UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **August 5, 2021**

ORAMED PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**001-35813**	**98-0376008**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1185 Avenue of the Americas, Third Floor, New York, New York	**10036**
(Address of Principal Executive Offices)	(Zip Code)

844-967-2633
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.012	ORMP	The Nasdaq Capital Market, Tel Aviv Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On August 5, 2021, Oramed Pharmaceuticals Inc. posted to its website an investor presentation, a copy of which is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Investor Presentation dated August 5, 2021 (Furnished herewith.)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ORAMED PHARMACEUTICALS INC.

By: /s/ Nadav Kidron
Name: Nadav Kidron
Title: President and CEO

August 5, 2021

oramed Pharmaceuticals Inc

Addressing the Multibillion-Dollar Injectable Drug Markets with Oral Formulations

August 2021

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; 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

- **Proprietary oral protein delivery platform**
- **Diabetes first** - initially targeting the lucrative insulin market
- **Robust pipeline** leveraging IP portfolio for additional significant market opportunities
- **Strong financial position – ~**$105M[1] in cash and investments, no debt
- **Experienced management** team backed by world-class scientific experts
- **Multiple value-creation events** for 2021
- **NASDAQ/TASE:** ORMP

[1] As of August 2, 2021 (unaudited)

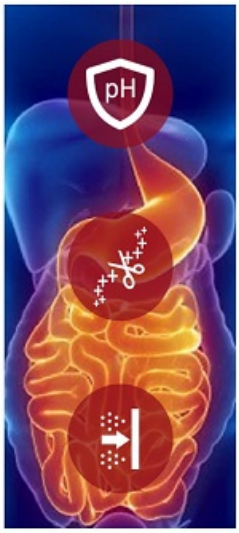
Proprietary Technology for Oral Drug Delivery

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)



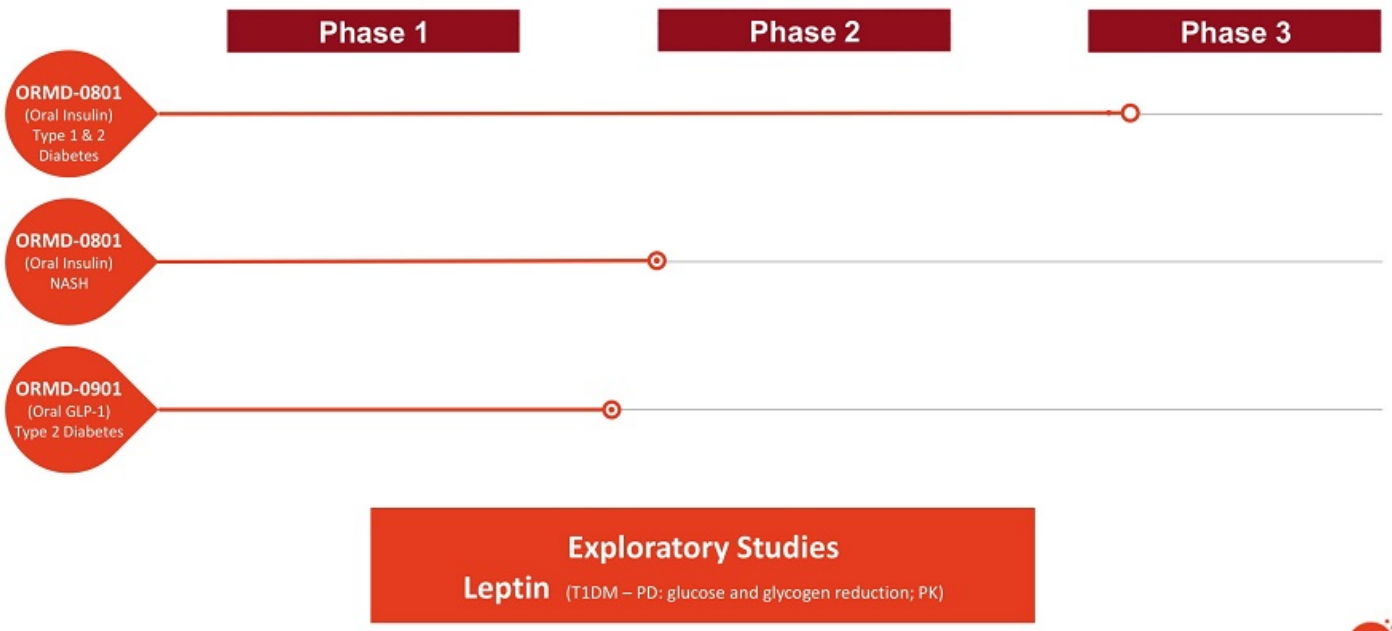
Oramed Technology Protects Drug Integrity and Increases Absorption

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



Exploratory Studies

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

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

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1 in 11 Adults on the Planet Have Diabetes

10% healthcare spent on diabetes

In 2019 diabetes expenditure reached US $ 760 billion

2019

expected increase:

+237

MILLION

2045

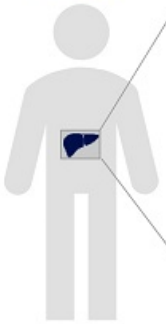
https://www.idf.org/e-library/epidemiology-research/diabetes-atlas/159-idf-diabetes-atlas-ninth-edition-2019.html

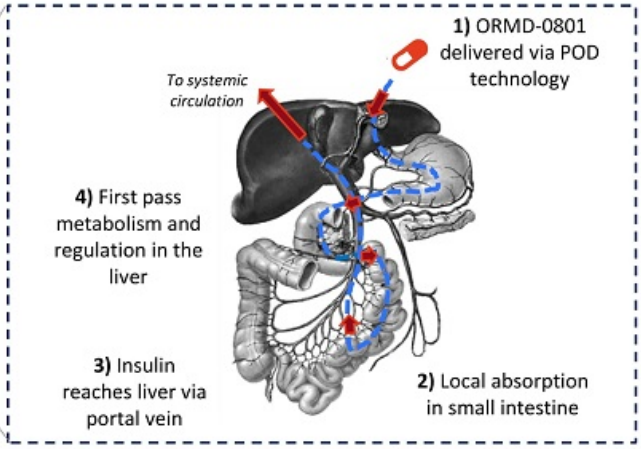
ORMD-0801:
Oral Insulin

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

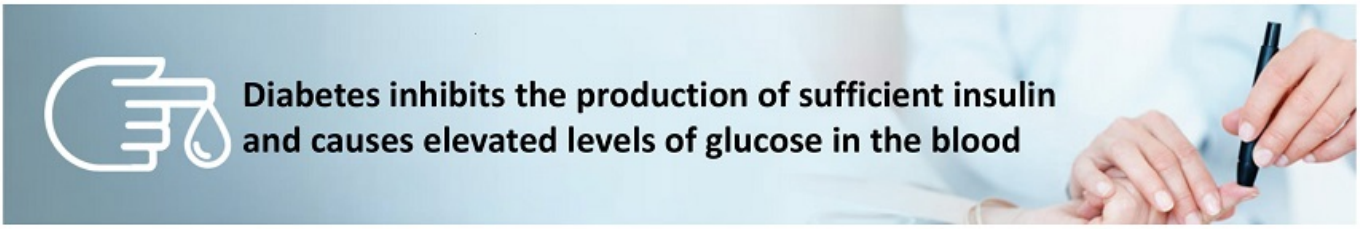
Advantages of ORMD-0801 Oral Insulin

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

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 37 million people worldwide have T1DM
- **Projected Market:** $13 billion by 2023

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
- **371 million people worldwide need treatment**
- **Projected Market:** $59 billion by 2025

ORMD-0801 for Type 1 Diabetes (T1DM)

Potentially eliminating the need for insulin before each meal

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

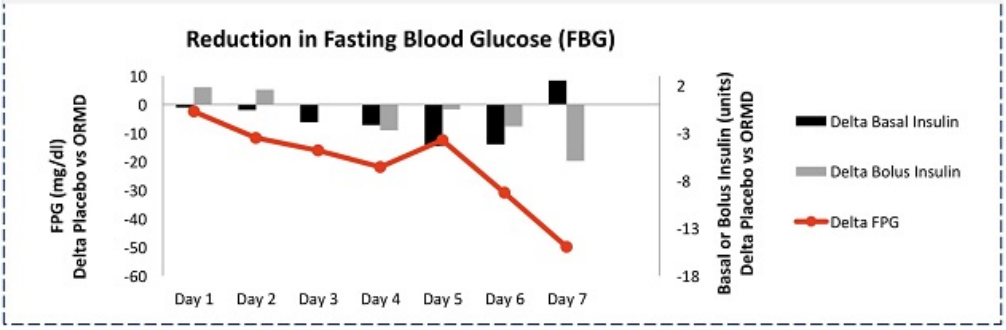
- Easier use and reduced systemic exposure
- Potentially reducing multiple daily injections
- Tighter regulation and control of blood sugar levels by directly targeting liver glucose (TiR), due to portal administration

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[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)

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[1]

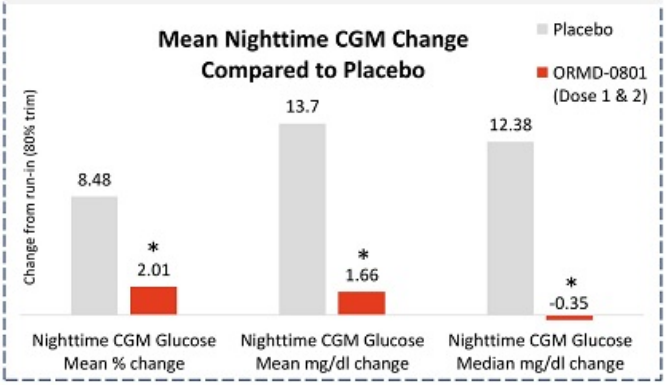
Design	• Double-blind, randomized, placebo-controlled, 4 week, once daily (3 capsules) treatment
Study Population	• Patients with T2D who (1) are being treated by diet and exercise, (2) are untreated with antidiabetic medications, or (3) are treated with metformin as a monotherapy or in combination with 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)

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

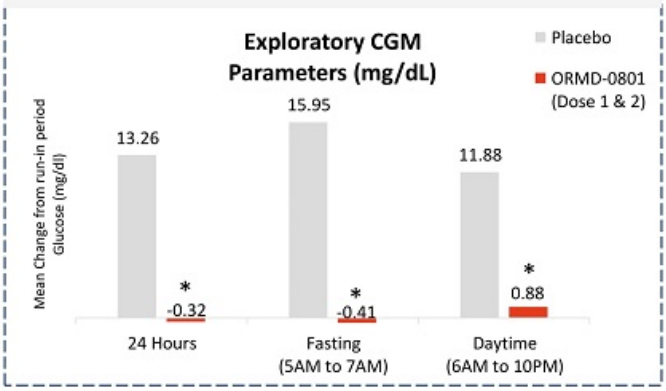
1st Primary Endpoint

- 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)



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[1] **298** Patients[1] **90** Day Treatment **7** Dose Groups

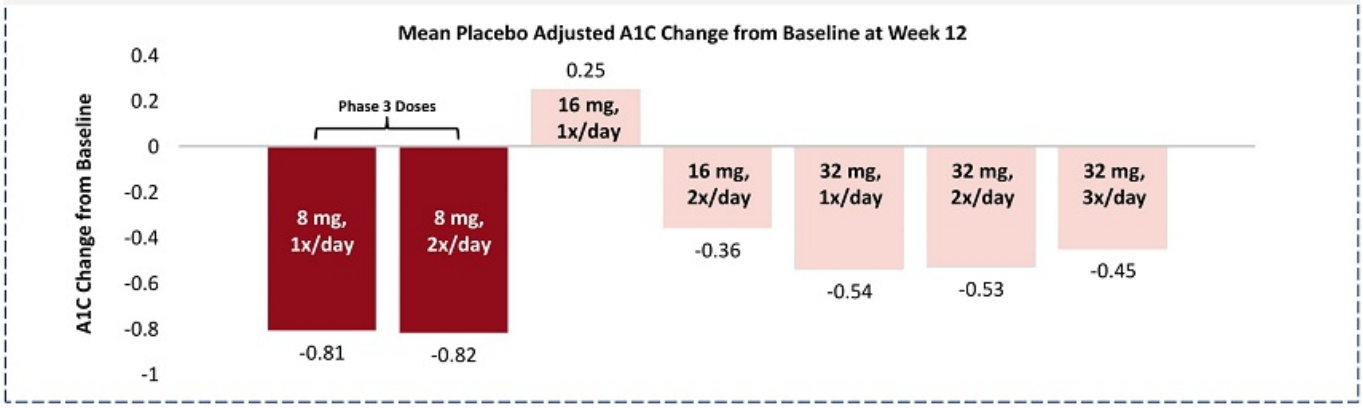
Design	• Double-blind, randomized, placebo-controlled, 12-week, once/twice/or three times daily treatment					
Study Population	• Patients with T2D who are taking metformin only (at least 1500 mg or maximally tolerated dose) or metformin in addition to no more than two of the following: Glibenclamide, 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)

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)

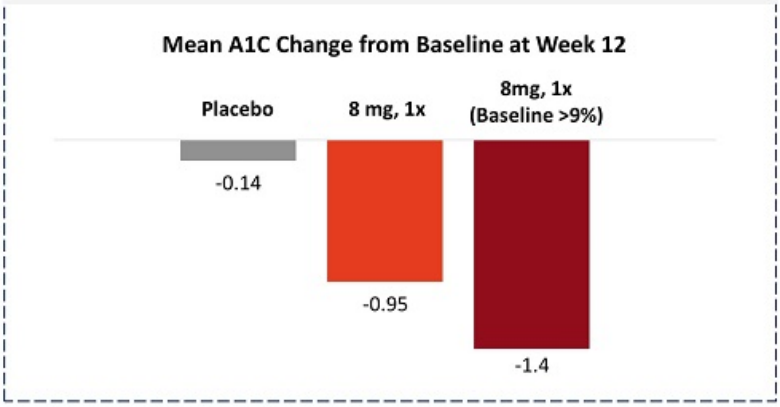


Note: ClinicalTrials.gov Identifier = NCT03467932.

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



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

oramed
Pharmaceuticals Inc

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

	1 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 • 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

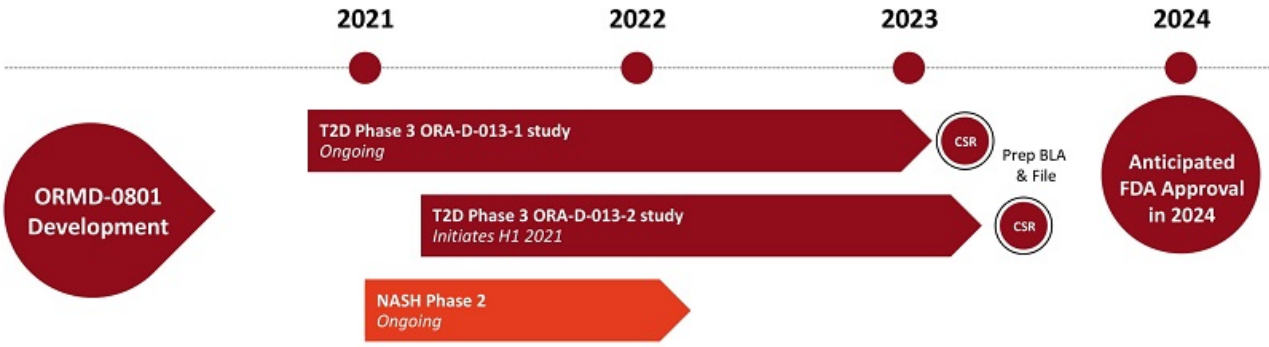
Source: (1) FDA indicated possible 1L designation based on the ORA-D-013-2 trial in which ~30% of enrolled patients are metformin treatment naïve

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

	2 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) • 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 metformin[1]

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

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 initiated
- Second T2D Phase 3 trial initiating in H1 2021
- 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

- **2** Protocols
- **48** Patients[1]
- **90** Day Treatment
- **1** Dose Cohort

	Trial #1: Pilot Study to Assess Efficacy and Safety of ORMD-0801	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	• Double-blinded, randomized, 2 groups, 12 week, twice daily treatment in **30 T2D** patients with NASH in US & Israel
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
Initial Data	• ***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

Note: ClinicalTrials.gov Identifier = NCT02653300 and NCT04618744. (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.

ORMD-0901:
Oral GLP-1 Analog

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

GLP-1 Analog

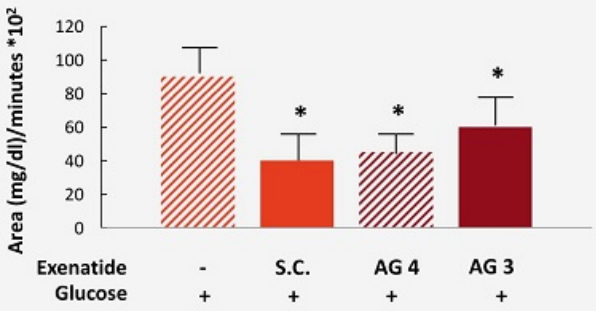
- T2DM medication
- Mimics the natural hormone in the body
- Compelling safety profile
- Decreases blood glucose levels
- Effectively reduces HbA1c
- Preserves beta cell function
- Promotes weight loss

ORMD-0901 Clinical Status

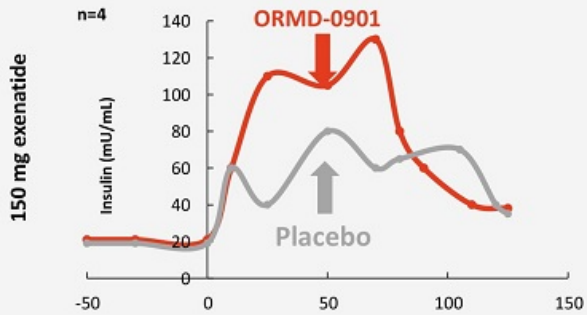
- IND
- Bioavailability study

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

oramed Pharmaceuticals Inc x Premas Biotech

- JV:
  - Oramed majority shareholder of Oravax
  - Majority of BoD
- License:
  - Royalties: 7.5% of net sales
  - Sublicensing: 15%
  - Sales milestone: $25M - $100M

- **Universal COVID vaccine**
  - 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, or body weight loss/gain, no adverse events noted in any animal
  - Significant antibody response, as well as cellular immune response
  - Showed desired immunological parameters and efficacy
  - 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)

Anticipated Development Milestones

0801 oral insulin

- T2DM: Phase 3 trials
- NASH: Phase 2 underway

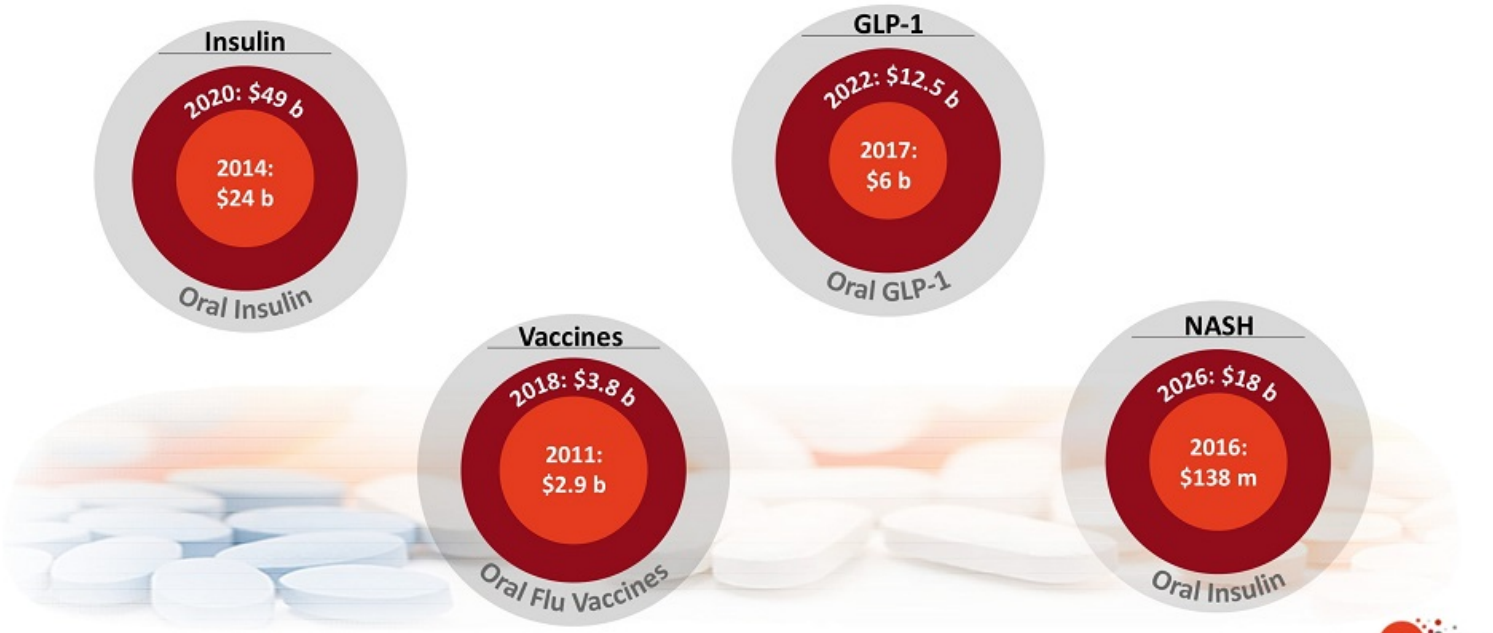
0901 GLP-1

- Bioavailability Study (T2DM) Initiation & Completion

Leptin

- Phase I ex-USA Initiation

Funneling Huge Injectable Drug Markets to Novel Oral Formulations



Management Team

Nadav Kidron, Esq, MBA - CEO & Director
Many years of business experience as well as corporate 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
Head of the Diabetes Unit at Tel-Aviv Sourasky Medical Center

Michael Rabinowitz - Chief Commercial Officer
Over 2 decades experience in launching and marketing new medications and treatments

Board of Directors

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 of public and private companies including Maayan Ventures, Capital Point and Rosetta Green Ltd.

Arie Mayer

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

Xiaoming Gao

Chairman of HTIT, China

Nadav Kidron

CEO, Oramed

Miriam Kidron

CSO, Oramed

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 Facility of Medicine, Technion, Haifa, Israel

Harold Jacob, MD

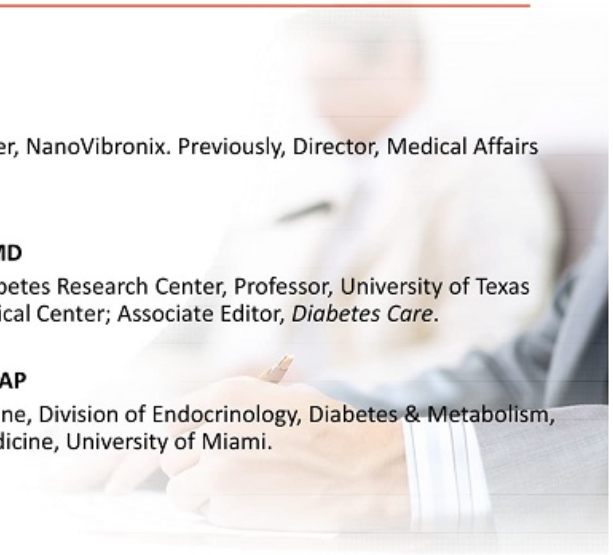
Chief Medical Officer, NanoVibronix. Previously, Director, Medical Affairs at Given Imaging.

Julio Rosenstock, MD

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

Jay Skyler, MD, MCAP

Professor or 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

- **Proprietary oral protein delivery platform**
- **Diabetes First:** Initially targeting the lucrative insulin market; additional markets in the pipeline
- **Strong financial position** with ~$105M [1] in cash and investments, no debt, 32.5M shares outstanding (37.1M fully diluted) [2]
- **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 August 2, 2021 (unaudited) [2] as of July 14, 2021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