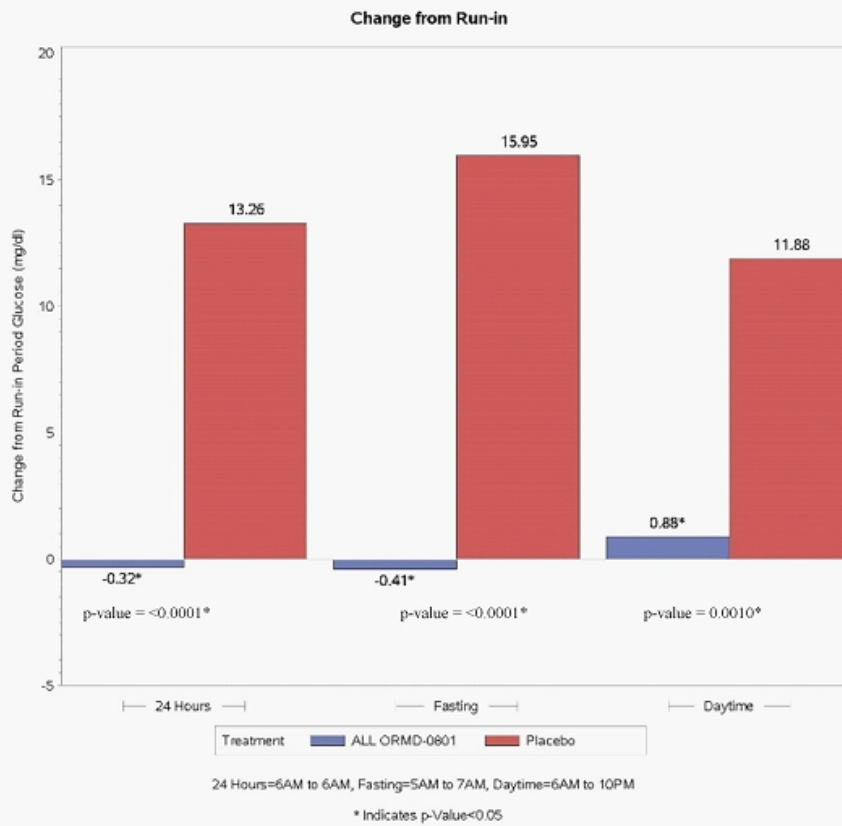
Oramed ORA-D-007 - Nighttime Glucose
Change from Run-in



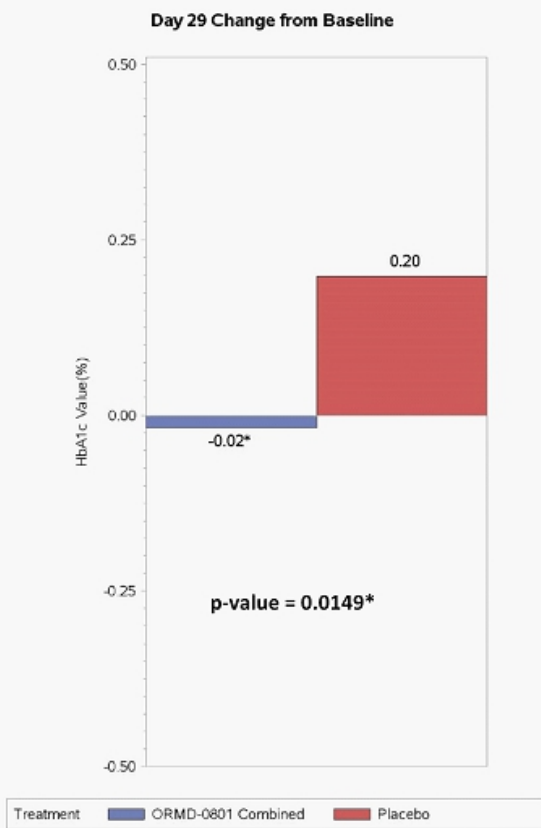
Treatment ALL ORMD-0801 Placebo

Nighttime=6 Hours Post-Dose
* Indicates statistically significant difference from Placebo (p-Value<0.05)

Other Continuous Glucose Monitoring Parameters (Exploratory Objectives)



HbA1c (Exploratory Objective)



* Indicates comparison to placebo p-Value<0.05

Safety Summary

Adverse Events

	Placebo (N=64)	ORMD-0801 460IU (N=61)	ORMD-0801 690IU (N=63)
Number of Reported Adverse Events:	34	34	42
Number (%) of Subjects With at Least One:			
Treatment Emergent Adverse Event (TEAE)	19 (29.7)	19 (31.1)	19 (30.2)
Severe TEAE	0 (0.0)	1 (1.6)	0 (0.0)
Serious TEAE	0 (0.0)	1 (1.6)	0 (0.0)
Drug-related TEAE	2 (3.1)	0 (0.0)	0 (0.0)
Drug-related severe TEAE	0 (0.0)	0 (0.0)	0 (0.0)
Drug-related serious TEAE	0 (0.0)	0 (0.0)	0 (0.0)
TEAE leading to withdrawal of study drug	0 (0.0)	1 (1.6)	0 (0.0)
TEAE with outcome of death	0 (0.0)	0 (0.0)	0 (0.0)

Hypoglycemic Events

	Placebo (N=64)	ORMD-0801 460IU (N=61)	ORMD-0801 690IU (N=63)
Number (%) of Subjects with a Hypoglycemic Event:	1 (1.6)	1 (1.6)	1 (1.6)



oramed
Pharmaceuticals Inc.

THANK YOU

www.oramed.com