#### 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 7, 2021

ORAMED PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

001-35813

(Commission File Number)

DELAWARE (State or Other Jurisdiction of Incorporation)

1185 Avenue of the Americas, Third Floor,

New York, New York (Address of Principal Executive Offices)

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  $\Box$ 

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.

10036

98-0376008

(IRS Employer

Identification No.)

(Zip Code)

#### 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	Investor Presentation dated December 7, 2021 (Furnished herewith.)
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 KidronName:Nadav KidronTitle: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 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







# Oral Insulin Mimics the Delivery of Endogenous Insulin



# Oral Insulin: Significant Advantages Over Injectable Insulins

#### Advantages of ORMD-0801 Oral Insulin





## 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

- 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 ~1.6M<sup>1</sup> 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<sup>2</sup>

### Phase 2 - Completed 180 Patient Trial for T2D



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



## Phase 2b - Completed 298 Patient Trial for T2D



## 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)



## 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



Oramed © 2021

#### 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



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



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



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



## China License Deal: 500M patient potential







\* 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.







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

	2/h		
<b>GLP-1</b> Analog		ORMD-0901 Clinical S	tatus
T2DM medication		😪 IND	P _ P
Mimics the natural h	ormone in the body	🚯 Bioavailability study	
Compelling safety pro	ofile		-
Decreases blood gluc	ose levels		Carden The second
Preserves beta cell fu	inction		and the second s
Effectively reduces H	bA1c		
Promotes weight loss	5		0.000
	Oramed	© 2021	27

## 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



# 



#### 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<sup>™</sup> technology with an oral delivery platform from Oramed Pharmaceuticals based on their proprietary POD<sup>™</sup> delivery technology.



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

# ravantages

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:

## Oral Format



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)

- 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.



## 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 - 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 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



<sup>1</sup> As of December 3, 2021 (unaudited) <sup>2</sup> As of November 24, 2021



