

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): September 8, 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))
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**ITEM 7.01. REGULATION FD DISCLOSURE.**

Oramed Pharmaceuticals Inc. has posted an updated corporate presentation to its website. A copy of the 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 Corporate Presentation

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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

September 8, 2014

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# Corporate Presentation

Nasdaq: ORMP  
September 2014



# 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.



# Investment Highlights

**Proprietary technology platform (POD™) for oral delivery of peptides**

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**Significant market opportunity: *focus on significant medical needs***

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**Clinical proof of concept achieved**

**Orally ingestible insulin: *US FDA Phase II clinical development***

**Strong product pipeline: *potential to expand to other indications***

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**Strong management team backed  
by world-leading scientific experts**

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***Multiple value-creating milestones in 2H14 and 2015***

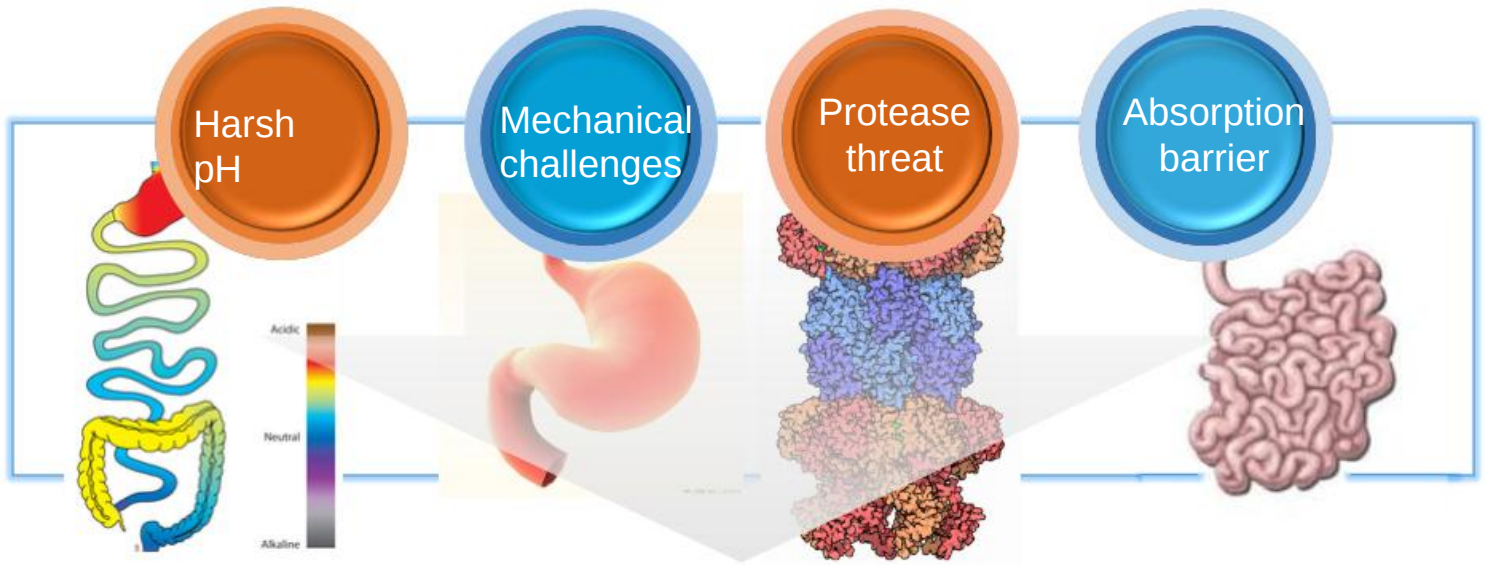


# *Oramed*

## *An Oral Solution*



# Fate of proteins/peptides in GIT



**Leads to protein breakdown and lack of absorption**



# Oramed POD™ Technology:

## *Oral Protein and Peptide Delivery and Absorption*



### **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

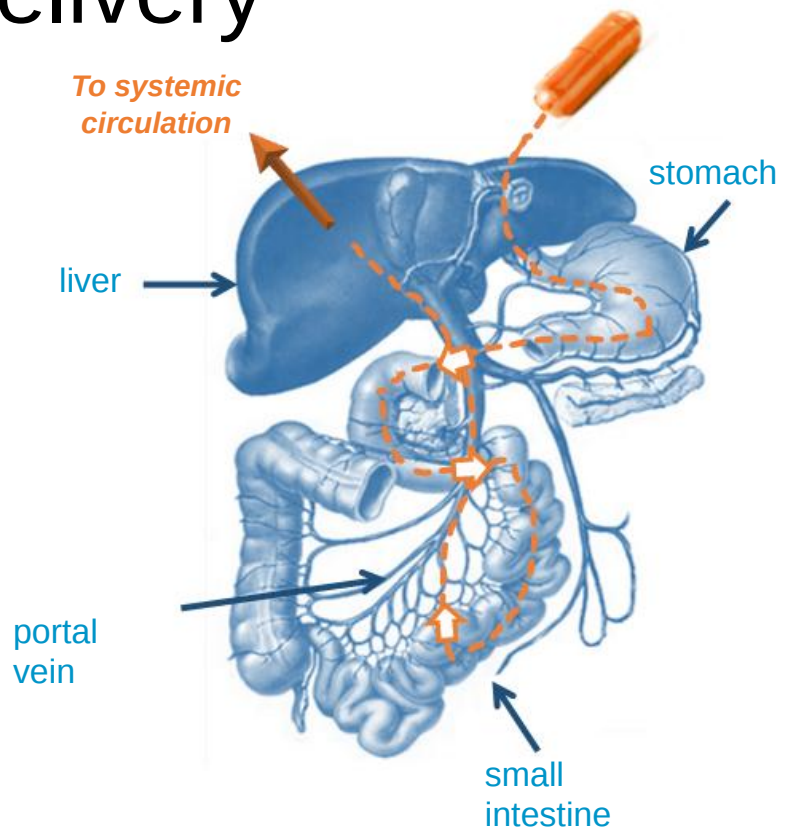
### **Absorption Enhancers**

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

Oramed's delivery platform **protects proteins** and **enhances their absorption**, allowing them to reach the bloodstream via the portal vein, thereby establishing a **more physiologic protein gradient when compared to other delivery systems.**

# Physiologic Insulin Delivery

- 1 Portal insulin delivery is physiologic, while systemic insulin delivery (injected, inhaled, etc.) is not
- 1 Blood glucose - insulin secretion system forms a 'closed-loop'
- 1 Peripheral insulin promotes glucose uptake in fat and muscle
- 1 First-pass hepatic metabolism extracts 80% of secreted insulin
- 1 Systemic exposure is minimized



# Targeting Diabetes Treatment:

*Oramed has Opportunities in many Large Markets*

## Insulin

**\$20 billion** 2013 global insulin market<sup>1</sup>

**\$47 billion** projected market for 2020<sup>1</sup>



## GLP-1 Analog

**\$2+ billion** 2012 global GLP-1 market<sup>2</sup>

**\$6.6 billion** projected for 2018<sup>3</sup>

Many patients stop treatment as a result of injection-related side effects



## Other

**Vaccines: \$24 billion** in 2013 - grew from \$5 billion in 2000<sup>4</sup>

**Flu vaccine** estimated at **\$2.9 billion** in 2011 to \$3.8 billion in 2018<sup>4</sup>

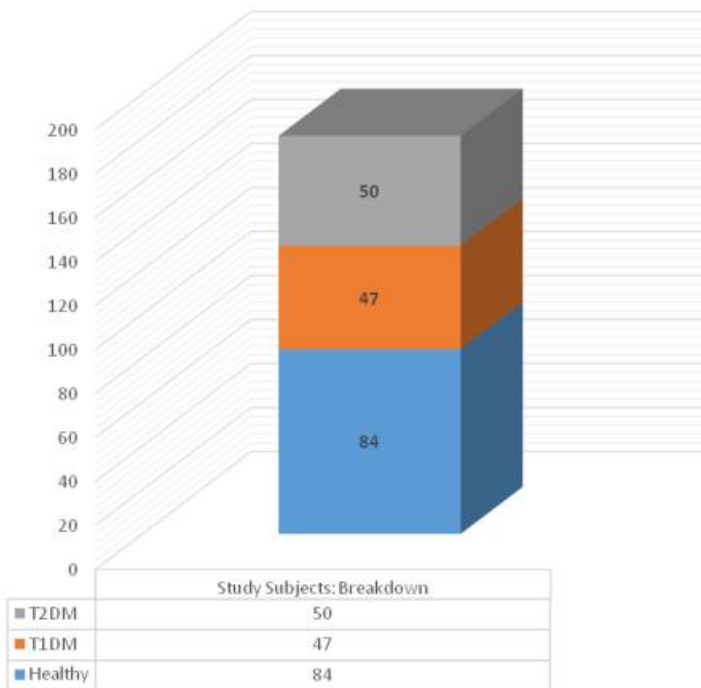
**Interferon: \$10+ billion**, projected for 2015<sup>5</sup>



1 Grand View Research, Inc., 2014  
2 Novo Nordisk Annual Report, 2013  
3 Goldman Sachs Global Investment Research, 2013  
4 World Health Organization, 2012  
5 Research and Markets, 2012



# ORMD-0801: Oral Insulin Administrations To-date



Total number of study subjects:

**181**



Total number of human doses:

**1748**



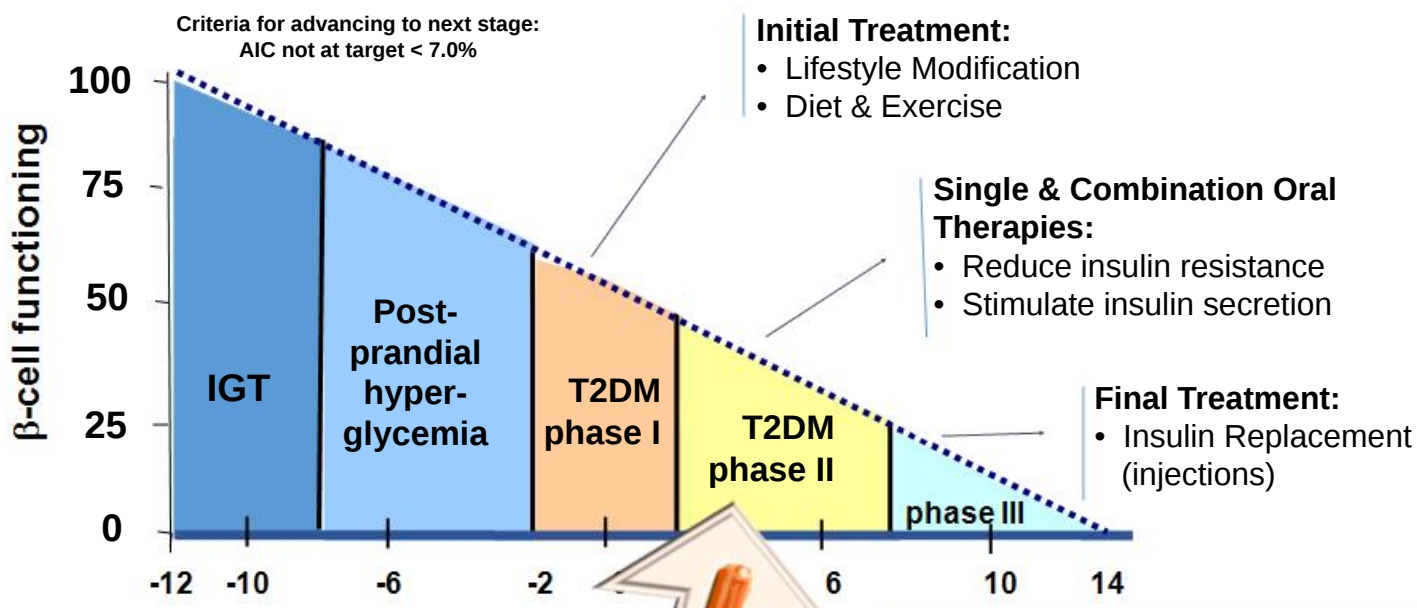
# ORMD-0801

## *Type 2 Diabetes* (T2DM)



# ORMD-0801 Treats Diabetes Sooner:

## Type 2 Diabetes Stages & Treatment Options



ORMD-0801 is not a substitute for insulin injections, but rather a new earlier treatment option



# Unique Initial Indication (ORMD-0801)

## ORMD-0801: Unique Indication

- Nighttime dose
- Focused on reducing the excessive nocturnal glucose production from the liver

## Fasting Blood Glucose (FBG):

- Measurement of blood glucose levels after a fast (e.g. first thing in the morning)
- Effected by liver regulation of glucose and insulin levels in the body during a fast

## Elevated FBG

- **Elevated FBG levels are a major issue in T2DM**
- **Main cause: excessive nocturnal glucose production from liver**
- Current treatments for correction of elevated FBG are suboptimal



## FBG: Stats

- Approximately 70% of individuals with impaired FBG develop T2DM
- An estimated > 80% of T2DM patients exhibit abnormal FBG *and* fail to achieve glycemic control with Metformin or thiazolidinediones (TZDs) preparations
- Even drugs used to control FBG have adverse effects at times, creating a large unmet need for drugs that are more physiological

# ORMD-0801 Trial Results: A Summary

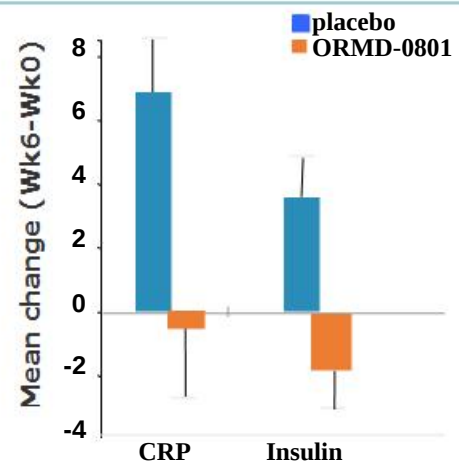
## Pre-clinical

- Healthy, non-diabetic, cannulated beagle dogs showed a 60-75% drop in blood glucose levels within 30-100 minutes of treatment
- No hypoglycemia or adverse events were observed over the three years of testing (in dogs)

## T2DM Patients

ORA-D-004

- Randomized, double-blind, multi-center study on 29 patients - 21 dosed, 8 placebo, 6 weeks of monitoring
- Showed relevant clinical impact
- Good safety profile
- Safe and well tolerated by all patients
- No SAEs





# ORMD-0801

## Phase IIa Results



# ORMD-0801: Phase IIa FDA Study

## Overview

- 30 T2DM patients
- US site
- In-patient setting
- Double blind
- Randomized
- 1 week of treatment

## Objectives

- Primary objective:
  - *Safety and tolerability*
- Secondary objectives:
  - *Pharmacodynamic effects on mean nighttime glucose*
  - *Pharmacokinetics on AUC, C<sub>max</sub>, T<sub>max</sub>, T<sub>1/2</sub>*
  - *Changes from baseline in FBG morning fasting insulin, C-peptide*



# Phase 2a: Primary Objective Safety

Hypoglycemic Events	<b>0</b>	
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 Serious Adverse Events-***

**The study showed that ORMD-0801 is safe and well tolerated  
No significant changes in clinical laboratory and physical parameters were noted**

# Phase IIa

## Mean fasting blood glucose concentrations (CGM)

Fasting CGM Glucose - mg/DL <sup>(1)</sup>	Placebo (n = 10)	ORMD-0801 8 mg + 8mg (n=10)	Difference (ORMD 0801 - placebo)	ORMD-0801 8 mg + 16mg (n=8)	Difference (ORMD 0801-placebo)
Last 2 days of data	156.26 (58.62)	126.02 (27.26)	-30.24	136.12 (43.17)	-20.14
All 7 days	154.37 (57.99)	129.27 (27.43)	-25.10	144.83 (39.28)	-9.54

## 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 (64.17)	135.64 (39.40)	-32.31	150.24 (49.26)	-17.71
All 7 days	165.85 (60.76)	139.73 (38.86)	-26.12	149.38 (38.25)	-16.47

## 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 (63.70)	153.23 (40.16)	-22.83	158.58 (40.67)	-17.48
All 7 days	175.99 (61.12)	152.55 (36.99)	-23.44	163.05 (30.28)	-12.94



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

# ORMD-0801: Phase IIa FDA Study

## *Safe and Well-Tolerated, Sustained Glucose Reduction*

### 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 nighttime, daytime 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



# ORMD-0801: Proposed Phase IIb FDA Study

## Overview

- ~180 T2DM patients
- >30 US sites
- Double blind
- Randomized
- 28 days of treatment

## Objectives

- Primary objective:
  - **Safety:** Evaluate the safety of ORMD-0801
  - **Efficacy:** evaluate the PF effects of ORMD-0801 on mean nighttime glucose (determined using continuous glucose monitoring)
- Secondary objectives:
  - Evaluate changes from baseline in fasting blood glucose (FBG), morning fasting serum insulin, C-peptide, and triglycerides



# ORMD-0801

## *Type 1 Diabetes* (T1DM)



# T1DM - an overview

## T1DM

- **T1DM is an autoimmune disease** – the body destroys its own insulin-producing cells leaving patients completely dependent on external insulin sources
- **5-10% of diabetes cases are T1DM** – approx. 18-37 million people worldwide.
- The disease was previously only seen in children, but **the majority of new-onset cases are seen in adults**; increasing at a rate of 3% per year

## Treatment

- **T1DM is treated with 2 types of insulin** replacement therapy:
  - **long-acting insulin** (basal) to help maintain stable insulin levels during fast periods
  - **rapid-acting insulin** (bolus) prior to each meal
- Administration is via injection or pump

## ORMD-0801 Oral Insulin and T1DM

- **Oramed is looking to replace the mealtime (bolus) insulin doses**, potentially reducing multiple daily injections
- **Mechanistic advantages:** Portal administration may enable tighter regulation of blood sugar levels by directly affecting glucose control in the liver. Oral administration also offers the benefit of reduced systemic exposure and ease of use.

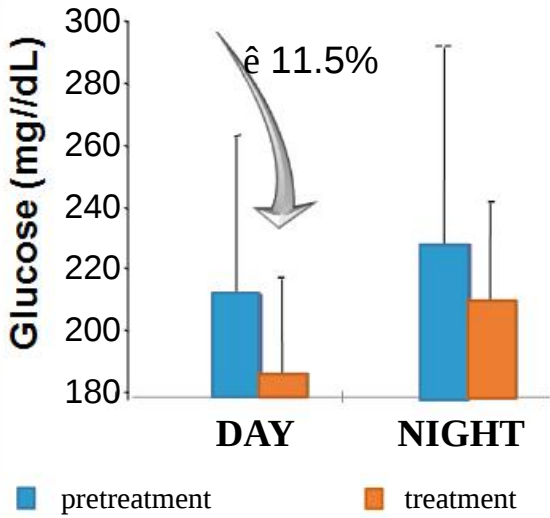




# ORMD-0801:

Mean glucose n=8

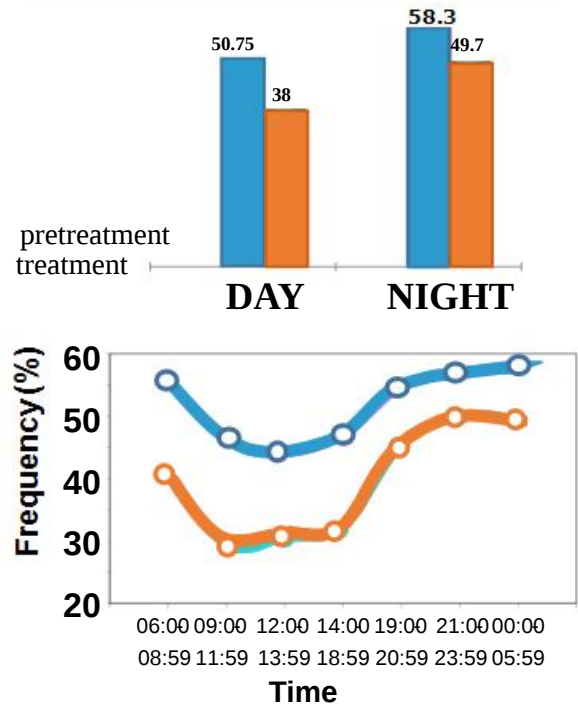
## T1DM



**Results:** Safe, well tolerated, reduced glycemia.

Frequency glucose >200mg/dL

pretreatment treatment



**Design:** 8 T1DM, monitor glycemic stability of orally administered ORMD-0801 (1 capsule (8 mg insulin) before meals, three times daily). Glucose monitored with continuous, blinded glucose monitor



# ORMD-0801: Phase IIa FDA Study

## Overview

- 24 T1DM patients
- US site
- In-patient setting
- Double blind
- Randomized
- Placebo-controlled
- 7 days of treatment

## Objectives

- Primary objective:
  - *To evaluate the change in exogenous insulin requirements in T1DM patients*
- Secondary objectives:
  - *To evaluate the changes in glucose in T1DM patients*
  - *To evaluate safety and tolerability*

**Last Patient Out: August  
2014**



# ORMD-0901

## *Oral GLP-1 Analog (T2DM)*



# Oral GLP-1 Analog (Exenatide)

## GLP-1: Hormone Facts

- Secreted by the intestine
- Has effect on the satiety center in the brain
- Has effect on pancreatic  $\beta$ -cells

## GLP-1 Analog: Drug Facts

- Good safety profile
- Mimics the natural hormone in the body
- Decreases blood glucose levels - aids in blood sugar balance
- **Does not cause hypoglycemia**
- Effectively reduces HbA1c
- Preserves beta cell function
- **Promotes weight loss**
- **Current therapy is via injection only**

## ORMD-0901

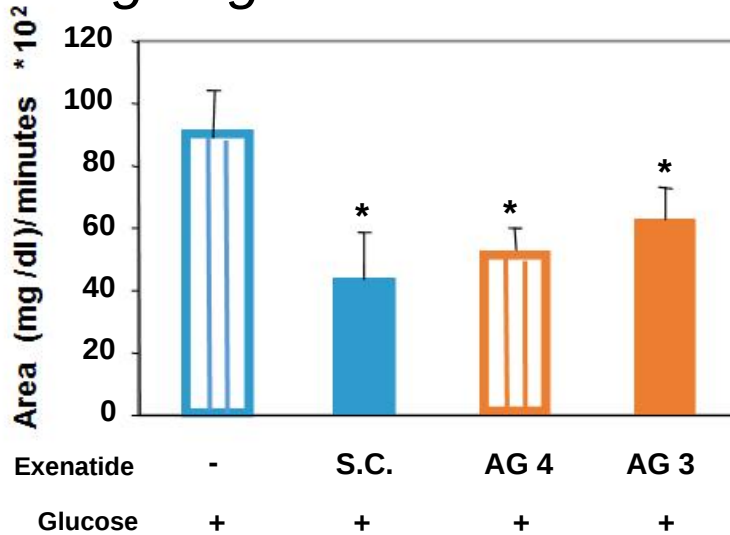
### Oral GLP-1

- Pre-IND package submitted to the US FDA Q3 2013
- IND-enabling tox studies Q3, 2014
- PIb ex-US study Q4, 2014



# Oral GLP-1 - ORMD-0901

## Blunting of glucose excursions in dogs



### Methods:

- Ø Healthy, fasting, cannulated dogs
- Ø Single dose ORMD-0901 formulation
- Ø Administered 30 minutes pre-glucose challenge
- Ø Blood samples collected every 15 minutes

**Results:** Subcutaneous exenatide delivery amounted to a 51% reduction in mean glucose AUC<sub>0-150</sub>, while formulations AG4 and AG3 prompted 43% and 29% reductions, respectively (\* p = 0.068, demonstrating a treatment-related trend for the sample size).

**ORMD-0901 formulations preserved the biological activity of orally delivered exenatide. ORMD-0901 successfully curbed blood sugar excursions following glucose challenge.**



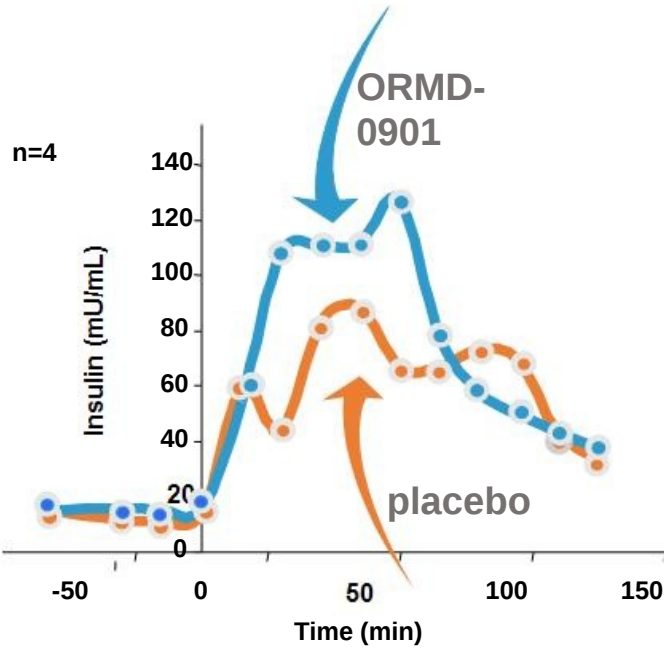
# ORMD-0901 -

## T2DM

### Study

- First in Human
- 4 healthy
- ~~Placebo~~ controlled
- Pre-prandial

150 mg  
exenatide



### Mean AUC

Placebo:  
148.5±30.5

No Nausea

Insulin:  
180.3±106.3

↑ 21%

# Pipeline Overview



		Phase I	Phase II	Phase III	Timeline
<b>ORMD-0801</b> oral insulin	Type 2 diabetes				Q4, '13: Phase IIa completed Q4, '14: Phase IIb multi-center study projected initiation
	Type 1 diabetes				Q1, '14: Phase IIa initiated (LPO 8/2014)
<b>ORMD-0901</b> oral GLP-1	Type 2 diabetes				Q3, '14: Preclinical/IND studies projected initiation Q4, '14: Phase Ib ex-US study projected initiation Q3, '15: Phase II multi-center study projected initiation

# Corporate Overview





# Management



**Nadav Kidron, Esq, MBA**  
CEO & Director

Experience in various industries, including corporate law and technology



**Miriam Kidron, PhD - CSO & Director**  
Senior Researcher at the Diabetes Unit of Hadassah Medical Center for more than 25 years



**Josh Hexter - COO, VP Bus. Dev.**

More than 15 years of prominent leadership roles in biotech and pharma



**Yifat Zommer, CPA, MBA - CFO**

Extensive experience in corporate financial management

## Board of Directors

**Michael Berelowitz, MD**

- Chairman of Oramed SAB
- SVP Clinical Development & Medical Affairs, Pfizer (former)

**Harold Jacob, MD**

- Chief Medical Officer, Given Imaging (former)

**Gerald Ostrov**

- CEO, Bausch&Lomb (former)
- Senior level Executive J&J (former)

**Leonard Sank**

- Entrepreneur and businessman



# Scientific Advisory Board



**Michael Berelowitz, MD**  
**Chairman of SAB**

- Former SVP Clinical Development and Medical Affairs, Specialty Care Business at Pfizer Inc.
- Strong background in the Diabetes field.



**Derek LeRoith, MD, PhD**

- Professor of Medicine and Chief of Endocrinology, Diabetes and Bone Disease Unit, Mount Sinai School of Medicine, NY.



**John Amatruda, MD**

- Former SVP and Franchise Head of the Diabetes and Obesity Unit at Merck & Co.



**Nir Barzilai, MD**

- Director for the Institute of Aging Research. Member of Diabetes Research Center, Albert Einstein University College of Medicine.



**Avram Herskho, MD, PhD –  
Nobel Laureate, Chemistry, 2004**

- Distinguished Professor in the Biochemistry Unit in the B. Rappaport Faculty of Medicine, Technion, Haifa, Israel
- Nobel Laureate in Chemistry (2004)



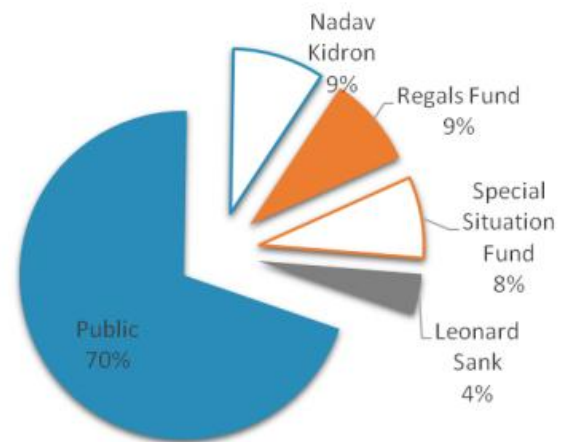
**Ele Ferrannini, MD, PhD**

- Professor of Internal Medicine, University of Pisa School of Medicine. Professor of Medicine, Diabetes Unit Texas Health Science Center.
- Past President of the EASD.

# Corporate Overview\*

Ticker: NASDAQ: ORMP

- \$43M raised to date \*\*
- No Debt
- Cash and investments: \$21.3M
- Shares issued: 10.1M
- Fully diluted: 12M \*\*\*
- Strong intellectual property estate
  - Methods & Compositions for Oral Administration of Proteins
  - Methods & Compositions for Oral Administration of Exenatide
  - Methods & Compositions (insulin + exenatide)
  - Improved Protease Inhibitors



\* As of August 31, 2014

\*\* Including the shares of D.N.A Biomedical Solutions Ltd.

\*\*\* Including outstanding 1M options and 1M warrants



# Anticipated Milestones 2014-2015

## ORMD-0801 Oral Insulin

### T2DM

• Completion of Phase IIa FDA study

- Initiation & Completion of Phase IIb multi-site study under US IND

### T1DM

- Completion of Phase IIa FDA study



## ORMD-0901 Oral GLP-1 Analog

- Initiation & Completion of IND-enabling studies
- Initiation & Completion of Phase Ib ex-US study
- Initiation of Phase II multi-site study under US IND

# Summary

**Proprietary technology platform (POD™) for oral delivery of peptides**

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**Significant market opportunity: *focus on significant medical needs***

---

**Clinical proof of concept achieved**

**Orally ingestible insulin: *US FDA Phase II clinical development***

**Strong product pipeline: *potential to expand to other indications***

---

**Strong management team backed  
by world-leading scientific experts**

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***Multiple value-creating milestones in 2H14 and 2015***



# Breakthrough Technology for a Brighter Future



**Contact :**

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