

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 23, 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.**

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.**

May 23, 2016

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



# Addressing the Multibillion-Dollar Injectable Drug Markets with Oral Formulations

May 2016



## Safe Harbor

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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.

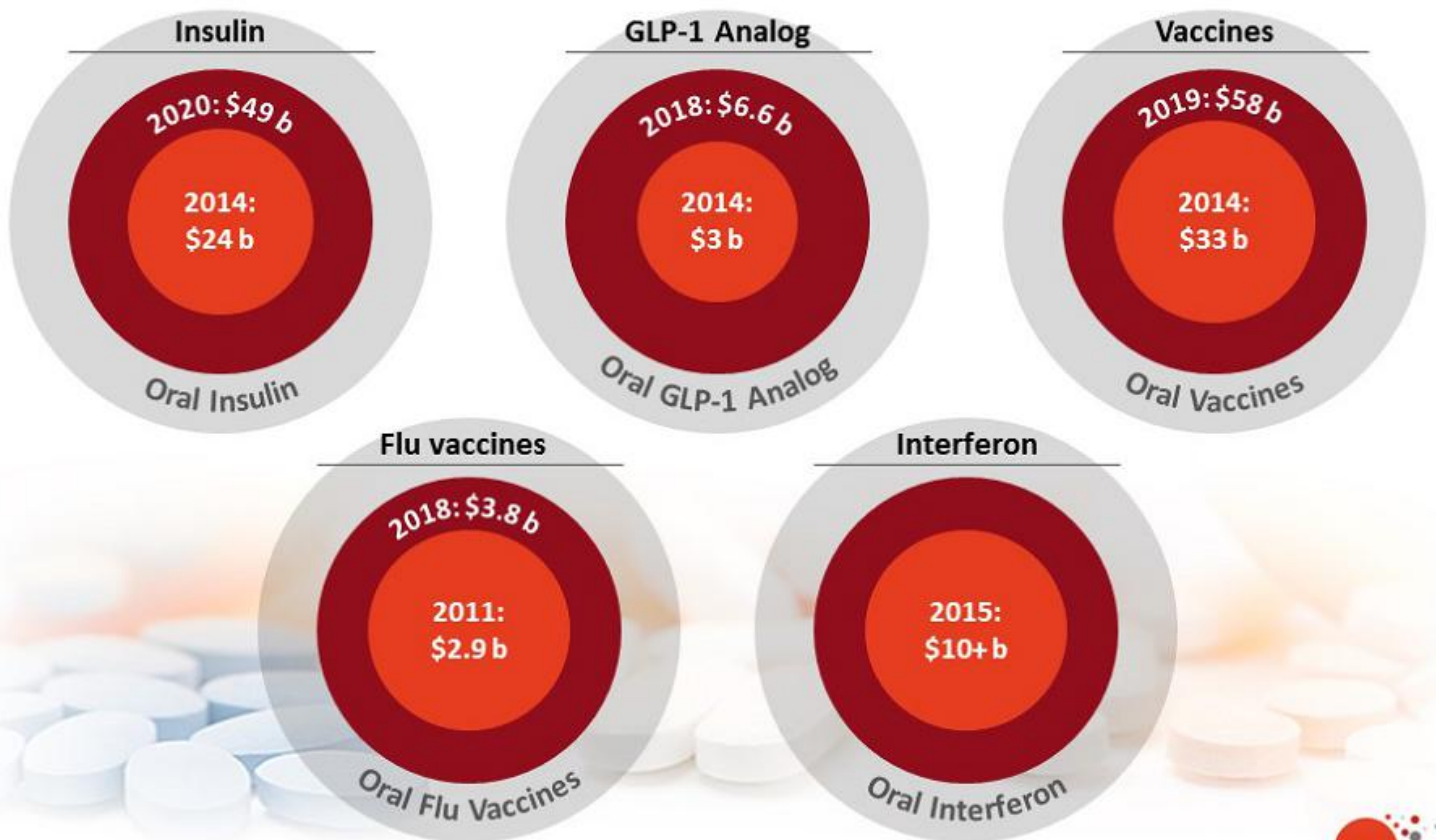
## Oramed Snapshot

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- **Proprietary oral protein delivery platform**
- **Insulin first** - initially targeting the lucrative insulin market. Additional huge markets in the pipeline
- **Strong financial position** \$36M in cash and investments, no debt
- **Strong management** team backed by world-class scientific experts
- **Multiple value-creation events** for this year including completion of FDA Phase IIb study for oral insulin
- **NASDAQ: ORMP**



## Funneling Huge Injectable Drug Markets to Novel Oral Formulations



## An Unsolved Challenge: Proteins and Peptides do Not Survive the Digestive System

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### **Harsh pH**

Stomach acidity cleaves and shreds protein

### **Protease attack**

Proteases attack and break down proteins

### **Absorption barrier**

Most therapeutic proteins fail to be absorbed via the intestinal wall (barrier)



## Oramed Technology Protects Drug Integrity and Increases Absorption

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### **pH shield for passage through stomach**

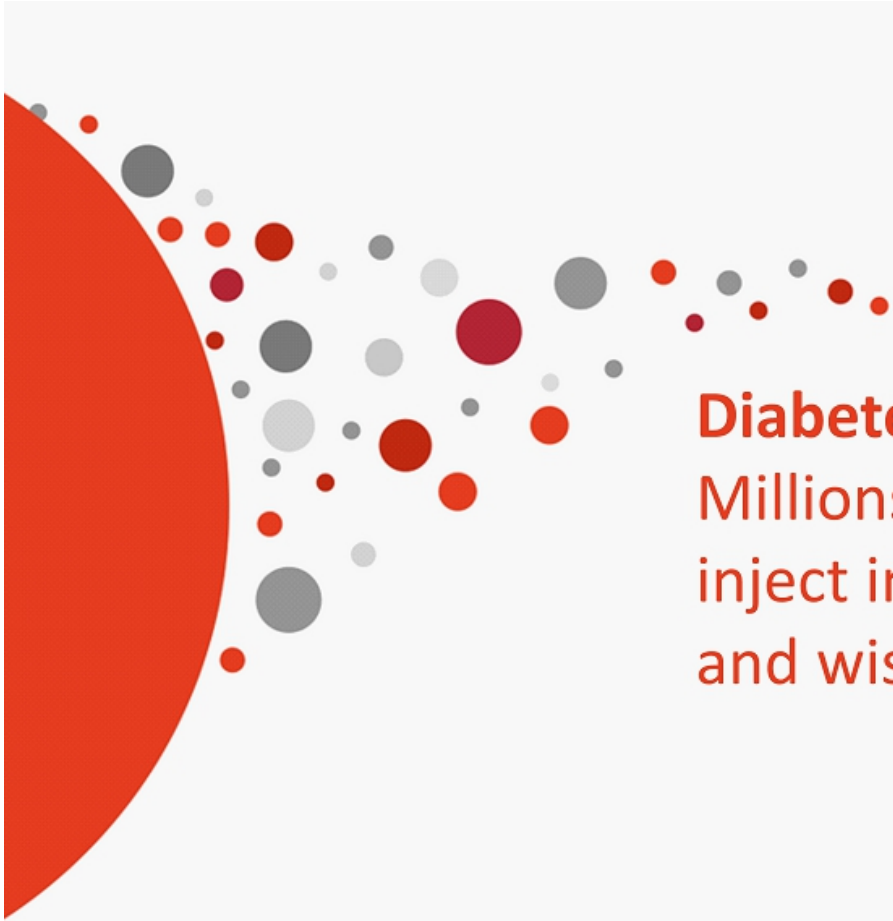
pH sensitive enteric coating protects capsule contents.  
Capsule dissolves only once in small intestine

### **Protease protection**

Protease inhibitors stave off and protect the active agent  
from protease attack

### **Absorption enhancement**

Assists the permeation of proteins/peptides across intestinal  
membrane and into bloodstream



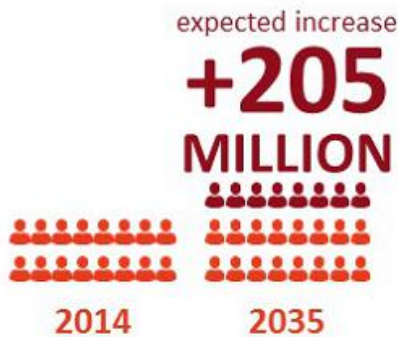
**Diabetes:**  
Millions of diabetics  
inject insulin today  
and wish for oral dosage



# 1 in 12 People on the Planet Have Diabetes

**1** healthcare  **in 9**  
Is spent on diabetes

In 2014 diabetes expenditure reached US \$ 612 billion



## Type 1 and Type 2 Diabetes Are Different

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**Diabetes: A metabolic disease in which the body's inability to produce any or enough insulin causes elevated levels of glucose in the blood**



### TYPE 1 Diabetes

- **T1DM is autoimmune:** The body destroys its own insulin-producing (beta) cells, leaving patients completely dependent on external insulin sources
- **10% of diabetics have T1DM:** Up to 37 million people worldwide have T1DM
- **Projected Market:** \$13 billion by 2023

### TYPE 2 Diabetes

- **T2DM is metabolic:** The body becomes insulin resistant. Injections may be used to make up for the pancreas's inability to create sufficient insulin to keep blood sugar at normal levels
- **371 million people worldwide needing treatment**
- **Projected Market:** \$39 billion by 2019

## ORMD-0801:

### Oramed's Flagship Product for Oral Treatment of Diabetes

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**>300**

study subjects



**>5000**

human doses



**Clean  
safety**

profile



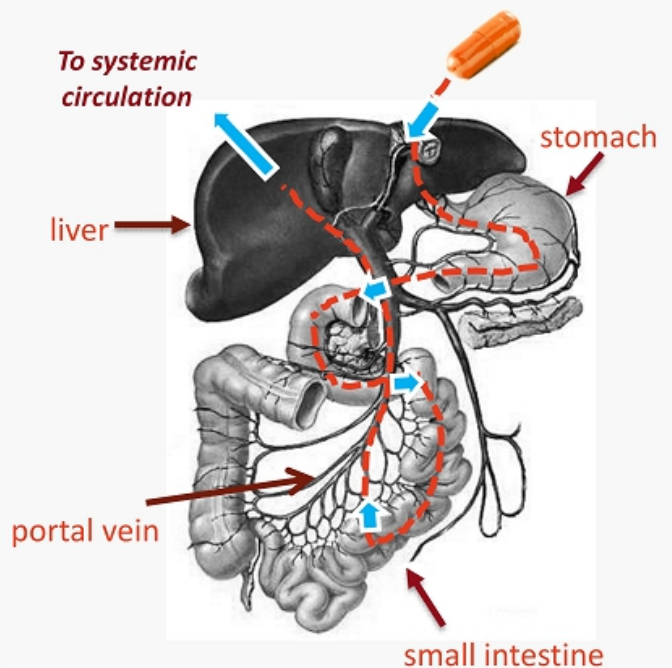
## The Drawbacks of Injected Insulin vs. the Advantages of Oral Insulin

**ENDOGENOUS INSULIN** produced by the pancreas and delivered to the body via the liver

**INJECTED INSULIN** introduced directly to the bloodstream with only a fraction of it reaching the liver. This can cause excess sugar to be stored in fat and muscle which often results in weight gain. This may also cause hypoglycemia

**ORAL INSULIN** like natural insulin is delivered first to the liver. This should lead to:

- Better blood glucose control
- Reduced hypoglycemia: liver metabolism
- Reduced hyperglycemia: insulin closes down glucose overproduction/secretion
- Reduced weight gain (neutral): vs. SC insulin focus on glucose disposal leads to weight gain







**ORMD-0801**

**Type 1 Diabetes (T1DM):**  
Potentially eliminating the  
need for insulin before  
each meal



## Oramed: Potentially Superseding Bolus Replacement Therapy

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### T1DM patients are treated with 2 types of insulin replacement therapy

- Long-acting insulin (basal) helps maintain stable insulin levels during fasting periods
- Rapid-acting insulin (bolus) prior to each meal to stabilize blood sugar
- Administration is via injection or pump



### Oramed seeks to replace the mealtime (bolus) insulin doses

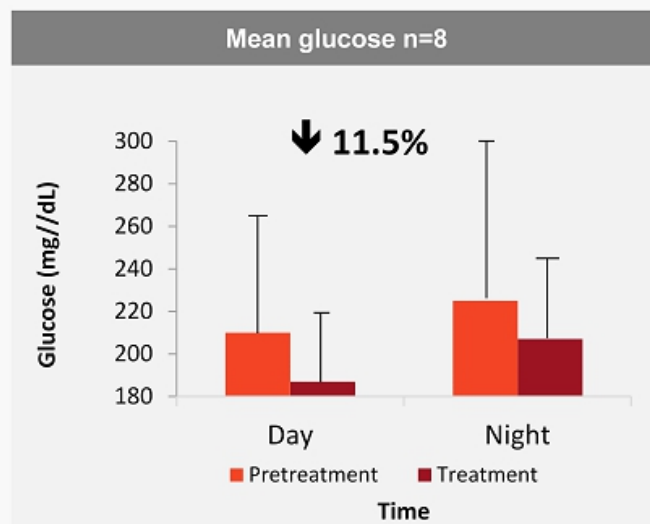
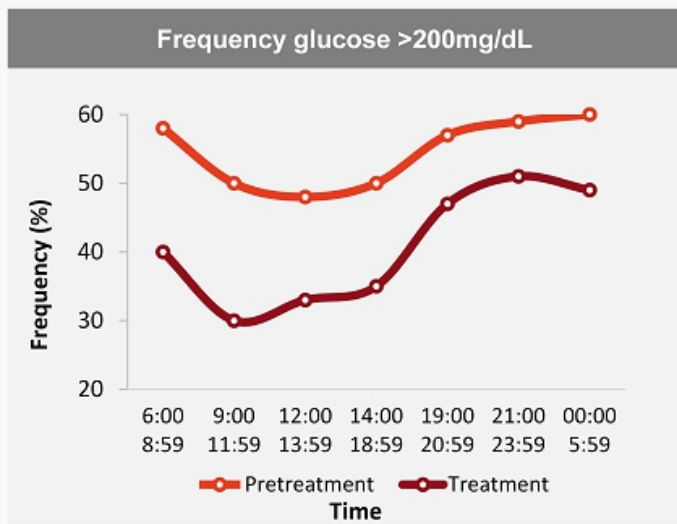
- Easier use and reduced systemic exposure
- Potentially reducing multiple daily injections
- Tighter regulation and control of blood sugar levels by directly targeting liver glucose, due to portal administration



## ORMD-0801: Consistent Lowering of Glucose Levels - Day and Night in Preliminary Study

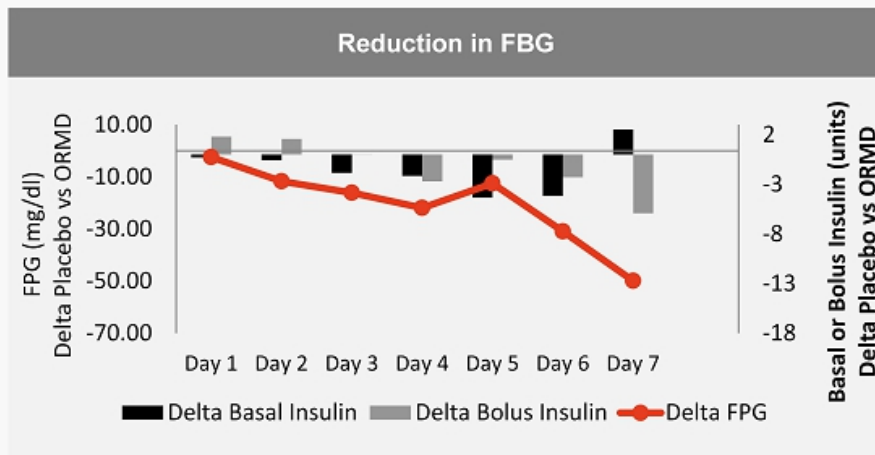
### Design:

- Monitor glycemic stability of orally administered ORMD-0801
- Uncontrolled T1DM patients
- 1 capsule of 8 mg insulin administered before meals, three times daily at mealtime
- Continuous glucose monitoring



## Phase IIa FDA Study: Shows Consistent and Accumulative Effect of ORMD-0801

Blood glucose levels are lower, day and night, compared to control group



25

T1DM patients

7

days of treatment

3

times a day (at mealtime)

Primary  
objective:

To evaluate the change in exogenous insulin requirements in T1DM patients

## ORMD-0801: Phase IIa FDA Study Demonstrates Oral Insulin Reduces Exogenous Insulin Requirements

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Safe and well tolerated for the pre-meal dosing regimen in this study.

Encouraging trends in key areas vs. placebo:



### Decreased

use of rapid-acting insulin  
levels of post-meal glucose  
levels of daytime glucose



### Increased

rate of mild hypoglycemia vs. placebo  
(failure to reduce injectable insulin sufficiently)





## **ORMD-0801:**

Better type 2 diabetes  
(T2DM) treatment by  
interacting with the body  
like natural insulin

## The Type 2 Diabetes Treatment Paradigm

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ADA guidance: Earlier use of insulin equals better outcome (source)

## Excessive Production of Glucose at Night: A Significant Challenge in Diabetes Management

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- Excessive nocturnal glucose production by the liver is frequently demonstrated in diabetes patients
- Results of high blood sugar are measured by a fasting blood sugar (FBG) test, done after an 8-hour fast. High FBG test results are a key concern in diabetes management
- **Treatment today is suboptimal: Insufficient percentage of patients blood sugar is regulated with medication and return FBG to normal levels**





## Simple Oral Administration at Bed Time Managing Diabetes

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Oramed's first indication, ORMD-0801, reduces excessive nocturnal glucose production in the liver, by acting the same way that natural insulin does.

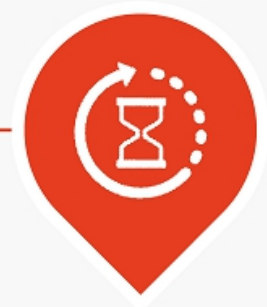
### Key benefits



Reduction of  
FBG levels



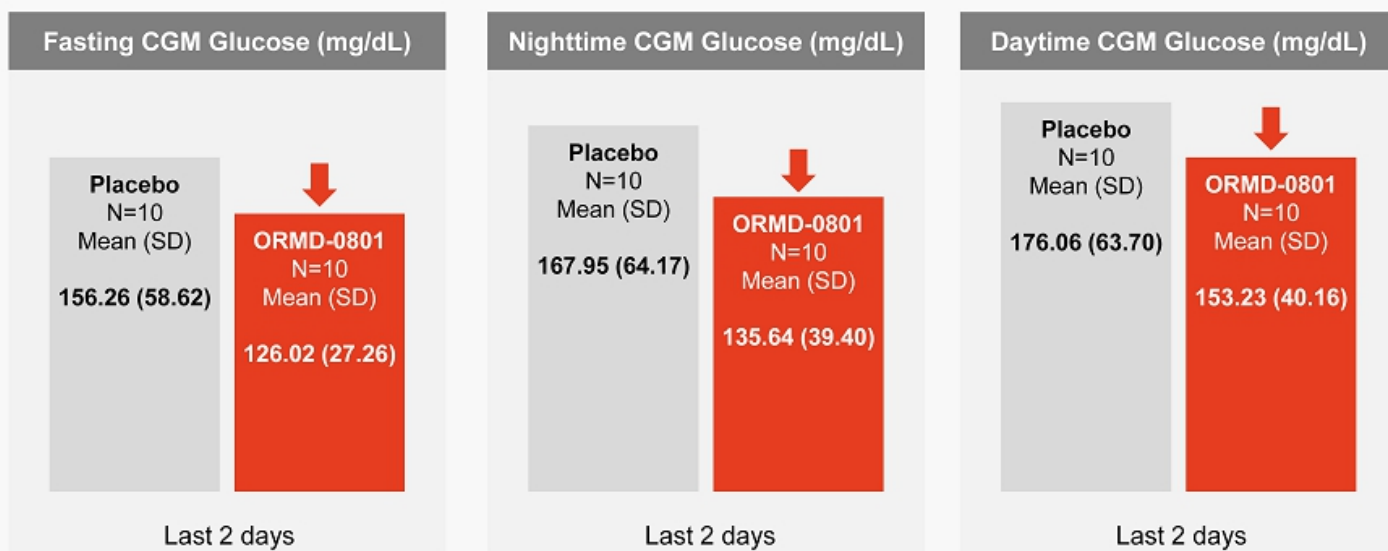
Increased patient  
compliance via simple  
oral administration



Slowing down  
the progression  
of diabetes

## Phase IIa FDA Study: ORMD-0801 Drug Safe With no Serious Adverse Events

- 30 T2DM patients
- Primary objective: Safety and tolerability
- Secondary objective: Pharmacodynamic effects on mean nighttime glucose





## Completed: 180 Patient FDA Phase IIb Study

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- 33** US sites
- 180** patients
- 28** day treatment
- 1** time a day at night

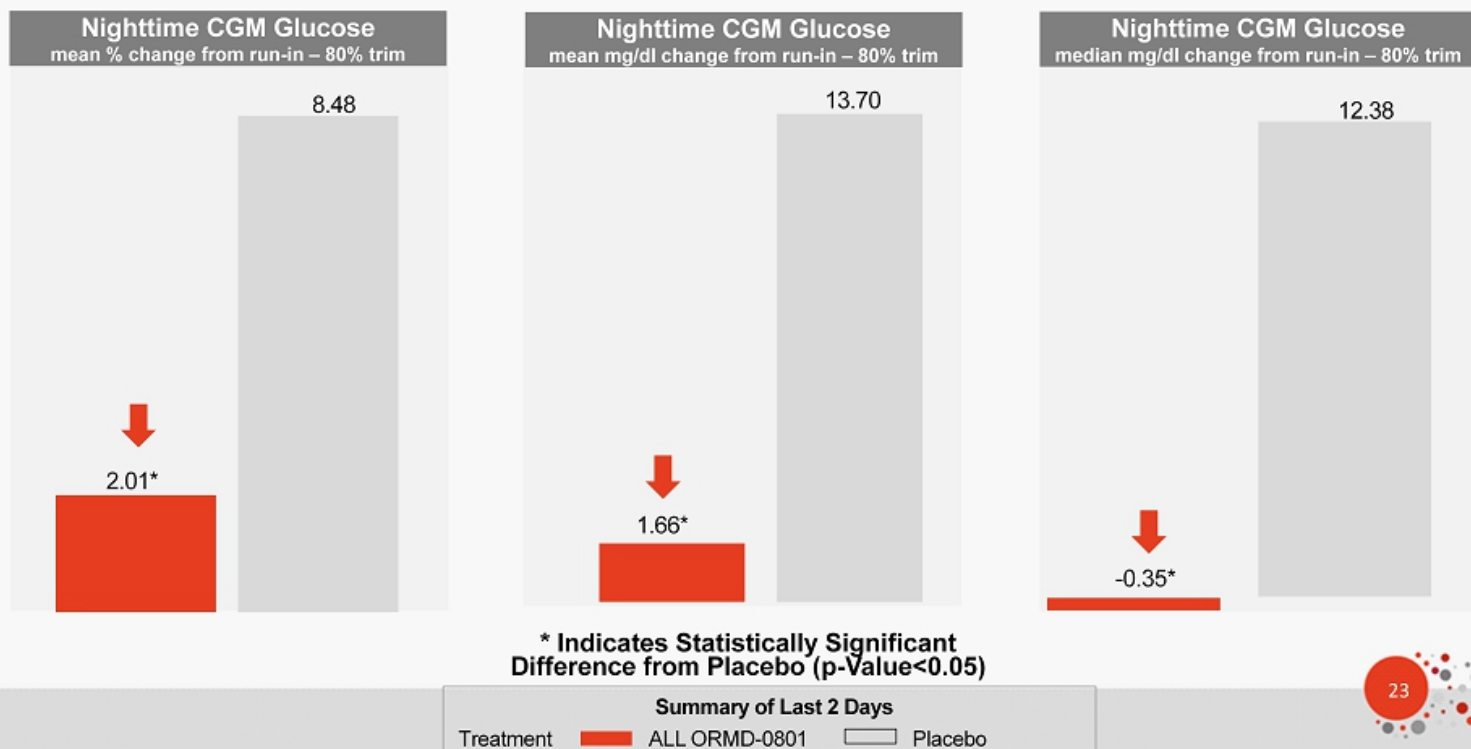
### Primary objectives:

- Safety of ORMD-0801
- Evaluate PD effects of ORMD-0801 on mean night glucose

## Phase IIb FDA Study: Primary Endpoints Successfully Met

### Demonstration of Safe and Effective Oral Insulin Delivery

- Safe and well tolerated – No drug related serious adverse events.



## Phase IIb FDA Study: ORMD-0801 Primary & Secondary Endpoints



### Safe and well tolerated

- Observed to be safe and well tolerated for dosing regimen
- No drug related serious adverse events

### Sustained glucose reduction

- Dose group showed a statistically significant effect over placebo
- Sustained reduction observed at night

**Awaiting further secondary and exploratory PD endpoints which we hope to share in the near-term**

#### Secondary objectives:

- Evaluate PD effects of ORMD-0801 on fasting blood glucose, morning blood insulin, c-peptide, triglycerides

#### Exploratory objectives:

- Evaluate PD effects of ORMD-0801 on HbA1c, CRP, 24-hour fasting glucose, day CGM glucose levels, weight
- Evaluate immunogenicity of ORMD-0801 via anti-insulin antibody levels



## China License Deal: 500M patient potential

- **License: Exclusive right to ORMD-0801 in Greater China**
- **Licensee: Hefei Tianhui ("HTIT")**  
Owns with Sinopharm a state-of-the-art GMP API insulin manufacturing facility
- **\$50M Payments + Royalties:**
  - \$12M in restricted stock (at premium)
  - \$38M milestone payments
  - **10% royalties on net sales**


### Chinese diabetes market\*

**114M** **diabetic**  
(12% of adult population)

**~500M** **prediabetic**  
(50% of adult population)



\* Journal of the American Medical Association



**ORMD-0901:**  
Oral GLP-1 Analog



## GLP-1 Analog: ORMD-0901 for Oral GLP-1 (TD2M)

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### GLP-1 Analog

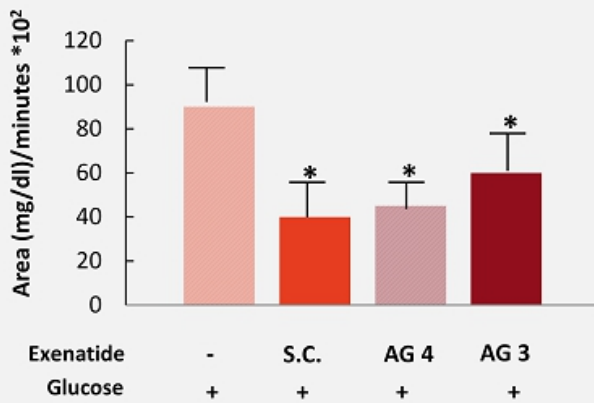
- T2DM medication
- Mimics the natural hormone in the body
- Good safety profile
- Decreases blood glucose levels
- Does not cause hypoglycemia
- Effectively reduces HbA1c
- Preserves beta cell function
- Promotes weight loss
- Current therapy is via injection only

### ORMD-0901 Clinical Status

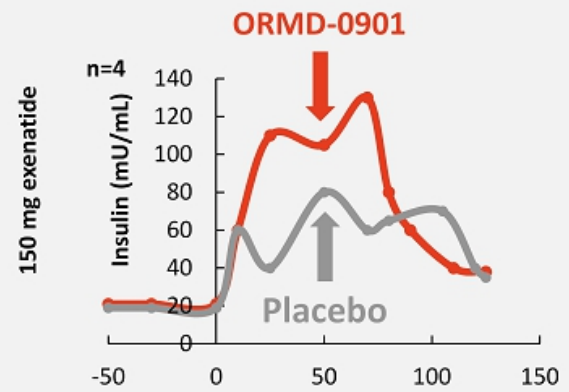
- IND-enabling tox studies in process
- Q2, '16: Phase Ib ex-US study projected completion
- Phase IIb US study Q1, 2017 projected initiation

## Oral GLP-1 - ORMD-0901

Dogs: Oral exenatide delivery amounted to a >50% reduction in mean glucose (similar to SC)



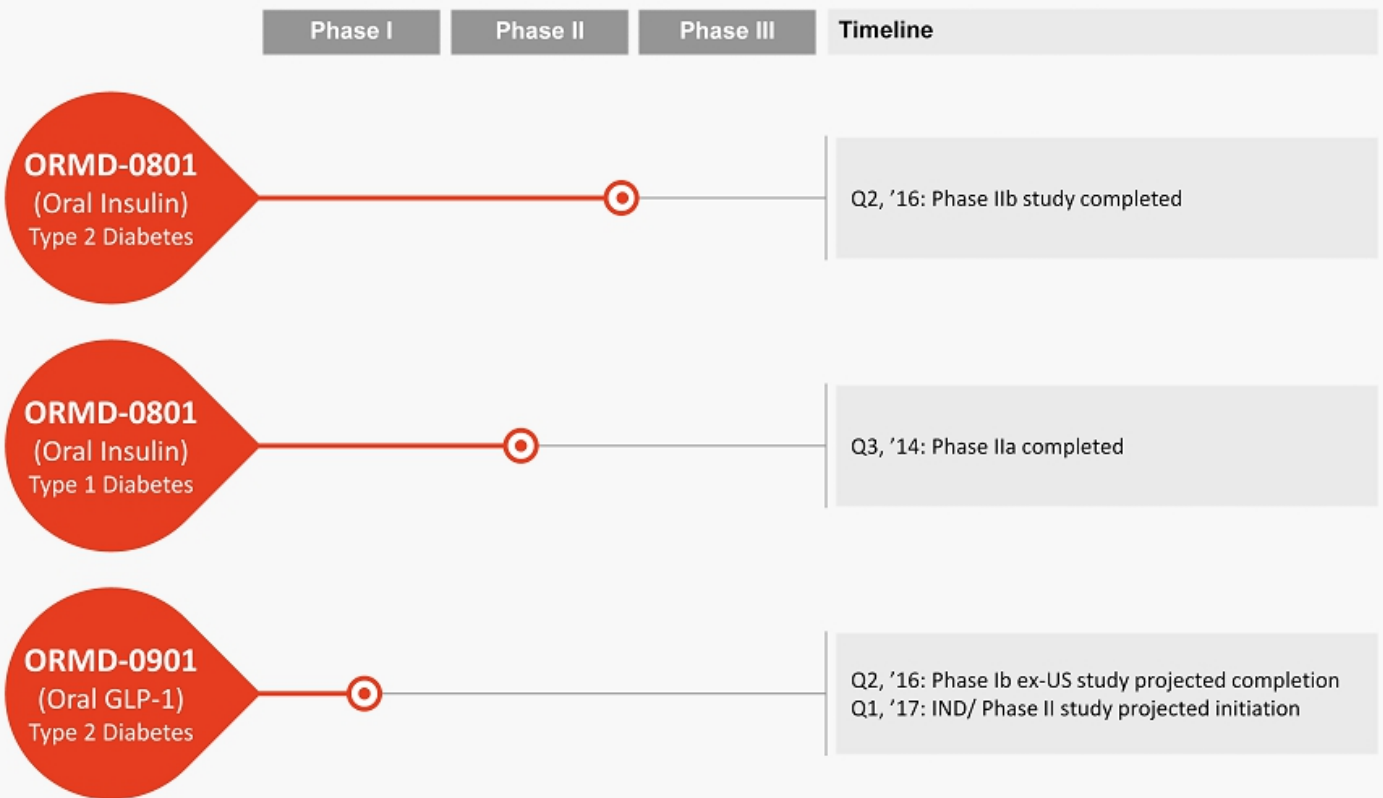
Human (4 healthy volunteers)



**ORMD-0901  
formulations**

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

## Rich Pipeline: Multiple Value-Creation Events







**Corporate Overview:**  
On route to meet  
unmet market needs

# Oramed (NASDAQ: ORMP): Corporate Overview<sup>1</sup>

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## Financial Highlights

- \$36M cash and investments
- 13.1M shares outstanding (15.7M fully diluted<sup>2</sup>)
- No Debt



## Analyst Coverage

- Rodman & Renshaw (PT \$25)
- Aegis Capital (PT \$18)
- FBR & Co. (PT \$15)
- Zacks (PT \$30)



## Intellectual Property Estate

- Methods and compositions for oral administration of proteins
- Methods and compositions for oral administration of exenatide
- Methods and compositions (insulin + exenatide)
- Improved protease inhibitors

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<sup>1</sup> As of January 12, 2016.

<sup>2</sup> Including 1.7M options, 0.7M warrants and 0.3M RSUs

## Lead Team

### Management



**Nadav Kidron, Esq, MBA - CEO & Director**  
Many years of business experience as well as 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 17 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 business leader

**Xiaopeng Li**  
Director of Chairman's Office in HTBT, China

## Scientific Advisory Board

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### **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

### **John Amatruda, MD**

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

### **Avram Herskho, MD, PhD**

#### **Nobel Laureate, Chemistry, 2004**

Distinguished professor in the biochemistry unit in the B. Rappaport Faculty of Medicine, Technion, Haifa, Israel

### **Nir Barzilai, MD**

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

### **Derek LeRoith, MD, PhD**

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

### **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



## Oramed: Addressing the Multibillion-Dollar Injectable Drug Markets with Oral Formulations

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- **Proprietary platform** for oral delivery of drugs, proven in clinical studies
- **Initially targeting the lucrative insulin market.** Additional huge markets in the pipeline
- **Strong lead team** backed by globally prominent scientific experts
- **Value creating events until the end of 2016**
  - **Insulin/T2DM:** Completion of Phase IIb multi-site study
  - **GLP-1 Analog:** Completion of Phase Ib ex-US study followed by initiation of Phase II US multi-site study (Q1, 2017)
  - **Big Pharma:** Feasibility Study underway with the proprietary compound of a big pharma company



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Josh Hexter  
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