Addressing the Multibillion-Dollar Injectable Drug Markets with Oral Formulations

August 2022

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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.

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Oramed Snapshot

COMPANY OVERVIEW

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

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

KEY FINANCIAL METRICS

- **Strong financial position**
- ~$160M[1] in cash and investments
- No debt

COMPANY MANAGEMENT

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

[1] As of June 30, 2022 (unaudited)

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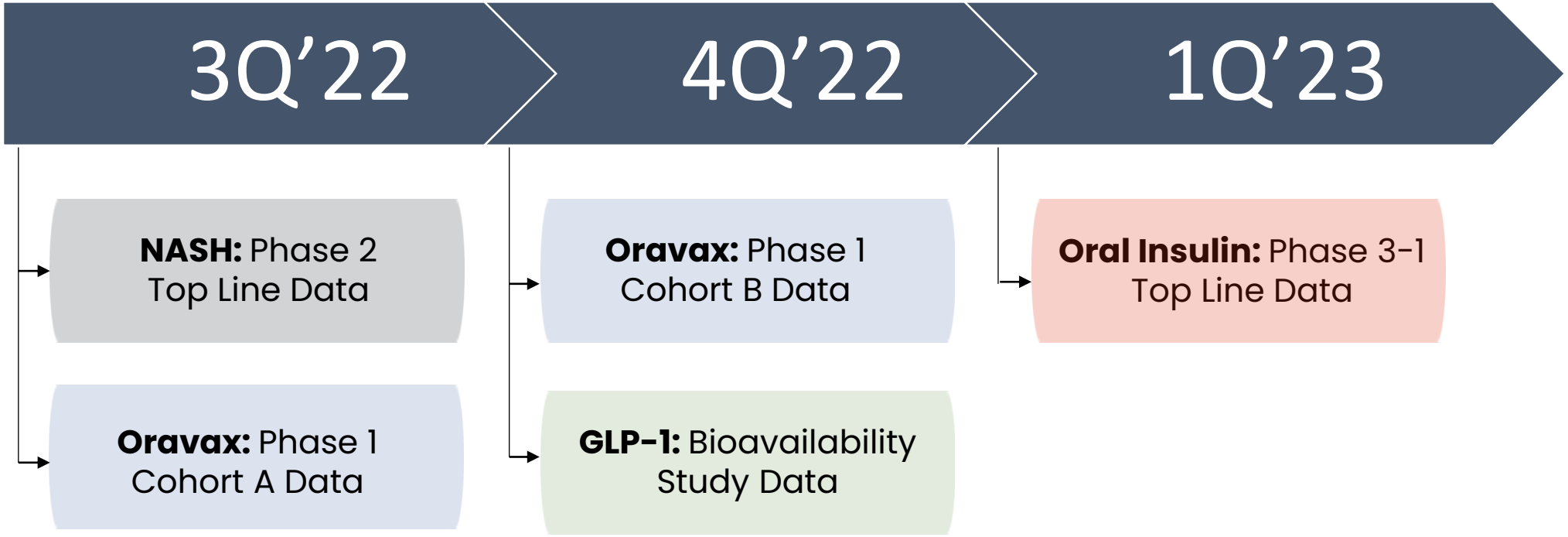
Upcoming Catalysts



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Proprietary Technology for Oral Drug Delivery

Proteins and Peptides do Not Survive the Digestive System

Harsh pH

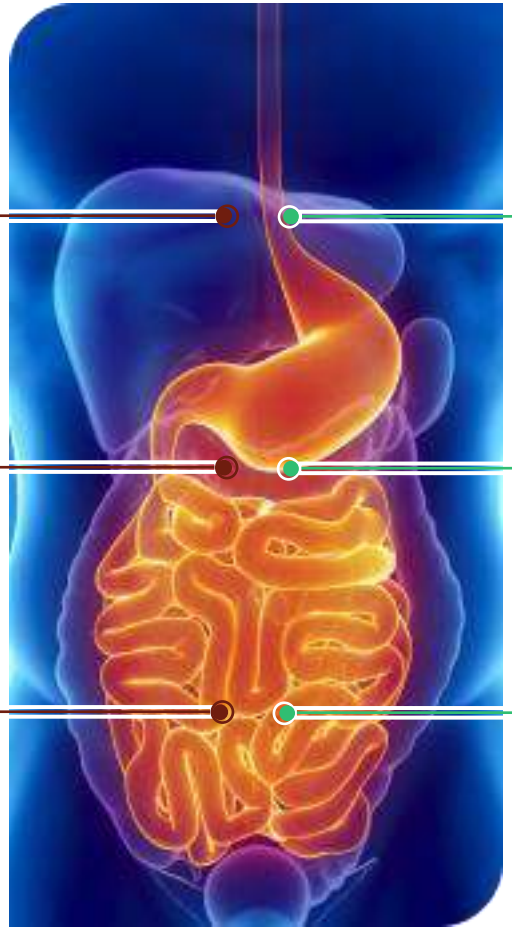
Stomach acidity cleaves and shreds protein

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

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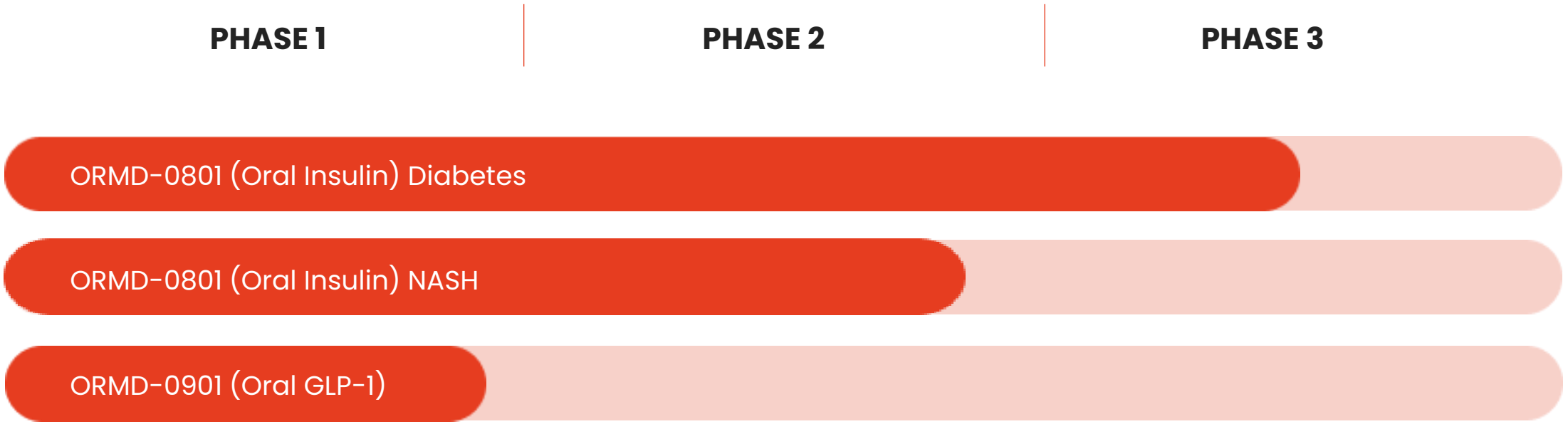
Multiple Clinical-Stage Programs



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

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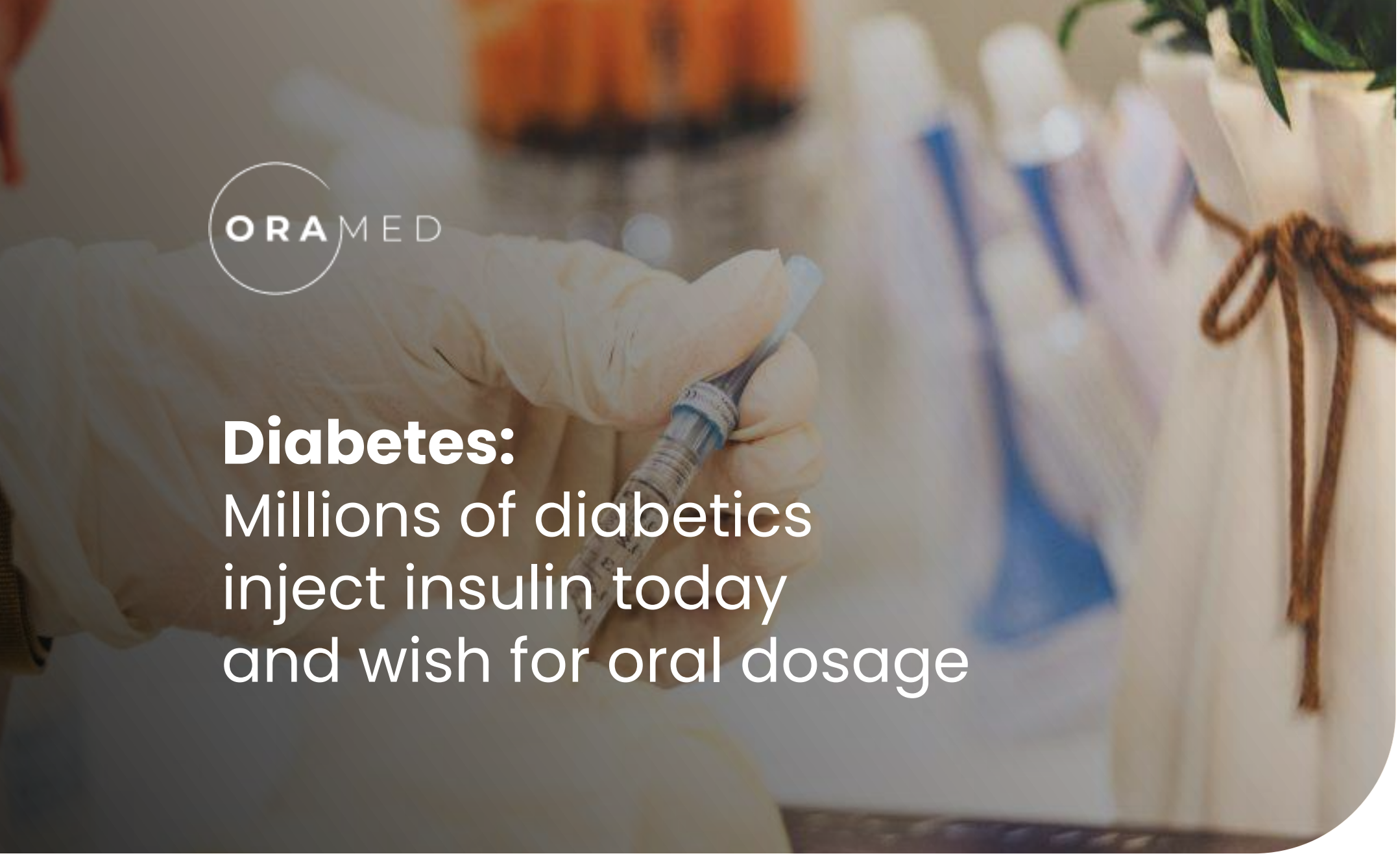
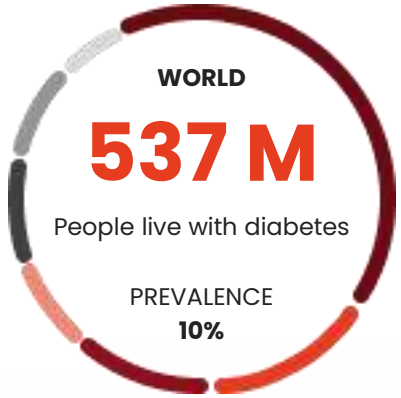


Diabetes:
Millions of diabetics
inject insulin today
and wish for oral dosage

1 in 10 Adults on the Planet Have Diabetes

In 2021 diabetes expenditure reached US $ 966 billion



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

+246 Million
Expected increase

2021

2045

Every 5 SECONDS

1 adult dies from diabetes

6.7M deaths in 2021

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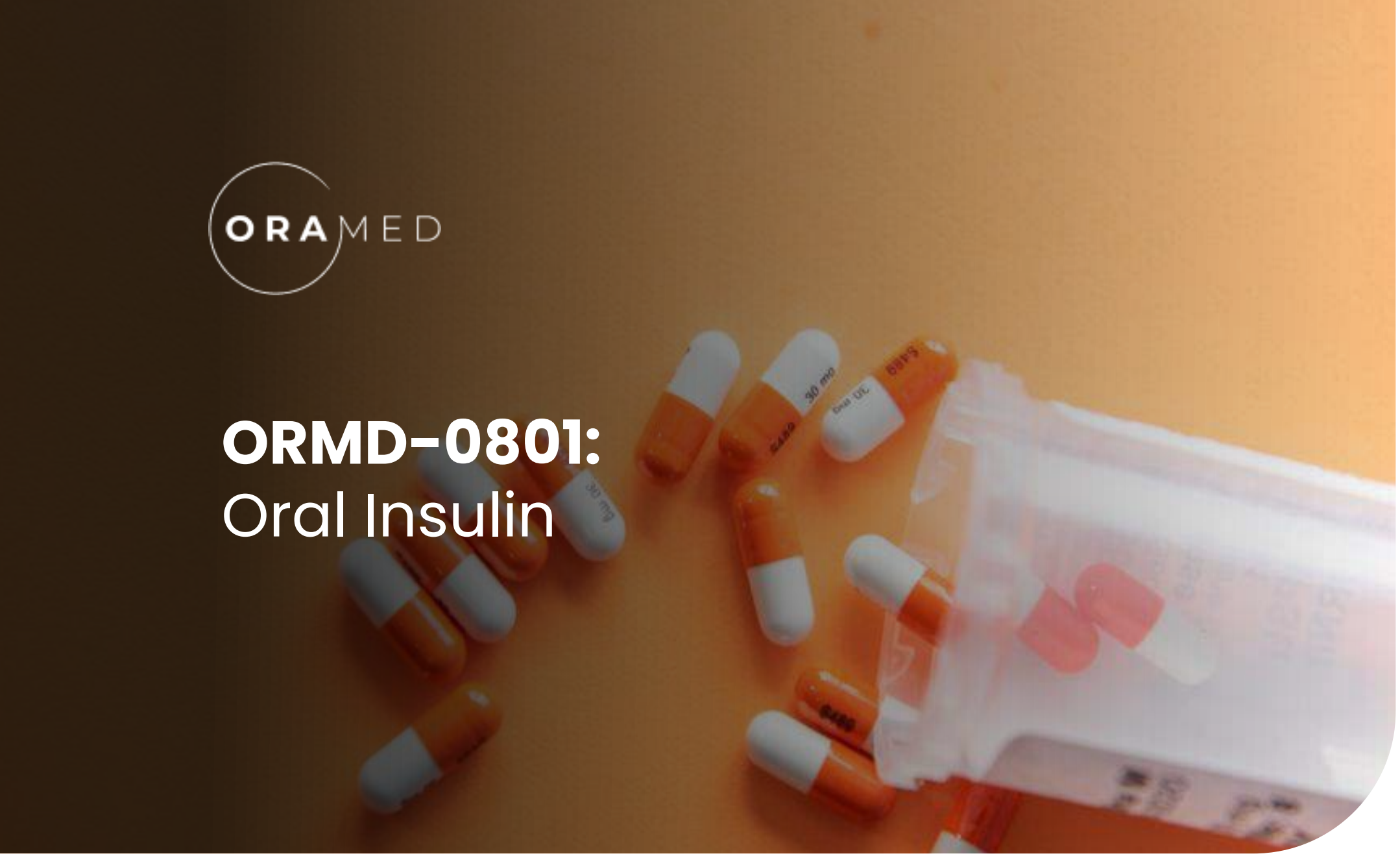
ORAMED

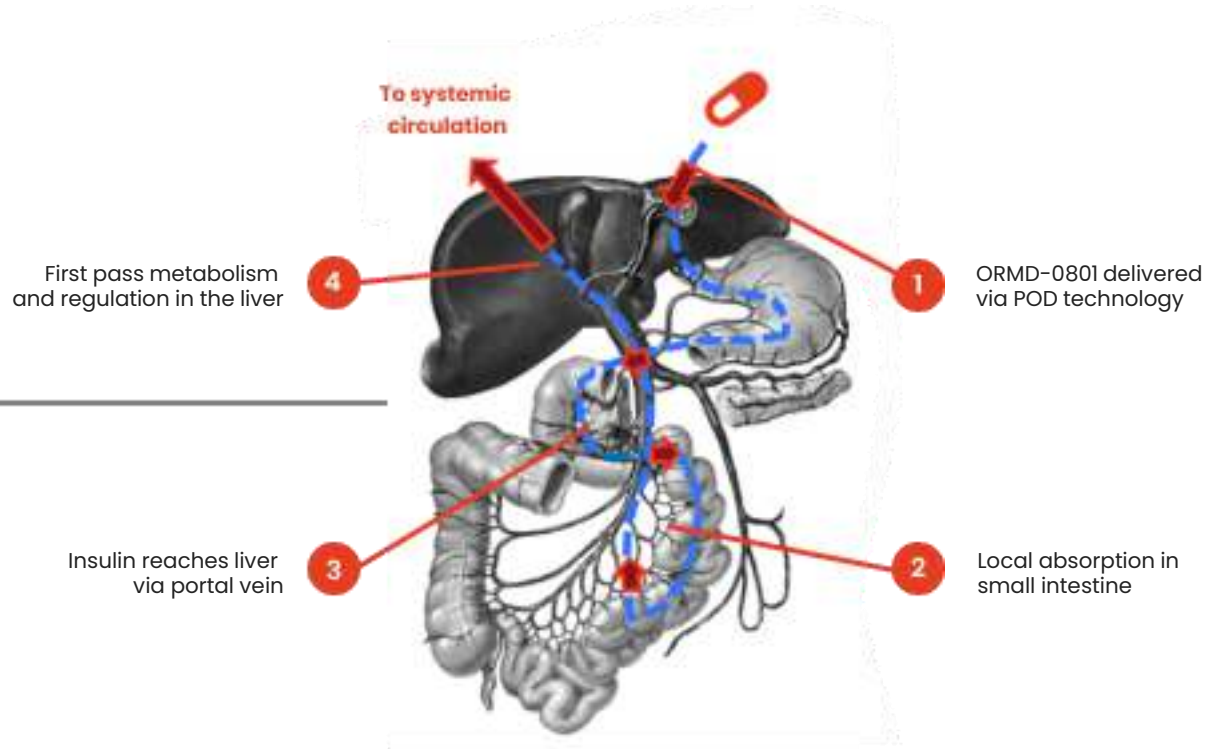
ORMD-0801: Oral Insulin



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

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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

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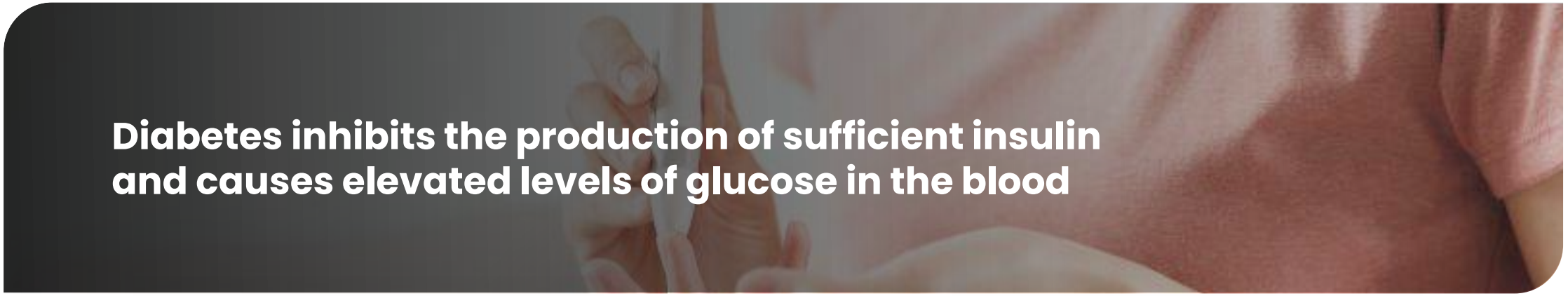
ORMD-0801 for Type 1 & Type 2 Diabetes



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

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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 (TiR), due to portal administration

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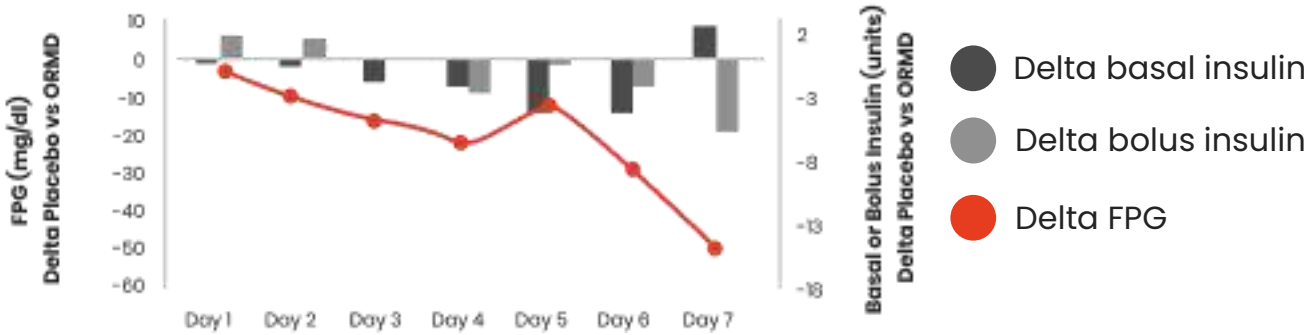
Phase 2a Trial in T1D Completed

By directly targeting liver glucose, ORMD-0801 may provide tighter blood sugar regulation and control for the ~1.6M[1] 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)

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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

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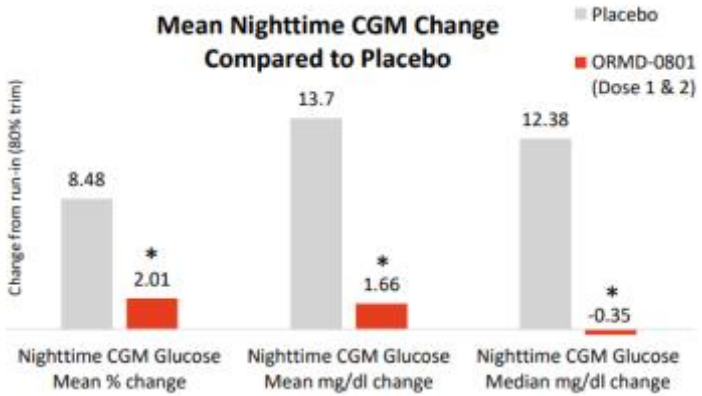
Phase 2 Trial Demonstrated No Drug Related Serious Adverse Events and Promising Efficacy on CGM Parameters

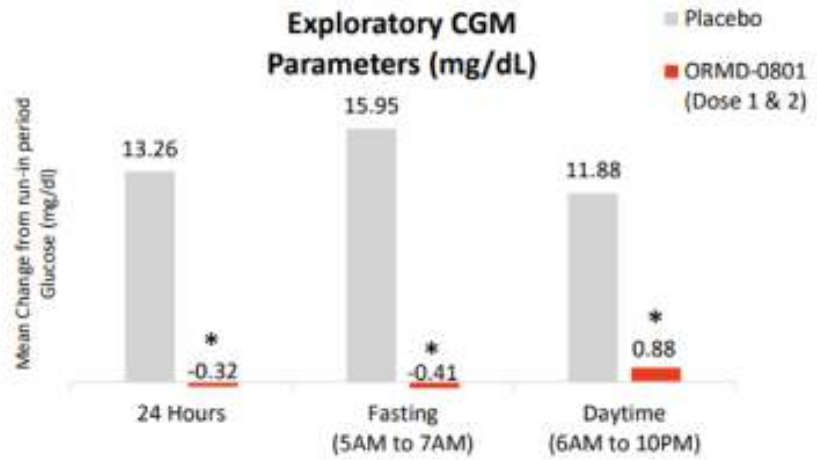
1st Primary Endpoint

- 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)

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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)

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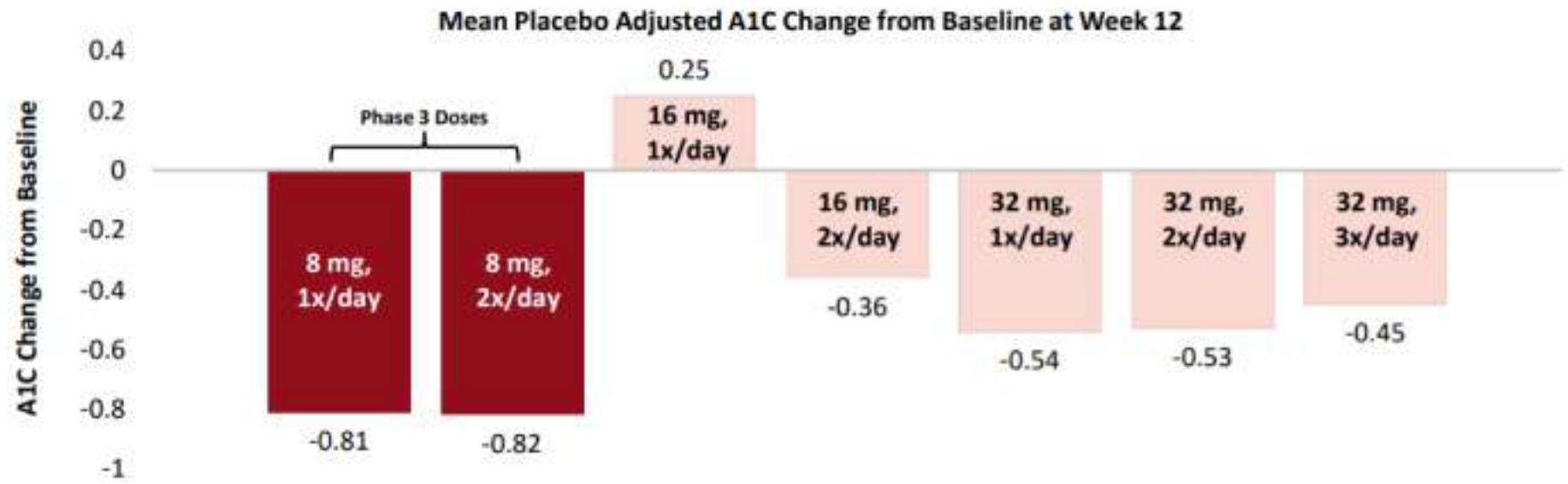
ORMD-0801 Phase 2b
Achieved Safety and Primary Endpoints

- 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)



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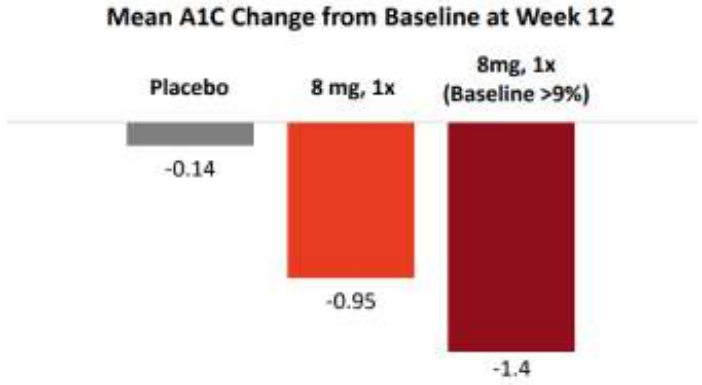
ORMD-0801 Phase 2b Exhibited Strong A1C Lowering Activity at 8 mg 1x/Day Dose

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

ORAMED | Note: ClinicalTrials.gov Identifier = NCT03467932.

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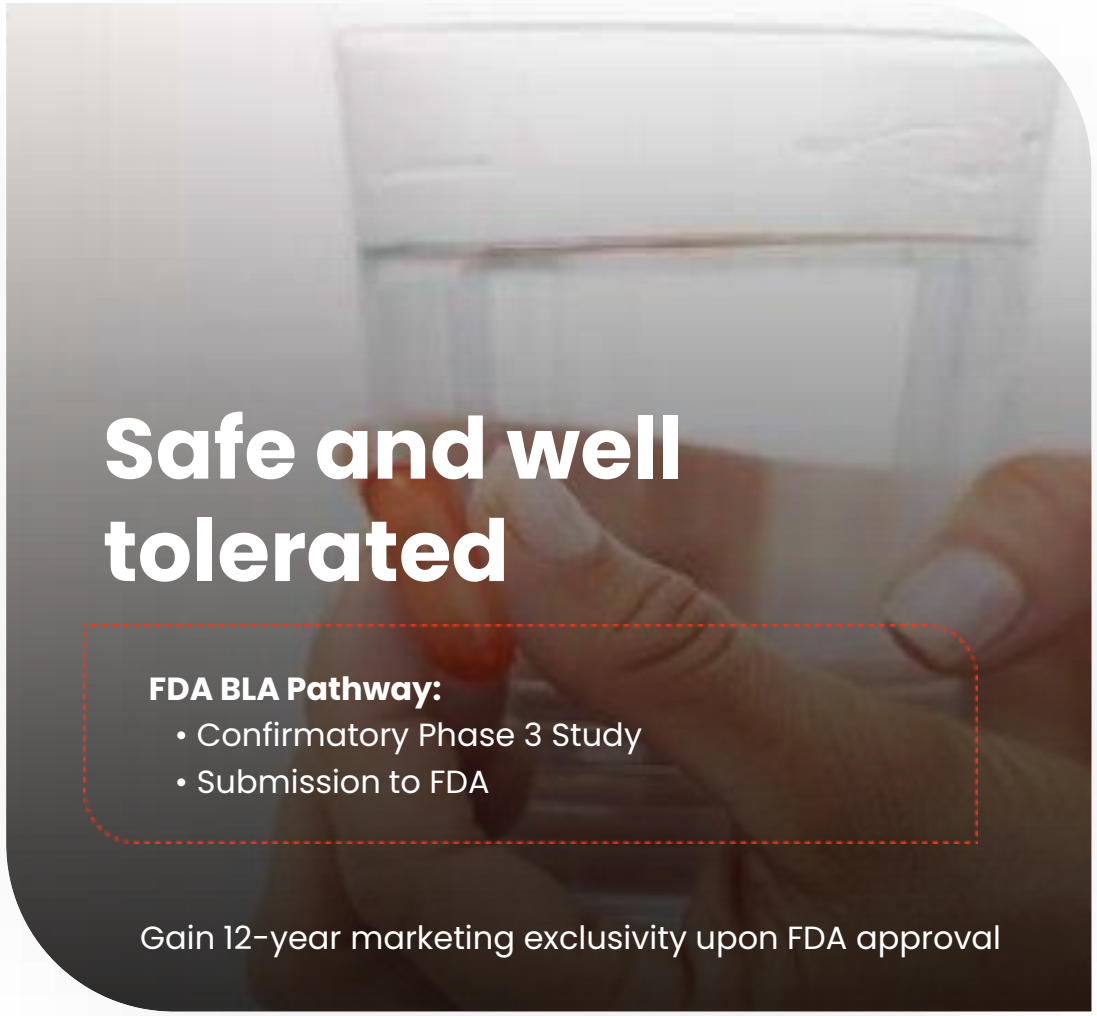
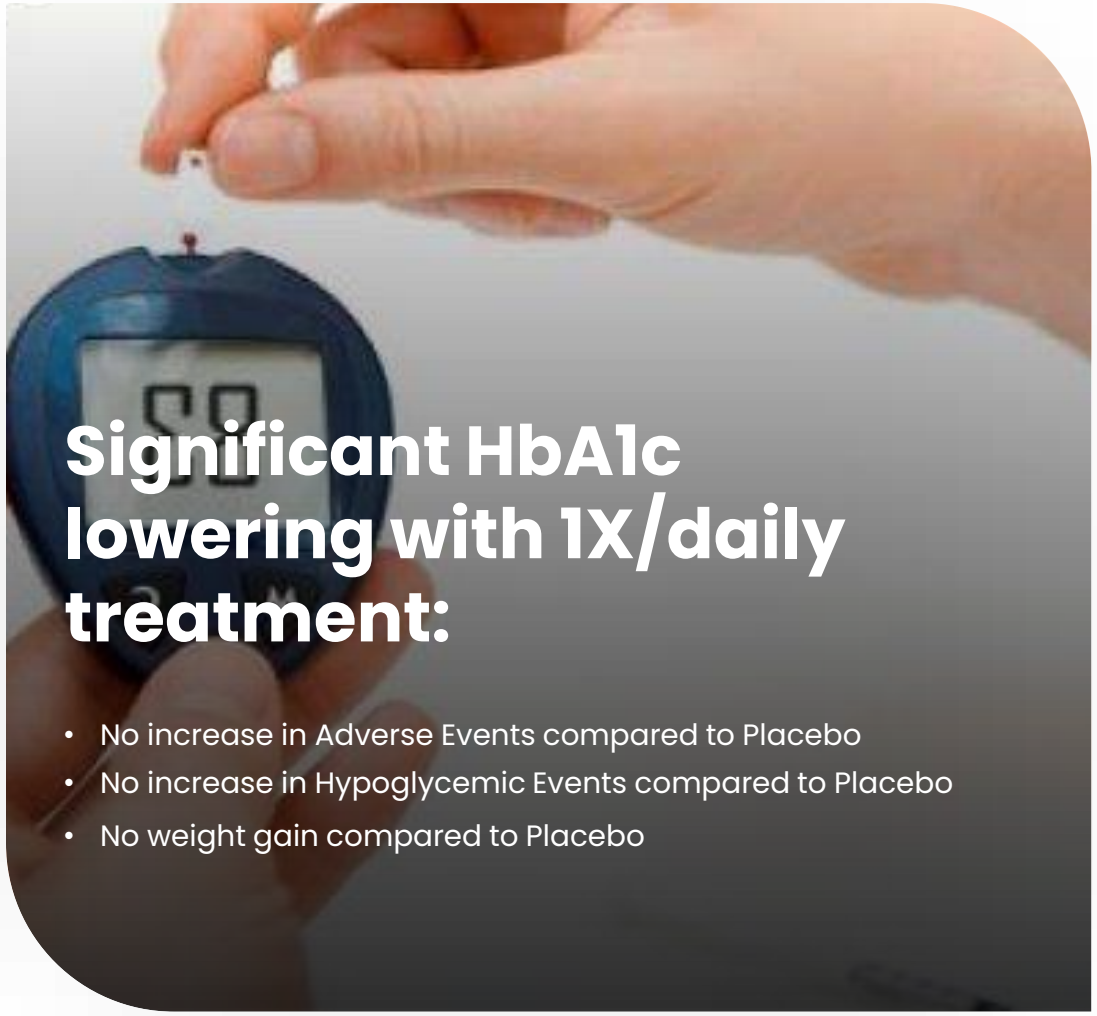
FDA Phase 2b Trial Results
Primary Endpoint Successfully Met



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

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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% randomization[1] • 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**

[1] As of May 3, 2022

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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% randomization [1] • US, European and Israel-based **Double Blind, 1:1 randomization**
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 metformin[1]**

8mg at night	Placebo at night

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 .

[1] As of July 26, 2022

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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

Note: Sample size selected to ensure appropriate N size to support PMR data analytics

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

IQVIA

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

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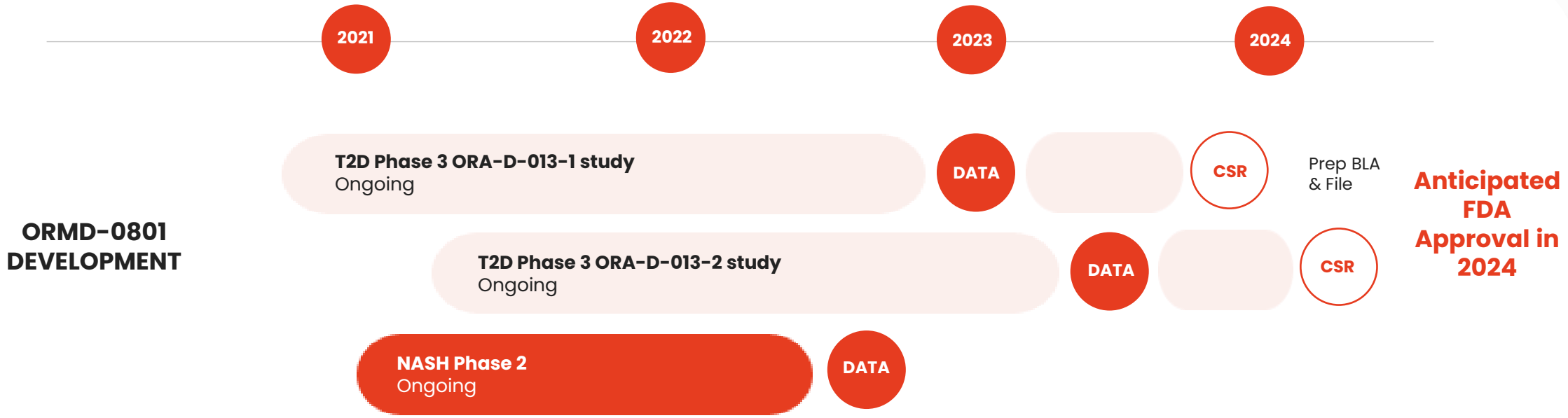
ORMD-0801's Robust Clinical Development Program has Paved the way Towards Anticipated Approval



› 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

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China License Deal: 500M patient potential

114M **DIABETIC**
(10.9% of adult population)

~388M **PREDIABETIC**
(35.7% 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

$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

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Phase 2 Trials for T2D with NASH Completed

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

Positive clinical results in completed pilot study of NASH*

- Open label, 90-day treatment , N = 8 T2D patients with NASH, 8mg x2/ x1 morning
  - **Efficacy:** 30% relative reduction measured by MRI-PDFF; 6.9±6.8% mean reduction in liver fat content (p value: 0.035)
  - **Safety:** No drug-related serious adverse events

* Second pilot study, ongoing in Belgium. 7 patients enrolled with same protocol and guidelines as 1st pilot study. Data expected: Q4 2022

30 **Patients**

90 **Day Treatment**

Positive Phase 2 trial results reported: Safety & Efficacy of ORMD-0801

Design	• Double-blind, randomized, placebo-controlled, multi-center study • 90-day treatment	• **30 T2D patients** with NASH • 8mg x1/ x1 morning & 8mg x1/ x1 night • US and Israel
Study Population	Patients (N=30) with T2D, fat concentration in the liver of moderate steatosis (>8% liver with steatosis) **Ongoing:** all patients enrolled	
Endpoints Reached	**Primary endpoint met:** ORMD-0801 was safe and well tolerated with no treatment-related adverse events **Secondary endpoint met:** Showed clinically meaningful reduction of liver fat from baseline at 12 weeks	

Note: ClinicalTrials.gov Identifier = NCT02653300 and NCT04618744.

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GLP-1 Analog:
ORMD-0901 for Oral GLP-1 (T2DM)

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

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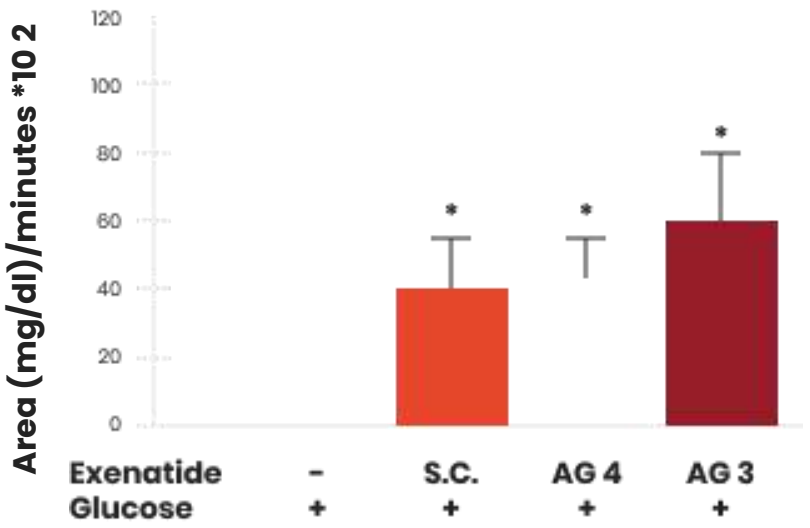
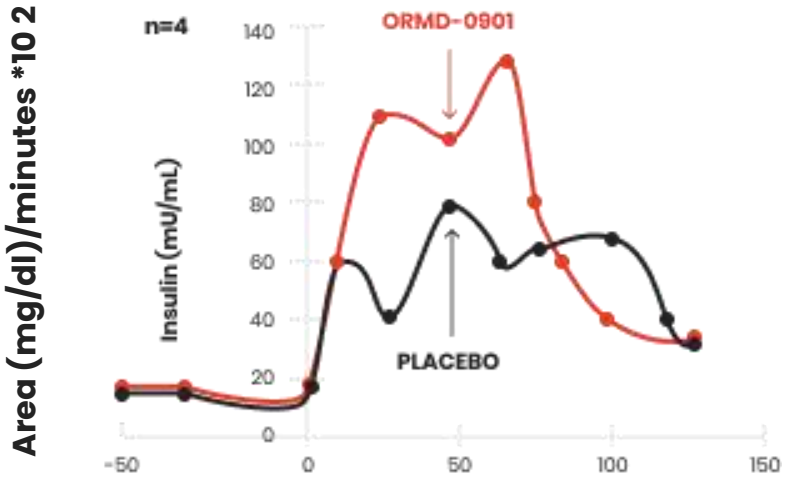
Oral GLP-1 - ORMD-0901

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

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oravax | Novel Oral Covid-19 Company

ORAMED x Premas Biotech

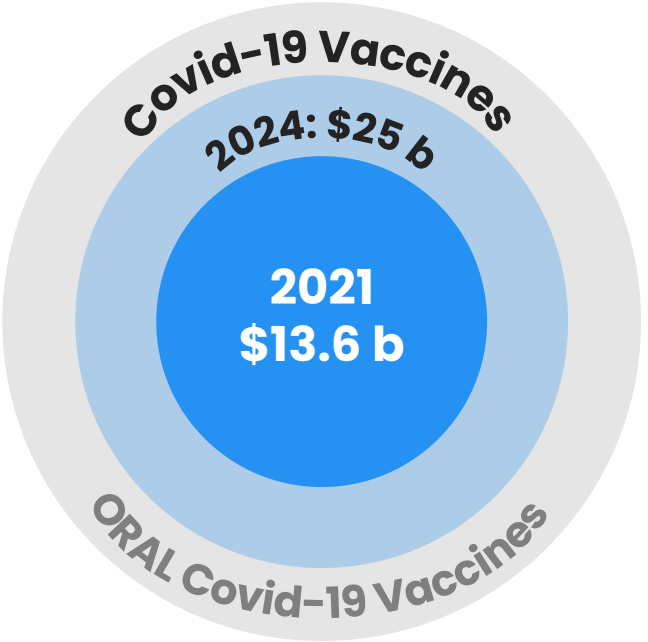
The Oravax technology integrates Premas Biotech's D-Crypt™ technology with an oral delivery platform from Oramed Pharmaceuticals based on their proprietary POD™ delivery technology.

JOINT VENTURE

Oramed is the majority shareholder of Oravax (63%)

LICENSE

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



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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

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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

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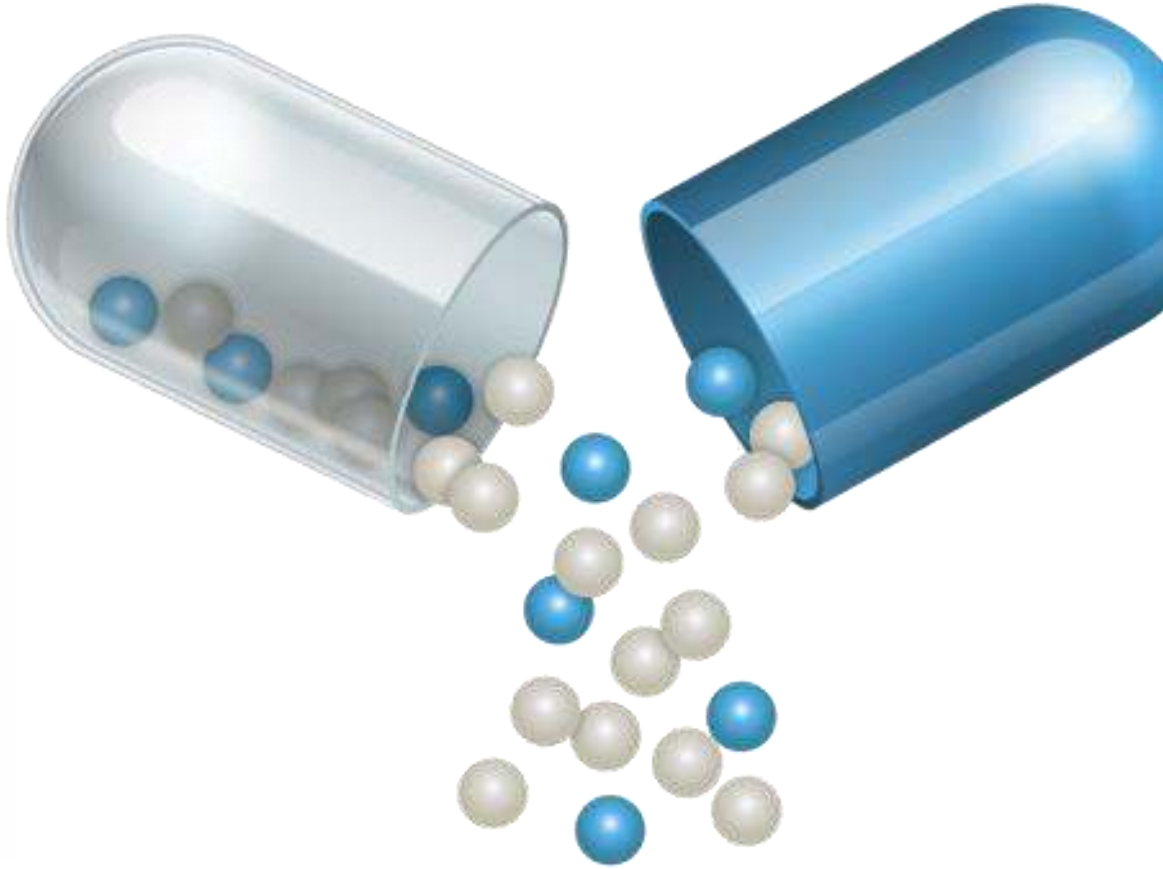
oravax | Phase 1 Trial Initiated

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



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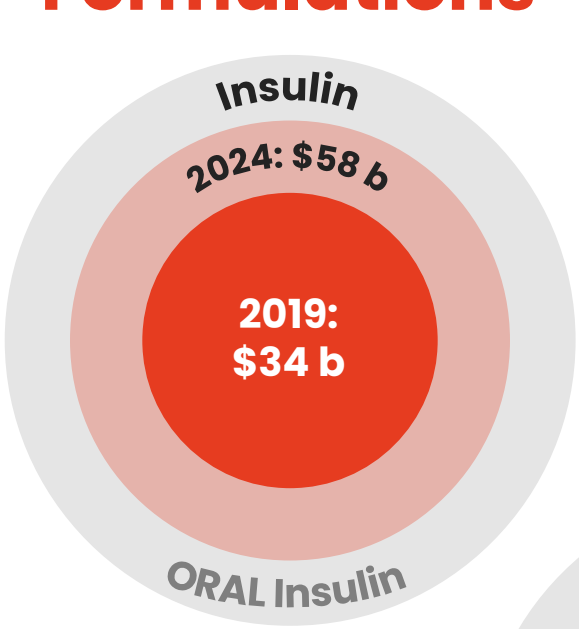
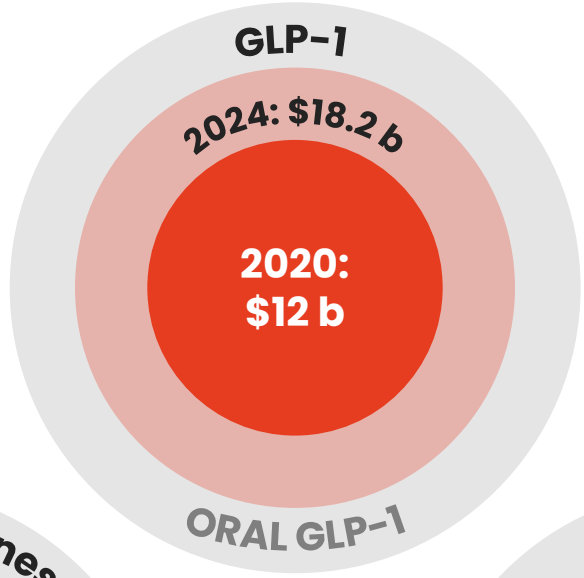
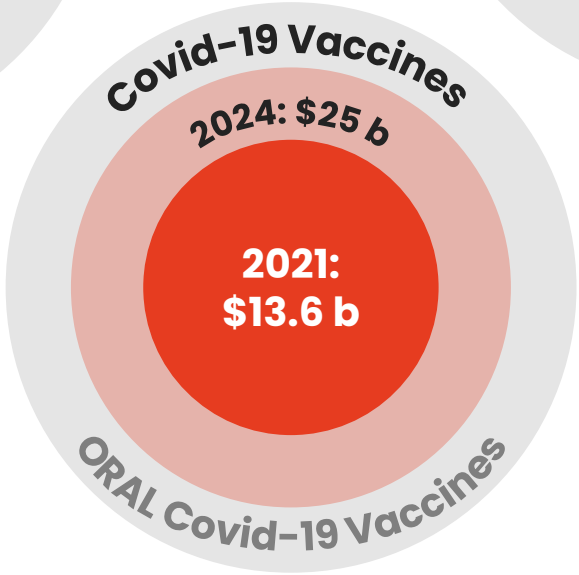
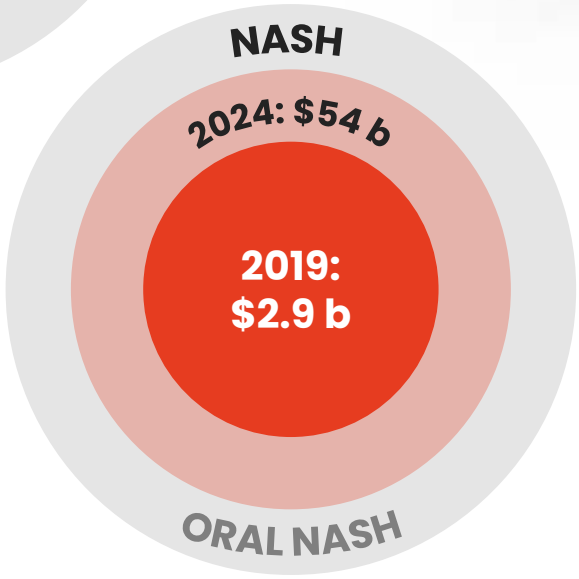
Funneling Huge Injectable Drug Markets to Novel Oral Formulations









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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

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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

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ELE FERRANNINI, MD, PHD

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Alexander Fleming, MD

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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 ~$160M[1] 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

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

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Thank you

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