

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): April 24, 2014

**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.**

As previously announced, on April 24, 2014, Oramed Pharmaceuticals Inc., or Oramed, will be presenting detailed results from its recently completed Phase IIa Food & Drug Administration trial on ORMD-0801, its orally ingestible insulin capsule at the 2014 GTC Diabetes Summit taking place from April 23-25, 2014, in Cambridge, Massachusetts. A copy of the materials being presented by Oramed 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.**

In connection with the presentation at the 2014 GTC Diabetes Summit, Oramed announced detailed results from its previously completed Phase IIa trial investigating ORMD-0801, its orally ingestible insulin capsule, in type 2 diabetes patients. A copy of the press release is furnished filed with this Current Report on Form 8-K as Exhibit 99.2 and incorporated herein by reference.

**ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.**

(d) Exhibits.

99.1	Presentation
99.2	Press release issued by Oramed on April 24, 2014

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**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

April 24, 2014

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**The tolerability and efficacy of oral  
insulin in Type 2 diabetes patients: A  
pilot  
clinical study**

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**GTC Diabetes Summit  
Dr. Miriam Kidron  
April 24, 2014**

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# Oamed Background

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# OraMed POD™ Technology:

## Enteric Coating

pH sensitive - only degrades in the small intestine, thus protecting capsule constituents during travel through the upper gastrointestinal tract



## Protease Inhibitors

Protects protein from degradation by proteases once capsule degrades in the small intestine



## Absorption Enhancers

Assists with translocation of active ingredient (protein/ peptides) across intestinal membrane into bloodstream



## POD™ TECHNOLOGY FEATURES

**Versatile:** supports a wide range of protein sizes and doses

**Simple** blend of ingredients

**Regulatory competence:** No NCEs, widely applied pharmacopoeia

OraMed's delivery platform **protects insulin and enhances its absorption**, allowing it to reach the bloodstream via the portal vein, thereby establishing a **more physiologic insulin gradient when compared to other delivery systems.**

# Study ORA-D-009

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**STUDY:** Phase IIa, randomized, double-blind, placebo-controlled

**SETTING:** In-patient (8 days)

**PARTICIPANTS:** 30 male or female adult T2DM patients inadequately controlled with diet and metformin

**TREATMENT:** 16 mg or 24 mg insulin, or placebo, at bedtime.





**ORA-D-009 was a substudy requested by the FDA prior to commencement of a large scale study with a similar design.**

**The study was initiated to ensure safety of ORMD-0801 and was not powered to demonstrate efficacy.**

## **PRIMARY OBJECTIVE:**

- To evaluate the safety and tolerability of ORMD-0801

## **SECONDARY OBJECTIVES:**

- To evaluate the PD effect of ORMD-0801 on mean night time (10 PM - 6 AM) glucose (CGM data) as compared to placebo
- To evaluate changes from baseline in fasting blood (finger stick) and plasma glucose (FBG), morning fasting serum insulin, and C-peptide



# Dosing

ORMD-0801 was supplied as gel caps formulated as either 8 mg or 16 mg

- First group received two 8 mg gel caps
- Second dose group received one 8mg and one 16 mg gel cap

## **Gel Cap Dissolution: Performance Issue with 16 mg gel caps**

During the course of the study, GMP analysis of study drug formulations revealed a manufacturing problem with the 16 mg gel caps resulting in diminished and inconsistent release of study drug. This exclusively effected patients randomized to receive ORMD-0801 24 mg.

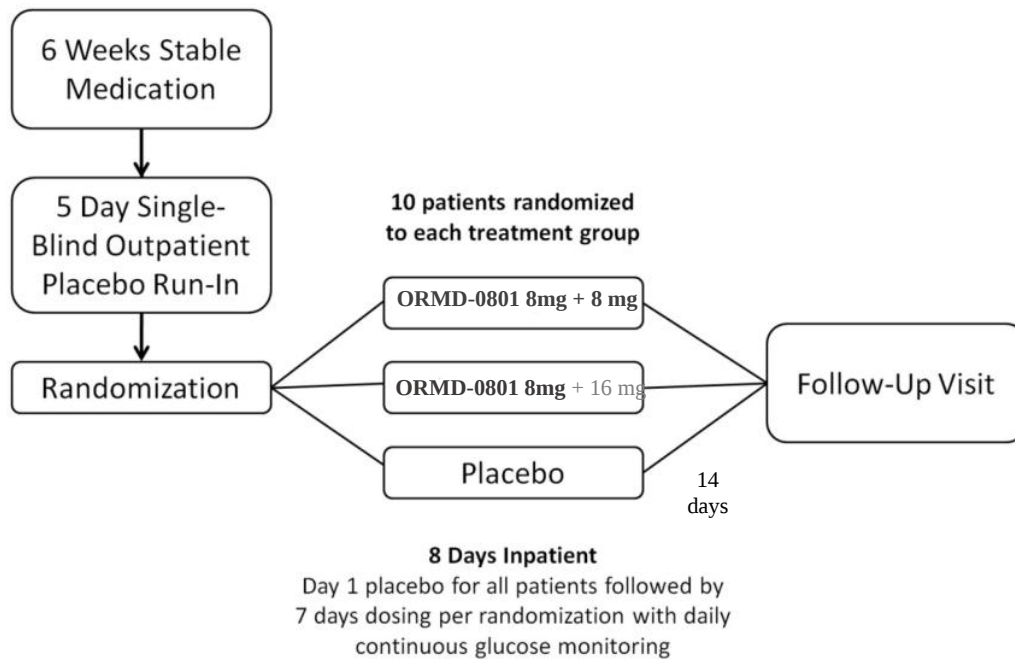
The 8 mg capsules did not have this problem and demonstrated an appropriate release of medication.

Patients in the 24 mg group treated with one 8 mg gel cap and one 16 mg gel cap. The effective dose was, therefore, approximately only 8 mg.

The formulation issue with the 16 mg gel caps has been investigated, identified, and solved.



# Study Design



## Patient demographics

	Placebo	ORMD-0801 8 + 8mg	ORMD-0801 8mg+16mg
Sex, n (%)			
Male	3 (30.0)	5 (50.0)	7 (70.0)
Female	7 (70.0)	5 (50.0)	3 (30.0)
Race, n (%)			
White	6 (60.0)	6 (60.0)	6 (60.0)
Black/African Am	4 (40.0)	2 (20.0)	1 (10.0)
Asian	0 (0.0)	1 (10.0)	3 (30.0)
N. Hawaiian/Pacific Is	0 (0.0)	1 (10.0)	0 (0.0)
Age (yrs), mean (SD)	53.6 (12.0)	54.1 (4.9)	57.4 (4.7)
Alcohol history, n (%)			
Never consumed	5 (50.0)	6 (60.0)	7 (70.0)
Currently consumes	2 (20.0)	3 (30.0)	0 (0.0)
Occasionally consumes	3 (30.0)	1 (10.0)	3 (30.0)

# Results

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## Primary objective - safety and tolerability

Hypoglycemic Events		0
Serious Adverse Events		0
Severe Adverse Events		0
ORMD 0801 Related Adverse Events		0
<b><u>Adverse Events (non treatment related):</u></b>		
Placebo	5 patients	7 reported adverse events
8 mg + 8 mg	3 patients	5 reported adverse events
8 mg + 16 mg	4 patients	5 reported adverse events

**No significant changes in clinical laboratory and physical parameters were noted**



# Mean night time glucose concentrations (CGM)

Night time mean (SD) CGM Glucose - mg/DL <sup>(1)</sup>	Placebo (n = 10)	ORMD 0801 8 mg + 8 mg (n = 10)	Difference (ORMD 0801 - placebo)	ORMD 0801 8 mg + 16 mg (n = 8)	Difference (ORMD 0801 - placebo)
Last 2 days of data	167.95 (64.172)	135.64 (39.400)	-32.31	150.24 (49.264)	-17.71
All 7 days	165.85 (60.760)	139.73 (38.861)	-26.12	149.38 (38.249)	-16.47

(1) Per Protocol (PP) population, consisting of all study completers with an endpoint of adequate weighted mean nighttime glucose and no major protocol violations





# Mean daytime glucose concentrations (CGM)

Daytime mean (SD) CGM Glucose - mg/DL <sup>(1)</sup>	Placebo (n = 10)	ORMD 0801 8 mg + 8 mg (n = 10)	Difference (ORMD 0801 - placebo)	ORMD 0801 8 mg + 16 mg (n = 8)	Difference (ORMD 0801 - placebo)
Last 2 days of data	176.06 (63.698)	153.23 (40.160)	-22.83	158.58 (40.672)	-17.48
All 7 days	175.99 (61.115)	152.55 (36.986)	-23.44	163.05 (30.282)	-12.94

(1) Per Protocol (PP) population, consisting of all study completers with an endpoint of adequate weighted mean nighttime glucose and no major protocol violations



# Mean fasting glucose concentrations (CGM)

Fasted mean (SD) CGM Glucose - mg/DL <sup>(1)</sup>	Placebo (n = 10)	ORMD 0801 8 mg + 8 mg (n = 10)	Difference (ORMD 0801 - placebo)	ORMD 0801 8 mg + 16 mg (n = 8)	Difference (ORMD 0801 - placebo)
Last 2 days of data	156.26 (58.622)	126.02 (27.264)	-30.24	136.12 (43.168)	-20.14
All 7 days	154.37 (57.993)	129.27 (27.426)	-25.10	144.83 (39.279)	-9.54

(1) Per Protocol (PP) population, consisting of all study completers with an endpoint of adequate weighted mean nighttime glucose and no major protocol violations



# Morning fasting serum insulin

Morning fasting serum insulin - $\mu$ IU/mL <sup>(2)</sup>	Placebo (n = 10)	ORMD 0801 8 mg + 8 mg (n = 10)	Difference (ORMD 0801 - placebo)	ORMD 0801 8 mg + 16 mg (n = 10)	Difference (ORMD 0801 - placebo)
Screening	34.51 (64.375)	20.80 (18.984)	-13.71	17.34 (12.225)	-17.17
Day 2	9.01 (4.665)	11.93 (10.122)	2.92	12.94 (7.472)	3.93
Day 9	9.85 (3.977)	15.70 (8.559)	5.85	15.51 (14.924)	5.66

(2) Modified intention-to-treat (mITT) population consisting of all randomized patients who took at least one dose of study medication and who had at least one night of CGM monitoring



# Morning fasting C-peptide

Morning fasting C-peptide - mg/DL <sup>(2)</sup>	Placebo (n = 10)	ORMD 0801 8 mg + 8 mg (n = 10)	Difference (ORMD 0801 - placebo)	ORMD 0801 8 mg + 16 mg (n = 10)	Difference (ORMD 0801 - placebo)
Screening	5.159 (4.9825)	4.233 (2.3869)	-0.926	3.125 (1.3372)	-2.134
Day 2	2.400 (0.9419)	3.180 (1.6593)	0.78	3.064 (0.9200)	0.66
Day 9	2.715 (0.8506)	3.875 (1.6927)	1.16	3.090 (1.1021)	0.375

(2) Modified intention-to-treat (mITT) population consisting of all randomized patients who took at least one dose of study medication and who had at least one night of CGM monitoring



# ORMD-0801: Phase IIa T2DM

## Conclusions

### Safety Conclusions

- ORMD-0801 oral insulin gel caps were observed to be safe and well-tolerated for the dosing regimen considered in this study
- No hypoglycemic events** occurred at any point during the study in any treatment group
- No ORMD 0801 related adverse events observed

### Efficacy

- Both ORMD-0801 dose groups showed trends towards sustained reduction in night-time, day time and mean fasting glucose concentrations compared to placebo
- 8mg + 8mg dose group showed a more pronounced effect over placebo, versus the intended 8mg + 16mg dose



# Planned Phase IIb trial

## ORA-D-007

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# ORMD-0801: Phase IIb T2DM

**Study ORA-D-007:** Randomized, Double-Blind, Placebo-Controlled Study to Assess the

Safety and Pharmacodynamics of Multiple Oral Bedtime Doses of ORMD-0801 in Adult Patients with T2DM who are Inadequately Controlled with Diet and Metformin

**PRIMARY OBJECTIVE:**

- To evaluate the pharmacodynamic effects of ORMD-0801 on mean night time glucose and safety parameters (e.g., hypoglycemia, cardiovascular events).
- Safety, including incidence of hypoglycemia and cardiovascular events

**SECONDARY OBJECTIVES:**

- To evaluate changes from baseline in fasting blood glucose (FBG), morning fasting serum insulin, c-peptide, triglycerides, and HbA1c.

**STUDY DESIGN:**

- 28 day Treatment Period. Variable-length washout/medication stabilization period and 7-day single-blind placebo run-in period.
- Multicenter (up to 20 centers)
- Planned patient enrollment: n = 200+ T2DM patients

**DOSING:** ORMD-0801 16mg, ORMD-0801 24mg or placebo

**LOCATION:** US (conducted under a US IND)



# Thank you!

Dr. Miriam Kidron  
CSO, Oramed  
miriam@oramed.com







## Oramed Pharmaceuticals Presents Data from Phase IIa Trial with ORMD-0801 in Type 2 Diabetes at the 2014 Diabetes Summit

ORMD-0801 Oral Insulin Appeared Safe and Well-tolerated. No Hypoglycemic Events or Treatment Related Adverse Events Observed

JERUSALEM April 24, 2014 — Oramed Pharmaceuticals Inc. (NASDAQCM: ORMP) ([www.oramed.com](http://www.oramed.com)), a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, announced today detailed results from its previously completed Phase IIa trial investigating ORMD-0801, its orally ingestible insulin capsule, in type 2 diabetes patients. The preliminary results of this trial were originally announced on January 30, 2014. The results are being presented today by Oramed's Chief Scientific Officer, Dr. Miriam Kidron, at the 2014 GTC Diabetes Summit, taking place in Cambridge, Massachusetts, USA. The trial was conducted in the United States under a Food and Drug Administration (FDA) Investigational New Drug (IND) protocol.

The results showed that ORMD-0801 oral insulin appeared to be safe and well-tolerated for the dosing regimen considered in this study. No hypoglycemic events occurred at any point in any treatment group and no treatment related adverse events were observed. Although the study was not powered to show statistical significance, there were trends observed showing pattern of well-defined and short-term increases in plasma insulin and decreases in blood glucose.

"We are very pleased with the outcome of this study, which showed ORMD-0801 to be safe and well-tolerated," stated Dr. Miriam Kidron, Chief Scientific Officer of Oramed. "Importantly, the decreases in blood glucose we observed were not associated with any hypoglycemic events. We look forward to moving ahead with our planned U.S. Phase IIb trial in individuals with type 2 diabetes which will investigate ORMD-0801 over a longer treatment period and which will have statistical power to give us greater insight into the drug's efficacy."

### ORA-D-009 Study Design

Study ORA-D-009 was a single-center, randomized, double-blind, placebo-controlled, parallel group study that enrolled 30 patients with type 2 diabetes. It was designed as a sub-study, requested by the FDA prior to commencement of a large scale clinical trial with a similar design. At the time of enrollment, patients who enrolled were being treated by diet and exercise, or by diet, exercise and a stable dose of metformin for at least 6 weeks. Patients using metformin continued their treatment regimen throughout the study period.

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There was an initial outpatient, single-blind (patient blinded) placebo run-in period. Patients were then admitted to the clinical research center and received an additional dose of placebo, regardless of randomization, on the evening of Day 1 for the determination of baseline pharmacokinetic (PK) values. Prior to the first randomized treatment on the evening of Day 2, all patients were outfitted with a continuous glucose monitor (CGM). Patients were then randomized 1:1:1 to receive one of two doses of ORMD-0801 – 16 mg (two 8 mg gel capsules) or 24 mg (one 8 mg + one 16 mg dose capsule) – or matching placebo for the subsequent seven days, with a final PK evaluation performed on last day of treatment. Seven days after the end of the inpatient treatment period, patients returned to the study center for a follow-up visit and fasting blood draw. All 30 patients completed the study.

The primary objective of this study was to evaluate the safety and tolerability of ORMD-0801. Secondary objectives were to evaluate the pharmacodynamic effects of ORMD-0801 on mean night time glucose, to evaluate the pharmacokinetics of ORMD-0801 and to evaluate changes from baseline in fasting blood (finger stick) and plasma glucose (FBG), morning fasting serum insulin, and C-peptide.

While the study was ongoing, GMP analysis of study drug formulations revealed a formulation issue involving an excipient with the 16 mg gel caps that resulted in diminished and inconsistent release of study drug. This exclusively affected patients randomized to receive the 24 mg dose of ORMD-0801. The 8 mg capsules did not have this issue and demonstrated the correct release of medication. Patients in the 24 mg group were treated with one 8 mg gel cap and one 16 mg gel cap. The effective dose was, therefore, approximately one third of the intended dose. The formulation issue with the 16 mg gel caps has been investigated, identified and fully addressed.

#### **Safety Results**

ORMD-0801 was safe and well tolerated. No patient experienced a hypoglycemic event at any point during the study and there were no serious or severe adverse events (AEs) nor any AEs related to the study drug. Three patients in the 16 mg group reported a total of five adverse events, four patients in the intended 24 mg group reported a total of five adverse events and five patients in the placebo group had a total of seven adverse events. None of these adverse events were assessed to be related to the study drug. The adverse events in the 16 mg group consisted of "Gastrointestinal disorders/Nausea," one patient (10%); and "Nervous system disorders/Headache," three patients (33.3%). There were no clinically significant changes in laboratory test results, vital signs, or physical examination.

#### **Pharmacodynamics**

Continuous Glucose Monitoring (CGM) data were summarized for the following daily intervals: Nighttime (10 p.m. to 6 a.m.), Daytime (6 a.m. to 10 p.m.) and Fasting (5 a.m. to 7 a.m.).

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Nighttime CGM results showed a trend towards lower mean glucose for patients treated with 16 mg of ORMD-0801 compared with placebo. The overall mean difference for the seven days of treatment was -26.12 mg/dL, with a mean difference of -32.31 mg/dL during the last two days of data collection.

Similar to nighttime results, daytime CGM analysis showed a trend towards lower levels of mean glucose for patients treated with 16 mg ORMD-0801 compared with placebo. The overall mean difference for the seven days of treatment was -23.44 mg/dL, with a mean difference of -22.83 mg/dL during the last two days of data collection.

Fasting CGM analysis showed a trend towards lower levels of mean glucose for patients treated with 16 mg of ORMD-0801 compared with placebo. The overall mean difference for the seven days of treatment was -25.10 mg/dL, with a mean difference of -30.24 mg/dL during the last two days of data collection.

Morning fasting blood glucose was additionally monitored each morning of the study by finger stick. On each of the mornings of Days 2 through 8, there was a trend toward lower mean finger stick blood glucose values for the 16 mg ORMD-0801 group than placebo. The greatest differences were -18.3 mg/dL and -18.2 mg/dL on Days 4 and 7, respectively.

Mean C peptide levels decreased after an initial delay. By Day 9, the average decrease in C Peptide in the 16mg ORMD 0801 group compared to placebo was 0.293 after the delay (180-300 minutes post dose).

In those patients treated with the intended 24 mg (8 mg + 16 mg gel capsules) ORMD-0801 dose, there were trends towards reduction in mean nighttime, mean daytime and mean fasting glucose levels, as measured with CGM. The differences versus placebo for these measurements were less pronounced than those observed in the 16 mg ORMD-0801 dose. As stated above, due to a study drug formulation issue affecting only the 10 patients randomized to receive 24 mg of ORMD-0801, the actual dose administered to these patients was likely closer to 8 mg.

#### **Pharmacokinetics**

Morning fasting serum insulin was measured using a blood draw on the mornings of the screening visit, on Days 2 and 9 of the inpatient visit, and at the Day 16 follow-up visit. During the inpatient visit on the morning of Days 2 and 9, fasting morning serum insulin in the active treatment group was 2.92  $\mu$ IU/mL and 5.85  $\mu$ IU/mL higher than placebo, respectively.

The presentation slides are available at: <http://www.oramed.com/ufiles/GTC-Summit-2014.pdf>.

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**About ORMD-0801 Oral Insulin**

Oramed's ORMD-0801 is an orally ingestible insulin capsule 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, 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 currently delivered via injection. Established in 2006, Oramed's Protein Oral Delivery (PODTM) 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 in separate Phase II 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, and with its 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](http://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, including the expected design or timing thereof, the anticipated safety of ORMD-0801 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 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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