



## Oramed Pharmaceuticals Issues Letter to Shareholders

New York, NY January 9, 2020 — Oramed Pharmaceuticals Inc. (Nasdaq/TASE: ORMP) ([www.oramed.com](http://www.oramed.com)), a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, is pleased to provide the following Letter to Shareholders from Chief Executive Officer Nadav Kidron. For a video message from Mr. Kidron click [here](#).

**Dear Shareholders,**

2019 was a great year of progress for Oramed. We are excited to report that the U.S. Food and Drug Administration (FDA) has agreed to an End of Phase 2 Chemistry Manufacturing and Control (CMC) meeting on February 4, 2020. We expect additional meetings with both the FDA and the European Medicines Agency (EMA), during which we anticipate receiving the regulatory agencies' guidance on our Phase 3 study design. We believe this milestone is the culmination of the hard work and dedication of our employees and investors, and positions us closer to achieving our goal of developing the world's first oral insulin capsule for the treatment of diabetes.

### 2019 Major Milestones Achieved

- ORMD-0801 successfully met its primary endpoint of HbA1C reduction and demonstrated an excellent safety profile in a Phase 2b trial in type 2 diabetes
- Initiated second cohort of Phase 2b trial to evaluate efficacy and safety of ORMD-0801 in lower dosage in type 2 diabetes
- Initiated a study of ORMD-0801 in type 1 diabetes to determine dose in advance of our Phase 3 study which will be conducted in both type 1 and type 2 diabetes
- FDA granted an End of Phase 2 CMC meeting

### 2020 Major Anticipated Milestones

- ORMD-0801 (oral insulin)
  - Results from Phase 2b secondary cohort in type 2 diabetes (Q1)
  - Results from dosing study in type 1 diabetes (Q1)
  - Meetings with FDA and EMA in advance of pivotal Phase 3 study (H1)
  - Phase 3 pivotal diabetes (HbA1c) study initiation (H2)
  - NASH clinical study data (Q1)
- ORMD-0901 (oral GLP-1)
  - Complete bioavailability study in type 2 patients
- Leptin Phase 1 clinical study completion (Q1)

### Oral Insulin (ORMD-0801)

We are extremely pleased with the results from our successful placebo-controlled, double-blind, randomized, 90-day dose-ranging Phase 2b trial in type 2 diabetes. ORMD-0801 demonstrated an exceptionally clean safety profile with no serious drug-related adverse events, no weight gain, and successfully met the primary endpoint with statistically significant reductions in A1C. Our lower dose



cohort study aims to identify the optimal dose for our Phase 3 trial, and we are pleased to announce the last patient out in this study. We anticipate announcing results in the first quarter of 2020.

Consistent with our strategy to further our clinical trials in an optimal fashion, the FDA has agreed to hold an initial End of Phase 2 CMC meeting on February 4, 2020. A second End of Phase 2 FDA meeting for clinical design is expected following the release of data from the low dose cohort of the Phase 2b trial. We also expect to have a meeting with the EMA regarding our Phase 3 study design, as we intend to have some clinical sites in Europe and file for marketing approval in Europe.

Our Phase 3 study will evaluate ORMD-0801 in both type 1 and type 2 diabetes. The dosing study in type 1 diabetes that we initiated in 2019, with results expected in the first quarter of 2020, will inform our study design.

#### **GLP-1 Oral Analog (ORMD-0901)**

We expect to conduct bioavailability studies of ORMD-0901 in type 2 diabetic patients. Results are expected later this year.

#### **NASH Exploratory Clinical Study**

The NASH exploratory clinical study of ORMD-0801 in the treatment of chronic liver disease will assess the efficacy of ORMD-0801 in reducing liver fat content, inflammation, and fibrosis in 30 patients with NASH. We expect initial results from the first group of patients in the first quarter of 2020.

#### **Leptin Exploratory Clinical Study**

We expect to initiate a proof of concept single dose study, evaluating the pharmacokinetic and pharmacodynamics of our oral leptin drug candidate in 10 type 1 adult diabetic patients. We anticipate completing this study during the first quarter of 2020.

#### **Chinese Partnership**

To date, we have received a total of \$33 million in payments from China-based HTIT and expect an additional \$17 million upon the achievement of additional milestones. HTIT has initiated clinical trials of ORMD-0801 in China.

**We are excited to build upon all the progress we made in 2019 and believe that 2020 will be a very productive and event driven year. We look forward to continuing the advancement of our clinical programs, particularly the initiation of a Phase 3 trial for ORMD-0801, which we believe positions Oramed to be the first to offer an oral insulin capsule for the treatment of diabetes.**

Sincerely,

Nadav Kidron  
Chief Executive Officer

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## About Oramed Pharmaceuticals

Oramed Pharmaceuticals is a platform technology pioneer in the field of oral delivery solutions for drugs currently delivered via injection. Established in 2006, with offices in New York and Israel, Oramed has developed a novel Protein Oral Delivery (POD™) technology that is based on more than 30 years of research by scientists at Jerusalem's Hadassah Medical Center. Oramed is seeking to revolutionize the treatment of diabetes through its proprietary lead candidate, ORMD-0801, which has the potential to be the first commercial oral insulin capsule for the treatment of Type 2 and Type 1 diabetes. The Company has 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 (Glucagon-like peptide-1) analog capsule, ORMD-0901.

For more information, 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 the expected timing of initiation and completion of and release of data from clinical trials, expected meetings with the FDA, the safety and efficacy of ORMD-0801, the ability of ORMD-0801 to reduce A1C, expected additional payments from HTIT, the potential of ORMD-0801 to be the first commercial oral insulin capsule for the treatment of diabetes or revolutionizing the treatment of diabetes with our products. In addition, historic results of scientific research and clinical trials do not guarantee that the conclusions of future research or trials will suggest identical or even similar conclusions. 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 finally 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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