



Addressing the Multibillion-Dollar Injectable Drug Markets with Oral Formulations

August 2022

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, 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



KEY FINANCIAL METRICS

- **Strong financial position**
- ~\$160M¹ in cash and investments
- No debt



SIGNIFICANT PIPELINE, IP, AND 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

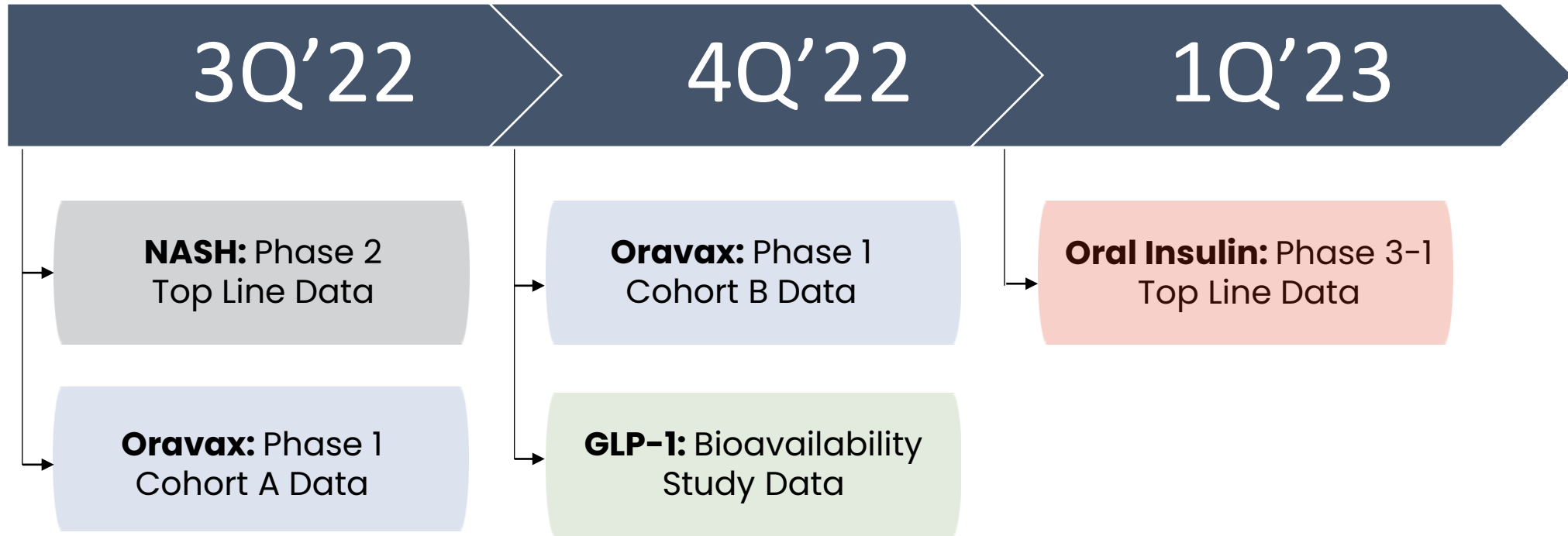


COMPANY MANAGEMENT

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

¹ As of June 30, 2022 (unaudited)

Upcoming Catalysts



Proprietary Technology for Oral Drug Delivery

Proteins and Peptides do Not Survive the Digestive System



Harsh pH

Stomach acidity cleaves and shreds protein



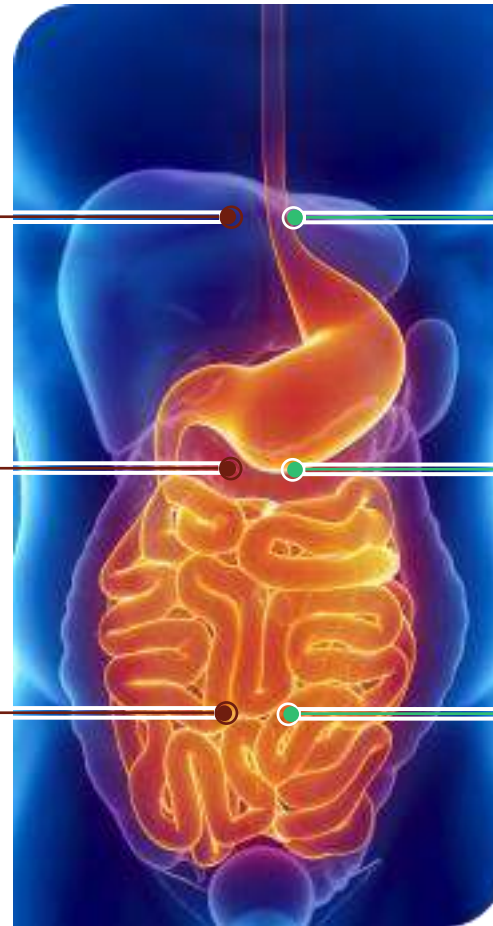
Protease attack

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



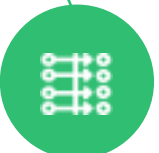
Protease protection

Protease inhibitors protect the active agent



Absorption enhancement

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



Multiple Clinical-Stage Programs

PHASE 1

PHASE 2

PHASE 3

ORMD-0801 (Oral Insulin) Diabetes

ORMD-0801 (Oral Insulin) NASH

ORMD-0901 (Oral GLP-1)

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

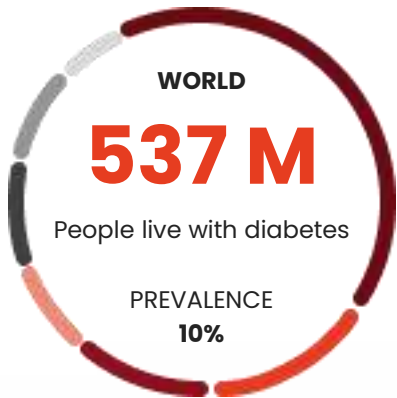


Diabetes:
Millions of diabetics
inject insulin today
and wish for oral dosage

1 in 10 Adults on the Planet Have Diabetes



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



- WP
- SEA
- MENA
- SACA
- EUR
- MAC
- AFR

2021



2045



+246 Million
Expected increase



Every 5 SECONDS
1 adult dies from diabetes

6.7M deaths in 2021



ORMD-0801: Oral Insulin



Oral Insulin Mimics the Delivery of Endogenous Insulin

Injectable Insulin
Current

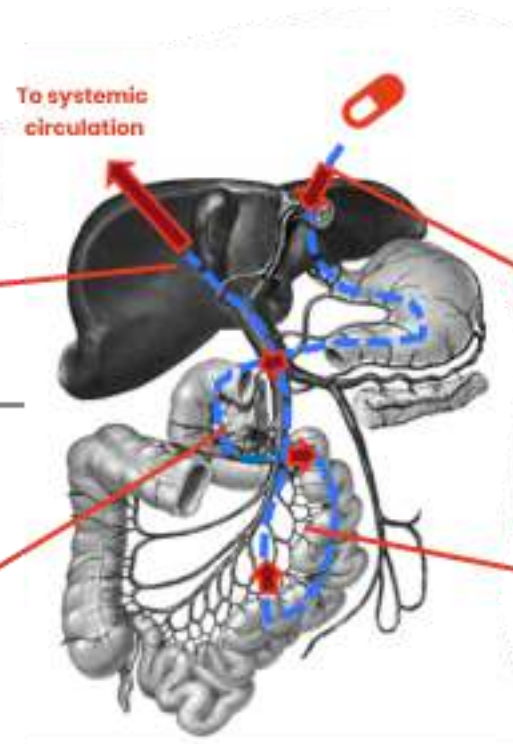


Oral Insulin
Future



First pass metabolism
and regulation in the liver

Insulin reaches liver
via portal vein



ORMD-0801 delivered
via POD technology

Local absorption in
small intestine

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



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

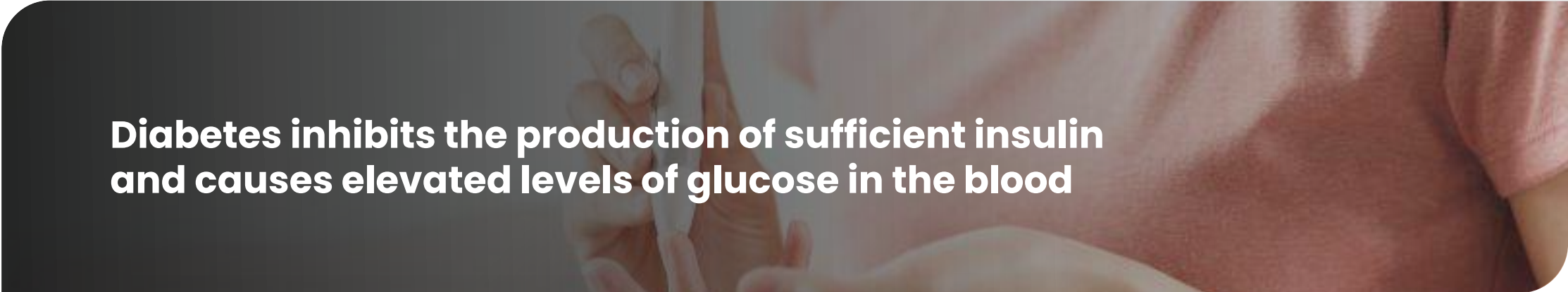
Better insulin control prevents cells from absorbing excess glucose that can be converted to fat and lead to weight gain



EASE OF ADMINISTRATION

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

ORMD-0801 for Type 1 & Type 2 Diabetes



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)



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

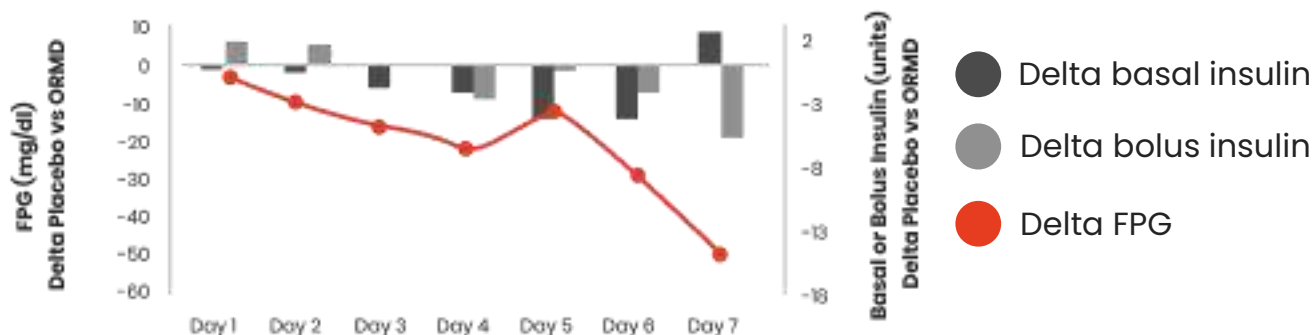
- Easier use and reduced systemic exposure
- Potentially reducing multiple daily injections
- Tighter regulation and control of blood sugar levels by directly targeting liver glucose (T_{IR}), due to portal administration

Phase 2a Trial in T1D Completed

By directly targeting liver glucose, ORMD-0801 may provide tighter blood sugar regulation and control for the ~1.6M¹ 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 ²

25

T1DM patients

7

Days of treatment

3

Times a day
(at mealtime)

Phase 2 – Completed 180 Patient Trial for T2D

33

US Sites

180

Patients

28

Day Treatment

2

Dose Groups 28 Day Treatment ¹

Design

Double-blind, randomized, placebo-controlled, 4 week, once daily (3 capsules) treatment

Study Population

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

Endpoints

- **Primary:** mean nighttime glucose levels ²
- **Secondary:** mean 24-hour glucose ¹, 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

Dose Cohorts

- **Placebo:** 3x placebo capsules
- **Active:** 16mg (1 dose/capsule) and 24mg (1.5 dose/capsule)

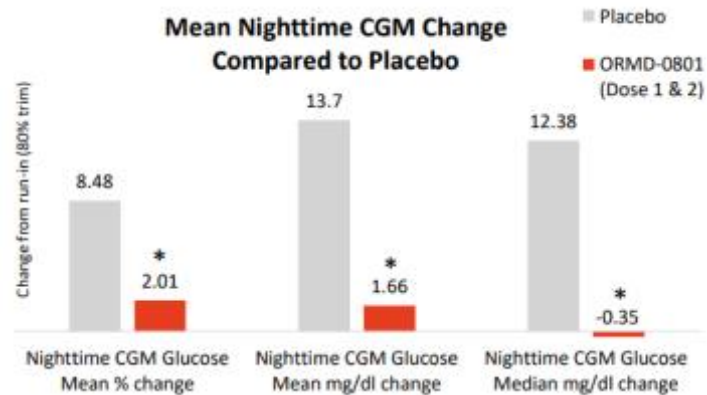
¹ Trial only had 1 dose level, but patients were given either a full dose, or 1.5 doses.

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

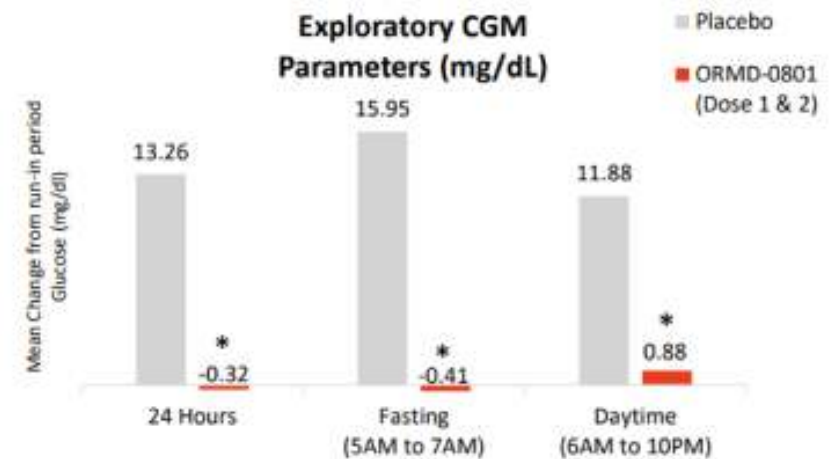
1st Primary Endpoint

- 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)



2nd 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)



(*) Indicates statistically significant difference versus placebo (p-Value <0.05)

Phase 2b – Completed 298 Patient Trial for T2D

34

US Sites ¹

298

Patients ¹

90

Day Treatment

7

Dose Groups 28 Day Treatment

Design

Double-blind, randomized, placebo-controlled, 12-week, once/twice/or three times daily treatment

Study Population

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

Endpoints

- **Primary:** mean change in A1C from Baseline to Week 12 of treatment period
- **Secondary:** safety (AES, hypoglycemic events); fasting plasma glucose (FPG) + CGM; weight

Dose Cohorts

Placebo
comparator for
each cohort

8 mg/day
(8 mg, 1x/day)

16 mg/day
(8 mg, 2x/day or
16 mg, 1x/day)

32 mg/day
(32 mg, 1x/day or
16 mg, 2x/day)

64 mg/day
(32 mg, 2x/day)

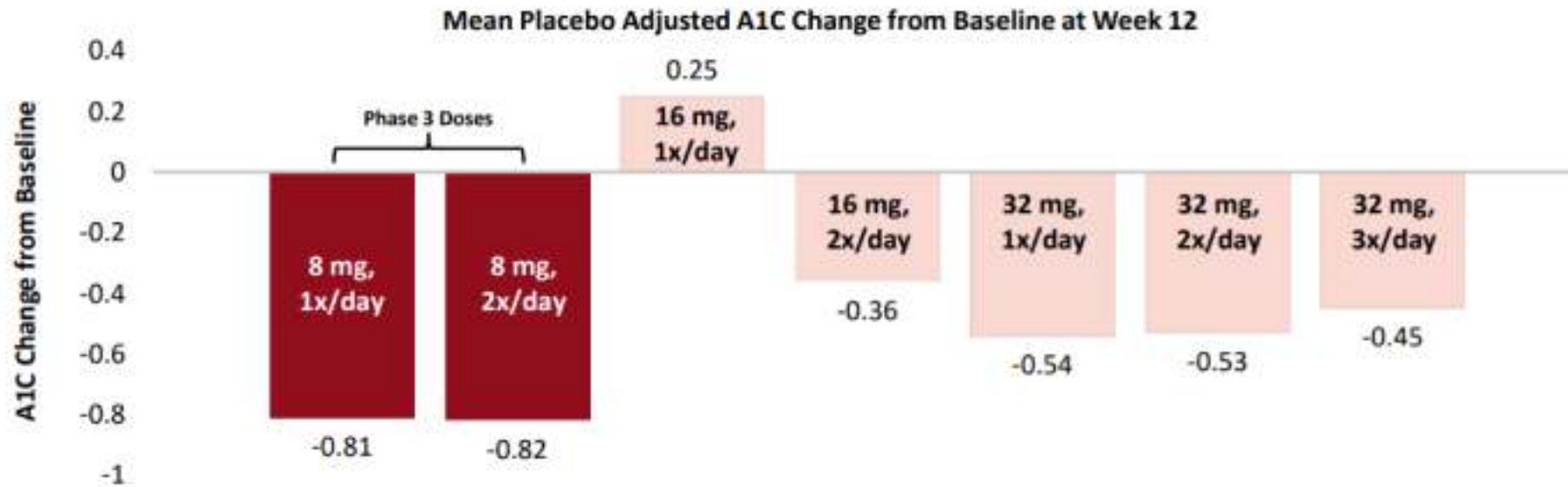
96 mg/day
(32 mg, 3x/day)

(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

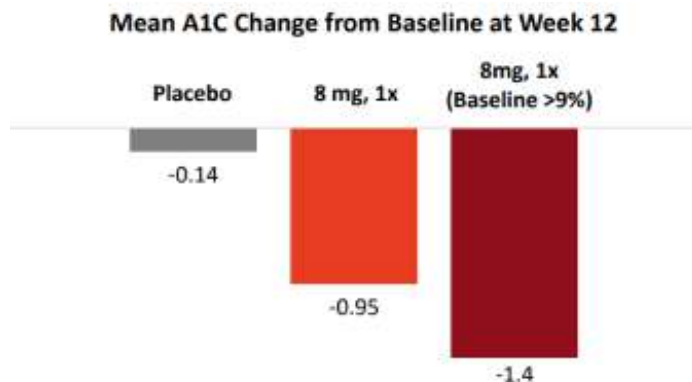
- Achieved primary efficacy endpoint in reduction in A1C at Week 12
- The 8 mg once-daily and twice-daily arms achieved statistically significant values at Week 12 vs. Placebo (p-value 0.028 and 0.029, respectively)



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

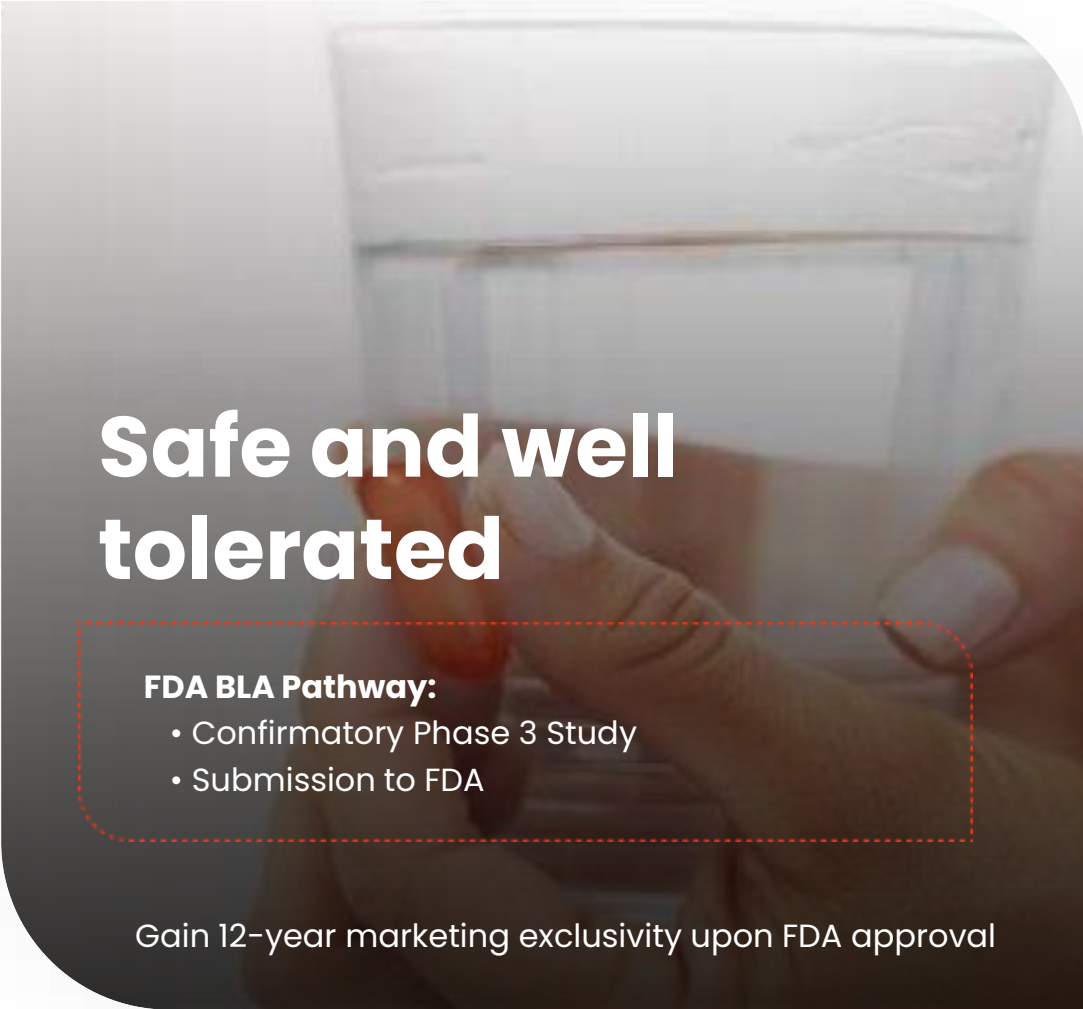


ORMD-0801 upheld safety profile previously exhibited in first Phase 2 study

- ✓ 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

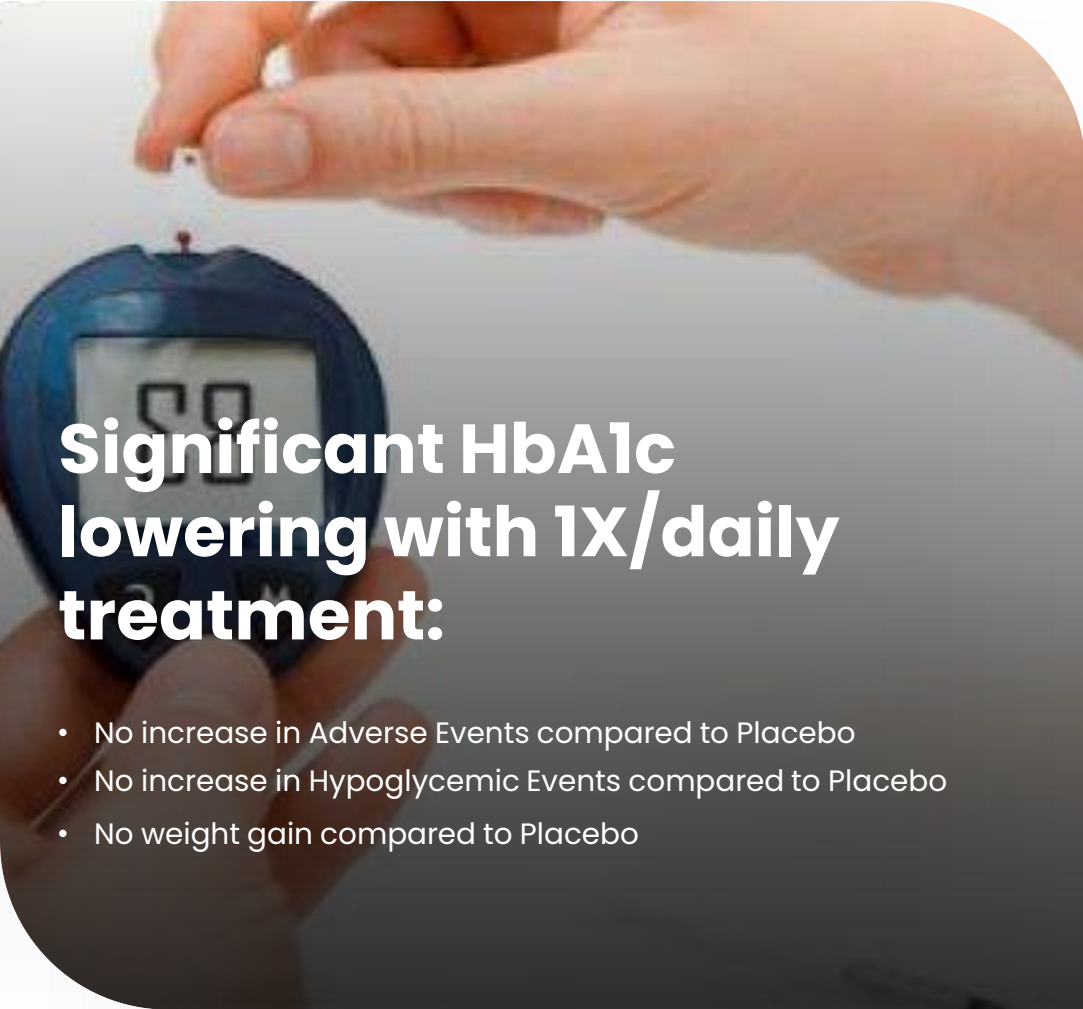


Safe and well tolerated

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: ORA-D-013-1



Patient Type

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



Design & Dosing

• 675 subjects • Reached 100% randomization¹ • 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



Trial Endpoints

- 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



Market Positioning if Successful

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

Two Pivotal Phase 3 Trials will Maximize ORMD-0801's Success in the Market: ORA-D-013-2



Patient Type

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



Design & Dosing

• 450 subjects (~30% naïve patients to 1L therapy - metformin) • Reached over 50% randomization¹ • US, European and Israel-based

Double Blind, 1:1 randomization

8mg at night

Placebo at night



Trial Endpoints

- 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



Market Positioning if Successful

1L monotherapy or 1L with metformin¹

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 .

Oramed Commissioned IQVIA to Perform Market Research in the US, UK and EU

Country	Endos	PCPs	Total
	19	21	40
	13	12	25
	14	12	26
	13	12	25
	14	12	26
	15	13	28
Total	88	82	170

HCPs Were Receptive to Prescribing Oral Insulins and Product X, If Approved

Most of the prescribers (85%+) were willing to prescribe oral insulins or Product X, if approved

**Future Willingness to Prescribe
(n=170)**

	Willingness to prescribe oral insulin (A)	Willingness to prescribe Product X (B)
Definitely would NOT prescribe	0%	0%
Probably would NOT prescribe	2%	1%
Might or might not prescribe	20%	22%
Probably WOULD prescribe	53%	57%
Definitely WOULD prescribe	23%	20%

No HCPs listed that they would definitely not prescribe the product, indicating high interest

Product X appears to meet physician expectations for an oral insulin given minimal change in their response after seeing the Product X profile

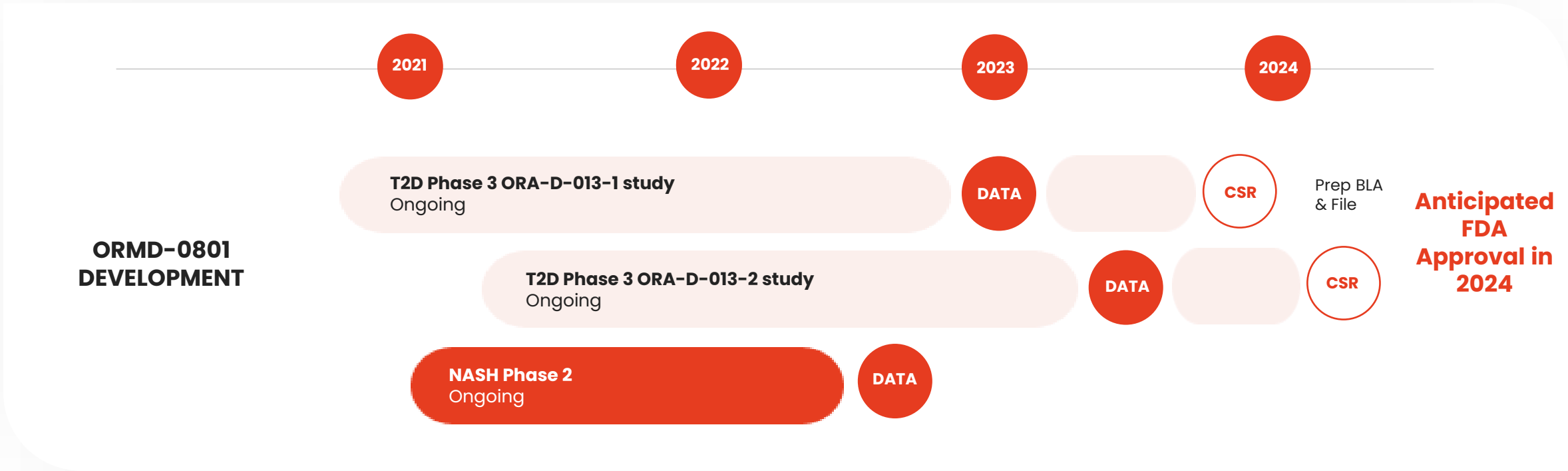


Q: What is your willingness to prescribe oral insulins for T2D patients, if oral insulins were launched in the market?

Q: What is your willingness to prescribe Product X for T2D patients, if it was launched in the market?

Source: IQVIA market research of treating physicians (n=170 Endos and PCPs) in the US and Europe (UK/EU4), December 2021

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




> 900
Study Subjects ¹


> 10,000
Human Doses


No Drug-Related SAEs


Strong Efficacy Signals

DEVELOPMENT HIGHLIGHTS:

- First T2D Phase 3 trial 100% randomization
- Second T2D Phase 3 trial 25% randomization
- Phase 2 in NASH and potential future T1D studies support additional upside

(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

114M

DIABETIC

(10.9% of adult population)

LICENSEE: HEFEI TIANHUI ("HTIT")

Owns with Sinopharm a state-of-the-art GMP API insulin manufacturing facility

- HTIT clinical trials of ORMD-0801 underway

~388M

PREDIABETIC

(35.7% of adult population)

\$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

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.

2

Protocols

48

Patients¹

90

Day Treatment

1

Dose Cohort

Trial #1: Pilot Study to Assess Efficacy and Safety of ORMD0801

Trial #2: Safety & Efficacy of ORMD-0801

Design

Open label, non-randomized, single group, 12-week, once daily treatment in 18 T2D patients with NASH in Israel & EU

Open label, non-randomized, single group, 12-week, once daily treatment in 18 T2D patients with NASH in Israel & EU

Study Population

Patients with T2D with fat concentration in the liver of moderate steatosis (>8% liver with steatosis)

Patients with T2D, fat concentration in the liver of moderate steatosis (>8% liver with steatosis)

Endpoints

Primary: number of treatment-related adverse events
Secondary: change in liver fat content (MRI-PDFF) from Baseline to Week 12

Primary: number of treatment-related adverse events
Secondary: change in liver fat content (MRI-PDFF) from Baseline to Week 12

Dose Cohorts

Efficacy from first eight patients: 30% relative reduction measured by MRI-PDFF; 6.9±6.8% mean reduction in liver fat content (p value: 0.035)
Safety from first eight patients: No drug-related Serious Adverse Events

Initiated in Q4 2020

(1) Originally treated 8 patients (Israel), an additional 10 patients to be treated (EU).
Second trial to treat 30 patients (US, Israel). Final statistical analysis will be pooled from the 2 separate protocols.

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

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

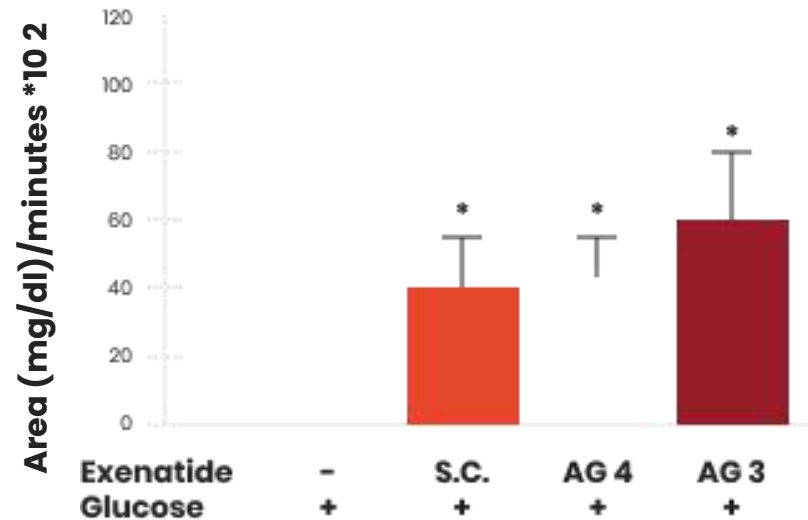
ORMD-0901 Clinical Status

-  IND
-  Bioavailability study

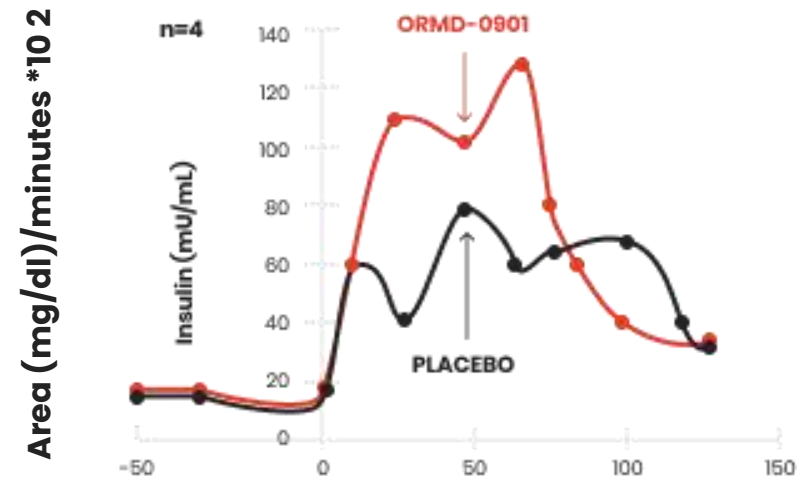


Oral GLP-1 – ORMD-0901

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



x



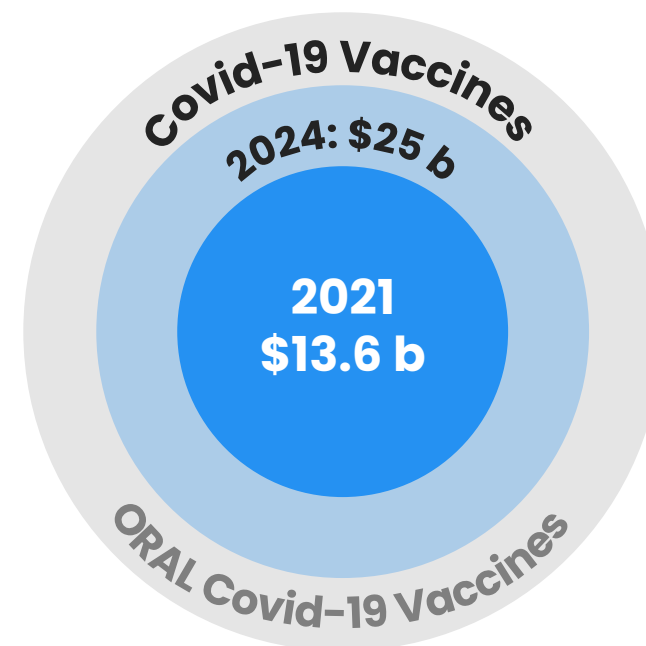
The Oravax technology integrates Premas Biotech's D-Crypt™ technology with an oral delivery platform from Oramed Pharmaceuticals based on their proprietary POD™ delivery technology.

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

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)

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

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

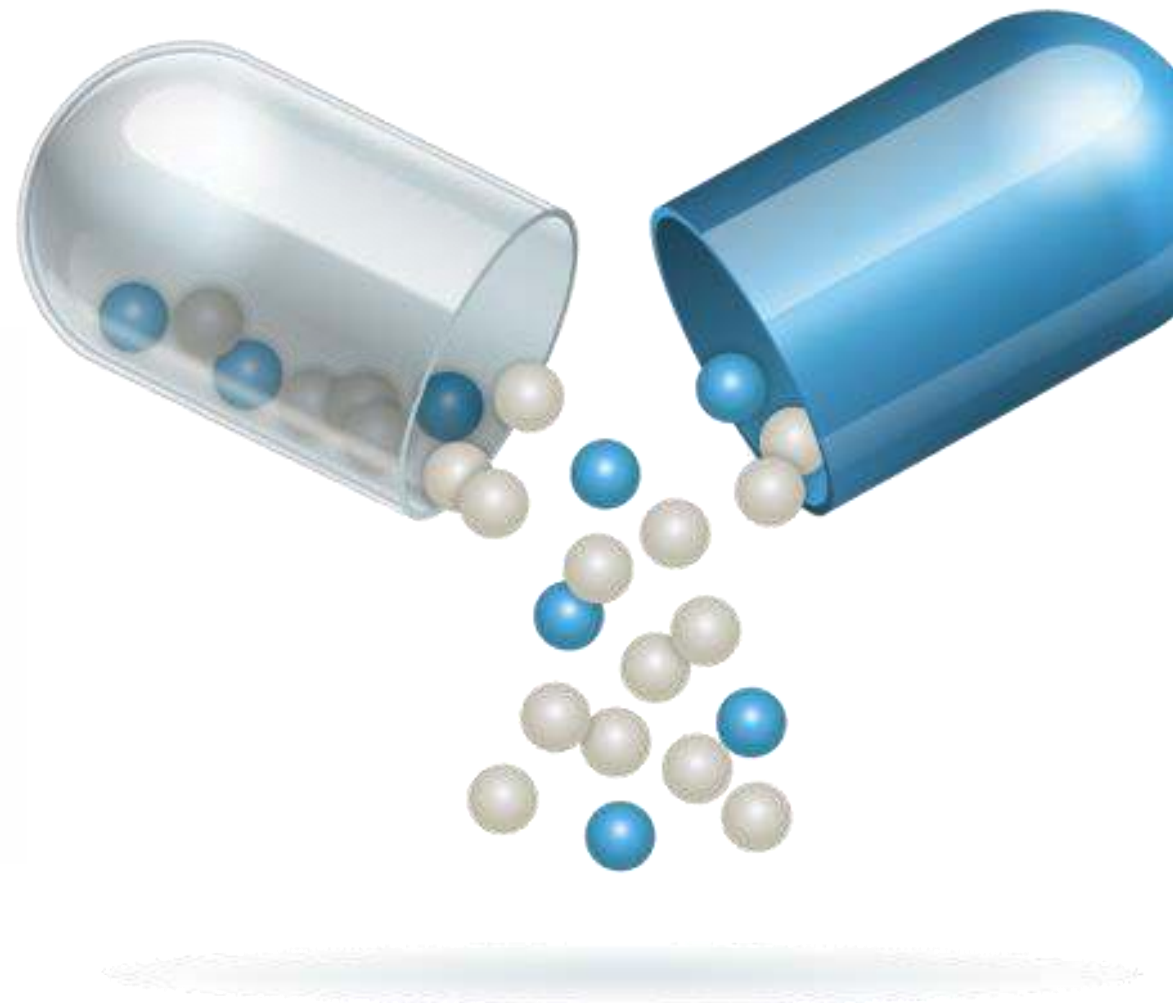
Collaboration Agreement with Tan Tanh Holdings



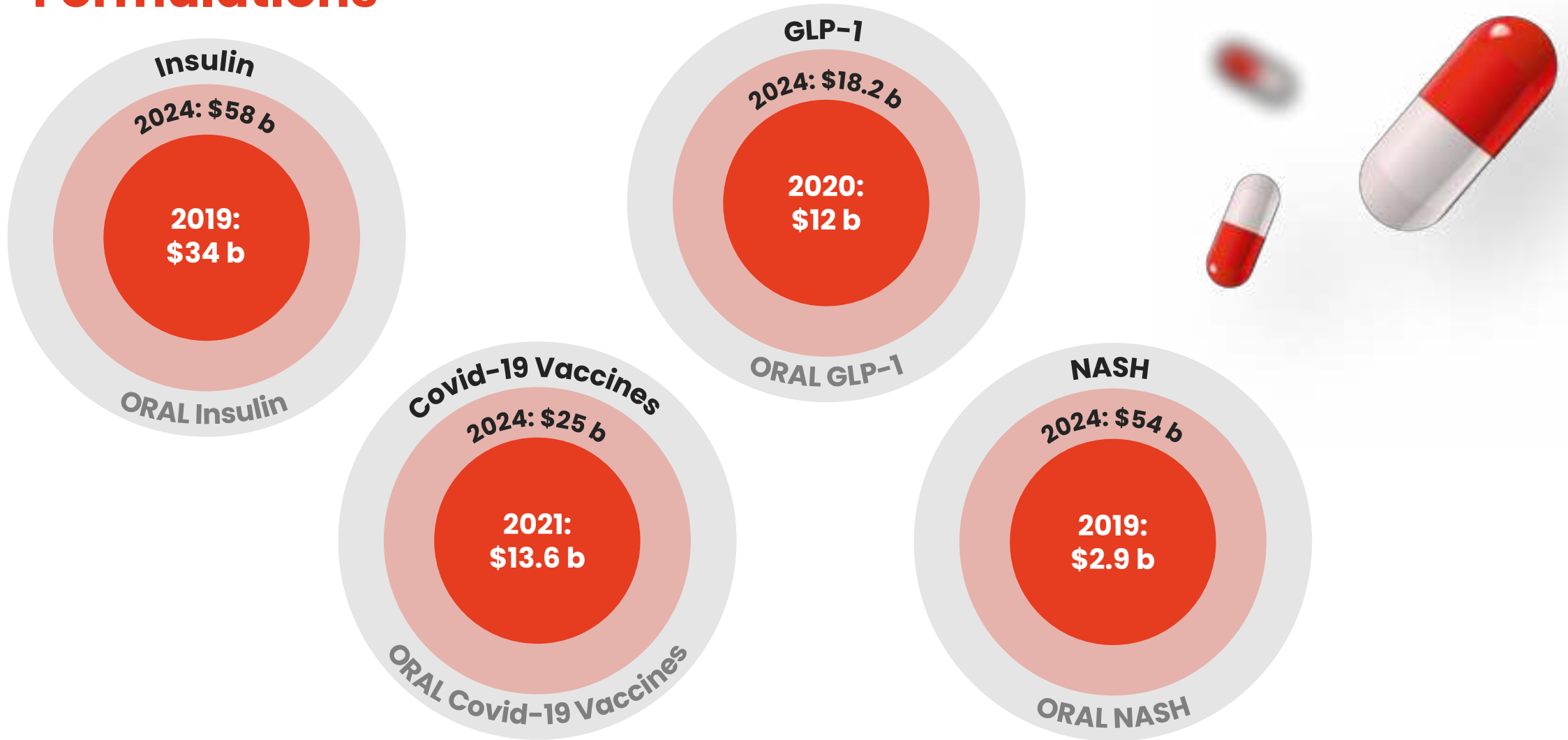
- Pre-purchase of 10 million oral Covid19 vaccines
- TTH to commercialize Oral COVID-19 Vaccine in ASEAN
- Oravax obtained approval from Vietnam MOH to run P2/3 in Vietnam
- TTH to contribute to funding of clinical trials

South Africa

- Open-label
- N=24 naive participants (no prior COVID-19 vaccine or infection)
- Endpoints:
 - Safety & tolerability
 - Efficacy
- Cohort A (12 participants) data expected Q3 2022
- Cohort B (12 participants) data expected Q4 2022



Funneling Huge Injectable Drug Markets to Novel Oral Formulations



Management Team



Nadav Kidron, Esq, MBA

Chief Executive Officer & Director

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



Josh Hexter

Chief Operating & Business Officer

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



Miriam Kidron, PhD

Chief Scientific Officer & Director

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



Netanel Derovan

Chief Legal Officer

Highly accomplished executive leader, having spent over 20 years in senior legal positions.



David Silberman, CPA

Chief Financial Officer

Extensive experience in corporate financial management



Michael Rabinowitz

Chief Commercial Officer

Over two decades of experience in launching and marketing new medications and treatments

Board of Directors

NADAV KIDRON, ESQ

Chief Executive Officer, President & Chairman

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

LEONARD SANK

Director

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

MIRIAM KIDRON, PH.D

Chief Scientific Officer & Director

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

ARIE MAYER, PH.D

Director

Managing Director and Chairman of the Board of Merck Life Science Israel

YADIN ROZOV

Director

Investment professional with experience in capital markets, corporate finance, investment banking, and investment management. Founder and Managing Partner at Terrace Edge Ventures LLC.

Scientific Advisory Board

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.

ANNE PETERS, MD

Professor of Medicine at Keck School of Medicine of USC and Director of the USC Clinical Diabetes Programs.

Oramed (NASDAQ/TASE: ORMP)

Addressing the Multibillion-Dollar Injectable Drug Markets with Oral Formulations

- **Diabetes First:** Initially targeting the lucrative insulin market; additional markets in the pipeline
- **Strong financial position** with ~\$160M¹ in cash and investments, no debt – ~38M shares outstanding (~42M fully diluted)²
- **Proprietary oral protein delivery platform**
- **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

¹As of June 30, 2022 (unaudited) ²As of June 30, 2022



Thank you

oramed.com