



## Oramed Pharmaceuticals' CEO Letter to Shareholders

January 15, 2019

Oramed Pharmaceuticals Inc. (Nasdaq/TASE: ORMP) ([www.oramed.com](http://www.oramed.com))

**Dear Shareholders,**

We opened the year 2019 with the announcement of our receipt of a \$3 million milestone payment from our partners HTIT, thereby increasing our total payments from HTIT received to date to \$33 million.

We had a busy year in 2018 advancing and initiating a number of clinical studies. Our U.S. based multicenter Phase IIb clinical trial **recently exceeded 75% randomization**. We expect results in 2019 for this study, which is a prerequisite to our upcoming Phase III study for ORMD-0801. This is just one of many milestones and catalysts we anticipate in the coming year.

### 2018 Major Milestones Achieved

- *Exceeded 75% randomization in Phase IIb HbA1c trial for ORMD-0801, our lead oral insulin product in type 2 diabetes*
- *Successful FDA IND submission for ORMD-0901 (oral GLP-1) in type 2 diabetes*
- *Glucose clamp study initiated for ORMD-0801 oral insulin in type 1 diabetes*
- *NASH exploratory clinical study commenced patient enrollment*
- *\$18 million gross proceeds raised, new investors brought in*
- *Over \$40 million in cash and investments at year end; no debt*

### 2019 Major Anticipated Milestones

- *ORMD-0801 (oral insulin)*
  - *Phase IIb HbA1c study completion*
  - *NASH clinical study completion*
- *ORMD-0901 (oral GLP-1)*
  - *Phase I pharmacokinetics study completion*
  - *Phase II study initiation*
- *Leptin Phase I clinical study in Israel initiation and completion*
- *HTIT – Chinese partner*
  - *Additional milestone payment was received in January 2019 from HTIT for aggregate payments of \$33 million to date*
  - *HTIT expected to inaugurate a new manufacturing pilot plant in China to manufacture oral insulin*
- *Strong balance sheet*

### **Oral Insulin (ORMD-0801) Phase IIb 90-day HbA1c Trial to Complete Enrollment**

In the next few months, we anticipate completing enrollment of all 285 patients in our 90-day dose-ranging Phase IIb clinical study of our oral insulin capsule, ORMD-0801. The double-blind, randomized study for type 2 diabetes was initiated in April 2018 and is designed to generate meaningful data for both efficacy (HbA1c) and safety endpoints. Results are expected in Q4 2019. These results will inform our planned Phase III study for oral insulin for the treatment of type 1 and 2 diabetes.

### **GLP-1 (ORMD-0901) Phase I under FDA IND**

Development of our oral GLP-1 analog (ORMD-0901) is rapidly proceeding. We initiated our Phase 1 pharmacokinetic (PK) study under an FDA IND. We expect results this year.

### **NASH Exploratory Clinical Study Enrolling Patients**

Our NASH exploratory clinical study of ORMD-0801 in the treatment of this growing chronic liver disease is underway in Israel. This three-month study will assess the effectiveness of ORMD-0801 in reducing liver fat content, inflammation and fibrosis in patients with NASH. According to the Journal of Hepatology, incidence of NASH is expected to increase 63% from 16 million in 2015 to 27 million cases in 2030. Favorable data may lead to advanced studies.

### **Leptin Exploratory Clinical Study Expected to Commence**

We plan to commence enrollment in a proof of concept single dose study in Israel for our oral leptin drug candidate. The study will evaluate our new drug candidate's pharmacokinetics and pharmacodynamics (glucagon reduction) in type 1 diabetic patients. Leptin, also known as the "obesity hormone" is a protein that regulates hunger.

### **Chinese Partnership Strengthens**

We have received to date a total of \$33 million from China-based HTIT, with whom we signed a licensing agreement for our ORMD-0801. As of year-end, we have successfully completed multiple milestones outlined in our agreement. HTIT is investing substantial funds to build the manufacturing infrastructure to make oral insulin a reality in China and is expected to inaugurate a pilot facility in Q2 2019. HTIT plans to manufacture and sell ORMD-0801 in China, with royalties on any future net sales paid to Oramed.

### **Strong Balance Sheet**

2019 kicks off with over \$40 million in cash and investments. Last year we brought in new investors with an \$18 million equity raise (before offering fees and expenses), which positions us to successfully execute on our planned late-stage clinical studies for oral insulin and GLP-1 as we move towards commercialization. Our balance sheet puts Oramed in a strong position as we enter into and continue discussions with potential strategic partners.

**We believe that 2019 will be an exciting and event driven year. We anticipate that the advancement of our late-stage clinical pipeline in 2019 will drive value creation for our shareholders. We look forward to keeping you posted on our achievements throughout the year.**

Sincerely,

Nadav Kidron  
Chief Executive Officer

### **About Oramed Pharmaceuticals**

Oramed Pharmaceuticals is a technology pioneer in the field of oral delivery solutions for drugs currently delivered via injection. Established in 2006, Oramed's Protein Oral Delivery (POD™) technology is based on over 30 years of research by top 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 (ORMD-0801). The Company completed multiple Phase II clinical trials under an Investigational New Drug application with the U.S. Food and Drug Administration. In addition, Oramed is developing an oral GLP-1 analog capsule (ORMD-0901).

For more information, the content of which is not part of this press release, please visit [www.oramed.com](http://www.oramed.com).

**Forward-looking statements:** This press release contains forward-looking statements. For example, we are using forward-looking statements when we discuss 2019 anticipated milestones, that our cash positions us to execute our studies and puts us in a positive position, the expected timing of clinical development programs, enrollment and clinical studies and FDA submissions, and HTIT's expected new manufacturing facility. 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 U.S. Securities and Exchange Commission.

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