#### **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): October 22, 2020

#### 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 Offi	ces)	(Zip Code)
(R	<b>844-967-2633</b> egistrant's telephone number, including area	code)
Check the appropriate box below if the Form following provisions:	8-K filing is intended to simultaneously sat	tisfy the filing obligation of the registrant under any of the
$\square$ Written communications pursuant to Rule 425 und	er the Securities Act (17 CFR 230.425)	
$\square$ Soliciting material pursuant to Rule 14a-12 under to	the Exchange Act (17 CFR 240.14a-12)	
☐ Pre-commencement communications pursuant to F	Rule 14d-2(b) under the Exchange Act (17 C	FR 240.14d-2(b))
$\ \square$ Pre-commencement communications pursuant to F	Rule 13e-4(c) under the Exchange Act (17 C	FR 240.13e-4(c))
Securities registered pursuant to Section 12(b) of the A	ct:	
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 registran this chapter) or Rule 12b-2 of the Securities Exchange	0 0 0 0 1 1	ed in Rule 405 of the Securities Act of 1933 (§230.405 of
Emerging growth company $\square$		
If an emerging growth company, indicate by any new or revised financial accounting standards prov		t to use the extended transition period for complying with nge Act. $\Box$

#### Item 7.01. Regulation FD Disclosure.

On October 22, 2020, 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 <u>Investor Presentation dated October 22, 2020. (Furnished herewith.)</u>

#### **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

October 22, 2020



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

October 2020



#### 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 over \$45.6M in cash and investments, no debt<sup>1</sup>
- Experienced management team backed by world-class scientific experts
- Multiple value-creation events for 2020
- NASDAQ/TASE: ORMP





### 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**

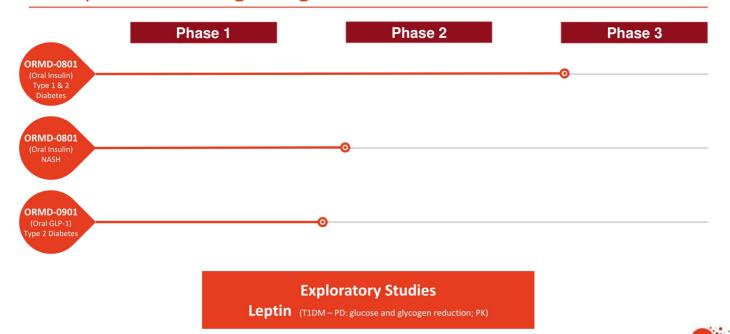
Protease inhibitors protect the active agent

#### **Absorption enhancement**

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



### Multiple Clinical-Stage Programs





### **Diabetes:**

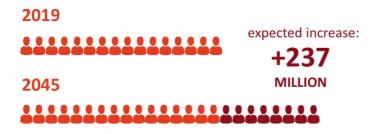
Millions of diabetics inject insulin today and wish for oral dosage

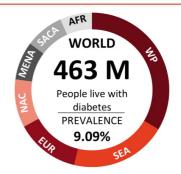


### 1 in 11 Adults on the Planet Have Diabetes

10% healthcare spent on diabetes

In 2019 diabetes expenditure reached US \$ 760 billion









 $\underline{https://www.idf.org/e-library/epidemiology-research/diabetes-atlas/159-idf-diabetes-atlas-ninth-edition-2019.html}$ 





### ORMD-0801 - Flagship Product for Oral Treatment of Diabetes

>900 study subjects



>10,000 human doses



No Serious
Drug-Related
Adverse
Events





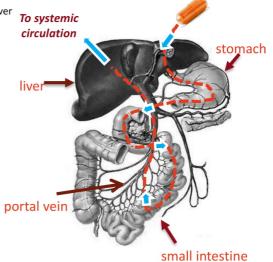
### The Drawbacks of Injected Insulin vs. the Advantages of Oral Insulin

**ENDOGENOUS INSULIN** produced by the pancreas and delivered to the body via the liver

**Injected Insulin** introduced directly to the bloodstream, with only a fraction of it reaching the liver. This can cause excess sugar to be stored in fat and muscle which often results in weight gain and may also cause hypoglycemia.

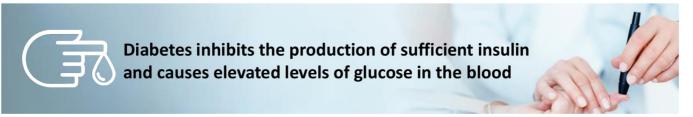
**Oral insulin**, like natural insulin, is delivered first to the liver, resulting in:

- ✓ Better blood glucose control
  - ✓ Reduced hypoglycemia
  - ✓ Reduced hyperglycemia
- ✓ No weight gain





### 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

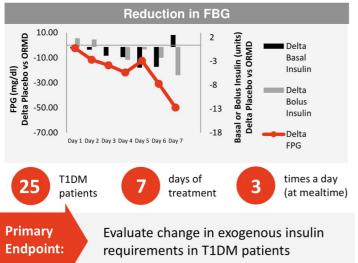
- Easier use and reduced systemic exposure
- Potentially reducing multiple daily injections
- Tighter regulation and control of blood sugar levels by directly targeting liver glucose (TiR), due to portal administration



### Phase 2a T1DM Study

Consistent and Accumulative Effect of ORMD-0801 for Treating Type 1 Diabetes

Blood glucose levels lower day and night compared to control group



Oral Insulin Reduces Exogenous Insulin Requirements



#### **Decreased**

- √ use of rapid-acting insulin
- √ levels of post-meal glucose
- √ levels of daytime glucose

**Safe and Well Tolerated** 



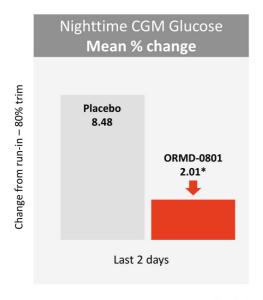
### Completed: 180 Patient Phase 2 Study for Type 2 Diabetes

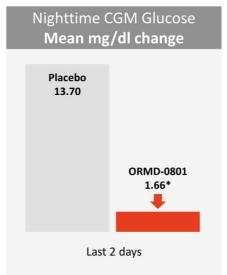


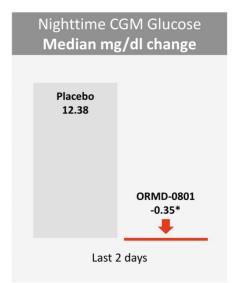


### **FDA Phase 2 Study**

### Achieved Every Primary Endpoint with No Drug Related Serious Adverse Events





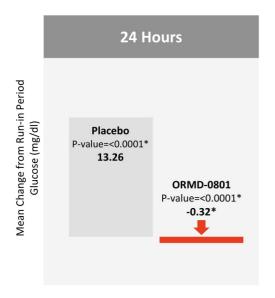


\* Indicates Statistically Significant Difference versus Placebo (p-Value<0.05)

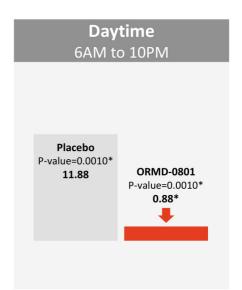


### **FDA Phase 2 Study**

### **Exploratory Endpoints: CGM Parameters**







\* Indicates p-Value<0.05



### Completed: 298 Patient Phase 2b Trial



\*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)



298 Patients\*

90 Day treatment

7 Doses



### **Endpoints**



Mean change in HbA1c from baseline to Week 12



Secondary Endpoints

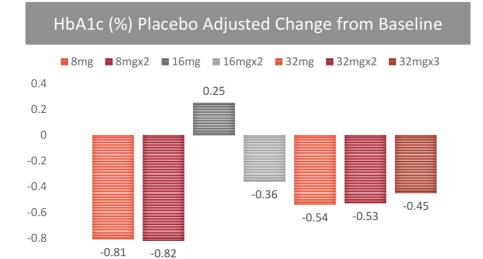
- Safety (AEs, hypoglycemic)
- Fasting Plasma Glucose (FPG) + CGM
- Weight

**Dose Finding** 

- 96 mg/day (32 mg X 3/day)
- 32 mg/day (32 mg X 1/day)
- 32 mg/day (16 mg X 2/day)
- 64 mg/day (32 mg X 2/day)
- 16 mg/day (8 mg x 2/day)
- 16 mg/day (16 mg X 1/day)
- 8 mg/day (8 mg X 1/day)



### Phase 2b: Primary Endpoint Successfully Met



-1

8 mg - 1/day -0.95 (-0.81 placebo adjusted)

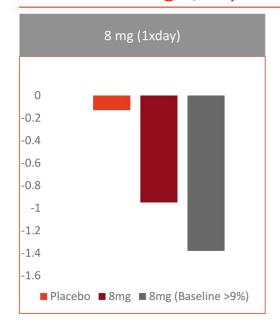
60-70% of the randomized patients were on 2 or more glucose lowering drugs

All Patients were on Metformin

Glucose lowering agents taken in addition to Metformin included:

Glibenclamide, Glipizide, Empagliflozin, Pioglitazone, Glimepiride, Dapagliflozin, Sitagliptin, Glibomet, Ertugliflozin

### Phase 2b: 8 mg 1/day – HbA1c Change from Baseline at Week 12



- 0.95 (0.81 placebo adjusted) reduction
  - p-value: 0.0276
  - [1.29 A1C reduction (Observed Means)]
- 1.26 placebo adjusted reduction (Baseline >9%)



### 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



#### **Pivotal Phase 3**

Factors considered by the FDA in a pivotal Phase 3 program

- 1. **Efficacy**: The study is powered, based on previous Phase 2 data, to include sufficient patients that will provide statistical significance for primary endpoint provided that the drug performs at least equally well in the Phase 3 study as it did in the Phase 2 study.
- **2. Safety**: The study has sufficient patients, as determined by the FDA, to demonstrate that the drug is safe in diabetic patients.
- **3. Exposure**: The study must show that the drug remains safe in patients exposed to the drug over a period of 6 and 12 months
- **4. Geographic variation**: USA, Israel and EU countries



#### Pivotal Phase 3: Two Protocols

#### ORA-D-013-1

A Double-Blinded, Placebo-Controlled, Double Dummy, Multi-Center Randomized, Phase 3 Study to Evaluate the Efficacy and Safety of ORMD-0801 in Subjects with Type 2 Diabetes Mellitus with Inadequate Glycemic Control on One, Two or Three Oral Glucose-Lowering Agents

#### ORA-D-013-2

A Double-Blinded, Placebo-Controlled, Multi-Center Randomized, Phase 3 Study to Evaluate the Efficacy and Safety of ORMD-0801 in Subjects with Type 2 Diabetes Mellitus with Inadequate Glycemic Control on Diet Control Alone or on Diet Control and Metformin Monotherapy



### Pivotal Phase 3: Dosing (Selected from P2b study data)

#### ORA-D-013-01

- Double Blind, Double Dummy
- 1:1:1 randomization
  - 8mg once-daily at night and placebo 45 mins before breakfast
  - 8mg twice-daily at night and 45 mins before breakfast
  - Placebo twice-daily at night and 45 mins before breakfast

#### ORA-D-013-02

- Double Blind
- 1:1 randomization
  - 8mg at night
  - Placebo at night



### Pivotal Phase 3: Sample Size

	ORA-D-013-1	ORA-D-013-2
Sample size	675 adult male and female subjects	450 adult male and female subjects
Territory	US-based	US, Eastern and Western European and Israel-based
Number of Sites	75 US sites	36 US sites, 25 ex-US sites

### ORA-D-013-1: Primary and Secondary Objectives

#### **Primary Objective**

To compare the efficacy of ORMD-0801 to placebo in improving glycemic control as assessed by A1c in inadequately controlled T2DM subjects on one, two or three oral glucose-lowering agents.

#### **Secondary Objective**

To assess the safety of repeat administration of ORMD-0801 in inadequately controlled T2DM subjects on one, two or three oral glucoselowering agents.



### ORA-D-013-2: Primary and Secondary Objectives

#### **Primary Objectives**

#### Active vs Placebo:

 To evaluate the efficacy of ORMD-0801 compared to placebo in improving glycemic control as assessed by A1c in inadequately controlled T2DM subjects on diet control alone or on diet control and metformin monotherapy over a 26-week treatment period.

#### **Secondary Objectives**

#### Active vs Placebo:

 To evaluate the efficacy of ORMD-0801 compared to placebo in maintaining glycemic control over a 52-week treatment period.



### Pivotal Phase 3: Key Inclusion Criteria

#### ORA-D-013-1

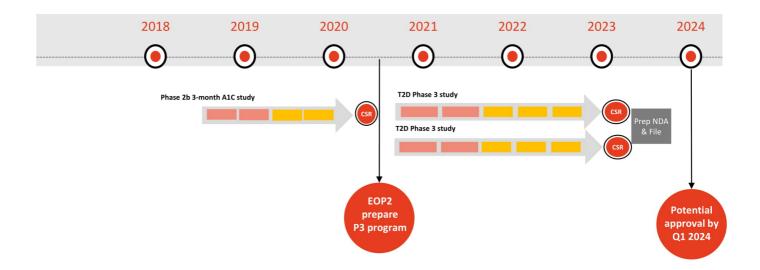
- HbA1c  $\geq$  7.5% but  $\leq$  11.0% at Screening.
- On a stable dose of at least one and up to three of the following oral glucoselowering agents for a 3-month period prior to Screening:
  - Metformin
  - DPP-4 inhibitor
  - SGLT-2 inhibitor
  - Thiazolidinedione
  - Sulfonylurea

#### ORA-D-013-2

- HbA1c  $\geq$  7.5% but  $\leq$  11.0% at Screening.
- Subjects should be on:
  - Diet and exercise alone for a period of at least 3 months prior to Screening; OR
  - Diet and exercise with a stable dose of metformin only (≥ 1500 mg or MTD) for a period of at least 3 months prior to Screening.



### Pivotal Phase 3: Anticipated Clinical Development Timelines





### China License Deal: 500M patient potential

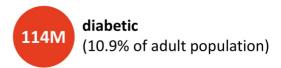
4

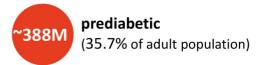
- License: Exclusive right to ORMD-0801 in Greater China
- Licensee: Hefei Tianhui ("HTIT")

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\*







\* Journal of the American Medical Association

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### **Commercial Positioning**



#### **Project Background**



Seagrove Partners completed focus groups with 94 total participants including HCPs, Patients & Payers in July 2020.

- Six Key Project Objectives:

  1. Understand the Therapeutic Unmet Needs for PWD (Type 1 and Type 2)

  2. Determine Total Addressable Market for Oral Insulin.

  3. Test Oral Insulin Target Product Profile with Payers, HCPs & Patients

  4. Determine Preferred Patient Segments for Maximum Product Uptake

  5. Understand Recommended Product Positioning

  6. Gather Video Outtakes Highlighting Key Respondent

#### **Key Findings**

- Prescribers value ancillary benefits of existing diabetes medications. In addition to the solid ATC lowering impact, HCPs place a high value on weight loss, cardiovascular and renal benefits that evisition medications exempted.

- 63% of payers would be "very likely" or "likely" to recommend formulary coverage for T2D members in combination with other oral agents (metformin, SGLT-2s) or GLP-1s.
- Positioning oral insulin as a new class has benefits. Positioning ORMD-0801 as a new class of medication (vs. being lumped in with insulina) allows more control over rebate levels and less (none initially) competition for preferred coverage.

#### **Patient Segmentation**



#### First Line After Metformin (before GLP-1s/SGTL-2s)

This will likely require showing comparable A1C improvement with Metformin to the GLP-1/SGLT-2 classes, improved TIR and long-term evidence of beta cell preservation (which would delay the need for injectable insulin). This assumes there is still no weight gain or increase in hypo risk. Key requirement: better A1C improvement that DPP-4s.

Second OR Third Line for Select Patient Segments
Identify segments where clinical improvement is the highest. 1)
Patients who cannot take GLP-1s or SGLT-2s 2) Patients who are hypo
unware [particularly for overnight control with decreased hypo] 3)
Patients who cannot/will not take injections. This may end up
becoming the product sweet spot and may be easiest to brand and
promote. This would include current DPP-4 users.

#### Third Line In Combination with GLP-1s/SGLT-2s

Given the ancillary CV, renal and weight gain benefits of the GLP-1/SGLT-2 classes, oral insulin will require strong A1C, additional clinical data (e.g. improved TIR or enhanced combo effect with another class) as well as evidence that oral insulin delays the need for injectable insulin to be broadly recommended. Keep in mind this will be viewed as added cost to the system.

#### 4th Line Post GLP-1s/SGLT-2s

With similar (but longer-term) clinical results to today, ORMD-0801 can be positioned as a precursor or "training insulin" particularly in primary care. The value proposition can be strengthened by showing a delay to injectable insulin.

#### **Possible Positioning and SWOT**

Ancillary "Upside" Package	A1C	Patient Segmentation
QD Dosing No Hypos No Hypos No Hypos Durabile Best call Preservation Much Better TIR Much Better TIR Much Better Deviations Better Post Prandal Control Data Supporting MOAc  Data Supporting MOAc	>1.3	Frontline Therapy with Metformin
	1.0-1.2	Frontline Therapy with Metformin
	0.8-1.0	Replacement for 2 <sup>nd</sup> Line Agents
	0.6-0.8	Replacement for DPP4s
	<0.6	3 <sup>rd</sup> Line Therapy for Those Who Can't Tolerate GLP-1s/SGLTs
Ancillary "Base" Package	A1C	Patient Segmentation
QD Dosing     No Hypos     Weight Neutral     Trend Towards Beta Cell Preservation     Trend Towards Beta Cell Preservation     Mod Beta Cell Preservation     No Change on Post Prandial Control     Data Supporting MOA	>1.3	Frontline Therapy with Metformin
	1.0-1.2	Replacement for 2 <sup>nd</sup> Line Agents
	0.8-1.0	Replacement for DPP4s
	0.6-0.8	Replacement for DPP4s
	<0.6	3 <sup>rd</sup> Line Therapy for Those Who Can't Tolerate GLP-1s/SGLTs
	Greatest opportunity t show A1C reduction, reduced safety risk an	
OTC and PCP education given or all vs. ejectable Potients who can't tabellolerate CuP-11s SC47-2 One elegener of here category for formulary coverage of Penal Line Line Cup School Cup School Cup School Cup School Cup Sch	ration slin teTDD	GLP-1s and SGLT-2s moving forward in treatment continuum



### **NASH Study**

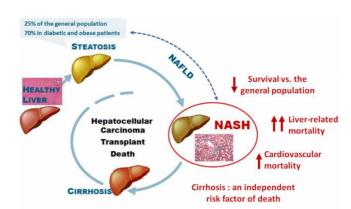
#### Leveraging Oral Insulin for Nonalcoholic Fatty Liver Disease

#### Nonalcoholic Steatohepatitis (NASH)

- Chronic liver disease caused by excessive fat in liver (MoA not fully known)
- Leads to fibrosis, cirrhosis and liver failure (death)
- 25% of adults in the U.S. have NAFLD
- 5% of adults in the U.S. have NASH
  - 37% among patients with T2DM

#### **Status**

- Data from initial 8 patients presented at ADA 2020 :
  - Safety:
    - 12-week, once-daily treatment had no SAEs
  - Efficacy:
    - 30% relative reduction measured by MRI-PDFF
    - 6.9±6.8% mean reduction in liver fat content (p value: 0.035)
- Initiation of 10 additional patients in EU (ongoing)
- Initiation of Double-Blind Placebo-Controlled Study (n=30) in US and Israel (Q4;2020)









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



#### **GLP-1** Analog

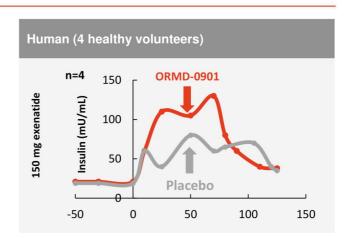
- T2DM medication
- Mimics the natural hormone in the body
- Compelling safety profile
- Decreases blood glucose levels
- Effectively reduces HbA1c
- Preserves beta cell function
- Promotes weight loss
- Current therapy via injection only

#### **ORMD-0901 Clinical Status**

- IND
- Bioavailability study



#### Oral GLP-1 - ORMD-0901

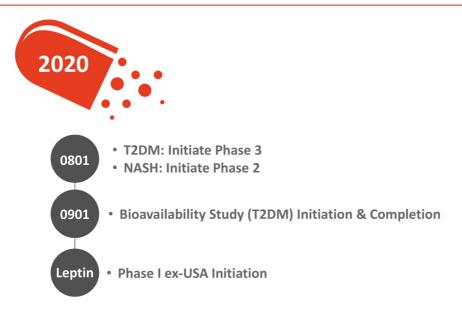


ORMD-0901 formulations

Preserved the biological activity of orally delivered exenatide. ORMD-0901 successfully curbed blood sugar excursions following glucose challenge

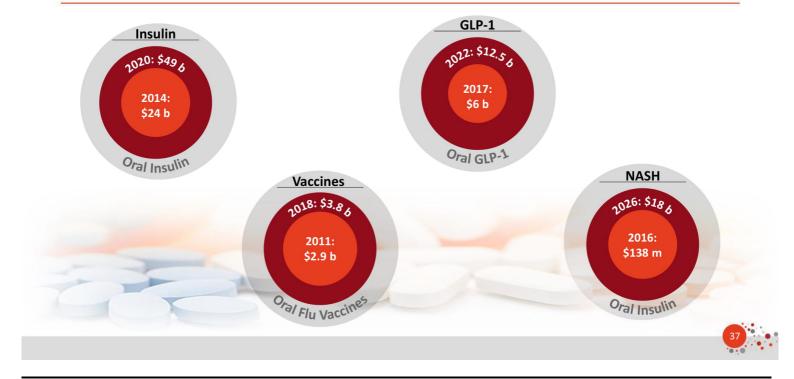


### **Anticipated Development Milestones**





### 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



**Avi Gabay, 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



### **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
- Primary Indication: Insulin initially targeting the lucrative insulin market; additional markets in the pipeline
- Strong financial position with over \$45.6M in cash and investments, no debt, 23.3M shares outstanding (28.5M fully diluted)<sup>1</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 May 31, 2020

