Corporate Presentation

May 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.

oramed Pharmaceuticals Inc

Oramed Overview

Technology pioneer in the field of oral delivery solutions for drugs and vaccines that are currently delivered as injections

Clinical programs focused on Type 1 and Type 2 diabetes

Founded in 2006 by its scientific inventors after more than two decades of research

Publicly traded – NASDAQCM:ORMP

Market Capitalization: $107 MM*
Cash and investments: $23.8M, no debt

Corporate and R&D Headquarters in Jerusalem, Israel

* as of April 28, 2014

oramed Pharmaceuticals Inc

Investment Highlights

Proprietary Protein Oral Delivery (POD™) platform technology

For the oral delivery of drugs that are currently only available via injection

Product Pipeline

- Oral Insulin (ORMD-0801)
  - Type 2 diabetes
  - Type 1 diabetes
- Oral GLP-1 Analog (ORMD-0901)
- Combination Therapy (ORMD 0801 + 0901)

Proof of Concept established in preclinical and clinical trials

Commercial Opportunity: lead product targets $15+ billion insulin market

Versatile oral delivery technology serves as a platform for other medications currently available in injection form

Experienced management team backed by world-leading scientific experts

oramed Pharmaceuticals Inc

Agenda Overview

Oral Administration

The Challenge
The Oramed Solution

Diabetes

Statistics and Market

Oramed Pipeline

Oral Insulin
Oral GLP-1 Analog

Corporate Overview

Management Team
Scientific Advisory Board
Intellectual Property
Financials

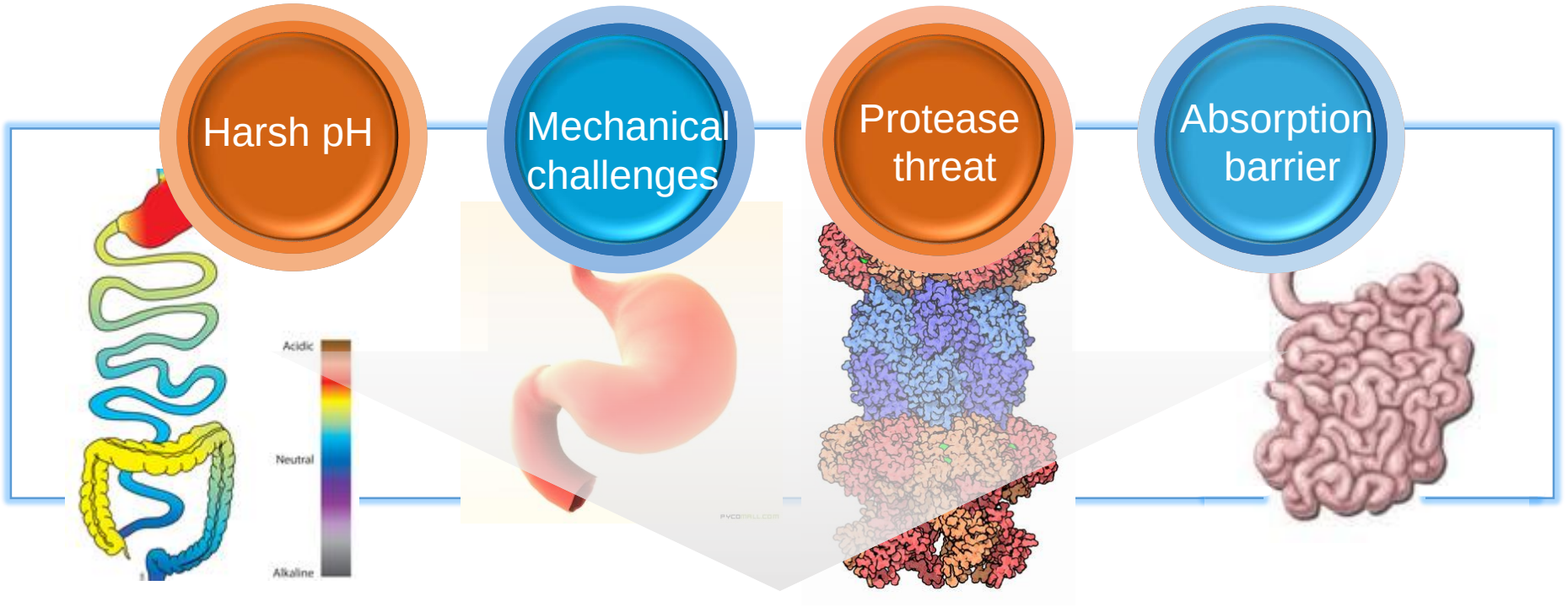
oramed
Pharmaceuticals Inc

Oramed

An Oral Solution

oramed Pharmaceuticals Inc

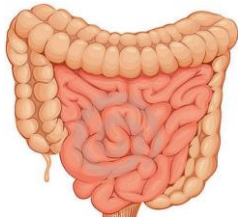
Fate of proteins/peptides in GIT



Leads to protein breakdown and lack of absorption

oramed Pharmaceuticals Inc

Oramed POD™ Technology: The Solution



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

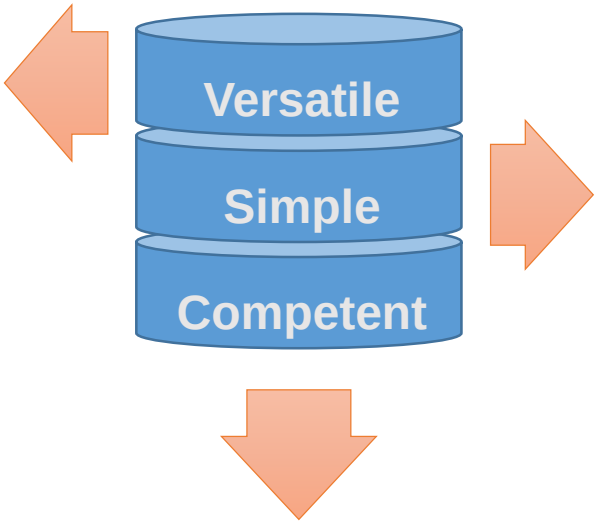
Oramed's delivery platform **protects proteins** and **enhances their absorption**, allowing them to reach the bloodstream via the portal vein, thereby establishing a **more physiologic protein gradient when compared to other delivery systems.**

oramed Pharmaceuticals Inc

Oramed POD™ Technology

Versatile

Supports a wide range of protein sizes and doses



Simple

Simple blend of ingredients

Regulatory competence

No NCEs;
widely applied pharmacopoeia

oramed Pharmaceuticals Inc

Potential Oramed Technology Applications: Opportunities & Market

Insulin

$15+ billion 2012 global insulin market

$32 billion projected market for 2018

GLP-1 Analog

$2+ billion 2012 global GLP-1 market

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

Other

Vaccines: **$24 billion** in 2013 – grew from $5 billion in 2000

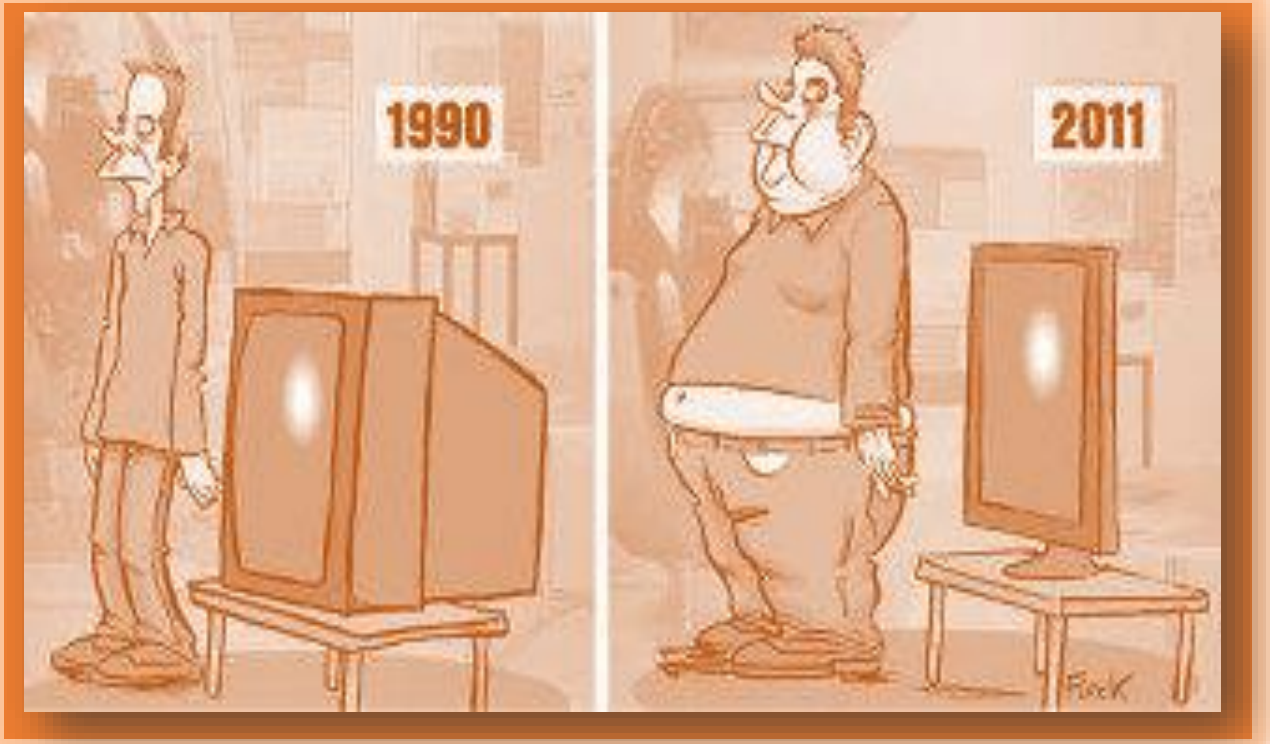
Flu vaccine estimated at **$2.9 billion** in 2011 to $3.8 billion in 2018

Interferon: **$6.3 billion**, 2011 global market

oramed Pharmaceuticals Inc

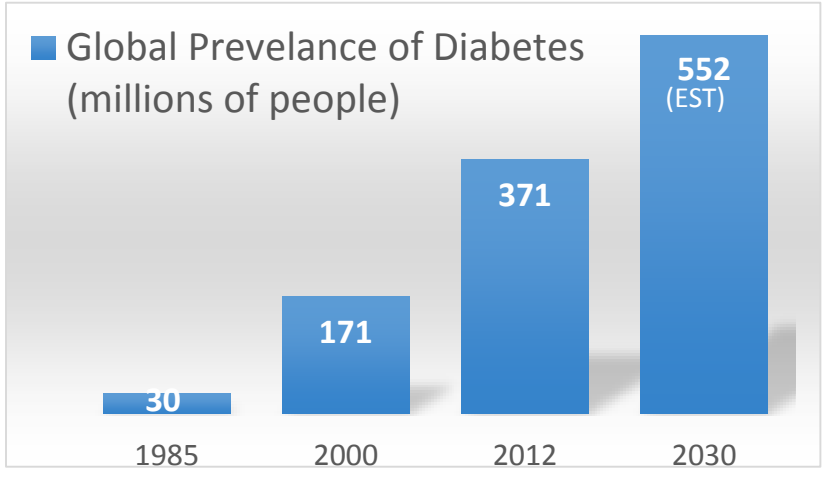
Diabetes:

A Global Epidemic



oramed Pharmaceuticals Inc

Diabetes: A Global Epidemic



POPULATION

- **371 million**: Number of diabetics worldwide
  - 25.8 million in the US – projected to 44.1 million by 2034
- Type 2 diabetes accounts for about 90% of diabetes cases

COST

- $**471 billion**: estimated annual global economic burden – includes direct medical costs, disability, reduced productivity
  - America: approx. $176 billion in direct medical costs and $69 billion in reduced productivity
  - Projected American economic burden for direct medical costs **alone** by 2034 - **$336 billion** (based on current obesity levels, *Diabetes Care*, 2009).

oramed Pharmaceuticals Inc

Oramed Pipeline

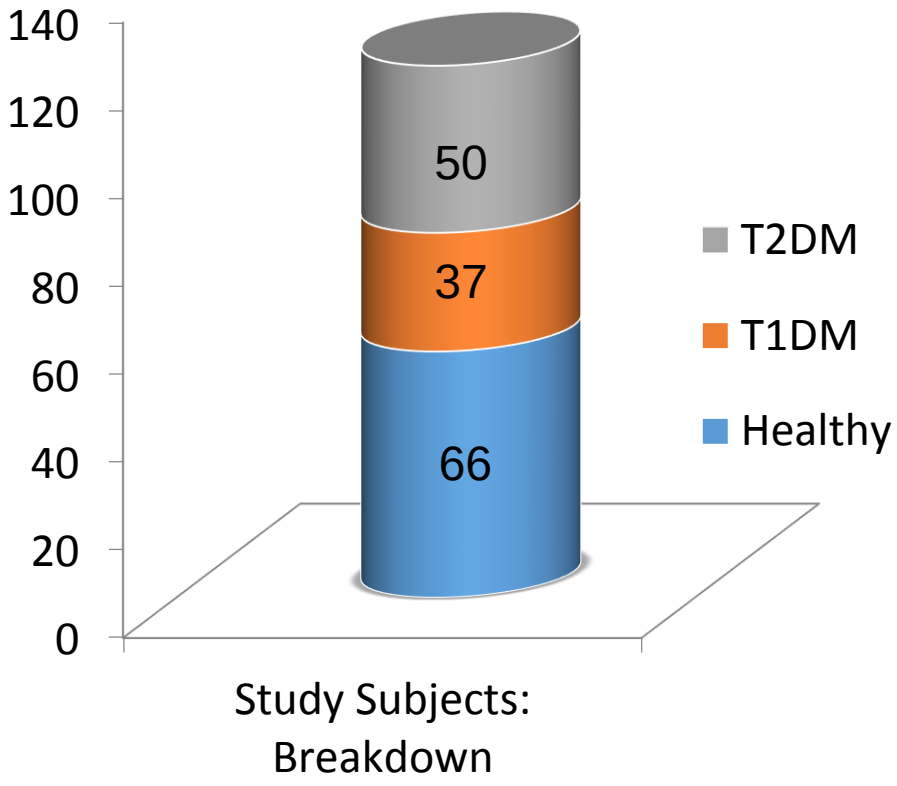
oramed
Pharmaceuticals Inc

ORMD-0801

Oral Insulin

oramed Pharmaceuticals Inc

ORMD-0801: Oral Insulin Administrations To-date



Total number of study subjects:

153

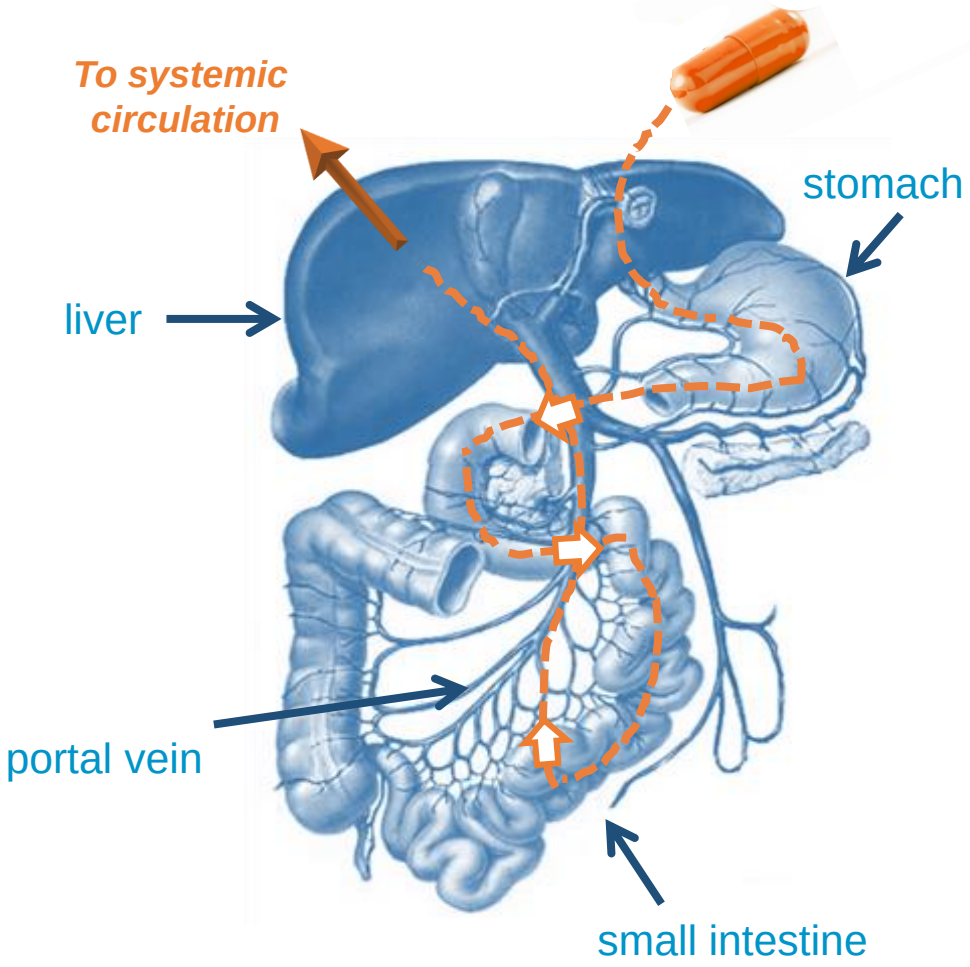
Total number of human doses:

1632

As of Nov 12, 2013

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

- Blood glucose - insulin secretion system forms a 'closed-loop'
- Peripheral insulin promotes glucose uptake in fat and muscle
- First-pass hepatic metabolism extracts 80% of secreted insulin
- Systemic exposure is minimized



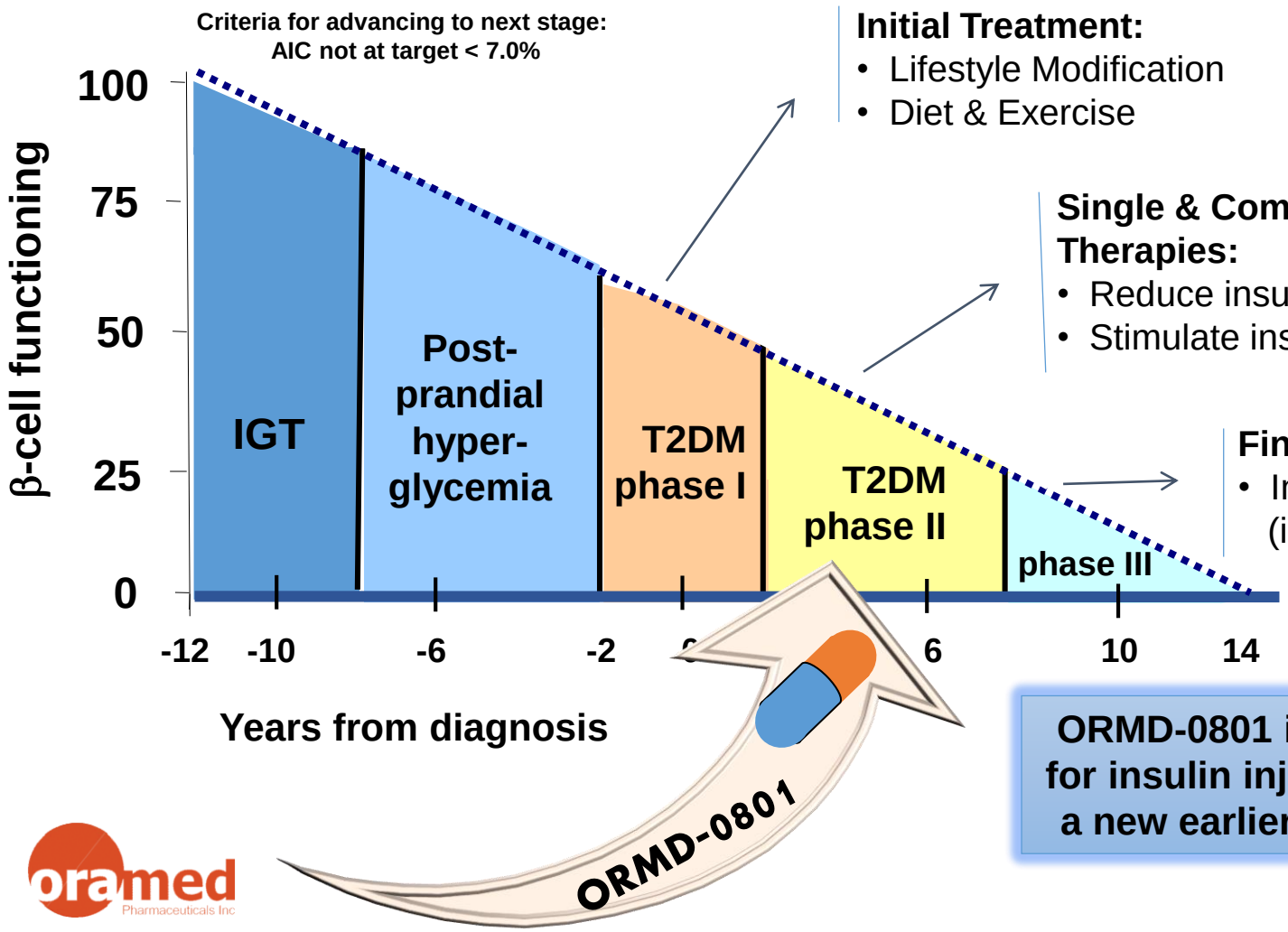
oramed Pharmaceuticals Inc

ORMD-0801

Type 2 Diabetes (T2DM)

oramed Pharmaceuticals Inc

Type 2 Diabetes: Stages & Treatment Options



Initial Treatment:
- Lifestyle Modification
- Diet & Exercise

Single & Combination Oral Therapies:
- Reduce insulin resistance
- Stimulate insulin secretion

Final Treatment:
- Insulin Replacement (injections)

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

oramed Pharmaceuticals Inc

Unique Initial Indication

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: Unique Indication

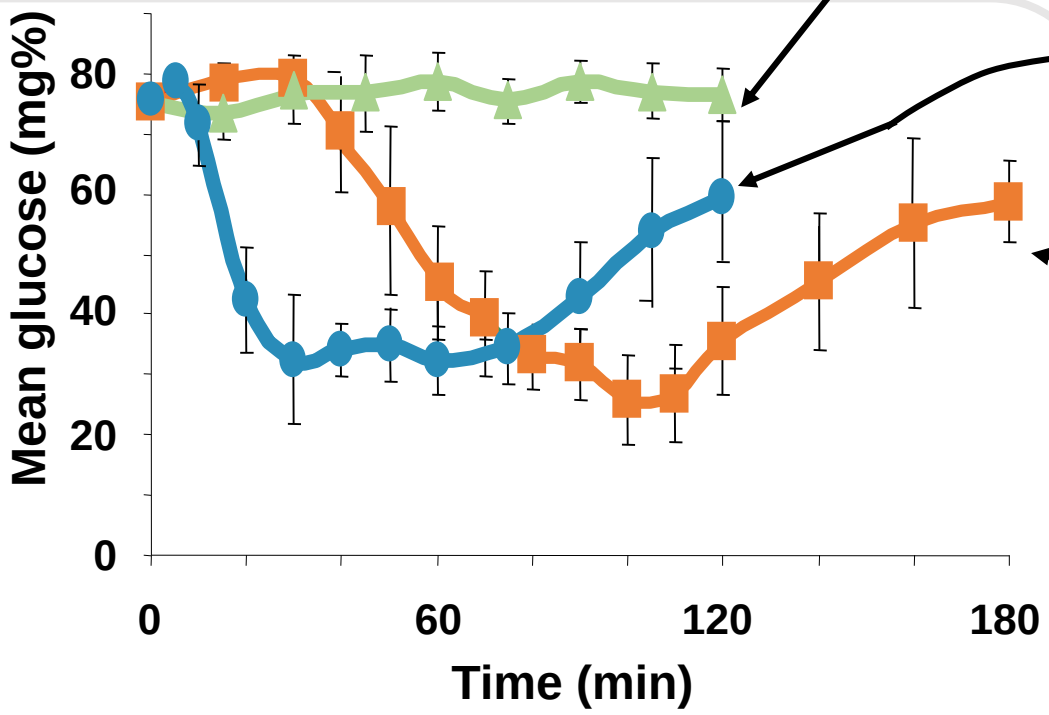
- Nighttime dose
- Focused on reducing the excessive nocturnal glucose production from the liver

oramed Pharmaceuticals Inc

ORMD-0801: Preclinical - Dogs

n=4

8 mg insulin



8 mg insulin, no additives

1.5 U NovoRapid

ORMD-0801 (C)

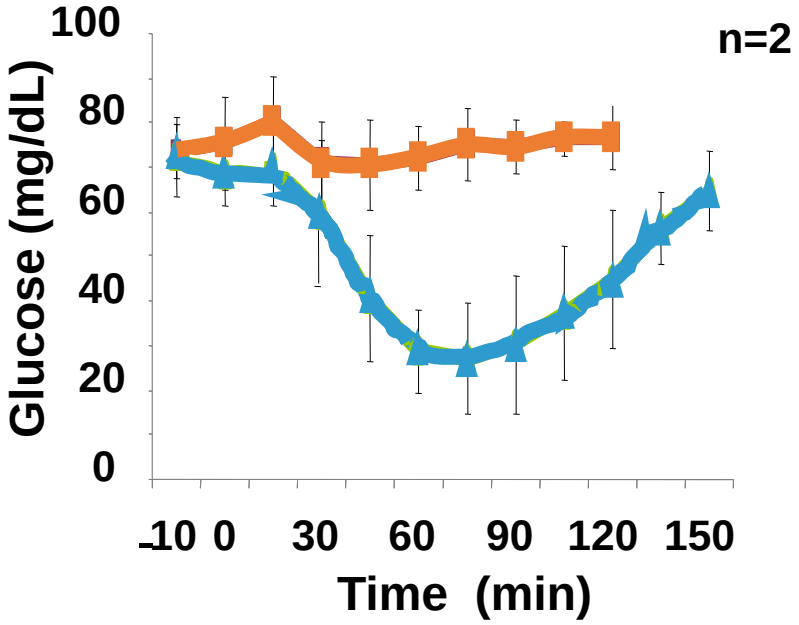
- Healthy, non-diabetic, cannulated beagle dogs showed a 60-75% drop in blood glucose levels within 30-100 minutes of treatment
- No hypoglycemia or adverse events were observed over the three years of testing

oramed Pharmaceuticals Inc

ORMD-0801: Preclinical - Pigs

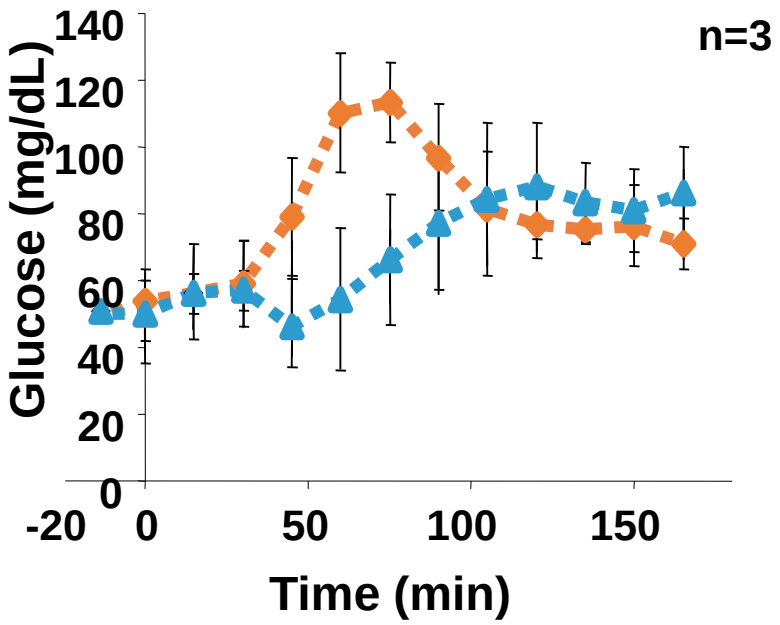
8 mg insulin

Fasting



NC; 4 independent test sessions
ORMD-0801; 10 independent sessions

Pre-prandial



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

No hypoglycemia or adverse events were observed

ORMD-0801 Trial Results: A Summary

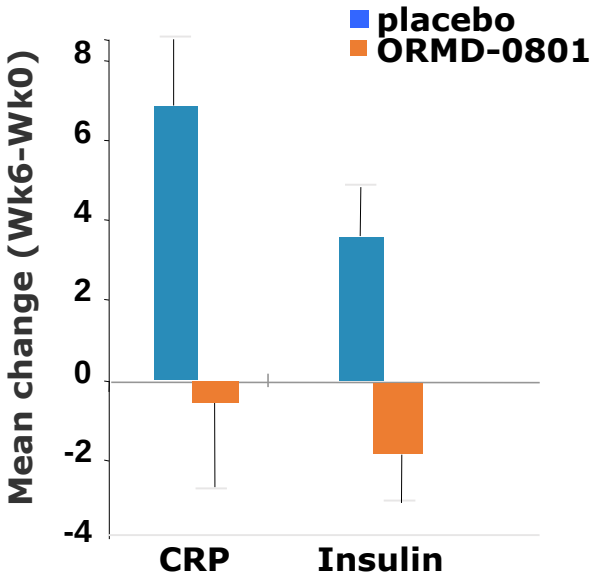
Pre-clinical

- 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, Cmax, Tmax, T½*
  - *Changes from baseline in FBG, morning fasting insulin, C-peptide*

oramed Pharmaceuticals Inc

Phase IIa: Primary Objective Safety

Hypoglycemic Events		**0**
Serious Adverse Events		0
Severe Adverse Events		0
ORMD 0801 Related Adverse Events		0
Adverse Events (non treatment related):		
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

oramed Pharmaceuticals Inc

Phase IIa: Secondary Objective

Mean night time glucose concentrations (CGM)

Night time mean (SD) CGM Glucose – mg/DL[(1)]	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

oramed Pharmaceuticals Inc

Phase IIa: Secondary Objective

Mean daytime glucose concentrations (CGM)

Daytime mean (SD) CGM Glucose – mg/DL [1]	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

Summary

ORMD-0801: Phase IIa T2DM

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

ORMD-0801

Type 1 Diabetes

(T1DM)

oramed Pharmaceuticals Inc

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

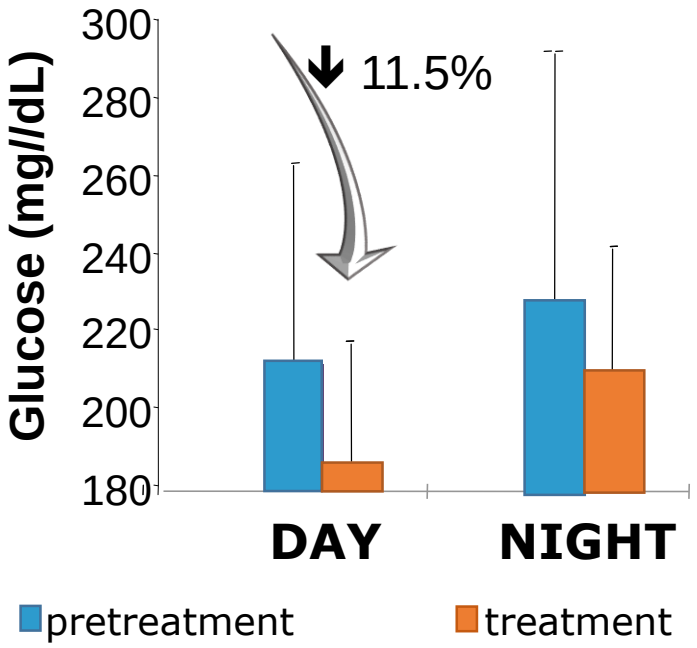
ORMD-0801 Oral Insulin and T1DM

- **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.

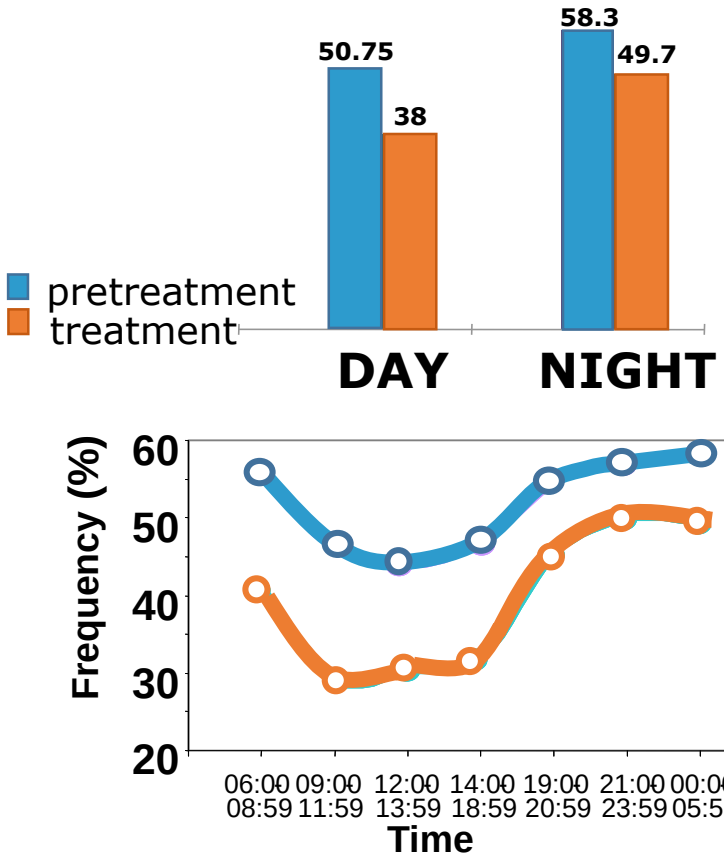
oramed Pharmaceuticals Inc

ORMD-0801: T1DM

Mean glucose n=8



Frequency glucose >200mg/dL



Results: Safe, well tolerated, reduced glycemia.

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

oramed Pharmaceuticals Inc

ORMD-0901

Oral GLP-1 Analog (T2DM)

oramed Pharmaceuticals Inc

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 β-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**

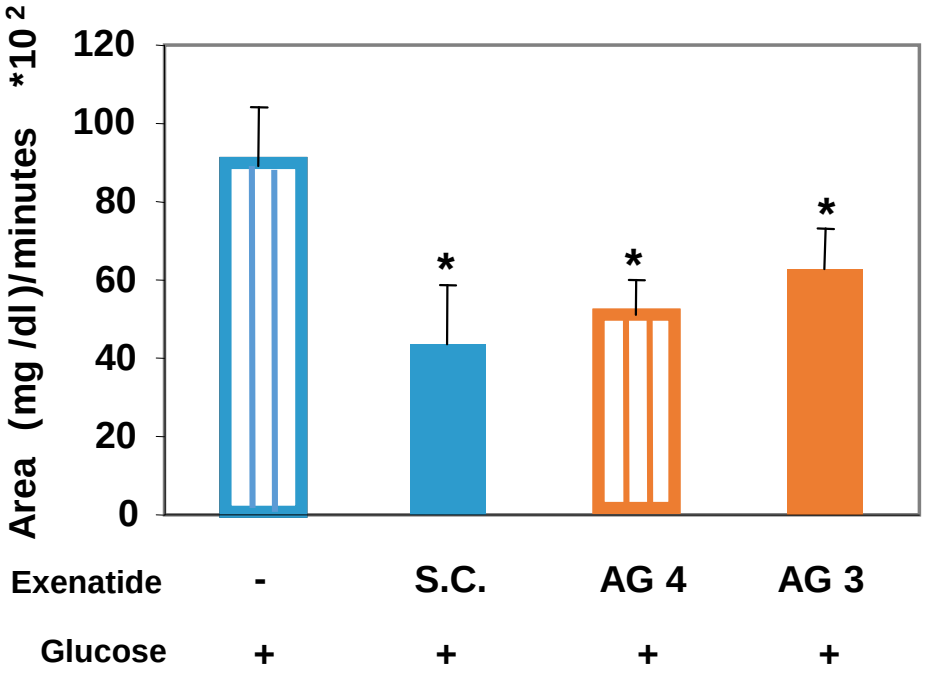
ORMD-0901 Oral GLP-1

- Pre-IND package submitted to the US FDA Q3 2013
- IND enabling tox studies Q2, 2014
- PIb ex-US study Q2, 2014

oramed Pharmaceuticals Inc

Oral GLP-1 – ORMD-0901

Blunting of glucose excursions in dogs



Methods:

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

Results: Subcutaneous exenatide delivery amounted to a 51% reduction in mean glucose $AUC_{0\text{-}150}$, 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.

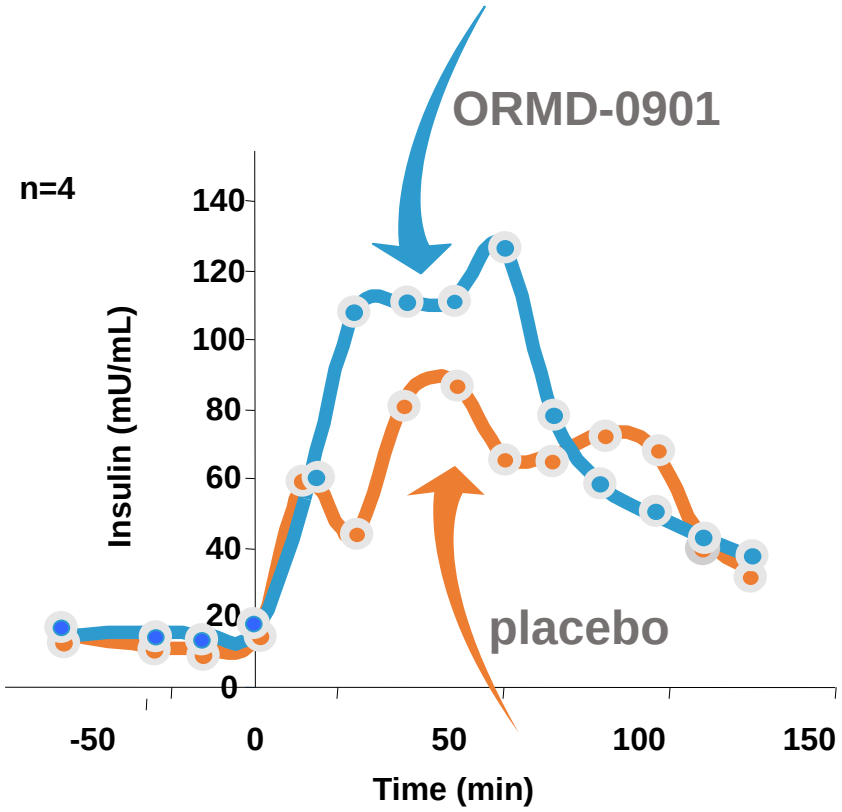
oramed Pharmaceuticals Inc

ORMD-0901 - T2DM

Study

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

150 μg exenatide



Mean AUC

Placebo: 148.5±30.5

No Nausea

Insulin: 180.3±106.3

↑ 21%

oramed Pharmaceuticals Inc

Pipeline Overview

		Phase I	Phase II	Phase III	Timeline
ORMD-0801 oral insulin	Type 2 diabetes				Q4, ‘13: Phase 2a completed Q3, ’14: Phase 2b multi-center study projected initiation
	Type 1 diabetes				Q1, ’14: Phase 2a projected initiation Q1, ’15: Phase 2b multi-center study projected initiation
ORMD-0901 oral GLP-1	Type 2 diabetes				Q3, ’14: Preclinical/IND studies projected initiation Q2, ’14: Phase 1b ex-US study projected initiation Q2, ’15: Phase 2 multi-center study projected initiation

Corporate Overview

oramed Pharmaceuticals Inc

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

Ehud Arbit, MD – Director of R&D

Former VP of Medical Research at Emisphere Technologies

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.

John Amatruda, MD

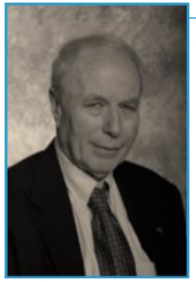
- Former SVP and Franchise Head of the Diabetes and Obesity Unit at Merck & Co.

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.

Derek LeRoith, MD, PhD

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



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

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

Nir Barzilai, MD

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

oramed Pharmaceuticals Inc

Intellectual Property: Five Primary Worldwide Patent Families

Methods and Compositions for Oral Administration of Proteins (Platform Technology) – 2 unique types

- Expire 2026 & 2028
- Approved or Granted in Israel, Japan (both types), EU, Russia, China, Canada, Australia (both types), New Zealand and South Africa
- Pending in multiple jurisdictions, including the US

Methods and Compositions for Oral Administration of Exenatide

- Expires 2028
- Approved or Granted in Australia, New Zealand and Israel
- Pending in multiple jurisdictions, including the US

Methods and Compositions (Insulin + Exenatide)

- Expires in 2032
- Pending status, including the US

Improved Protease Inhibitors

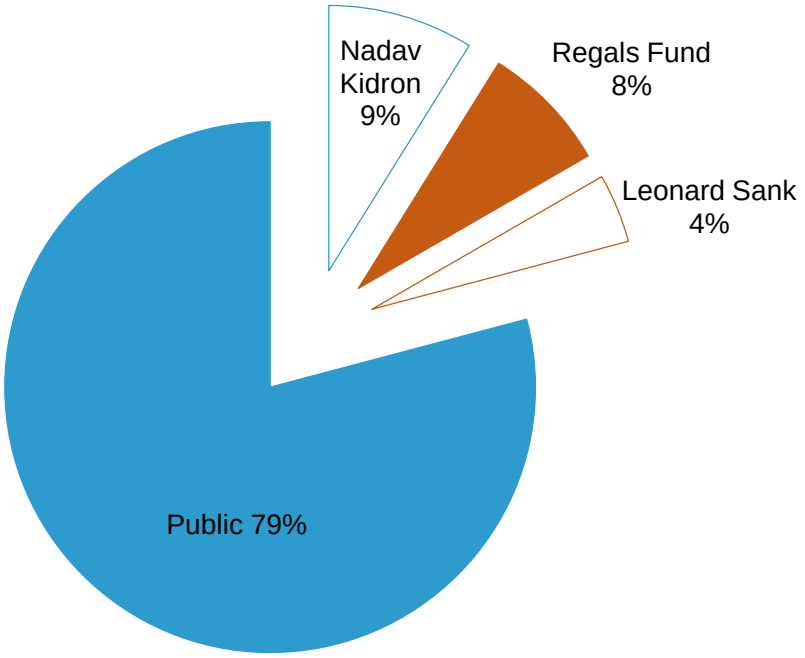
- Expires in 2032
- Pending status, including the US

oramed Pharmaceuticals Inc

Financial Overview*

Ticker: NASDAQ: ORMP

- $43M raised to date **
- No Debt
- Cash and investments: $23.8M
- Shares Issued: 9.7M
- Fully diluted: 11.9M ***



* As of January 14, 2014

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

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

oramed Pharmaceuticals Inc

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

ORMD-0901
Oral GLP-1Analog

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

oramed Pharmaceuticals Inc

In Summary

- Proprietary technology platform (POD™) for oral delivery of peptides
- Orally ingestible insulin capsule in Phase II clinical development in the US
- Clear proof of clinical concept
- Product pipeline with the potential to expand to other indications
- Significant market opportunity
- Experienced management team backed by
- world-leading scientific experts
- Strong IP
- Meaningful news flow 2014-15

oramed Pharmaceuticals Inc

Breakthrough Technology for a Brighter Future

oramed Pharmaceuticals Inc

Contact :

Nadav Kidron

CEO

nadav@oramed.com

Josh Hexter

COO

josh@oramed.com

Appendix:

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

Presented at the GTC Diabetes Summit
April 24, 2014

Oramed Background

Oramed POD™ Technology:

Enteric Coating

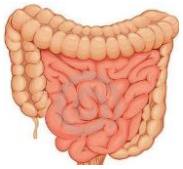
pH sensitive – only degrades in the small intestine, thus protecting capsule constituents during travel through the upper gastrointestinal tract

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.**

Ve

oramed Pharmaceuticals Inc

Phase IIa trial under US IND

Study ORA-D-009

Study Rationale

ORA-D-009 was a sub study 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.

ORMD-0801: Phase IIa FDA Study

Overview:

- Randomized, double-blind, placebo-controlled
- 30 male or female adult T2DM patients inadequately controlled with diet and metformin
- US-site
- In-patient setting
- 1 week of treatment
- Treatment: 16 mg or 24 mg insulin, or placebo, at bedtime.

Study Objectives

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

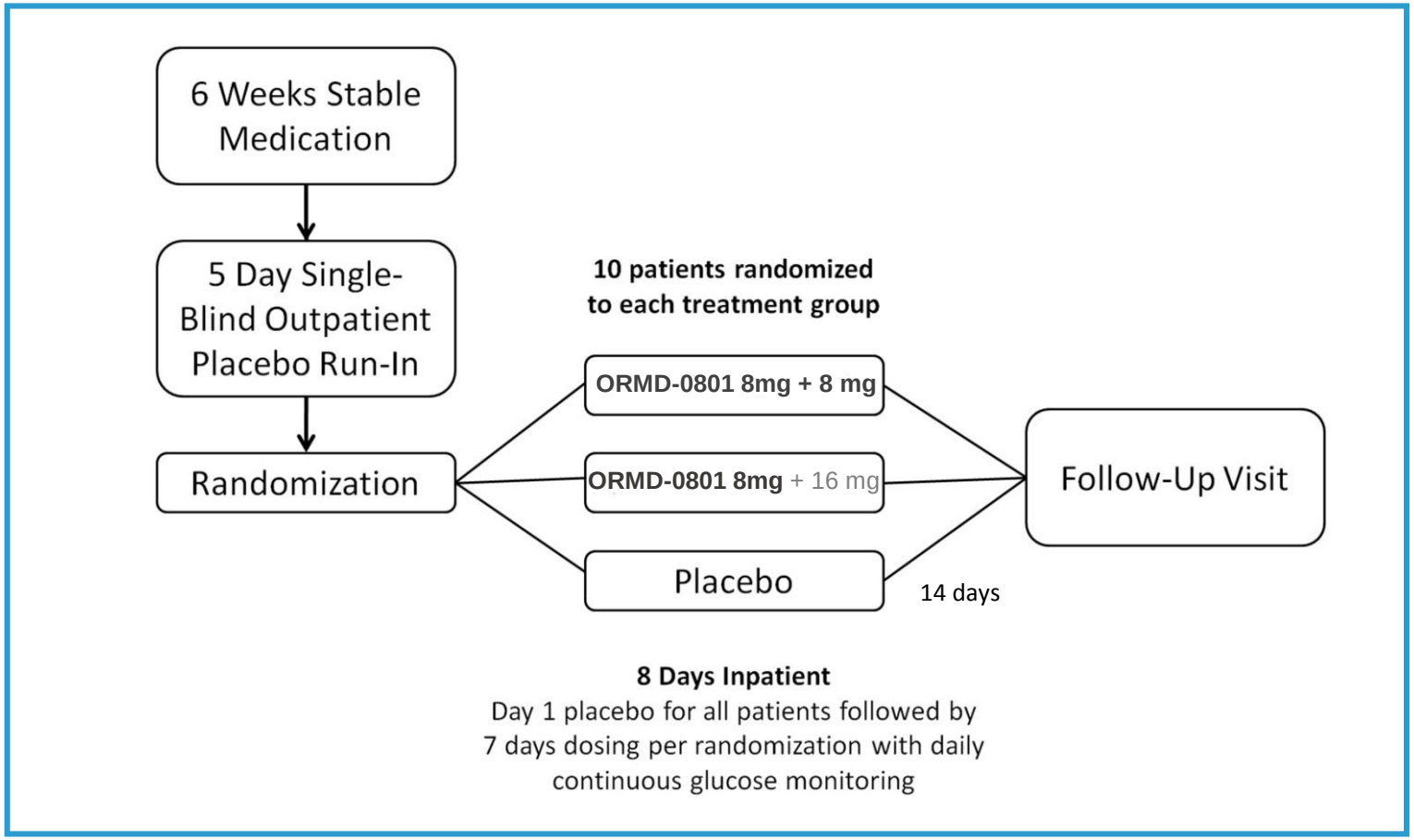
- First group received two 8 mg gel caps
- Second dose group received one 8mg and one 16 mg gel cap

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 addressed***

oramed Pharmaceuticals Inc

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)

oramed Pharmaceuticals Inc

Results

Phase IIa: Primary Objective Safety

Hypoglycemic Events		**0**
Serious Adverse Events		0
Severe Adverse Events		0
ORMD 0801 Related Adverse Events		0
Adverse Events (non treatment related):		
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

oramed Pharmaceuticals Inc

Phase IIa: Secondary Objective

Mean night time glucose concentrations (CGM)

Night time mean (SD) CGM Glucose – mg/DL[(1)]	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

Phase IIa: Secondary Objective

Mean daytime glucose concentrations (CGM)

Daytime mean (SD) CGM Glucose – mg/DL [1]	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

Phase IIa: Secondary Objective

Morning fasting serum insulin

Morning fasting serum insulin [2]	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)		17.34 (12.225)	
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

Phase IIa: Secondary Objective

Morning fasting C-peptide

Morning fasting C-peptide [2]	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)		3.125 (1.3372)	
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

Conclusions ORMD-0801: Phase IIa T2DM

Safety

- 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

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)