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): $\bf December~7,\,2021$

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 Flo New York, New York | oor, | 10036 |
| (Address of Principal Executive Offices | 5) | (Zip Code) |
| | 844-967-2633 (Registrant's telephone number, including area code) | |
| Check the appropriate box below if the Form 8-K provisions: | filing is intended to simultaneously satisfy the filing | ng obligation of the registrant under any of the following |
| $\ \square$ Written communications pursuant to Rule 425 under the S | ecurities Act (17 CFR 230.425) | |
| \square Soliciting material pursuant to Rule 14a-12 under the Excl | hange Act (17 CFR 240.14a-12) | |
| ☐ Pre-commencement communications pursuant to Rule 14d | d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) | |
| ☐ Pre-commencement communications pursuant to Rule 13e | 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 |
| 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of t | | he Securities Act of 1933 (§230.405 of this chapter) or Rule |
| Emerging growth company \square | | |
| If an emerging growth company, indicate by check m financial accounting standards provided pursuant to Section 13 | | led transition period for complying with any new or revised |
| | | |

Item 7.01. Regulation FD Disclosure.

On December 7, 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 | <u>Investor Presentation dated December 7, 2021 (Furnished herewith.)</u> |
|------|---|
| 104 | Cover Pager Interactive Data File, formatted in 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 7, 2021



Addressing the Multibillion-Dollar Injectable Drug Markets with Oral Formulations

December 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; expected timing of clinical studies for the potential Oravax Medical Inc. vaccine, its potential advantages, safety and efficacy and its potential to protect against COVID-19 and variants thereof; and our ability to obtain additional funding required to conduct our research, development and commercialization activities, and others, all of which could cause the actual results or performance of Oramed to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Oramed undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Oramed, reference is made to Oramed's reports filed from time to time with the Securities and Exchange Commission, which involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Please refer to the company's filings with the Securities and Exchange Commission for a comprehensive list of risk factors that could cause actual results, performance or achievements of the company to differ materially from those expressed or implied in such forward-looking statements. Oramed undertakes no obligation to update or revise any forward-looking statements.



Oramed Snapshot



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



Upcoming Catalysts

- Robust pipeline leveraging IP portfolio for additional significant market opportunities
- 87 granted patents, 36 pending patent applications, worldwide
- Multiple value-creation events for 2021/22



Key Financial Metrics

- Strong financial position
- ~\$174M¹ in cash and investments
- No debt



Experienced management team backed by world-class scientific experts



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¹As of December 3, 2021 (unaudited)

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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

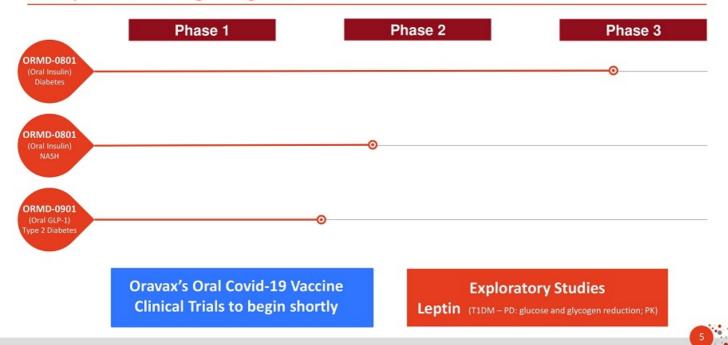
Protease inhibitors protect the active agent

Absorption enhancement

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



Multiple Clinical-Stage Programs



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Diabetes:

Millions of diabetics inject insulin today and wish for oral dosage

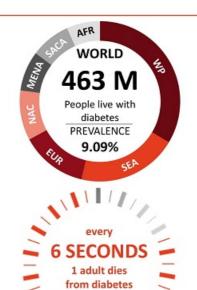


1 in 11 Adults on the Planet Have Diabetes

10% healthcare spent on diabetes

In 2019 diabetes expenditure reached US \$ 760 billion





4M deaths in 2017



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

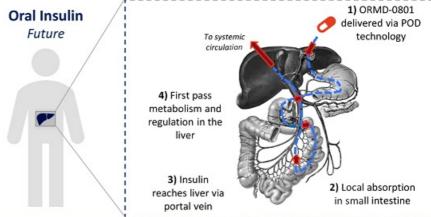




Oral Insulin Mimics the Delivery of Endogenous Insulin

Injectable Insulin Current Future 4) First metabol regulation live 3) In reaches

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





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



TYPE 1 Diabetes

- T1DM is autoimmune: The body destroys its own insulin-producing (beta) cells, leaving patients completely dependent on external insulin sources
- 10% of diabetics have T1DM: Up to 46 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
- 417 million people worldwide need treatment
- Projected Market: \$92 billion by 2029



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

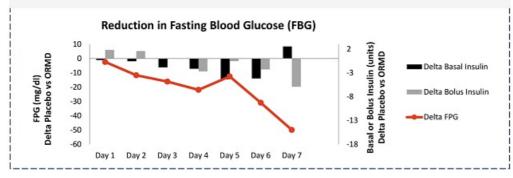


Phase 2a Trial in T1D Completed

By directly targeting liver glucose, ORMD-0801 may provide tighter blood sugar regulation and control for the $^{\sim}1.6M^1$ 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 Highlights²

- 25 T1DM patients
- 7 days of treatment
- times a day (at mealtime)

Note: (1) American Diabetes Association, https://www.diabetes.org/resources/statistics/statistics-about-diabetes (2) ClinicalTrials.gov Identifier = NCT02094534



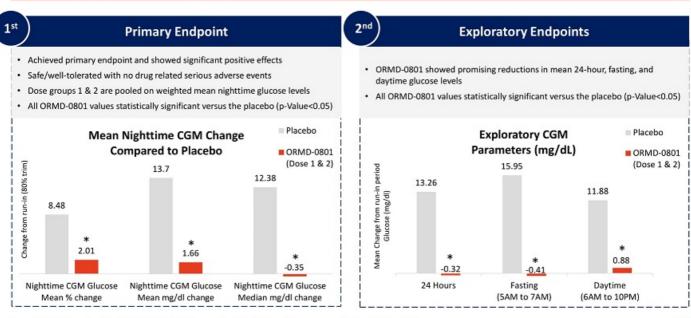
Phase 2 - Completed 180 Patient Trial for T2D

Trial Highlights 180 **US Sites** 28 Dose Groups¹ Patients Day Treatment Design Double-blind, randomized, placebo-controlled, 4 week, once daily (3 capsules) treatment 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 Population Primary: mean nighttime glucose levels2 **Endpoints** Secondary: mean 24-hour glucose¹, 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 Placebo: 3x placebo capsules **Dose Cohorts** 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

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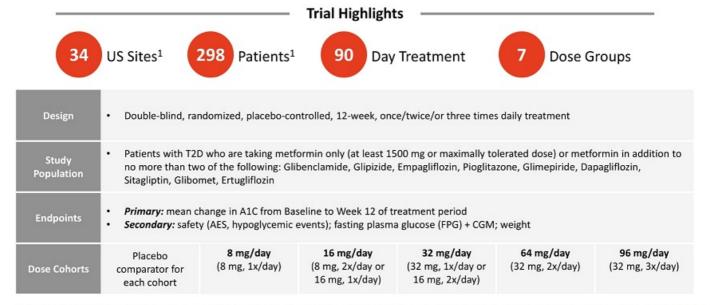
Phase 2 Trial Demonstrated No Drug Related Serious Adverse Events and Promising Efficacy on CGM Parameters



Note: ClinicalTrials.gov Identifier = NCT02496000. (*) Indicates statistically significant difference versus placebo (p-Value < 0.05)



Phase 2b - Completed 298 Patient Trial for T2D

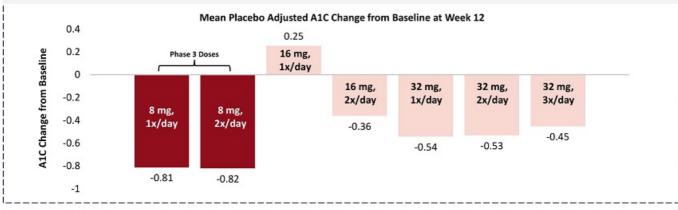


Note: ClinicalTrials.gov Identifier = NCT03467932. (1) 36 Sites: 2 sites (49 subjects) were excluded due to significant treatment by center interaction; 347 subjects received primary treatment and had baseline A1 (included in ITT); 298 subjects included in primary analysis; 266 included in final analysis (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.

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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 8mg, 1x Placebo 8 mg, 1x (Baseline >9%) -0.14 -0.95

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

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FDA Phase 2b Trial Results - Primary Endpoint Successfully Met



Safe and well tolerated

FDA BLA Pathway:

- Confirmatory Phase 3 StudySubmission to FDA

Gain 12-year marketing exclusivity upon FDA approval



Significant HbA1c lowering with 1X/daily treatment:

- ✓ No increase in Adverse Events compared to Placebo
- ✓ No increase in Hypoglycemic Events compared to Placebo
- ✓ No weight gain compared to Placebo



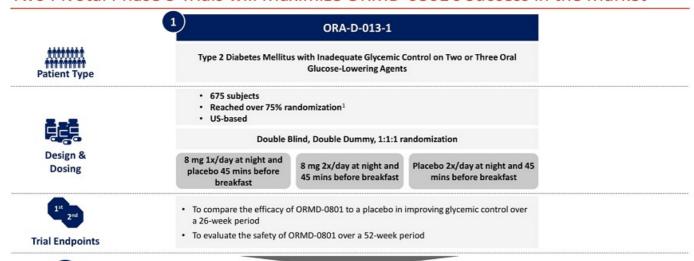


Phase 3 Trials:

Maximizing ORMD-0801's Success in the Market



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



Market Positioning if Successful

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

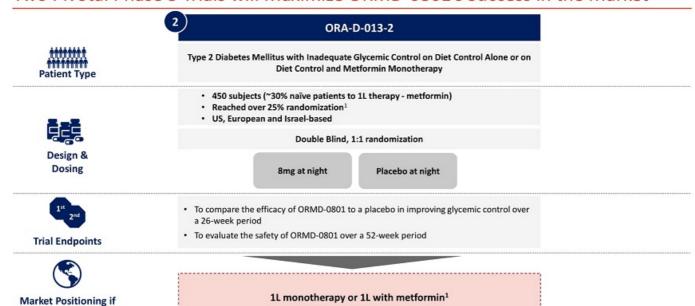
Source: (1) FDA indicated possible 1L designation based on the ORA-D-013-2 trial in which ~30% of enrolled patients are metformin treatment naive

¹ As of November 23, 2021

Oramed © 2021



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



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

¹ As of August 24, 2021

Oramed © 2021



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





>900 Study Subjects¹



>10,000 **Human Doses**



No Drug-**Related SAEs**



Strong Efficacy Signals

- Second T2D Phase 3 trial initiated
- 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





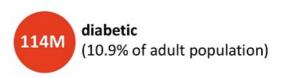
China License Deal: 500M patient potential

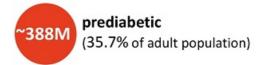
- License: Exclusive right to ORMD-0801 in Greater China
- Licensee: Hefei Tianhui ("HTIT")
 Owns with Sinopharm a state-of-the-art GMP API insulin manufacturing facility
 - HTIT clinical trials of ORMD-0801 underway

\$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*



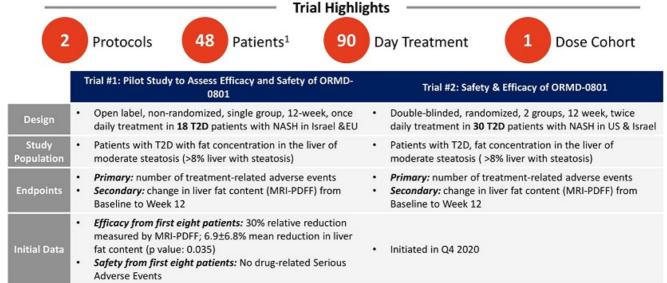




* Journal of the American Medical Association

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.



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.







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



GLP-1 Analog

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

ORMD-0901 Clinical Status



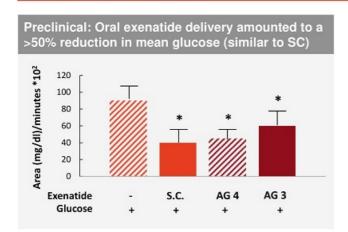


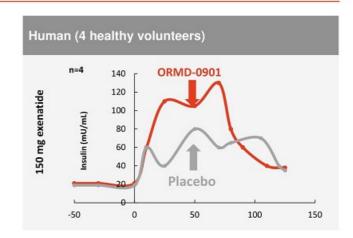
Bioavailability study



Oramed © 2021

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



Oral Covid-19 Company







Joint Venture

 Oramed is the majority shareholder of Oravax (63%)

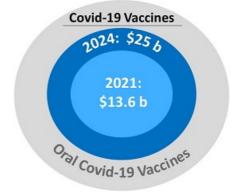
License

- Royalties: 7.5% of net sales

- Sublicensing: 15%

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

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.





Covid-19 Market Sources: https://www.pharmaceutical-technology.com/news/covid-19-vaccine-market-set-to-reach-19-5bn-by-2026-register-for-free-webinar/#::text=The%20size%20of%20the%20cOVID,be%20required%2C%20according%20to%20ofobalData. Oramed © 2021 https://www.marketwatch.com/press-release/covid-19-vaccine-market-size-comprehensive-analysis-growth-forecast-from-2020-to-2030-2021-07-15

↑ 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









Genomma Lab is a leading pharmaceutical and personal care product company in LATAM

- 50/50 JV to Develop and Commercialize Oral COVID-19 Vaccine in Mexico
- Drive Business Development in LATAM
- Intended US\$20 million share swap

Genomma Lab Will:

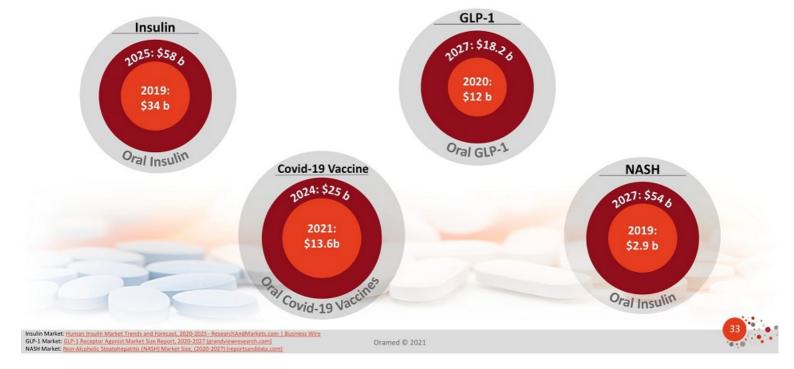
- Contribute to the oral vaccine's development, clinical, regulatory, and commercial activities
- Leverage supply chain, partnerships and market presence in LATAM
- · Participate in a future investment in Oravax.

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Anticipated Development Milestones



Funneling Huge Injectable Drug Markets to Novel Oral Formulations



Management Team



Nadav Kidron, Esq, MBA - CEO & Director Entrepreneur whose experience includes decades of senior executive roles in a wide range of

industries including business, 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 - CFOExtensive 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 Director, Diabetes Unit, Institute of Endocrinology, Metabolism & Hypertension, Tel-Aviv 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 General of Israel's Housing Ministry and served as a board member of public and private companies including Maayan Ventures and Capital Point

Arie Mayer

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

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 ~\$174M¹ in cash and investments, no debt ~38M shares outstanding (~41M 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

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 $^{\rm 1}\,{\rm As}$ of December 3, 2021 (unaudited) $^{\rm 2}\,{\rm As}$ of November 24, 2021

