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): December 12, 2022

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 Y	ork, New York	10036	
(Address of Principal Executive Office	s)	(Zip Code)	
	844-967-2633 (Registrant's telephone number, including area code))	
Check the appropriate box below if the Form 8-K filing is inte	ended to simultaneously satisfy the filing obligation of	of the registrant under any of the following provisions:	
☐ Written communications pursuant to Rule 425 under the S	Securities Act (17 CFR 230.425)		
☐ Soliciting material pursuant to Rule 14a-12 under the Exc	change Act (17 CFR 240.14a-12)		
☐ Pre-commencement communications pursuant to Rule 14	d-2(b) under the Exchange Act (17 CFR 240.14d-2(b	p))	
☐ Pre-commencement communications pursuant to Rule 13	e-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 the Securities Exchange Act of 1934 (§240.12b-2 of this chap		urities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of	
Emerging growth company \square			
If an emerging growth company, indicate by check mark if th accounting standards provided pursuant to Section 13(a) of the	e	sition period for complying with any new or revised financial	

Item 7.01. Regulation FD Disclosure.

On December 12, 2022, 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

Exhibit No.	Description of Document
99.1	Investor Presentation dated December 12, 2022 (Furnished herewith.)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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

December 12, 2022



Oramed Pharmaceutloals Inc. \$\,2022

Safe Harbor

This presentation contains forward-looking statements. For example, we are using forward-looking statements when we discuss clinical trials, including the timing thereof and potential approvals of products, catalysts and milestones, pipeline and the potential benefits of products, including in each case those of Oravax. These forward-looking statements are based on the current expectations of the management of Oramed only, 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. In addition, the following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; delays or obstacles in launching our clinical trials; changes in legislation; inability to timely develop and introduce new technologies, products and applications; lack of validation of our technology as we progress further and lack of acceptance of our methods by the scientific community; inability to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties that may develop with our process; greater cost of final product than anticipated; loss of market share and pressure on pricing resulting from competition; laboratory results that do not translate to equally good results in real settings; our patents may not be sufficient; and finally that products may harm recipients, 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.

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Oramed Snapshot



COMPANY OVERVIEW

- Proprietary oral protein delivery platform
- Diabetes first initially targeting the lucrative insulin
- 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,
- Multiple value-creation events for 2023



KEY FINANCIAL METRICS

- Strong financial position



- ~\$160M1 in cash and investments
- No debt

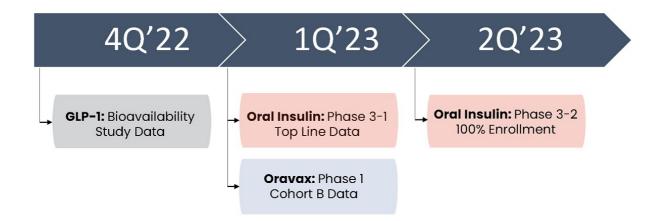


COMPANY MANAGEMENT

• Experienced management team backed by worldclass scientific experts

As of September 30, 2022 (unaudited)

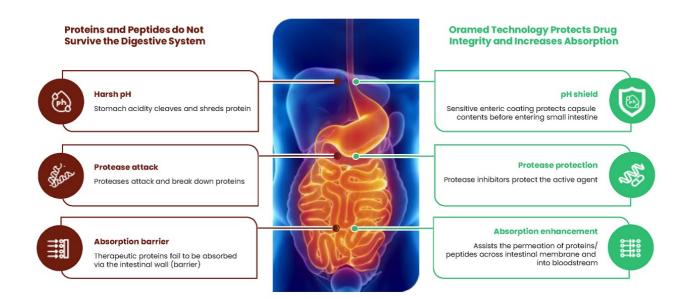
Upcoming Catalysts



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Proprietary Technology for Oral Drug Delivery



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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)

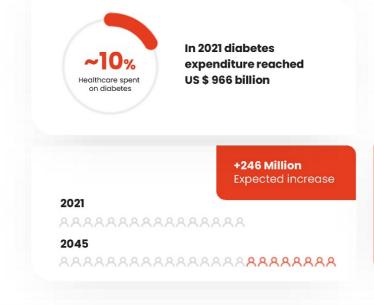
Oravax's Oral Covid-19 Vaccine Phase 1 Trials Ongoing

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1 in 10 Adults Globally Have Diabetes







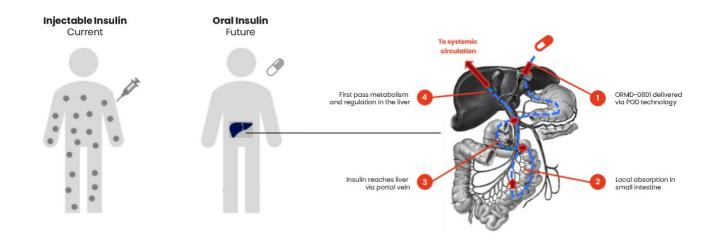
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| https://diabetesatlas.org/

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Oral Insulin Mimics the Delivery of Endogenous Insulin



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

Diabetes inhibits the production of sufficient insulin and causes elevated levels of glucose in the blood

TYPE 1 DIABETES

- TID is autoimmune: The body destroys its own insulinproducing (beta) cells, leaving patients completely dependent on external insulin sources
- 10% of diabetics have TID: Up to 54 million people worldwide have TID
- Projected Market: \$24 billion by 2029

TYPE 2 DIABETES

- T2D 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 (T1D)

TID 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

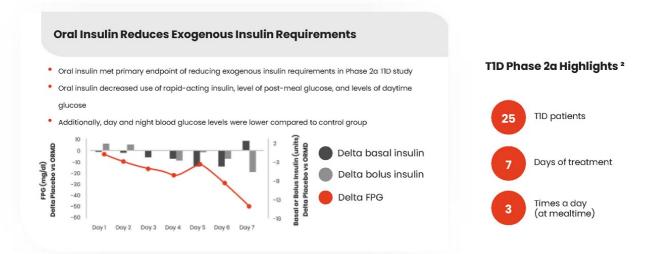
- Easier use and reduced systemic exposure
- Potentially reducing multiple daily injections
- Tighter regulation and control of blood sugar levels by directly targeting liver glucose (TiR), due to portal administration

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Phase 2a Trial in TID 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.

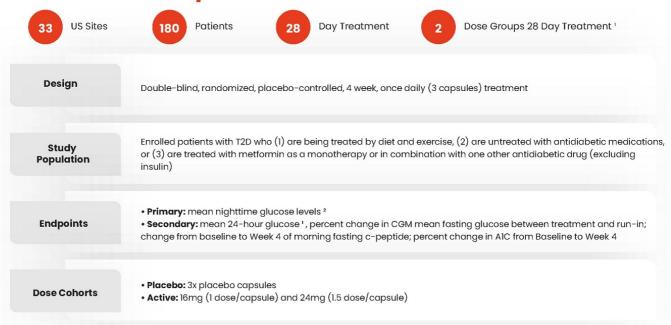


Note: 1 American Diabetes Association

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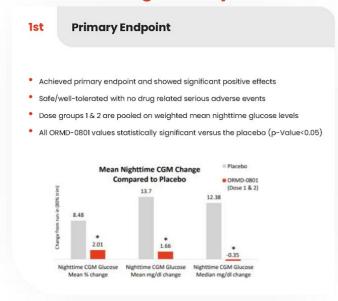
lote: ² ClinicalTrials.gov identifier = NCT02094534

Phase 2 - Completed 180 Patient Trial for T2D



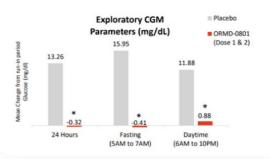
¹ Trial only had I dose level, but patients were given either a full dose, or 1.5 doses.
² Based on 2 nights of CGM data by comparison of the mean percent change between Baseline and Week 4 of ORMD-0801 and placebo groups

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





- 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)



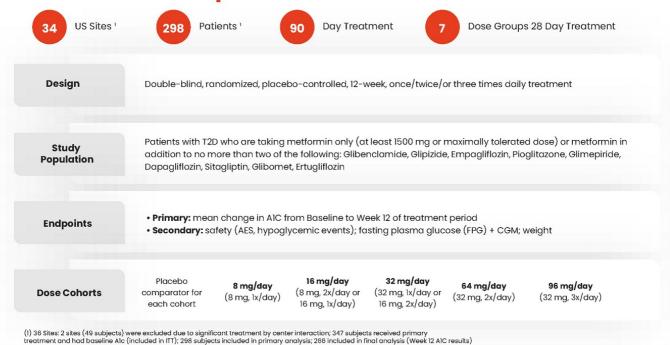
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Note: ClinicalTrials.gov Identifier = NCT0249600

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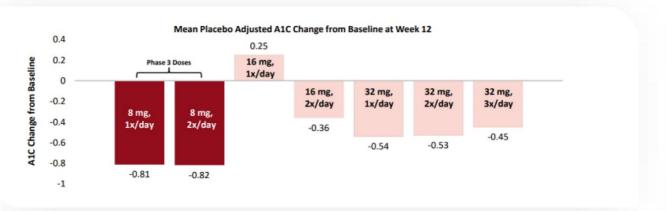
^(*) Indicates statistically significant difference versus placebo (p-Value <0.05)

Phase 2b - Completed 298 Patient Trial for T2D



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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Note: ClinicalTrials.gov Identifier = NCT03467932

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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 Mean A1C Change from Baseline at Week 12 8 mg, 1x Placebo 8 mg, 1x (Baseline >9%) -0.14

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

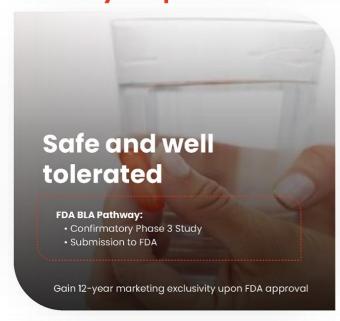
- No increase in Serious Adverse Events compared to Placebo
- No increase in Hypoglycemic Events compared to Placebo
 - 6.1% (5/82) of subjects in placebo group compared to 0% (0/15) of subjects in 8mg 1x/day had at least 1 hypoglycemic event
- No weight gain compared to Placebo at Week 12

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Note: ClinicalTrials.gov Identifier = NCT0346793

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FDA Phase 2b Trial Results Primary Endpoint Successfully Met



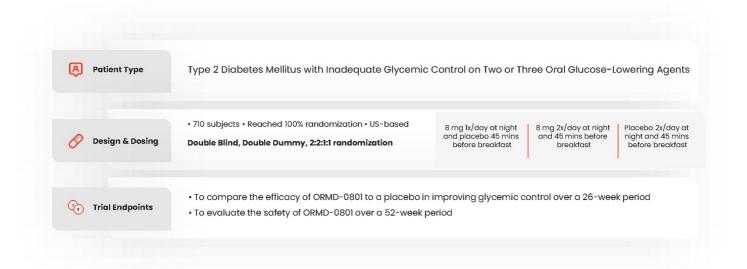


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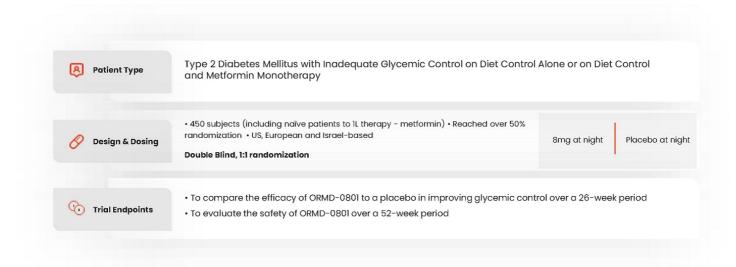
Two Pivotal Phase 3 Trials will Maximize ORMD-0801's Success in the Market: ORA-D-013-1



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



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

Country	Endos	PCPs	Total
	19	21	40
4 b	13	12	25
	14	12	26
0	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

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HCPs Were Receptive to Prescribing Oral Insulins and ORMD-0801, If Approved

Most of the prescribers (85%+) were willing to prescribe oral insulins or ORMD-0801, if approved

Future Willingness to Prescribe (n=170)

	Willingness to prescribe oral insulin (A)	Willingness to prescribe ORMD- 0801 (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

ORMD-0801 appears to meet physician expectations for an oral insulin given minimal change in their response after seeing the ORMD-0801

profile



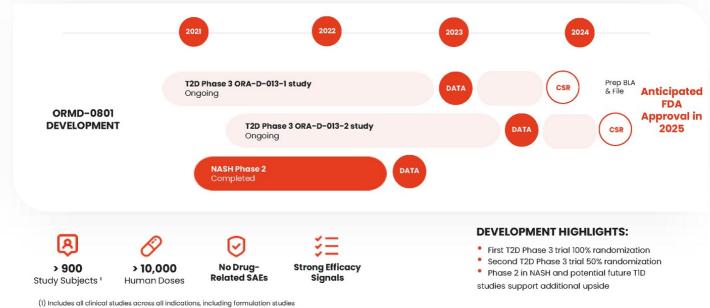
Q: What is your willingness to prescribe oral insulins for T2D patients, if oral insulins were launched in the market Q: What is your willingness to prescribe Product X (ORMD-0801) for T2D patients, if it was launched in the market

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



China License Deal: 500M patient potential





DIABETIC

(10.9% of adult population)



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
- Up to 10% royalties on net sales

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South Korea Commercial Distribution Agreement

Agreement:

Exclusive distribution rights to ORMD-0801 in South Korea



South Korean Partner: Medicox Co., Ltd.

- Medicox (Kosdaq: 054180) is an emerging pharmaceutical R&D company
- Has built an excellent consortium of partnerships across established leaders in South Korea
- Responsible for local regulatory approval
- 10 year license to commercialize oral insulin in South Korea

1 in 7 South Korean adults have diabetes

MILESTONE PAYMENTS + ROYALTIES:

- \$18M in potential milestone payments
 - \$2M received to date
- Up to 15% royalties on gross sales
- Medicox to purchase ORMD-0801 from Oramed at fixed transfer price

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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 = 9 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

32 Patients

90

Day Treatment

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

Design

- Double-blind, randomized, placebocontrolled, multi-center study
- 90-day treatment
- · 32 T2D patients with NASH
- 8mg xl/xl morning & 8mg xl/xl night
- US and Israel

Study Population

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

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

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

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Positive Phase 2 NASH trial results reported: Achieved Safety and Primary Endpoints

Safety Data Summary

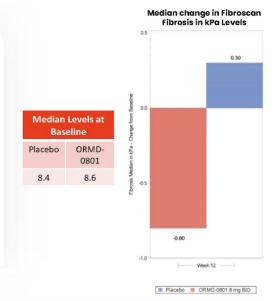
 Primary objective of safety met with no serious adverse events and no difference in the incidence rate of adverse events between ORMD-0801 and placebo.

Efficacy Data Summary

- Secondary objective of reducing liver fat content in patients with NASH and T2D Percent Change from Baseline to Week 12 in MR PDFF (%):
 - Liver Segment 3 (left lobe) showed placebo adjusted mean decrease of 1.8 with placebo adjusted median decrease of 5.7 for ORMD-0801
- Exploratory objective of median change from baseline in Fibroscan fibrosis levels:
 - Median Change from Baseline to Week 12 in Fibrosis Median (kPa) showed placebo adjusted median decrease of 1.1 for ORMD-0801.

Median change from Baseline to Week 12 in Steatosis Median (dB/m)

showed placebo adjusted median decrease of 29 for ORMD-0801.

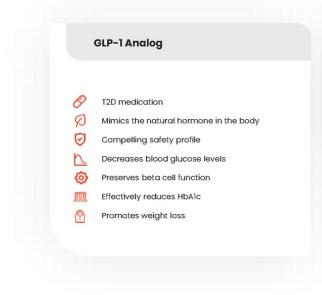


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Note: ClinicalTrials.aov Identifier = NCT0346793

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GLP-1 Analog: ORMD-0901 for Oral GLP-1 (T2D)

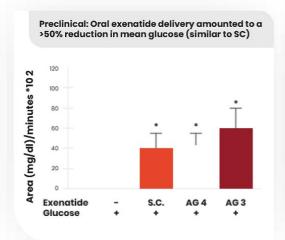


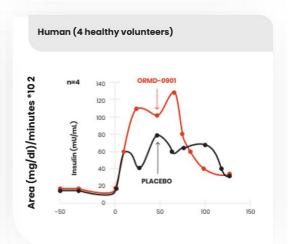


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Oral GLP-1 - ORMD-0901





ORMD-0901 formulations

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

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Oravax | Novel Oral Vaccine Company





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

JOINT VENTURE

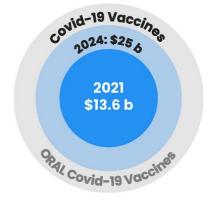
Oramed is the majority shareholder of Oravax (63%)

LICENSE

- Royalties: 7.5% of net sales

- Sublicensing: 15%

- Sales milestone: \$25M - \$100M



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Triple antigen vaccine expected to be effective against COVID variants

Manufacturing Advantages



Ease of scale up



Straight-forward tech transfer



Manufacturing and COGs optimization

55

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

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Oravax | Phase 1 Trial Ongoing

South Africa

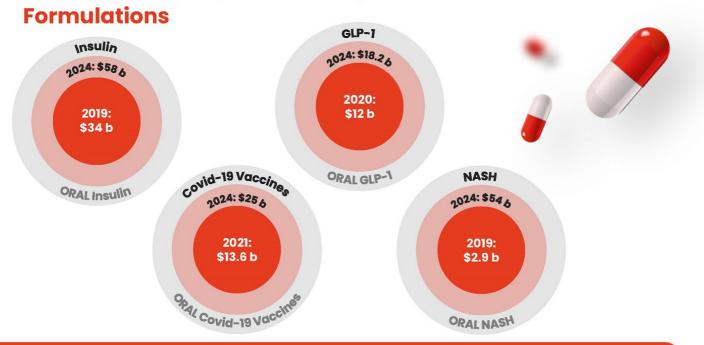
- Open-label
- N=24 naive participants (no prior COVID-19 vaccine or infection)
- Endpoints:
 - Safety & tolerability
 - Efficacy
- Cohort A (12 participants) positive data received Q3 2022
- Cohort B (12 participants) data expected Q1 2023



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Funneling Huge Injectable Drug Markets to Novel Oral



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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, MBA

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

ARIE MAYER, PH.D

Independent Directo

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

LEONARD SANK

Independent Director

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

YADIN ROZOV

Independent Director

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

MIRIAM KIDRON, PH.D

Chief Scientific Officer & Director

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



Scientific Advisory Board

ROY ELDOR, MD, PHD

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

AVRAM HERSKHO, MD, PHD; NOBEL LAUREATE

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

JAY SKYLER, MD, MCAP

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

ELE FERRANNINI, MD, PHD

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

HAROLD JACOB, MD

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

Professor of Medicine at Keck School

of Medicine of USC and Director of

the USC Clinical Diabetes Programs.

ANNE PETERS, MD

Alexander Fleming, MD

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

JULIO ROSENSTOCK, MD

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

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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 in cash and investments, no debt = ~39M shares outstanding (~43M fully diluted)?
- 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

"As all September 30, 2022 (undudited) "As all September 30, 2022

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