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): February 10, 2014

ORAMED PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

001-35813

DELAWARE (State or Other Jurisdiction of Incorporation)

(Commission File Number) 98-0376008 (IRS Employer Identification No.)

Hi-Tech Park 2/4 Givat Ram, PO Box 39098, Jerusalem, Israel

(Address of Principal Executive Offices)

+972-2-566-0001

(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:

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

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

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

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

91390

(Zip Code)

ITEM 7.01. REGULATION FD DISCLOSURE.

Oramed Pharmaceuticals Inc., or Oramed, has posted an updated corporate presentation to its website. A copy of the presentation is furnished with this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

ITEM 8.01. OTHER EVENTS.

In addition, on February 10, 2014, Oramed announced that it had submitted a protocol to the U.S. Food and Drug Administration to initiate a Phase 2a trial of its orally ingestible insulin capsule, ORMD 0801, for type 1 diabetes. A copy of the press release is furnished with this Current Report on Form 8-K as Exhibit 99.2 and incorporated herein by reference.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

- (d) Exhibits.
 - 99.1 Corporate Presentation
 - 99.2 Press release issued by Oramed on February 10, 2014

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

February 12, 2014

<u>Exhibit 99.1</u>





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, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forwardlooking 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.

2



Proprietary Protein Oral Delivery (FOD Platform technology

For the oral delivery of drugs that are currently only available via injection

Product

§ Oral Insulin (ORMD-0801)

Pipeline

o Type 2 diabetes

- o Type 1 diabetes
- § Oral GLP-1 Analog (ORMD-0901)
- § Combination Therapy (ORMD 0801 + 0901)

Proof of Concept established in preclinical and clinical trials

Publicly traded - NASDAQCM:ORMP

Founded in 2006 by its scientific inventors after more than two decades of research





Agenda Overview

| - | Oral Administration | The Challenge The Oramed Solution |
|---|---------------------------|---|
| | Diabetes | Statistics and Market |
| - | Oramed Pipeline | Oral Insulin Oral GLP-1 Analog |
| - | Corporate Overview | Management Team Scientific Advisory Board Intellectual Property Financials |

4



Oramed An Oral Solution





Fate of proteins/peptides in GIT





6

Oramed POD[™] Technology: The Solution



Enteric Coating

pH sensitive - only degrades in the small intestine, thus protecting capsule constituents during travel through the upper gastrointestinal tract



Protease Inhibitors

• Protects protein from degradation by proteases once capsule degrades in the small intestine



Absorption Enhancers

• Assists with translocation of active ingredient (protein/ peptides) across intestinal membrane into bloodstream

Oramed's delivery platform **protects proteins** and **enhances their absorption**, allowing them to reach the bloodstream via the portal vein, thereby establishing a **more physiologic protein gradient when compared to other delivery systems.**



Oramed POD[™] Technology



Potential Oramed Technology Applications: Opportunities & Market

| Insulin | \$15+ billion 2012 global insulin market\$32 billion projected market for 2018 | A |
|----------------------------|---|----------------------------|
| GLP-1 Analog | \$2+ billion 2012 global GLP-1 market Many patients stop treatment as a result of injection-related side effects | The contract of the second |
| | Vaccines: \$24 billion in 2013 - grew from \$5 billion in 2000 | |
| Other | Flu vaccine estimated at \$2.9 billion in 2011 to \$3.8 billion in 2018 | |
| oramed Phomacentrale be | Interferon: \$6.3 billion , 2011 global market | 9 |

Diabetes: *A Global Epidemic*







Diabetes: A Global Epidemic







ORMD-0801 Oral Insulin





ORMD-0801: Oral Insulin Administrations To-date



Portal insulin delivery is physiologic. Systemic insulin delivery is pot.





ORMD-0801 Type 2 Diabetes (T2DM)





Type 2 Diabetes: Stages & Treatment Options



Unique Initial Indication

Fasting Blood Glucose (FBG):

- Measurement of blood glucose levels after a fast (e.g. first thing in the morning)
- Effected by liver regulation of glucose and insulin levels in the body during a fast

Elevated FBG

- Elevated FBG levels are a major issue in T2DM
- Main cause: excessive nocturnal glucose production from liver
- Current treatments for correction of elevated FBG are suboptimal

FBG: Stats

- Approximately 70% of individuals with impaired FBG develop T2DM
- An estimated > 80% of T2DM patients exhibit abnormal FBG *and* fail to achieve glycemic control with Metformin or thiazolidinediones (TZDs) preparations

ORMD-0801: Unique Indication

- Nighttime dose
- Focused on reducing the excessive nocturnal glucose production from the liver



T2DM





ORMD-0801 Trial Results: A Summary

Pre-clinical

- Healthy, non-diabetic, cannulated beagle dogs showed a 60-75% drop in blood glucose levels within 30-100 minutes of treatment
- No hypoglycemia or adverse events were observed over the three years of testing (in dogs)

T2DM Patients

ORA-D-004

- Randomized, double-blind, multi-center study on 29 patients - 21 dosed, 8 placebo, 6 weeks of monitoring
- Showed relevant clinical impact
- · Good safety profile
- · Safe and well tolerated by all patients
- No SAEs





ORMD-0801

Phase 2a Results







ORMD-0801: Phase 2a FDA Study

Overview:

- •30 T2DM patients
- •US site
- In-patient setting
- •Double blind
- Randomized
- •1 week of treatment

End Points:

•Primary end point:

- Safety and tolerability
- •Secondary end points:
 - Pharmacodynamic effects on mean night time glucose
 - Pharmacokinetics on AUC, Cmax, Tmax, T¹/₂
 - Changes from baseline in FBG, morning fasting insulin, C-peptide



Phase 2a Results: Safety

| | Placebo (N=10) | ORMD-0801 460IU (N=10) | ORMD-0801 690IU (N=10) |
|---|-------------------|---------------------------|---------------------------|
| umber of Subjects with At Least One Adverse Event | 5 (50.0) | 3 (30.0) | 4 (40.0) |
| ar and labyrinth disorders | 1 (10.0) | 0 (0.0) | 0 (0.0) |
| Vertigo | 1 (10.0) | 0 (0.0) | 0 (0.0) |
| Gastrointestinal disorders | 1 (10.0) | 1 (10.0) | 2 (20.0) |
| Constipation | 0 (0.0) | 0 (0.0) | 2 (20.0) |
| Nausea | 1 (10.0) | 1 (10.0) | 0 (0.0) |
| Infections and infestations | 1 (10.0) | 0 (0.0) | 0 (0.0) |
| Urinary tract infection | 1 (10.0) | 0 (0.0) | 0 (0.0) |
| Nervous system disorders | 2 (20.0) | 3 (30.0) | 2 (20.0) |
| Headache | 2 (20.0) | 3 (30.0) | 2 (20.0) |
| Skin and subcutaneous tissue disorders | 1 (10.0) | 0 (0.0) | 0 (0.0) |
| Pruritus | 1 (10.0) | 0 (0.0) | 0 (0.0) |

No Serious Adverse Events The study clearly shows that ORMD-0801 is safe and well tolerated



24

ORMD-0801 Type 1 Diabetes (T1DM)





T1DM

- T1DM is an autoimmune disease the body destroys its own insulin-producing cells leaving patients completely dependent on external insulin sources
- 5-10% of diabetes cases are T1DM approx. 18-37 million people worldwide.
- The disease was previously only seen in children, but the majority of new-onset cases are seen in adults; increasing at a rate of 3% per year

Treatment

- T1DM is treated with 2 types of insulin replacement therapy:
 - · long-acting insulin (basal) to help maintain stable insulin levels during fast periods
 - rapid-acting insulin (bolus) prior to each meal
- Administration is via injection or pump

ORMD-0801 Oral Insulin and T1DM

- Oramed is looking to replace the mealtime (bolus) insulin doses, potentially reducing multiple daily injections
- Mechanistic advantages: Portal administration may enable tighter regulation of blood sugar levels by directly affecting glucose control in the liver. Oral administration also offers the benefit of reduced systemic exposure and ease of use.



26

T1DM





Design: 8 T1DM, monitor glycemic stability of orally administered ORMD-0801 (1 capsule (8 mg insulin) before meals, three times daily). Glucose monitored with continuous, blinded glucose monitor

ORMD-0901 Oral GLP-1 Analog (т2DM)





Oral GLP-1 Analog (Exenatide)

GLP-1: Hormone Facts

- Secreted by the intestine
- Has effect on the satiety center in the brain
- Has effect on pancreatic β -cells

GLP-1 Analog: Drug Facts

- Good safety profile
- Mimics the natural hormone in the body
- Decreases blood glucose levels aids in blood sugar balance
- Does not cause hypoglycemia
- Effectively reduces HbA1c
- Preserves beta cell function
- Promotes weight loss
- Current therapy is via injection only



ORMD-0901 Oral GLP-1

- Pre-IND package submitted to the US FDA Q3 2013
- IND enabling tox studies Q2, 2014
- P1b ex-US study Q2, 2014



Oral GLP-1 - ORMD-0901



Methods:

- Ø Healthy, fasting, cannulated dogs
- Ø Single dose ORMD-0901 formulation
- Ø Administered 30 minutes pre-glucose challenge
- Ø Blood samples collected every 15 minutes

Results: Subcutaneous exenatide delivery amounted to a 51% reduction in mean glucose AUC_{0-150} , while formulations AG4 and AG3 prompted 43% and 29% reductions, respectively (* p = 0.068, demonstrating a treatment-related trend for the sample size).

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



30



Pipeline Overview

ORMD-0901: Oral Exenatide (GLP-1 Analog)

Combination Therapy (ORMD-0801 + 0901)

Platform POD™ Technology

| Therapy | Indication | Phase I | Phase II | Phase III/ Market | Timeline |
|----------------------|------------|---------|----------|----------------------|--|
| ORMD - | T2DM | | | | Q4, '13: Phase 2a completed Q2/3, '14: Phase 2b multi-center study projected initiation |
| 0801 Oral Insulin | T1DM | | X | | Q1, '14: Phase 2a projected initiation Q1, '15: Phase 2b multi-center study projected initiation |
| ORMD- 09041 GLP-1 | T2DM | | | | Q2, '14: Preclinical/IND studies projected initiation Q2, '14: Phase 1b ex-US study projected initiation Q2, '15: Phase 2 multi-center study projected initiation |







Management



Nadav Kidron, Esq, MBA CEO & Director

Experience in various industries, including corporate law and technology



Miriam Kidron, PhD - CSO & Director Senior Researcher at the Diabetes Unit of Hadassah Medical Center for more than 25 years



Josh Hexter - COO, VP Bus. Dev. More than 15 years of prominent leadership roles in biotech and pharma



Yifat Zommer, CPA, MBA - CFO Extensive experience in corporate financial management

Board of Directors

Michael Berelowitz, MD

- Chairman of Oramed SAB
- SVP Clinical Development & Medical Affairs, Pfizer (former)

Harold Jacob, MD

 Chief Medical Officer, Given Imaging (former)

Gerald Ostrov

- CEO, Bausch&Lomb (former)
- Senior level Executive J&J (former)

Leonard Sank

• Entrepreneur and businessman



Ehud Arbit, MD - Director of R&D Former VP of Medical Research at Emisphere Technologies

Scientific Advisory Board



Michael Berelowitz, MD Chairman of SAB

- Former SVP Clinical Development and Medical Affairs, Specialty Care Business at Pfizer Inc.
- · Strong background in the Diabetes field.



John Amatruda, MD

 Former SVP and Franchise Head of the Diabetes and Obesity Unit at Merck & Co.



Derek LeRoith, MD, PhD

Professor of Medicine and Chief of Endocrinology, Diabetes and Bone Disease Unit, Mount Sinai School of Medicine, NY.



Avram Herskho, MD, PhD – Nobel Laureate, Chemistry, 2004

- Distinguished Professor in the Biochemistry Unit in the B. Rappaport Facility of Medicine, Technion, Haifa, Israel
- Nobel Laureate in Chemistry (2004)



Ele Ferrannini, MD, PhD

- Professor of Internal Medicine, University of Pisa School of Medicine. Professor of Medicine, Diabetes Unit Texas Health Science Center.
- Past President of the EASD.





Nir Barzilai, MD

 Director for the Institute of Aging Research. Member of Diabetes Research Center, Albert Einstein University College of Medicine.

Intellectual Property: Five Primary Worldwide Patent Families

Methods and Compositions for Oral Administration of Proteins (Platform Technology)

- Expire 2026 & 2028
- <u>Approved or Granted in Israel</u>, Japan (both types), EU, Russia, China, Canada, Australia, New Zealand and South Africa
- · Pending in multiple jurisdictions, including the US

Methods and Compositions for Oral Administration of Exenatide

- Expires 2028
- · Approval or Granted in Australia, New Zealand and Israel
- · Pending in multiple jurisdictions, including the US

Methods and Compositions (Insulin + Excenatide)

- Expires in 2032
- · Pending status, including the US

Improved Protease Inhibitors

- Expires in 2032
- · Pending status, including the US



Financial Overview*

Ticker: NASDAQ: ORMP

- \$43M raised to date **
- No Debt
- Cash and investments: \$23.8M
- Shares Issued: 9.7M
- Fully diluted: 11.9M ***



* As of January 14, 2014

** Including the shares of D.N.A Biomedical Solutions Ltd.



*** Including outstanding 0.9M options and 1.5M warrants

37

Anticipated Milestones 2014-2015

| ORMD-0801 Oral Insulin | T2DM Completion of Phase 2a FDA study Initiation & Completion of Phase 2b multi-site study under US IND T1DM Initiation & Completion of Phase 2a FDA study Initiation & Completion of Phase 2b multi-site study under US IND | |
|-------------------------------|---|----|
| ORMD-0901 Oral GLP-1Analog | Initiation & Completion of IND-enabling studies Initiation & Completion of Phase 1b ex-US study Initiation of Phase 2 multi-site study under US IND | 38 |
| oramed | · | |

Analyst Coverage

Oramed is followed by the analysts listed below:

| Analyst | Firm |
|--------------------|---------------------|
| Raghuram Selvaraju | Aegis Capital Corp. |
| Graig Suvannavejh | MLV & Co. |

Please note that any opinions, estimates or forecasts regarding Oramed's performance made by these analysts are theirs alone and do not represent opinions, forecasts or predictions of Oramed or its management. Oramed does not by its reference above or distribution imply its endorsement of or concurrence with such information, conclusions or recommendations.

In Summary

- •Product pipeline with the potential to expand to other indications
- Proprietary technology platform (POD[™]) for oral delivery of peptides
- •Clear proof of concept
- •Strong IP
- •Orally ingestible insulin capsule in Phase 2 clinical development under the US FDA
- •Significant market opportunity
- •World-leading scientific team
- •Experienced management team





Breakthrough Technology for a Brighter Future



Contact : Nadav Kidron CEO <u>nadav@oramed.com</u>

Josh Hexter COO j<u>osh@oramed.com</u>





Oramed Submits Phase 2a Protocol to FDA for the Treatment of Type 1 Diabetes with its Oral Insulin Capsule

JERUSALEM February 10, 2014—Oramed Pharmaceuticals Inc. (NASDAQCM: ORMP) (<u>www.oramed.com</u>), a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, announced today that it has submitted a protocol to the U.S. Food and Drug Administration (FDA) to initiate a Phase 2a trial of its orally ingestible insulin capsule, ORMD 0801, for type 1 diabetes.

The protocol was submitted under Oramed's existing IND for ORMD-0801 to include both type 1 and type 2 diabetes indications. The double-blind, randomized, placebo controlled, seven-day study design will be carried out at an inpatient setting on twenty-four type 1 diabetic patients. This US- based study is expected to start later this quarter.

"With the encouraging data from our recent Phase 2a FDA trial on type 2 diabetic patients, we are moving forward on both the type 1 and type 2 indications by submitting this type 1 protocol to the FDA while gearing up for the Phase 2b multi-center trial on type 2 patients to take place later this year," commented Oramed CEO Nadav Kidron.

About ORMD-0801 Oral Insulin and T1DM

Oramed proposes to introduce ORMD-0801 to reduce the mealtime insulin doses, introducing a treatment regimen which would allow for fewer daily injections. Moreover, oral administration offers the benefit of reduced systemic exposure and may enable tighter regulation of blood sugar levels by directly affecting glucose control in the liver. For more information on ORMD-0801, the content of which is not part of this press release, please visit <u>http://oramed.com/index.php?page=14</u>

About Oramed Pharmaceuticals

Oramed Pharmaceuticals is a technology pioneer in the field of oral delivery solutions for drugs and vaccines currently delivered via injection. Established in 2006, Oramed's Protein Oral Delivery (PODTM) technology is based on over 30 years of research by top research scientists at Jerusalem's Hadassah Medical Center. Oramed is seeking to revolutionize the treatment of diabetes through its proprietary flagship product, an orally ingestible insulin capsule (<u>ORMD-0801</u>) currently in Phase 2 clinical trials on patients with type 2 diabetes (T2DM) under an Investigational New Drug application with the U.S. Food and Drug Administration, and with its oral exenatide capsule (<u>ORMD-0901; a</u> <u>GLP-1 analog</u>). Oramed is also moving forward with clinical trials of ORMD-0801 for the treatment of type 1 diabetes. The company's corporate and R&D headquarters are based in Jerusalem.



For more information, the content of which is not part of this press release, please visit <u>www.oramed.com</u>

Forward-looking statements: This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements. For example, we are using forward-looking statements when we discuss our clinical trials, including the expected timing, and revolutionizing the treatment of diabetes with our products. 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 final 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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