

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): January 6, 2016

ORAMED PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

DELAWARE

(State or Other Jurisdiction
of Incorporation)

001-35813

(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)

91390

(Zip Code)

+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:

- 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))

ITEM 7.01. REGULATION FD DISCLOSURE.

On January 6, 2016, Nadav Kidron, the Chief Executive Officer of Oramed Pharmaceuticals Inc., issued the letter furnished as Exhibit 99.1 to this Current Report on Form 8-K, which letter is incorporated herein by reference.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

99.1 Letter, dated January 6, 2016.

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

January 6, 2016

January 6, 2016

Dear Shareholders,

2015 was a very significant year for us at Oramed setting the bar high for what we anticipate to be a momentous year ahead in 2016.

2015 Major Milestones Included:

- *Global Out-licensing and Investment Deal Valued at \$50 Million Plus 10% Royalties in China*
- *Initiation of Phase IIb Study in Type 2 Diabetes for ORMD-0801 (in progress)*
- *Initiation of Phase Ib Study for ORMD-0901 (in progress)*
- *Collaboration with Big Pharma Partner*
- *Patent Granted in U.S.*

2016 Milestones Expected to Include:

- *Starting Out with Strong Balance Sheet with Roughly \$40 Million Cash*
- *ORMD-0801 Phase IIb Study Completion:*
 - *Last Patient In in Q1, 2016*
 - *Topline Data Release in Q2, 2016*
- *Milestone Achievements/Payments in China License Deal*
- *ORMD-0901 IND and follow on Study*

I. First Global Out-licensing and Investment Deal Valued at \$50 Million Plus 10% Royalties in China

We recently closed a license and investment agreement with Hefei Tianhui Incubator of Technologies Co. Ltd. (HTIT) for exclusive rights to market our oral insulin capsule, ORMD-0801, in Greater China. The agreements were signed at a ceremony which took place at the Israeli Knesset/Parliament and included Bin Zhou, Sinopharm Vice General President and Xiaoming Gao, HTIT Chairman.

In addition to the \$12 million investment and the \$38 million in milestone payments, Oramed will receive up to a 10% royalty on any future net sales. This double digit royalty enhances the already positive financial aspects of the deal for Oramed. China currently has more people living with diabetes than any other country in the world and this points to a tremendous market opportunities in the area of diabetes care. We were very pleased to reach this agreement with HTIT and look forward to a long term working relationship with them.

II. ORMD-0801 Phase IIb Study in Type 2 Diabetes is on Schedule for Completion in Q1/2 2016

The recruitment in our Phase IIb trial of ORMD-0801 has proceeded on-schedule. The study is being conducted under an Investigational New Drug (IND) filing with the U.S. Food and Drug Administration (FDA). We anticipate sharing topline data from this study during the second quarter of this year

III. ORMD-0901 Phase Ib Study Currently in Progress

ORMD-0901, our proprietary oral GLP-1 analog, is a diabetes medication that mimics the natural GLP-1 hormone the body produces to regulate blood glucose levels. In preparation for filing our IND application with the FDA for a Phase II trial, we are currently conducting an ex-U.S. Phase Ib study and expect to announce data from this trial in the first calendar quarter of 2016. Concurrent with this Phase Ib study, we are also conducting 90-day toxicity studies. We hope to file an IND with the FDA and initiate a Phase IIB study in the United States later this year.

IV. Collaboration with Big Pharma Partner

We entered into an agreement with a large international pharmaceutical company to conduct feasibility studies using one of their propriety injectable compounds. The studies will use Oramed's proprietary PODTM Technology to deliver the compound orally. We are very excited about the potential that this collaboration can bring Oramed.

V. Patent Granted in U.S.

The U.S. Patent and Trademark Office granted Oramed a key patent for our invention "Methods and Compositions for Oral Administrations of Proteins" addressing our platform oral administration technology. This patent is a very important milestone that helps pave Oramed's entrance into the U.S. market. The United States is the single largest diabetes market in the world with annual insulin sales of well over \$8 billion.

We Look Forward To Numerous Value-Creating Events In 2016 Including:

Strong Balance Sheet

Kicking off 2016 with roughly \$40 million in cash should allow us to successfully execute on an enormous global opportunity which includes bringing our oral insulin and oral GLP-1 towards commercialization. This puts Oramed in a very strong position as we enter into and continue discussions with potential strategic partners.

Achieving Development Milestones in our HTIT Deal in China

We expect to receive additional milestone payments from HTIT based on achieving multiple development milestones in 2016.

ORMD-0801 Phase IIB Study Completion and Topline Data

We expect to complete our Phase IIB study of ORMD-0801 this quarter and announce top line data by mid-2016.

ORMD-0901 IND and Phase II Study

Data from our small Phase Ib study of ORMD-0901 is expected upon completion of the trial in the first quarter of 2016. We anticipate finishing off the FDA requested 90-day preclinical toxicology study later this year and would look to file an IND soon thereafter; putting us in a position to kick off a U.S. based multicenter Phase II study.

We believe that 2016 will be an exciting and event driven year. We anticipate that numerous milestones will likely contribute to building further value in our Company based on the advancement of our clinical pipeline. We encourage you to follow our achievements throughout the year.

Sincerely,

Nadav Kidron, CEO

Forward-looking statements: This letter 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 and feasibility studies, including the design and expected timing thereof, including the timing of the release of any data, as well as our use of cash and our expected milestone and royalty payments from, and ongoing relationship with, HTIT. 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; failure to meet the conditions set forth in the HTIT license agreement; 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.

Company Contact

Oramed Pharmaceuticals

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