

A graphic featuring a dandelion seed head on a yellow stem, with several blue plus signs scattered around it. The background is a soft-focus green field. The text is overlaid on a red, rounded rectangular area with a diagonal hatched pattern.

**Breakthrough  
Technology  
for a  
Brighter Future**

Issuer Free Writing Prospectus  
Filed Pursuant to Rule 433  
Registration No. 333-187343  
June 17, 2013

# 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.



# Free Writing Prospectus Statement

This presentation highlights basic information about us and the offering. Because it is a summary, it does not contain all of the information that you should consider before investing.

We have filed a registration statement (including a prospectus dated March 22, 2013 and a preliminary prospectus supplement dated June 17, 2013) with the SEC for the offering to which this communication relates. Before you invest, you should read the prospectus in that registration statement, the related preliminary prospectus supplement and other documents we have filed with the SEC for more complete information about us and this offering. You may get these documents for free by visiting EDGAR on the SEC Web site at [www.sec.gov](http://www.sec.gov). Alternatively, we, any underwriter or any dealer participating in the offering will arrange to send you the prospectus and preliminary prospectus supplement if you request it by calling Aegis Capital Corp., Prospectus Department, 810 Seventh Avenue, 18th Floor, New York, NY 10019, telephone: 212-813-1010, e-mail: [prospectus@aegiscap.com](mailto:prospectus@aegiscap.com) or Maxim Group LLC, 405 Lexington Avenue, 2nd Floor, New York, NY 10174, toll-free telephone: 1-800-724-0761



# Offering Summary

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<b>Issuer</b>	<b>Oramed Pharmaceuticals Inc.</b>
<b>Exchange / Ticker</b>	<b>NASDAQ Capital Market / ORMP</b>
<b>Offering Size</b>	<b>Approximately \$13 million (100% Primary)</b>
<b>Over-allotment</b>	<b>15% (100% Primary)</b>
<b>Use of Proceeds</b>	<b>Clinical development of ORMD-0801 and ORMD-0901, working capital &amp; general corporate purposes</b>
<b>Book-Runners</b>	<b>Aegis Capital Corp and Maxim Group LLC</b>



# Oramed

## *An oral solution....*



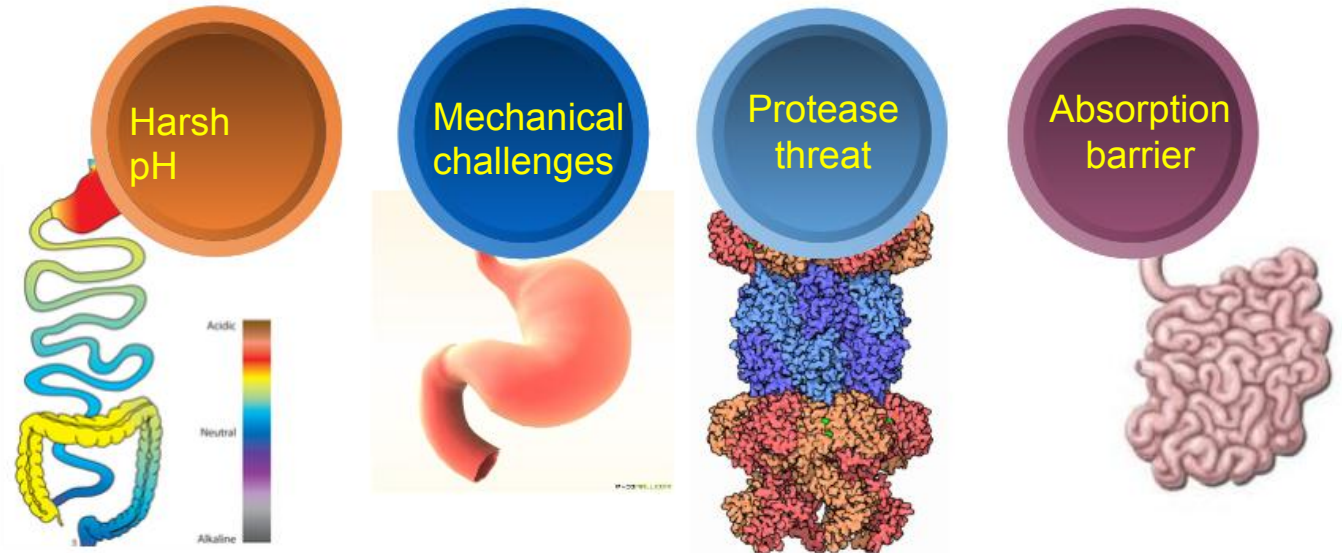
# Oramed Overview



- Has a proprietary platform technology for oral delivery of drugs -- currently available via injection only
- Flagship product – Oral insulin for Type 2.
- Product Pipeline includes:
  - Oral Insulin Capsule (ORMD-0801)
  - Oral Exenatide Capsule (ORMD-0901; a GLP-1 Analog)
  - Combination Therapy (ORMD 0801 + 0901)
- Proof-of-principle established in pre-clinical and clinical trials
- Based on over 30 years of medical research in the Diabetes Unit of Hadassah Medical Center, Jerusalem
- Founded in 2006 by its scientific inventors



# Fate of proteins/peptides in GIT



**Protein breakdown, low bioavailability**

# Oramed Technology: The Solution

## Enteric Coating

- Protects capsule constituents during travel through digestive tract - completely avoiding exposure to acidic gastric environment
- pH sensitive – only degrades in the small intestine, completely bypassing stomach and stomach acid

## Protease Inhibitors

- Protects protein from degradation by proteases once capsule degrades

## 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**.

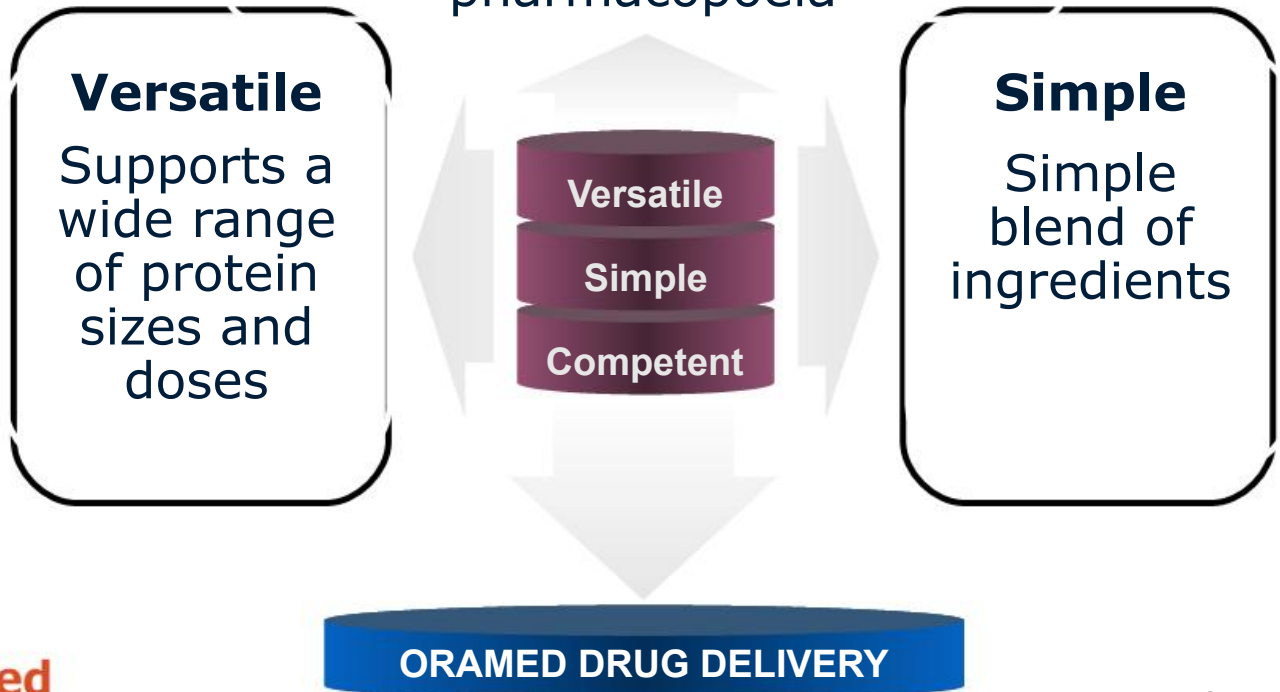




# Oramed Technology

## Regulatory competence

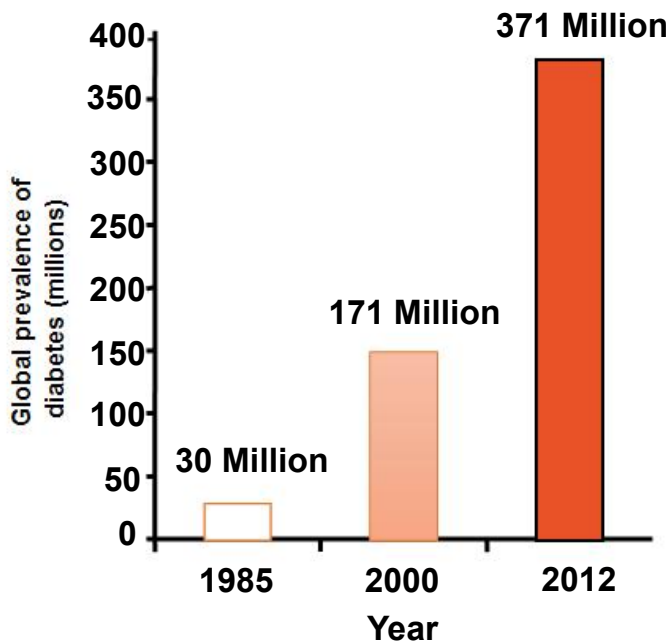
No NCEs; widely applied pharmacopoeia



# Diabetes:

## *A Global Epidemic*

# Type 2 Diabetes: A Global Epidemic



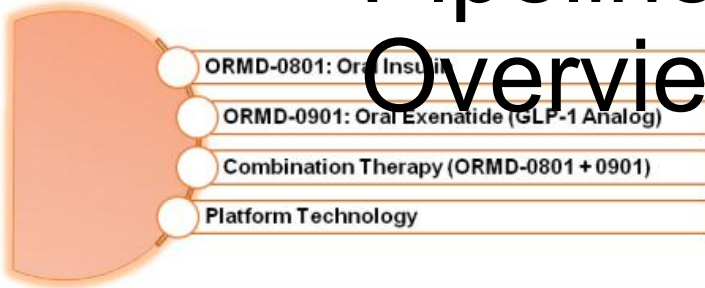
Type 2 diabetes accounts for 85-95% of diabetes cases

- **\$471 billion:** Estimated total annual economic cost of diabetes worldwide (IDF, 2012)
- **\$14.5 billion:** Estimated total global insulin market (ReportLinker, 2010)



(IDF Diabetes Atlas, 2012)

# Pipeline Overview



Therapy	Indication	Preclinical	Phase I	Phase II (ex-US)	Phase II (FDA)	Timeline
ORMD - 0801	T2DM	[Progress bar spanning Preclinical, Phase I, and Phase II (ex-US)]				Q3, '13: Phase IIa "sub-study" projected initiation Q2, '14: Phase IIb multi-center study projected initiation
	T1DM	[Progress bar spanning Preclinical and Phase I]				Q2, '14: Phase II (ex-US) multi-center trial projected initiation
ORMD-0901	T2DM	[Progress bar spanning Preclinical and Phase I]				Q1 '13: Phase I/II (ex-US) study initiated
Combination Therapy	T2DM	[Progress bar spanning Preclinical]				Q1, '13: First-in-human PoC trial initiated

# ORMD-0801

## *Oral Insulin*

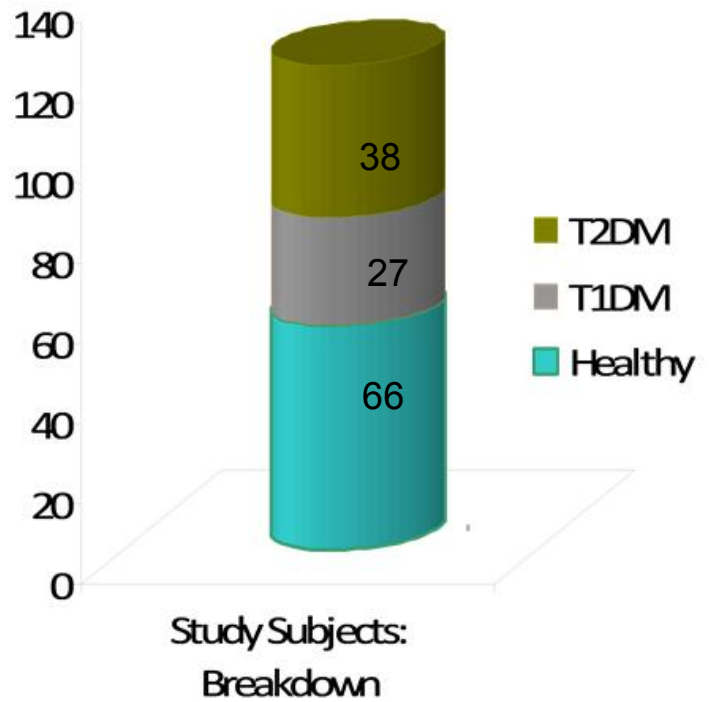
# ORMD-0801: Administrations To-date

Total number of  
study subjects:

131

Total number of  
administrations  
in humans:

1444

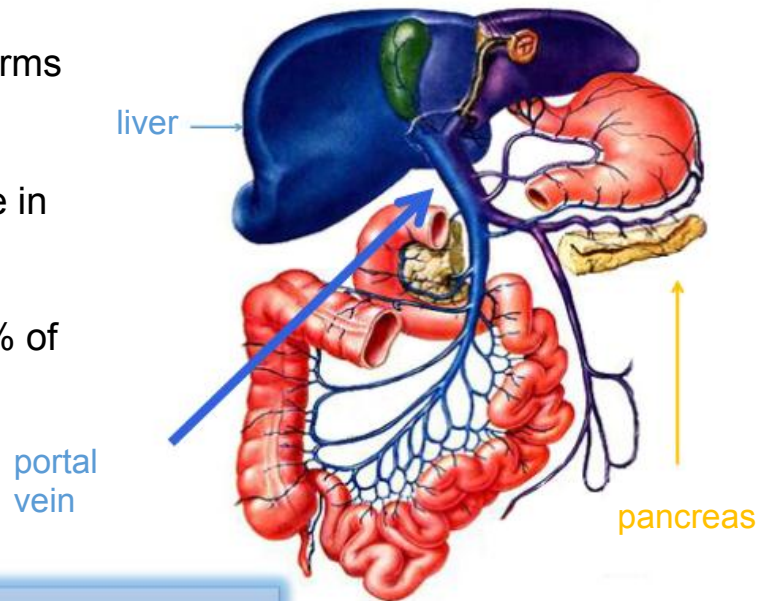


# ORMD-0801

## *Type 2 Diabetes*

# Insulin: Physiologic Regulator of Blood Glucose

- 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



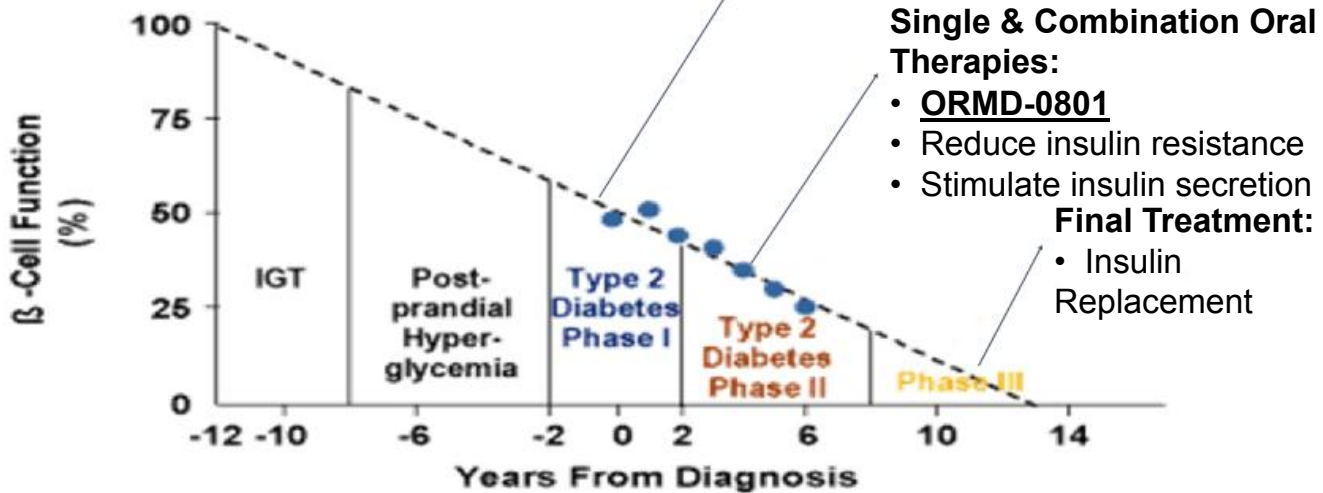
Portal insulin delivery is physiologic.  
Systemic insulin delivery is not.



# Type 2 Diabetes: Stages & Treatment Options

## Stages of Type 2 Diabetes

Criteria for advancing to next stage:  
A1C not at target < 7.0%



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



# Unique Initial Indication

## Fasting Blood Glucose (FBG):

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- Measurement of blood glucose levels after a fast, here defined as first thing in the morning
- Effected by liver regulation of glucose and insulin levels in the body during a fast

## Elevated FBG

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- **Elevated FBG levels are a major issue in Type 2 diabetics**
- Main cause: excessive nighttime glucose production from liver
- Current treatments for correction of elevated FBG are suboptimal

## FBG: Stats

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- 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

## ORMD-0801: UNIQUE INDICATION

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- Focused on excessive nighttime glucose production from the liver

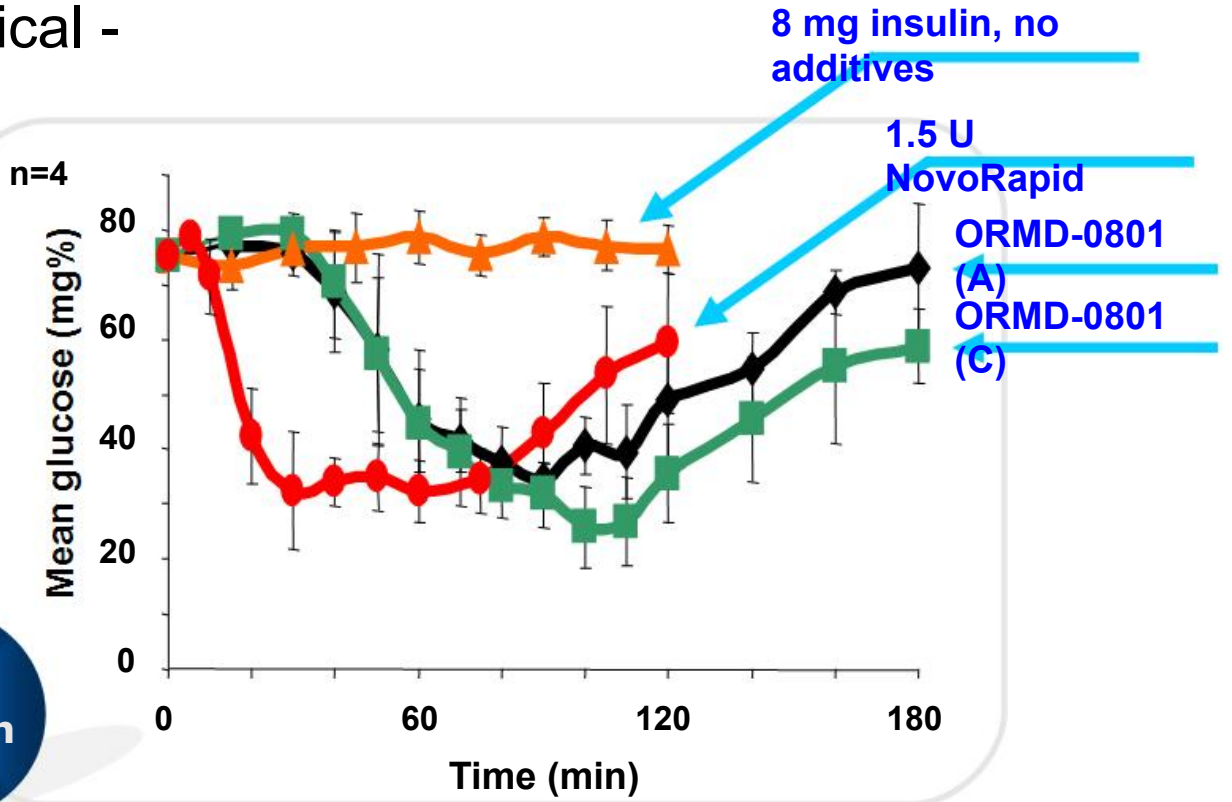
# ORMD-0801 Pre-clinical



**Toxicology Study:**  
***No adverse events***

- 90 rats, 28-day tox + 14-day post-treatment monitoring
- Doses: 3 times greater than human exposure
- “Overall, no safety signals were observed in either the PoC studies in Beagle dogs or pigs or the 28-day repeat dose toxicity and toxicokinetic studies in Sprague Dawley rats...” (Oramed’s IND Application)

# ORMD-0801 Preclinical - Dogs

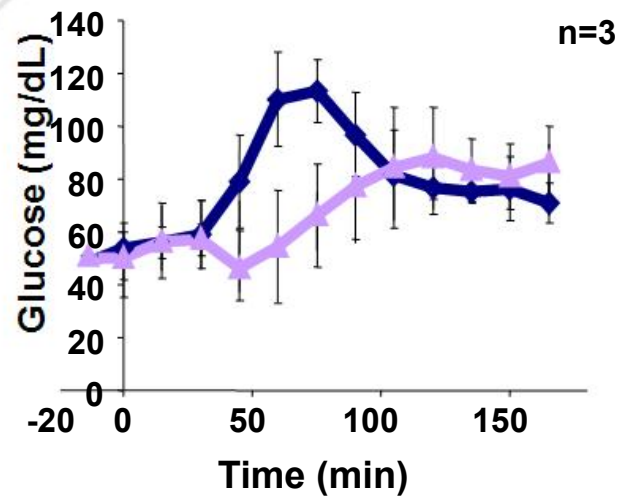
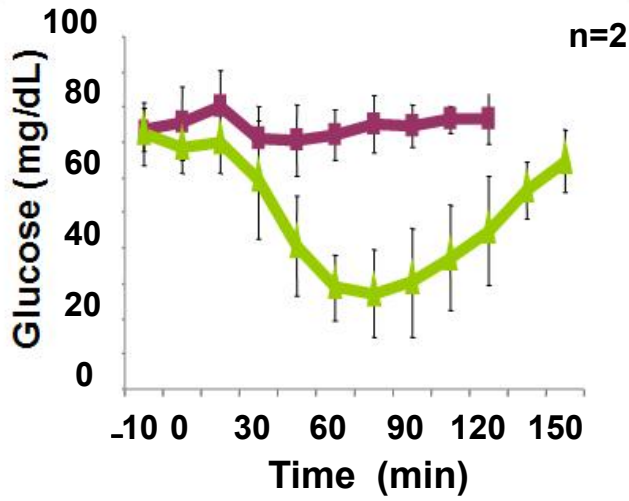


Healthy, non-diabetic, cannulated beagle dogs 60-75% drop in blood glucose levels within 30-100 minutes of treatment  
No hypoglycemia or adverse events were observed over the three years of testing

# ORMD-0801 Preclinical - Pigs

Fasting

Pre-  
prandial



■ NC; 4 independent test  
▲ ORMD-0801; 10 independent session

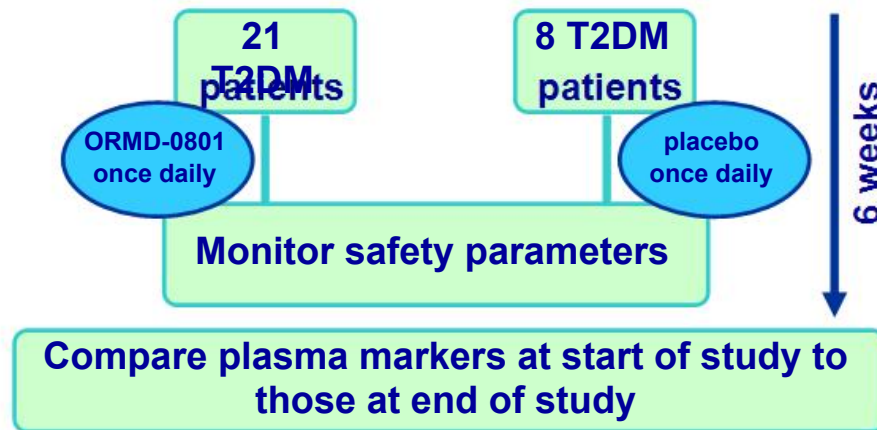
◆ NC; 6 independent test  
▲ ORMD-0801; 5 independent sessions

8 mg  
insulin

No hypoglycemia or adverse events were observed

# Phase II Study (ex-US):

**Design:** Multi-centered, placebo-controlled, randomized, double-blinded, 29 T2DM patient study to evaluate safety and tolerability of one bedtime orally administered ORMD-0801 formulation (2 capsules containing 8 mg insulin each) as well as its effectiveness in providing glycemic control.



# T2DM Clinical Results



- Total number of patients: 38
- Efficacy
  - Showed relevant clinical impact
- Safety
  - Good safety profile
  - Safe and well tolerated by all patients
  - No SAEs

# Phase II Study (ex-US): FBG, HbA1c, Cardiovascular Disease Risk, Hypoglycemia

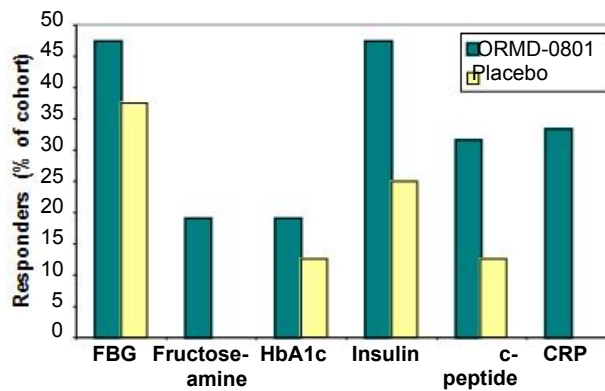
## **Results:**

### **Safety:**

- First extended exposure to ORMD-0801 proved safe and tolerable.
- No serious adverse events reported.
- No cumulative effects were observed.
- Only two hypoglycemic events were recorded - both were mild.

### **Efficacy:**

- Reduced glycemia & inflammatory markers
- Percentage of patients demonstrating clinically relevant reductions in insulin, c-peptide, fasting blood glucose (FBG), and Hb1Ac levels was higher in the ORMD-0801 cohort, compared to the placebo.





# Upcoming Trial

(under FDA IND)



## Phase IIa

- 30 patients
- US site (CRO: Integrium)
- In-patient setting
- Double blind
- Randomized
- One week of treatment
- 2 test doses (16mg, 24 mg)
- Primary end point: Safety
- **Follow-on study (planned): Phase IIb multi-site study in US**

# ORMD-0801

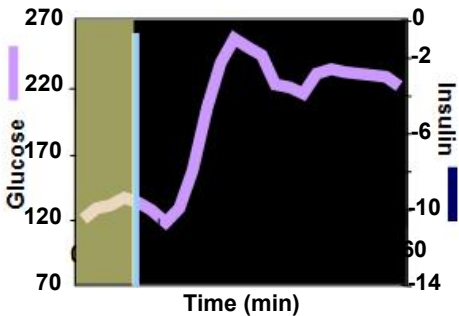
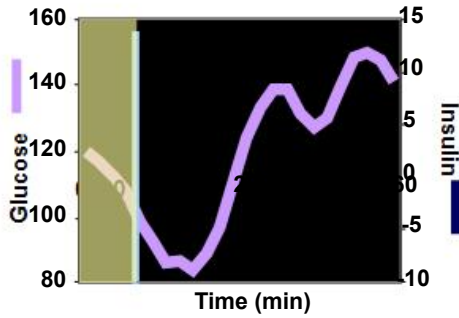
## *Type 1 Diabetes*

# ORMD-0801

## Glucodynamics in fasting T1DM

Expected rate of increase in fasting blood glucose concentrations among T1DM upon insulin withdrawal:  $45.1 \pm 9.7$

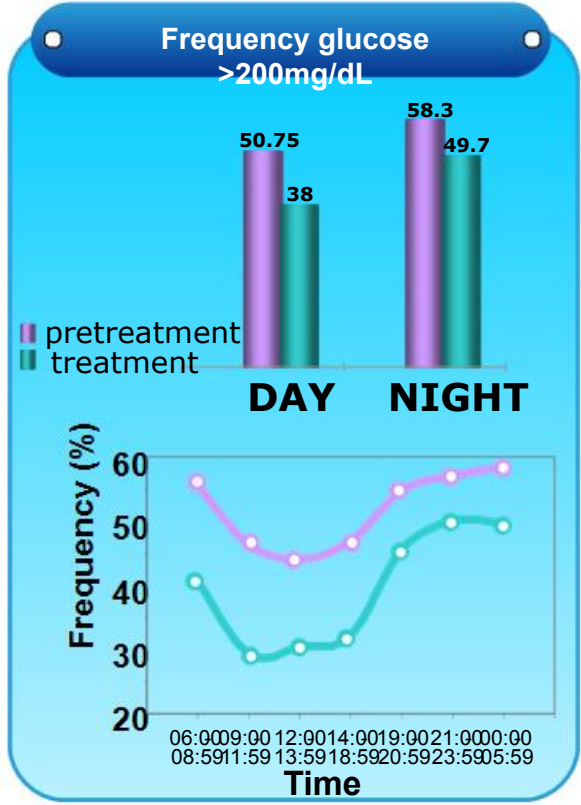
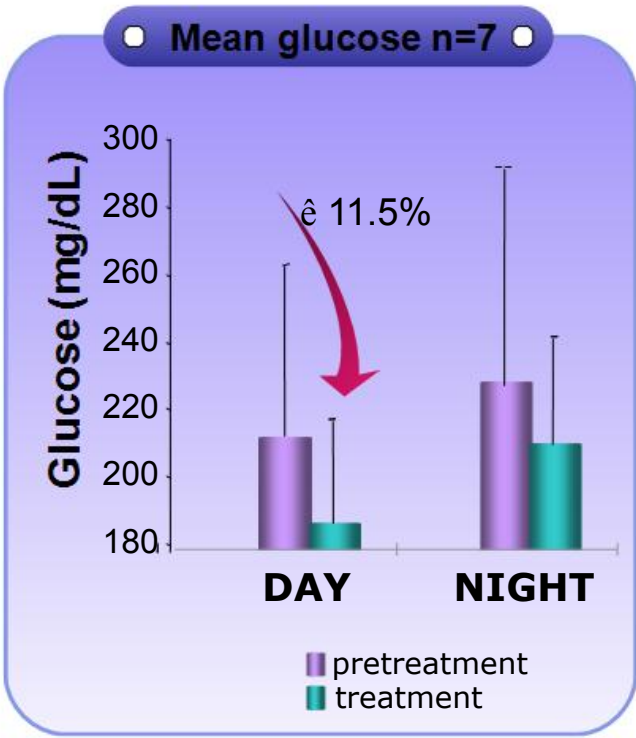
**mg/dL·hr<sup>-1</sup>** (Clement et al, 2002, Diabetes Technol Ther 4(4):459)



Subject #	Rate of glucose change (mg/dL·hr <sup>-1</sup> )
2	43.7
3	-0.7
4	-15.5
5	10.9
6	-6.1
7	-28.7
8	-18.4
9	5.5

ORMD-0801 effectively prevented the expected rise in blood glucose concentrations among fasting T1DM subjects

# ORMD-0801



**Design:** 7 T1DM, monitor glycemic stability of one orally administered ORMD-0801 formulation (1 capsule (8 mg insulin) before meals, three time daily). Glucose monitored with continuous, blinded glucose monitor

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

# ORMD-0901

*Oral Exenatide*  
*T2DM*

# Oral Exenatide (GLP-1 Analog)

## GLP-1: Hormone Facts

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- Secreted by the intestines
- Has an effect on the satiety center in the brain
- Has effect on pancreatic B-cells

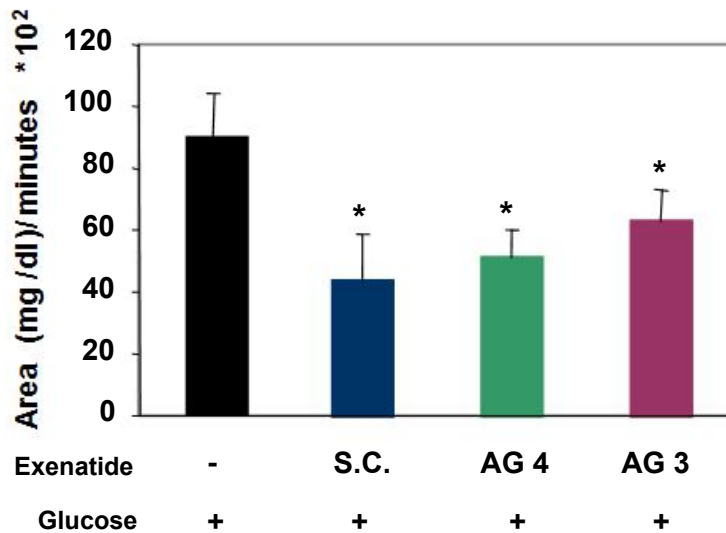
## GLP-1 Analog: Drug Facts

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- Has excellent 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**

# Oral Exenatide - ORMD-0901

Blunting of glucose excursions in dogs



## Methods:

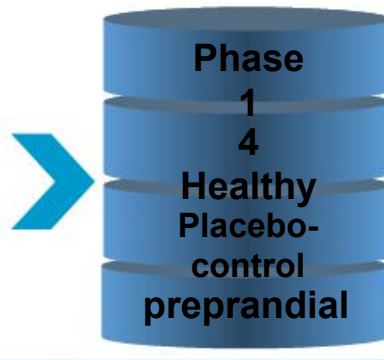
- Ø Healthy, fasting, cannulated dogs
- Ø Single dose ORMD-0901 formulations
- Ø Administered 30 minutes before a glucose challenge.
- Ø Blood samples collected every 15 minutes.

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

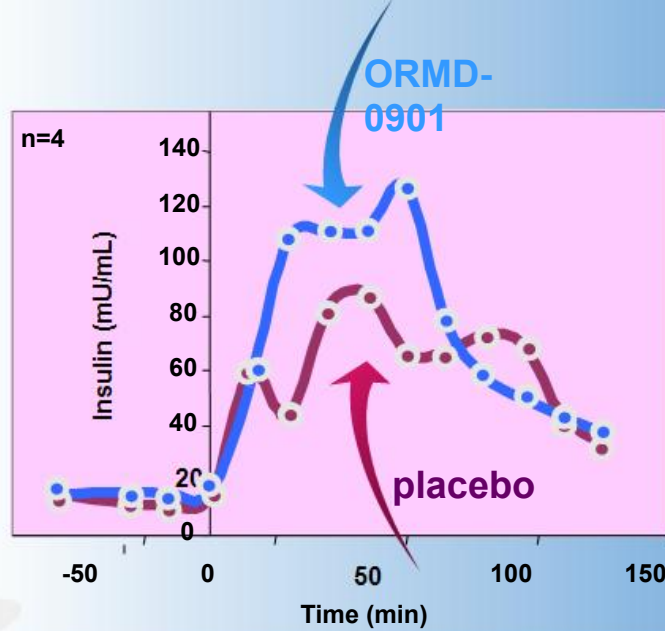
**ORMD-0901 formulations preserved the biological activity of orally delivered exenatide. ORMD-0901 successfully curbed blood sugar excursions following glucose challenge.**



ORMD-0901



**FIRST  
IN  
HUMAN**



**Mean AUC**

Placebo: **148.5±30.5**

Insulin: **180.3±106.3**

**21%**

**150 mg  
exenatide**

**NO  
NAUSEA**



# Oramed

## *Corporate Overview*



# Management

## Nadav Kidron, Esq., MBA - Chief Executive Officer & Director

- Experience in various industries, Including corporate law and technology
- Advisory Board member - EnteraBio, Trendlines Group

## Miriam Kidron, PhD - CSO & Director

- Senior Researcher at the Diabetes Unit of Hadassah Medical Center for more than 25 years
- Leading researcher in oral insulin development

## Yifat Zommer, MBA - CFO

- Extensive Experience in corporate financial management
- Bachelor of Accounting and Economics from Hebrew University
- MBA from Tel Aviv University, CPA Israel

## Josh Hexter - COO, Vice President Business Development

- More than 15 years of prominent leadership and managerial roles in biotech and pharma - most recently with BioLineRX
- Master's degree in management from Boston University

## Ehud Arbit, MD - Director of R&D

- Former VP of Medical Research at Emisphere Technologies
- Former Division Head at Memorial Sloan Kettering Cancer Center

### **Board of Directors**

#### **Michael Berelowitz, PhD**

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

**Harold Jacob, MD**  
Former Chief Medical  
Officer, Given Imaging.

**Geral Ostrov**  
CEO, Bausch&Lomb  
(former); Senior level  
Executive J&J (former)

**Leonard Sank**  
Entrepreneur and  
businessman



# Scientific Advisory

## Board



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

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



**Prof. Derek LeRoith, MD, PhD**

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



**Prof. John Amatruda, MD**

- The Former Senior Vice President and Franchise Head of the Diabetes and Obesity Unit at Merck & Co.



**Prof. Avram Herskho, MD, PhD**

- Distinguished Professor in the Biochemistry Unit in the B. Rappaport Facility of Medicine in the Technion in Haifa.
- Nobel Laureate in Chemistry (2004) for the discovery of ubiquitin-mediated protein degradation.



**Prof. Nir Barzilai, MD**

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



**Prof. Ele Ferrannini, MD, PhD**

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

# Intellectual Property:

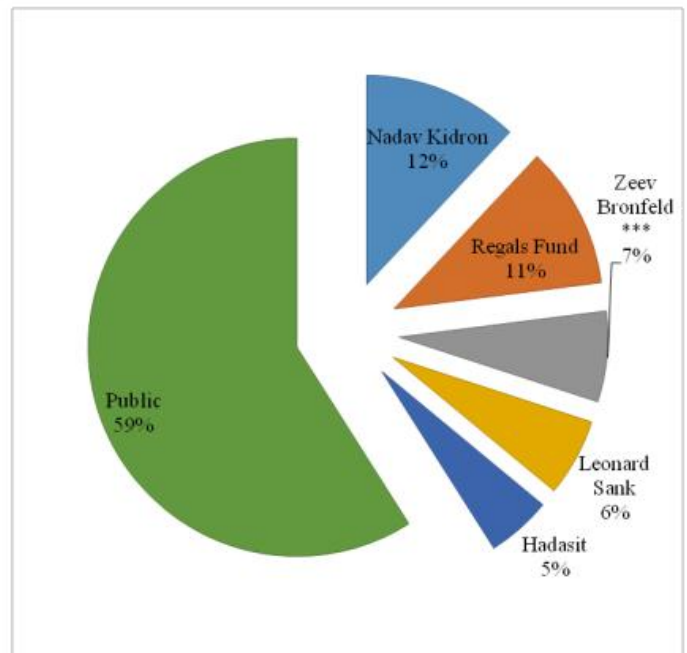
## Five primary worldwide patents

- Methods and Compositions for Oral Administration of Proteins (2 unique types)
  - Expire 2026 & 2028
  - [Approval granted in Israel, Japan, Australia and New Zealand](#)
  - Pending in multiple jurisdictions, including the US
- Methods and Compositions for Oral Administration of Exenatide
  - Expires 2028
  - [Approval granted in New Zealand](#)
  - Pending in multiple jurisdictions, including the US
- Methods and Compositions for Treating Diabetes
  - Expires in 2032, Pending status, including the US
- Protease inhibitor-containing compositions and compositions comprising same
  - Expires in 2032, Pending status, including the US

# Financial Overview 2013\*

## Ticker: NASDAQ: ORMP

- \$20.7M raised to date
- No Debt
- Cash and investments: \$4.2M
- Shares Issued: 7.2M
- Fully diluted: 9.5M\*\*



\* As of June 1, 2013

\*\* Including outstanding 0.9M options and 1.5M warrants.

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

# Capitalization Structure

Capitalization	Outstanding	% Outstanding
Common Stock	7,226,423	75.35%
Stock Options	857,158	8.94%
Warrants	1,506,410	15.71%
Fully-diluted Shares Outstanding	9,589,991	100%

# Anticipated Use of Proceeds 2013-2015

## ORMD-0801, Oral Insulin

- Type II Diabetes:
  - Phase IIa in the U.S
  - Phase IIb in the US
- Type I Diabetes:
  - Phase II ex-US study

## ORMD-0901, Oral Exenatide

- Phase II (ex-US) – T2DM
- Initiation of FDA studies in US (pre-IND and IND)

## Working Capital

- The remainder will be used for working capital and general corporate purposes.

- Anticipated 2013 expenditures (Q3-Q4): \$2.5M
- Anticipated 2014 expenditures (Q1-Q4): \$8M



# In Summary



- Orally ingestible insulin capsule entering Phase 2 clinical development under the US FDA IND
- Product pipeline with the potential to expand to other indications
- Proprietary technology platform for oral delivery of peptides
- World-leading scientific team
- Strong IP
- Clear proof of concept
- Significant market opportunity
- Experienced management team



# Anticipated Milestones



## **ORMD-0801 (Oral Insulin):**

- Initiation and completion of Phase IIa (T2DM)
- Initiation of PIIb multi-site study under US IND (T2DM)
- Initiation of PII multi-site ex-US study (T1DM)



## **ORMD-0901 (Oral Exenatide):**

- Filing pre-IND
- Initiation of IND-enabling studies
- Initiation of PII ex-US multi-center study

# Breakthrough Technology for a Brighter Future



**Contact :**

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CEO

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