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

January 2022



## 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, including with respect to clinical trials, milestones and the potential benefits of Oramed's products, 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; expected timing of clinical studies for the potential Oravax Medical Inc. vaccine, its potential advantages, safety and efficacy and its potential to protect against COVID-19 and variants thereof; 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



## Company Overview

- **Proprietary oral protein delivery platform**
- Diabetes first - initially targeting the lucrative insulin market
- **NASDAQ/TASE: ORMP**



## Upcoming Catalysts

- **Robust pipeline** leveraging IP portfolio for additional significant market opportunities
- 88 granted patents, 35 pending patent applications, worldwide
- Multiple value-creation events for 2022



## Key Financial Metrics

- **Strong financial position**
- ~\$174M<sup>1</sup> in cash and investments
- No debt



## Company Management

- **Experienced management** team backed by world-class scientific experts



# Proprietary Technology for Oral Drug Delivery

## Proteins and Peptides do Not Survive the Digestive System

### Harsh pH

Stomach acidity cleaves and shreds protein

### Protease attack

Proteases attack and break down proteins

### Absorption barrier

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



## Oramed Technology Protects Drug Integrity and Increases Absorption

### pH shield

Sensitive enteric coating protects capsule contents before entering small intestine

### Protease protection

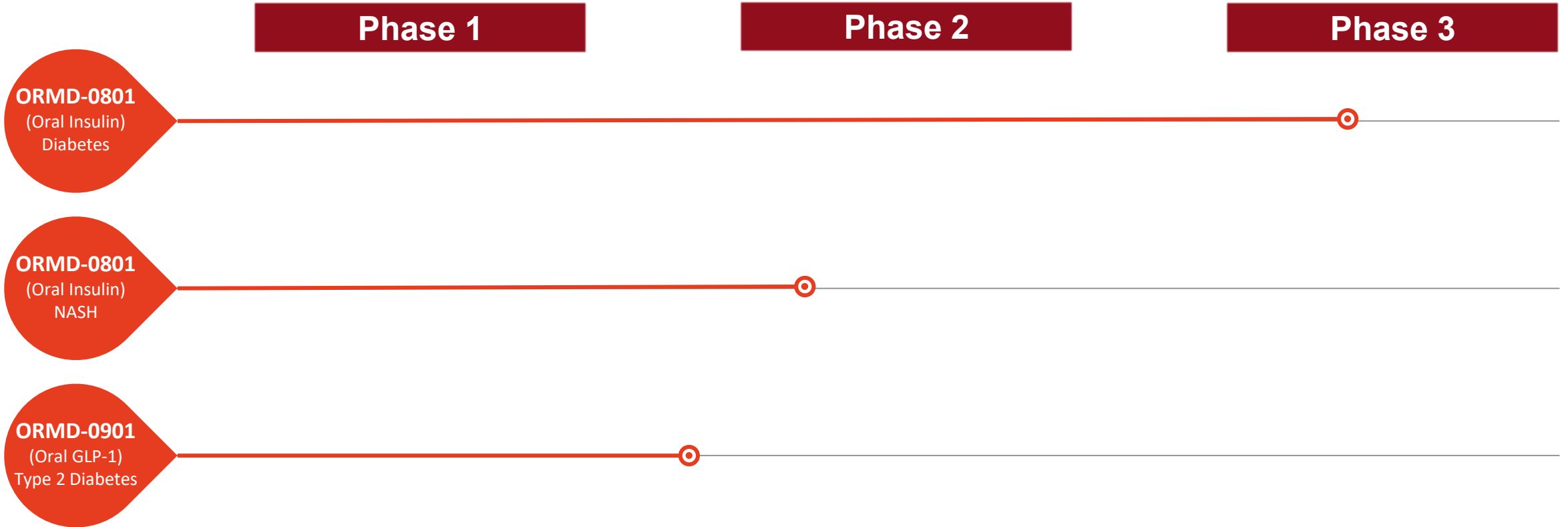
Protease inhibitors protect the active agent

### Absorption enhancement

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



# Multiple Clinical-Stage Programs



**Oravax's Oral Covid-19 Vaccine  
Phase 1 Trials Initiated**

**Exploratory Studies**  
**Leptin** (T1DM – PD: glucose and glycogen reduction; PK)



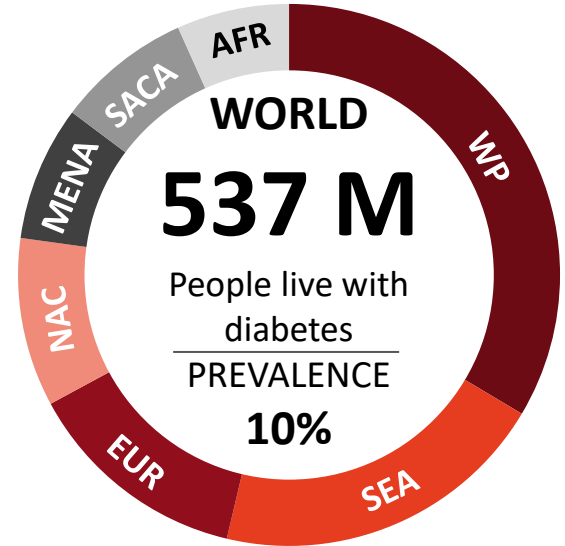
**Diabetes:**  
Millions of diabetics  
inject insulin today  
and wish for oral dosage

# 1 in 10 Adults on the Planet Have Diabetes

~ **10%** healthcare  
spent on diabetes



In 2021 diabetes expenditure reached **US \$ 966 billion**



2021



expected increase:

**+246**

**MILLION**

2045



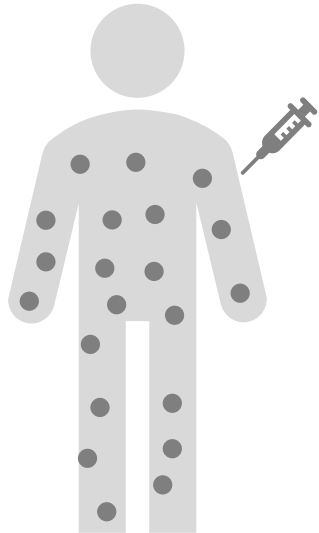


# ORMD-0801: Oral Insulin

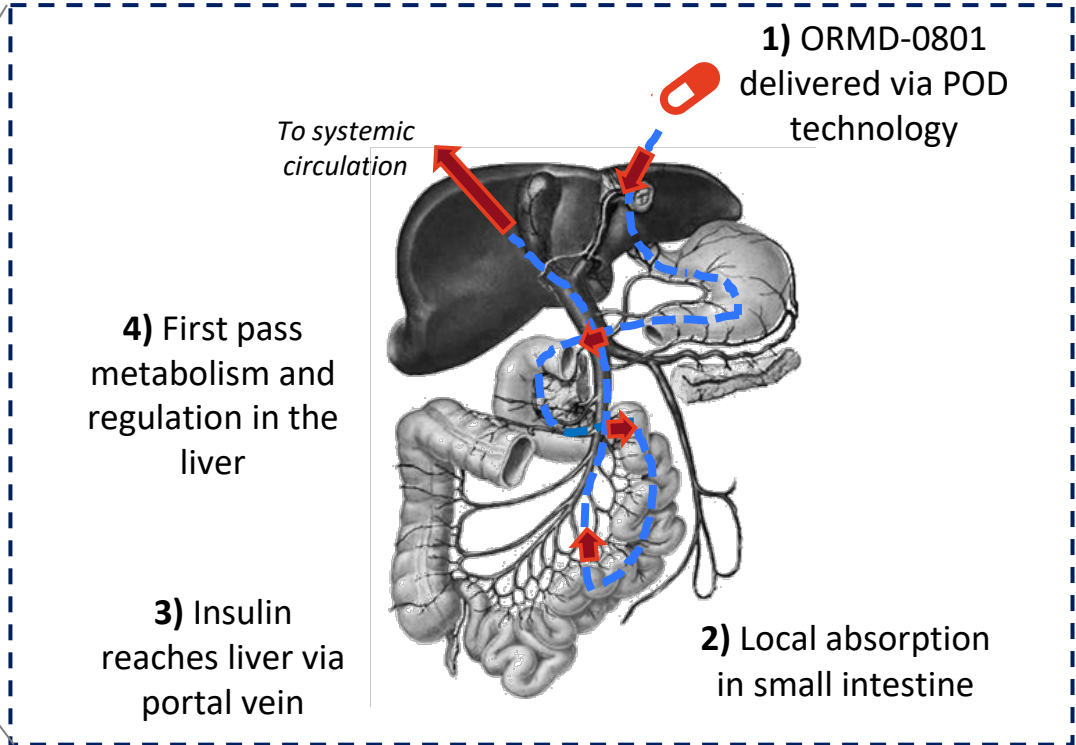
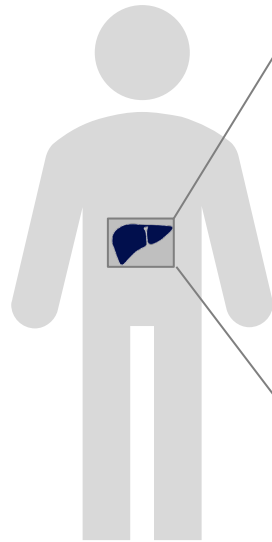


# Oral Insulin Mimics the Delivery of Endogenous Insulin

## Injectable Insulin Current



## Oral Insulin Future



**Injectable insulin** is introduced directly to the bloodstream, with only a small fraction reaching the liver, where endogenous insulin is regulated

**ORMD-0801** is delivered orally with first pass metabolism occurring in the liver, mimicking endogenous insulin regulation before reaching the bloodstream, thus reducing risks and complications associated with injectable insulin and enabling earlier patient engagement

# Oral Insulin: Significant Advantages Over Injectable Insulins

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## Advantages of ORMD-0801 Oral Insulin



### Improved Blood Glucose Control

Insulin is regulated endogenously in the liver, limiting the amount of excess systemic insulin that can lead to hypo/hyper-glycemic events



### No Weight Gain

Better insulin control prevents cells from absorbing excess glucose that can be converted to fat and lead to weight gain



### Ease of Administration

Oral delivery benefits diabetic patients with a fear of needles and should improve patient administration and compliance



**Diabetes inhibits the production of sufficient insulin and 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 54 million people worldwide have T1DM
- **Projected Market:** \$24 billion by 2029

### **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
- **483 million people worldwide need treatment**
- **Projected Market:** \$92 billion by 2029

## ORMD-0801 for Type 1 Diabetes (T1DM)

Potentially eliminating the need for insulin before each meal

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### T1DM patients are treated with various 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 oral insulin

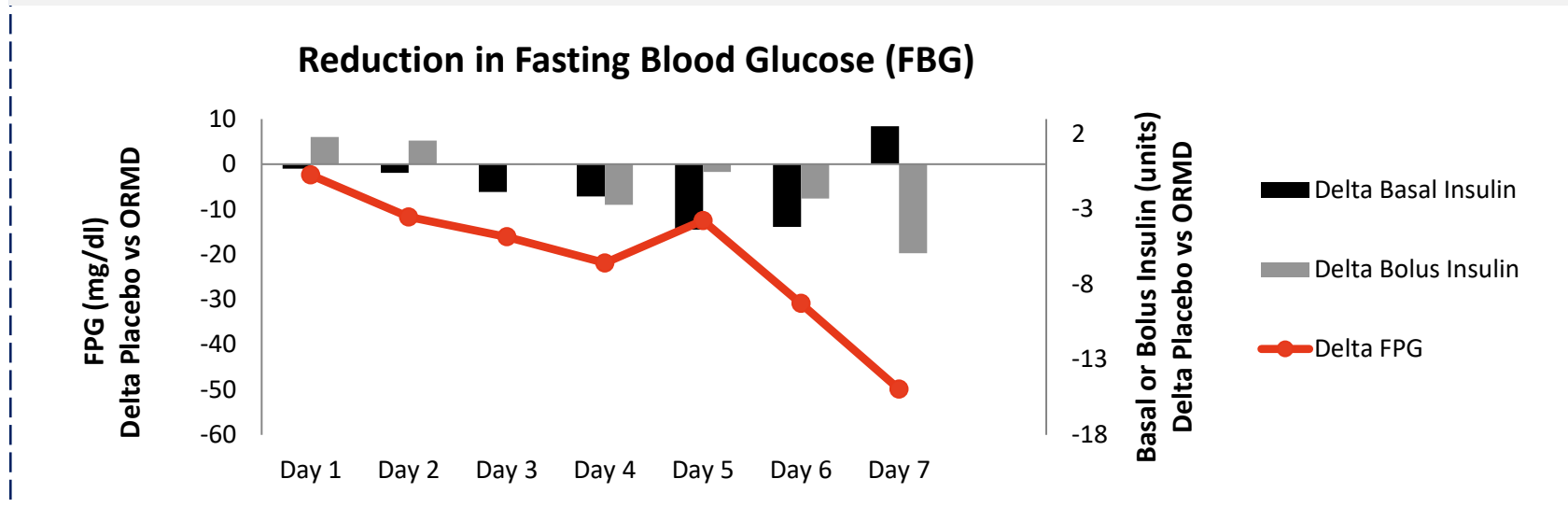
- Easier use and reduced systemic exposure
- Potentially reducing multiple daily injections
- Tighter regulation and control of blood sugar levels by directly targeting liver glucose (TiR), due to portal administration

## Phase 2a Trial in T1D Completed

By directly targeting liver glucose, ORMD-0801 may provide tighter blood sugar regulation and control for the ~1.6M<sup>1</sup> Type 1 diabetes patients in the US – potentially reducing the need for multiple daily injections, including mealtime insulin.

### Oral Insulin Reduces Exogenous Insulin Requirements

- Oral insulin met primary endpoint of reducing exogenous insulin requirements in Phase 2a T1D study
- Oral insulin decreased use of rapid-acting insulin, level of post-meal glucose, and levels of daytime glucose
- Additionally, day and night blood glucose levels were lower compared to control group



### T1D Phase 2a Highlights<sup>2</sup>

25

T1DM patients

7

days of treatment

3

times a day  
(at mealtime)

Note: (1) American Diabetes Association, <https://www.diabetes.org/resources/statistics/statistics-about-diabetes> (2) ClinicalTrials.gov Identifier = NCT02094534

## Phase 2 – Completed 180 Patient Trial for T2D

### Trial Highlights

33

US Sites

180

Patients

28

Day Treatment

2

Dose Groups<sup>1</sup>

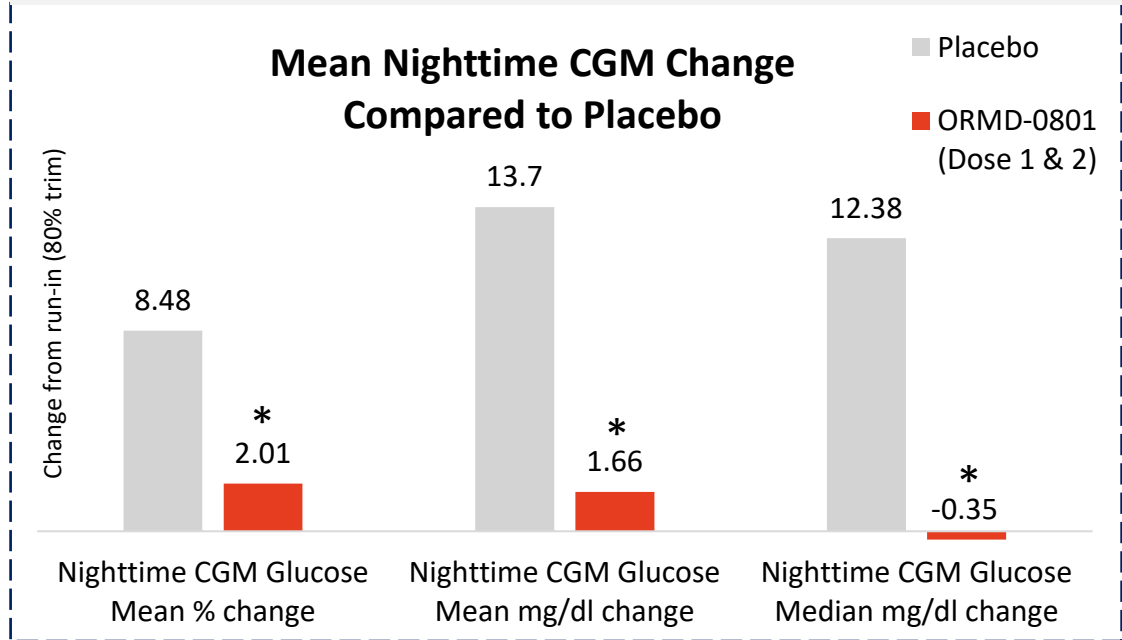
Design	<ul style="list-style-type: none"><li>• Double-blind, randomized, placebo-controlled, 4 week, once daily (3 capsules) treatment</li></ul>
Study Population	<ul style="list-style-type: none"><li>• Patients with T2D who (1) are being treated by diet and exercise, (2) are untreated with antidiabetic medications, or (3) are treated with metformin as a monotherapy or in combination with one other antidiabetic drug (excluding insulin) are eligible for enrollment</li></ul>
Endpoints	<ul style="list-style-type: none"><li>• <b>Primary:</b> mean nighttime glucose levels<sup>2</sup></li><li>• <b>Secondary:</b> mean 24-hour glucose<sup>1</sup>, percent change in CGM mean fasting glucose between treatment and run-in; change from baseline to Week 4 of morning fasting c-peptide; percent change in A1C from Baseline to Week 4</li></ul>
Dose Cohorts	<ul style="list-style-type: none"><li>• <b>Placebo:</b> 3x placebo capsules</li><li>• <b>Active:</b> 16mg (1 dose/capsule) and 24mg (1.5 dose/capsule)</li></ul>

Note: ClinicalTrials.gov Identifier = NCT02496000. (1) Trial only had 1 dose level, but patients were given either a full dose, or 1.5 doses (2) Based on 2 nights of CGM data by comparison of the mean percent change between Baseline and Week 4 of ORMD-0801 and placebo groups

# Phase 2 Trial Demonstrated No Drug Related Serious Adverse Events and Promising Efficacy on CGM Parameters

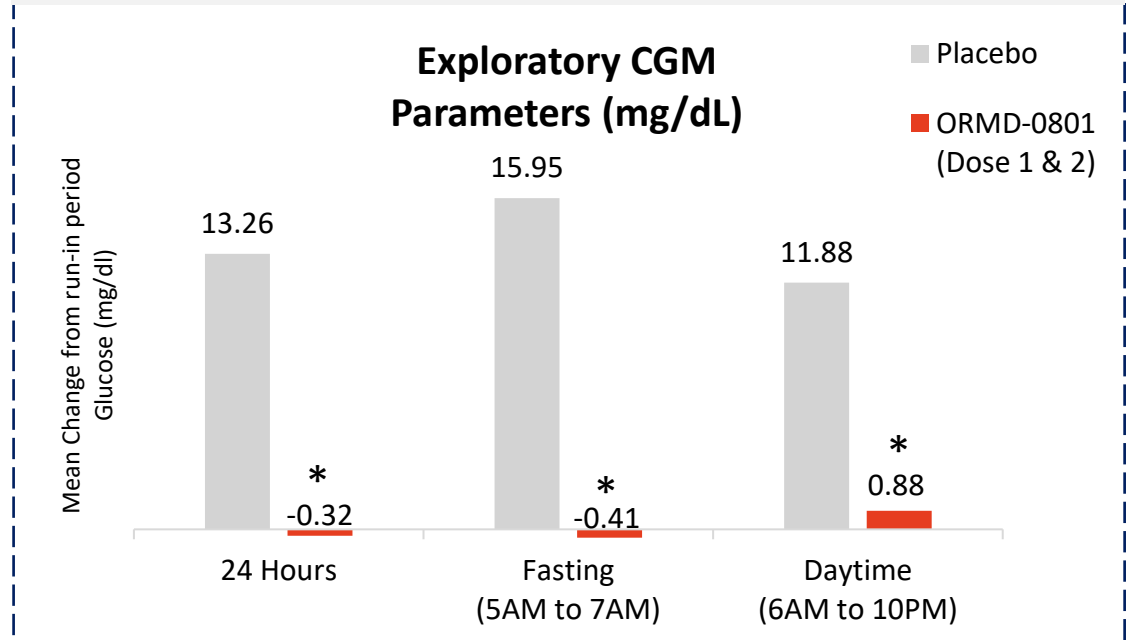
## 1<sup>st</sup> Primary Endpoint

- Achieved primary endpoint and showed significant positive effects
- Safe/well-tolerated with no drug related serious adverse events
- Dose groups 1 & 2 are pooled on weighted mean nighttime glucose levels
- All ORMD-0801 values statistically significant versus the placebo (p-Value<0.05)



## 2<sup>nd</sup> Exploratory Endpoints

- ORMD-0801 showed promising reductions in mean 24-hour, fasting, and daytime glucose levels
- All ORMD-0801 values statistically significant versus the placebo (p-Value<0.05)



Note: ClinicalTrials.gov Identifier = NCT02496000. (\*) Indicates statistically significant difference versus placebo (p-Value <0.05)

## Phase 2b – Completed 298 Patient Trial for T2D

### Trial Highlights

34

US Sites<sup>1</sup>

298

Patients<sup>1</sup>

90

Day Treatment

7

Dose Groups

Design	<ul style="list-style-type: none"> <li>Double-blind, randomized, placebo-controlled, 12-week, once/twice/or three times daily treatment</li> </ul>					
Study Population	<ul style="list-style-type: none"> <li>Patients with T2D who are taking metformin only (at least 1500 mg or maximally tolerated dose) or metformin in addition to no more than two of the following: Glibenclamide, Glipizide, Empagliflozin, Pioglitazone, Glimepiride, Dapagliflozin, Sitagliptin, Glibomet, Ertugliflozin</li> </ul>					
Endpoints	<ul style="list-style-type: none"> <li><b>Primary:</b> mean change in A1C from Baseline to Week 12 of treatment period</li> <li><b>Secondary:</b> safety (AES, hypoglycemic events); fasting plasma glucose (FPG) + CGM; weight</li> </ul>					
Dose Cohorts	Placebo comparator for each cohort	<b>8 mg/day</b> (8 mg, 1x/day)	<b>16 mg/day</b> (8 mg, 2x/day or 16 mg, 1x/day)	<b>32 mg/day</b> (32 mg, 1x/day or 16 mg, 2x/day)	<b>64 mg/day</b> (32 mg, 2x/day)	<b>96 mg/day</b> (32 mg, 3x/day)

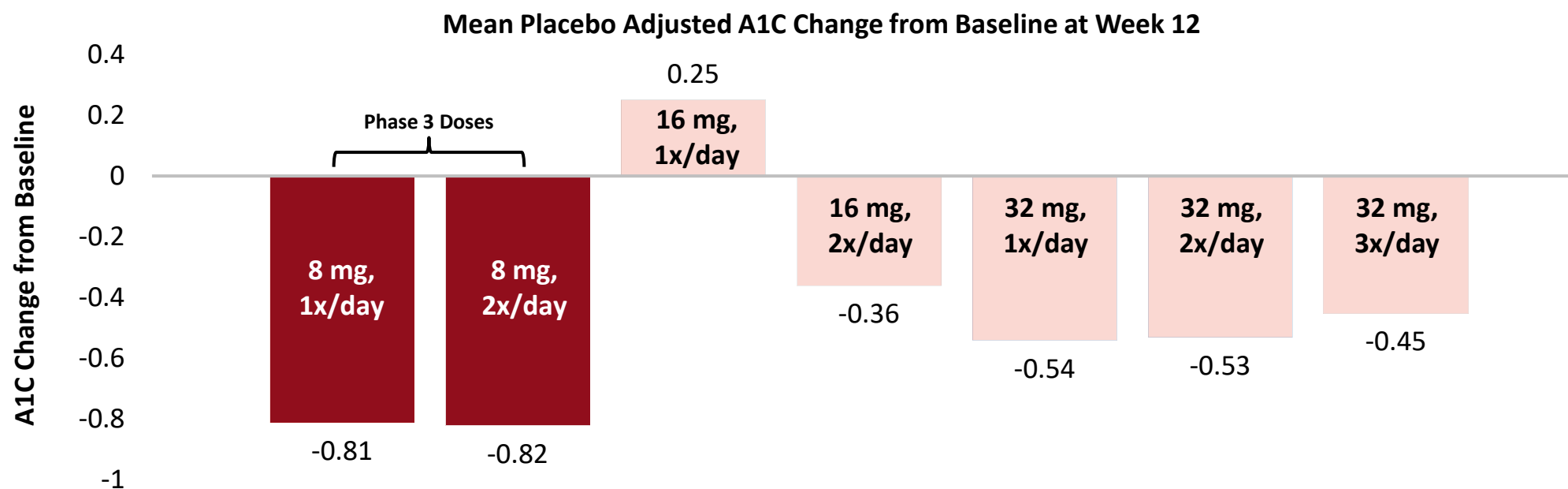
Note: ClinicalTrials.gov Identifier = NCT03467932. (1) 36 Sites: 2 sites (49 subjects) were excluded due to significant treatment by center interaction; 347 subjects received primary treatment and had baseline A1c (included in ITT); 298 subjects included in primary analysis; 266 included in final analysis (Week 12 A1C results)



## ORMD-0801 Phase 2b Achieved Safety and Primary Endpoints

### Primary Endpoint

- Achieved primary efficacy endpoint in reduction in A1C at Week 12
- The 8 mg once-daily and twice-daily arms achieved statistically significant values at Week 12 vs. Placebo (p-value 0.028 and 0.029, respectively)



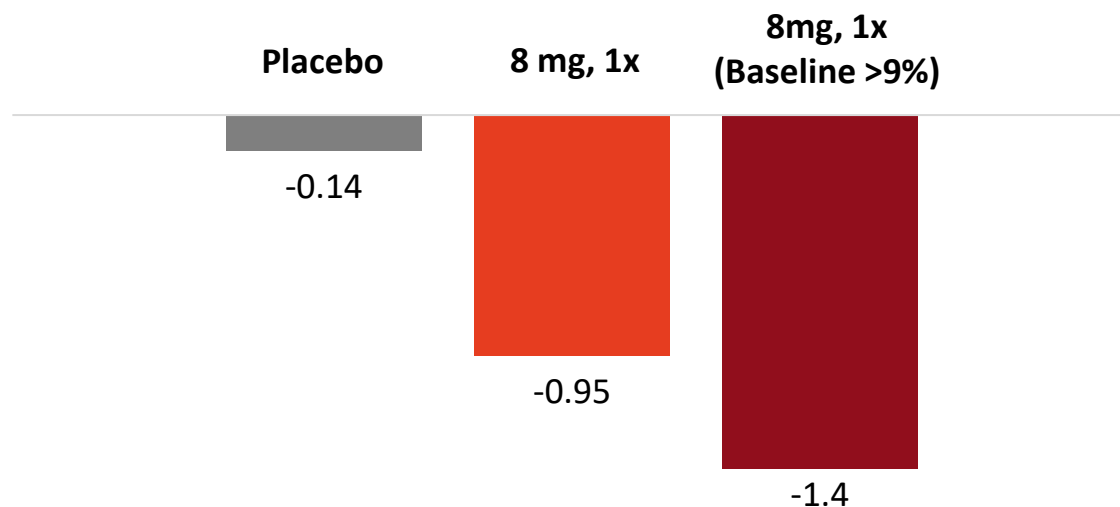
Note: ClinicalTrials.gov Identifier = NCT03467932.

## ORMD-0801 Phase 2b Exhibited Strong A1C Lowering Activity at 8 mg 1x/Day Dose

### Significant A1C lowering with 8 mg, 1x/day dose

- 8 mg 1x/day showed 0.95 (0.81 placebo adjusted) reduction in A1C (p=0.028)
- 8 mg 1x/day for patients with baseline A1C >9% showed 1.40 (1.26 placebo adjusted) reduction in A1C

#### Mean A1C Change from Baseline at Week 12



Note: ClinicalTrials.gov Identifier = NCT03467932.

### ORMD-0801 upheld safety profile previously exhibited in first Phase 2 study

- ✓ No increase in Serious Adverse Events compared to Placebo
- ✓ No increase in Hypoglycemic Events compared to Placebo
  - 6.1% (5/82) of subjects in placebo group compared to 0% (0/15) of subjects in 8mg 1x/day had at least 1 hypoglycemic event
- ✓ No weight gain compared to Placebo at Week 12

## FDA Phase 2b Trial Results - Primary Endpoint Successfully Met



### Safe and well tolerated

#### FDA BLA Pathway:


- Confirmatory Phase 3 Study
- Submission to FDA

Gain **12-year marketing** exclusivity upon FDA approval



### Significant **HbA1c** lowering with 1X/daily treatment:

- ✓ No increase in Adverse Events compared to Placebo
- ✓ No increase in Hypoglycemic Events compared to Placebo
- ✓ No weight gain compared to Placebo



# Phase 3 Trials: Maximizing ORMD-0801's Success in the Market

# Two Pivotal Phase 3 Trials will Maximize ORMD-0801's Success in the Market

1

## ORA-D-013-1



Type 2 Diabetes Mellitus with Inadequate Glycemic Control on Two or Three Oral Glucose-Lowering Agents



- 675 subjects
- Reached over 75% randomization<sup>1</sup>
- US-based

Double Blind, Double Dummy, 1:1:1 randomization

8 mg 1x/day at night and placebo 45 mins before breakfast

8 mg 2x/day at night and 45 mins before breakfast

Placebo 2x/day at night and 45 mins before breakfast



- To compare the efficacy of ORMD-0801 to a placebo in improving glycemic control over a 26-week period
- To evaluate the safety of ORMD-0801 over a 52-week period



2/3L in place of DPP4s/GLP-1/SGLT-2s or in combination with GLP-1/SGLT-2s

Source: (1) FDA indicated possible 1L designation based on the ORA-D-013-2 trial in which ~30% of enrolled patients are metformin treatment naïve

<sup>1</sup> As of November 23, 2021

# Two Pivotal Phase 3 Trials will Maximize ORMD-0801's Success in the Market

2

## ORA-D-013-2



Type 2 Diabetes Mellitus with Inadequate Glycemic Control on Diet Control Alone or on Diet Control and Metformin Monotherapy



- 450 subjects (~30% naïve patients to 1L therapy - metformin)
- Reached over 25% randomization<sup>1</sup>
- US, European and Israel-based

Double Blind, 1:1 randomization

8mg at night

Placebo at night



- To compare the efficacy of ORMD-0801 to a placebo in improving glycemic control over a 26-week period
- To evaluate the safety of ORMD-0801 over a 52-week period

Trial Endpoints



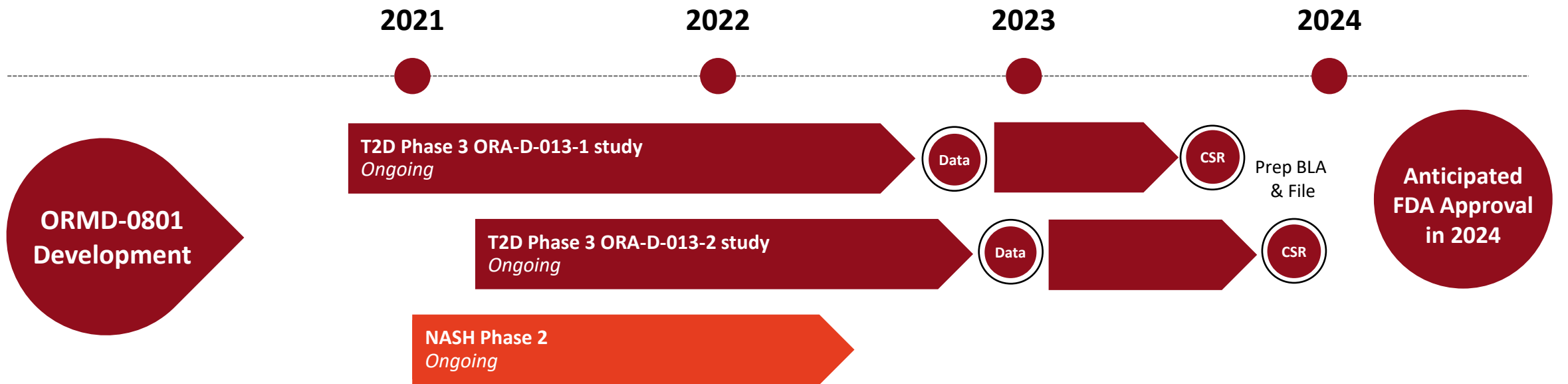
Market Positioning if Successful

1L monotherapy or 1L with metformin<sup>1</sup>

Source: (1) FDA indicated possible 1L designation based on the ORA-D-013-2 trial in which ~30% of enrolled patients are metformin treatment naïve

<sup>1</sup> As of August 24, 2021

# ORMD-0801's Robust Clinical Development Program has Paved the way Towards Anticipated Approval



**>900**  
Study Subjects<sup>1</sup>

**>10,000**  
Human Doses

**No Drug-Related SAEs**

**Strong Efficacy Signals**

### Development Highlights:

- First T2D Phase 3 trial initiated
- Second T2D Phase 3 trial initiated
- Phase 2 in NASH and potential future T1D studies support additional upside

Note: CSR = Clinical Study Report; SAE = Serious Adverse Event (1) Includes all clinical studies across all indications, including formulation studies



## 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
  - HTIT clinical trials of ORMD-0801 underway
- **\$50M Payments + Royalties:**
  - \$12M in restricted stock (at premium)
  - \$38M milestone payments
    - \$33M received to date
    - \$17M expected over the next 2-3 years
  - Up to 10% royalties on net sales

### Chinese diabetes market\*

114M

**diabetic**  
(10.9% of adult population)

~388M

**prediabetic**  
(35.7% of adult population)



\* [Journal of the American Medical Association](#)



## Two Ongoing Phase 2 Trials for T2D with NASH

With direct action on the liver, ORMD-0801 has the potential to address ~50% of diabetics suffering from NASH, a population with increased mortality.

### Trial Highlights



	Trial #1: Pilot Study to Assess Efficacy and Safety of ORMD-0801	Trial #2: Safety & Efficacy of ORMD-0801
Design	<ul style="list-style-type: none"> <li>Open label, non-randomized, single group, 12-week, once daily treatment in <b>18 T2D</b> patients with NASH in Israel &amp; EU</li> </ul>	<ul style="list-style-type: none"> <li>Double-blinded, randomized, 2 groups, 12 week, twice daily treatment in <b>30 T2D</b> patients with NASH in US &amp; Israel</li> </ul>
Study Population	<ul style="list-style-type: none"> <li>Patients with T2D with fat concentration in the liver of moderate steatosis (&gt;8% liver with steatosis)</li> </ul>	<ul style="list-style-type: none"> <li>Patients with T2D, fat concentration in the liver of moderate steatosis (&gt;8% liver with steatosis)</li> </ul>
Endpoints	<ul style="list-style-type: none"> <li><b>Primary:</b> number of treatment-related adverse events</li> <li><b>Secondary:</b> change in liver fat content (MRI-PDFF) from Baseline to Week 12</li> </ul>	<ul style="list-style-type: none"> <li><b>Primary:</b> number of treatment-related adverse events</li> <li><b>Secondary:</b> change in liver fat content (MRI-PDFF) from Baseline to Week 12</li> </ul>
Initial Data	<ul style="list-style-type: none"> <li><b>Efficacy from first eight patients:</b> 30% relative reduction measured by MRI-PDFF; 6.9±6.8% mean reduction in liver fat content (p value: 0.035)</li> <li><b>Safety from first eight patients:</b> No drug-related Serious Adverse Events</li> </ul>	<ul style="list-style-type: none"> <li>Initiated in Q4 2020</li> </ul>










# 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
-  Compelling safety profile
-  Decreases blood glucose levels
-  Preserves beta cell function
-  Effectively reduces HbA1c
-  Promotes weight loss

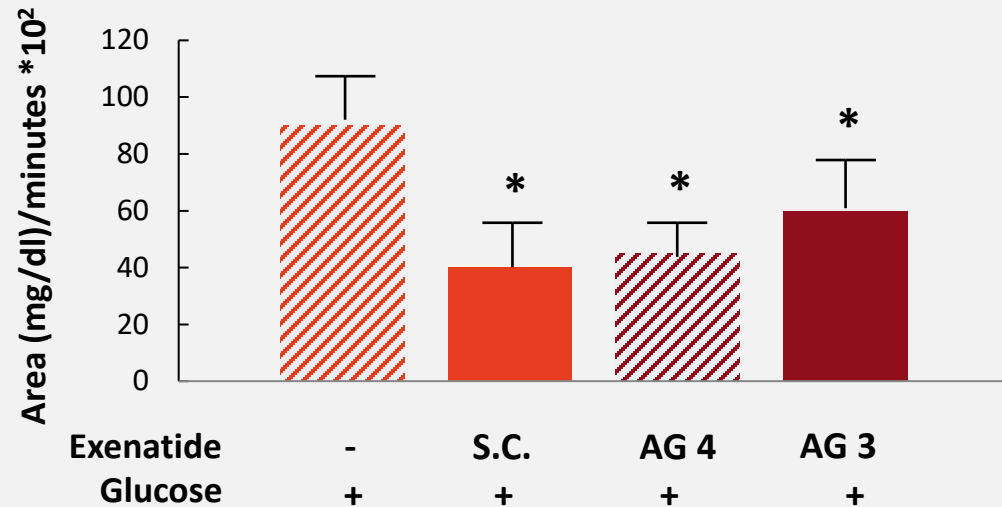
## ORMD-0901 Clinical Status

-  IND
-  Bioavailability study

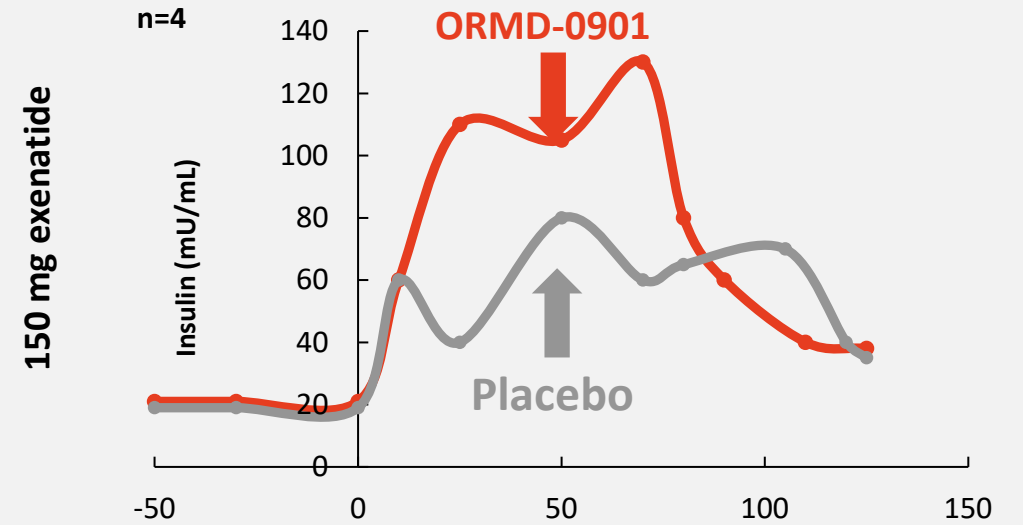


## Oral GLP-1 - ORMD-0901

Preclinical: 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

# Oravax – Novel Oral Covid-19 Company



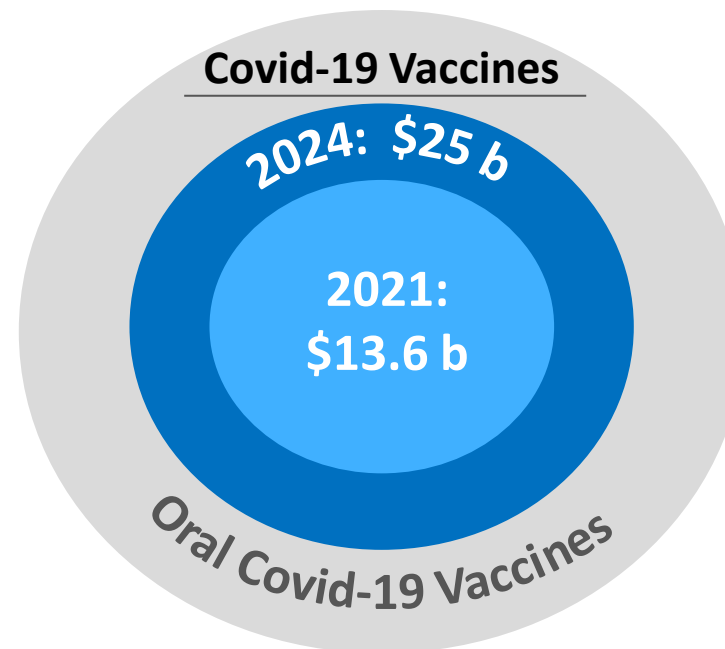
The **Oravax** technology integrates Premas Biotech's D-Crypt™ technology with an oral delivery platform from Oramed Pharmaceuticals based on their proprietary POD™ delivery technology.

## ■ Joint Venture

- Oramed is the majority shareholder of Oravax (63%)

## ■ License

- Royalties: 7.5% of net sales
- Sublicensing: 15%
- Sales milestone: \$25M - \$100M



# ORAVAX - Advantages

## Triple antigen vaccine expected to be effective against COVID variants

### ■ Manufacturing Advantages



Ease of scale up



Straight-forward tech transfer



Manufacturing and COGs optimization



Consistent process

### ■ Safe, non-toxic, and efficacious in preclinical and GLP Tox studies in animals:

- No temperature rise, no body weight loss/gain, no adverse events noted in any animal
- Significant antibody response, as well as cellular immune response
- Long term retention of the antibody response in animals, post 150 days

### ■ Oral Format



No needles



Easy to administer at home (no need for professional administration)



No need for low temperature storage (freezer)



Potential for further reduction in side effects (greater safety)

# Oravax - Highlighted Milestones

## 50/50 Joint Venture with Genomma Lab



- Commercialize Oral COVID-19 Vaccine in Mexico
- Drive Business in LATAM
- Contribute to oral vaccine's clinical, regulatory, and commercial activities
- Participate in a future investment in Oravax.
- Intended US\$20 million share swap

## Collaboration Agreement with Tan Tanh Holdings



- Pre-purchase of 10 million oral Covid-19 vaccines
- TTH to commercialize Oral COVID-19 Vaccine in ASEAN
- Oravax obtained approval from Vietnam MOH to run P2/3 in Vietnam
- TTH to contribute to funding of clinical trials



# Oravax – Phase 1 Trial Initiated

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- South Africa
- FPI: Dec. 2021
- Open-label
- N=24 naive participants (no prior COVID-19 vaccine or infection)
- Endpoints:
  - Safety & tolerability
  - Efficacy





# Anticipated Development Milestones

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**0801  
oral insulin**

- T2DM: Topline Data
- NASH: Topline Data

**0901  
GLP-1**

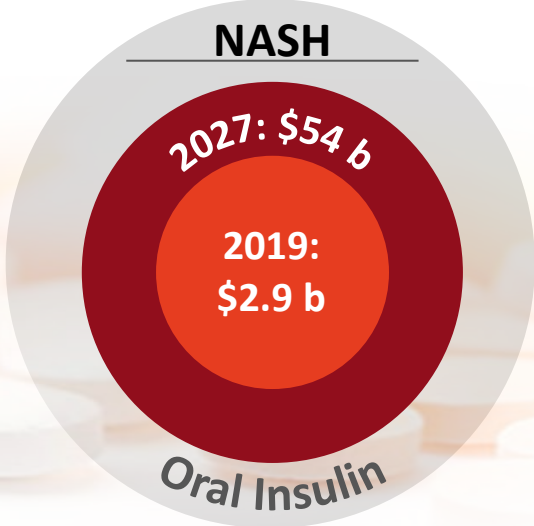
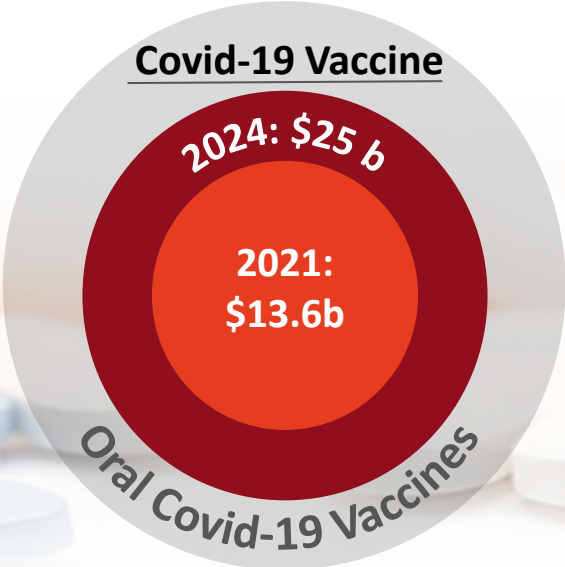
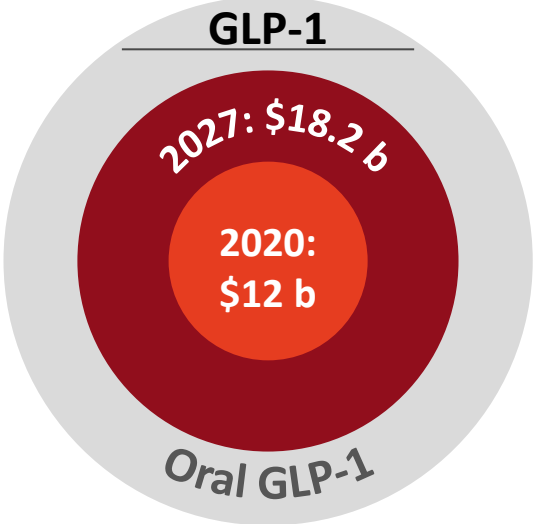
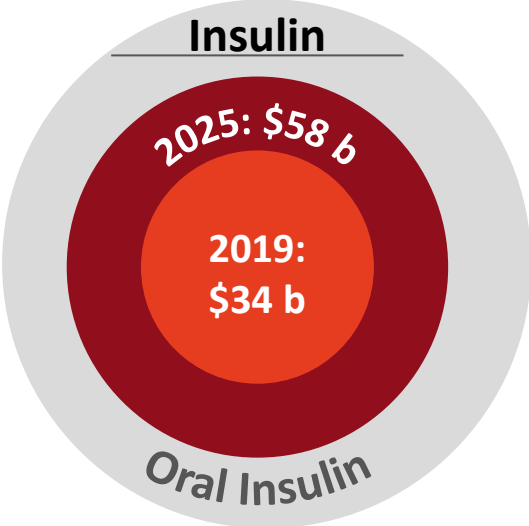
- Bioavailability Study (T2DM)  
Topline Data

**Leptin**

- Topline Data



# Funneling Huge Injectable Drug Markets to Novel Oral Formulations



## Management Team

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

Entrepreneur whose experience includes decades of senior executive roles in a wide range of industries including business, law and technology



### **Miriam Kidron, PhD - CSO & Director**

Senior Researcher at the Diabetes Unit of Hadassah Medical Center for more than 25 years



### **David Silberman, CPA - CFO**

Extensive experience in corporate financial management



### **Josh Hexter - Chief Operating & Business Officer**

More than 18 years of prominent leadership roles in biotech and pharma



### **Roy Eldor, MD - Chief Medical Advisor**

Director, Diabetes Unit, Institute of Endocrinology, Metabolism & Hypertension, Tel-Aviv Medical Center



### **Michael Rabinowitz - Chief Commercial Officer**

Over 2 decades experience in launching and marketing new medications and treatments

# Board of Directors

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## **Kevin Rakin - Chairman**

Co-Founder and Partner at HighCape Partners; former President of Regenerative Medicine at Shire plc

## **Leonard Sank**

Entrepreneur and business leader; Director of Macsteel Service Centres SA (Pty) Ltd

## **Aviad Friedman**

Director General of Israel's Housing Ministry and served as a board member of public and private companies including Maayan Ventures and Capital Point

## **Arie Mayer**

Managing Director and Chairman of the Board of Merck Life Science Israel (formerly Sigma-Aldrich Israel Ltd.)

## **Nadav Kidron**

CEO, Oramed

## **Miriam Kidron**

CSO, Oramed

## Scientific Advisory Board

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### **Roy Eldor, MD, PhD**

Director, Diabetes Unit, Institute of Endocrinology, Metabolism & Hypertension, Tel-Aviv Medical Center

### **Ele Ferrannini, MD, PhD**

Professor, Internal Medicine, University of Pisa School of Medicine. Past President of the EASD

### **Alexander Fleming, MD**

Recognized authority in the metabolic and endocrine fields with extensive FDA experience.

### **Avram Herskho, MD, PhD; Nobel Laureate**

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

### **Harold Jacob, MD**

Chief Medical Officer, NanoVibronix. Previously, Director, Medical Affairs at Given Imaging.

### **Julio Rosenstock, MD**

Director, Dallas Diabetes Research Center, Professor, University of Texas Southwestern Medical Center; Associate Editor, *Diabetes Care*.

### **Jay Skyler, MD, MCAP**

Professor of Medicine, Division of Endocrinology, Diabetes & Metabolism, Department of Medicine, University of Miami.

# Oramed (NASDAQ/TASE: ORMP)

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

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- **Proprietary oral protein delivery platform**
- **Diabetes First:** Initially targeting the lucrative insulin market; additional markets in the pipeline
- **Strong financial position** with ~\$174M<sup>1</sup> in cash and investments, no debt – ~38M shares outstanding (~41M fully diluted)<sup>2</sup>
- **Strong management** team backed by world-class scientific experts
- **Multiple near-term value-creation catalysts** for this year
- **Robust IP Portfolio**
  - Methods and compositions for oral administration of proteins
  - Methods and compositions for oral administration of exenatide
  - Methods and compositions (insulin + exenatide)
  - Improved protease inhibitors



<sup>1</sup> As of December 3, 2021 (unaudited) <sup>2</sup> As of November 24, 2021



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THANK YOU

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