



## Oramed Pharmaceuticals Issues CEO Shareholder Letter Providing Business Update Amid COVID-19

- Oral insulin FDA End-of-Phase 2 meeting expected this quarter
- Strong balance sheet with roughly \$50M in cash
- NASH intermediate study data expected this quarter

**NEW YORK, April 1, 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.

**Dear Shareholders,**

As the world faces an unprecedented challenge with much uncertainty, we at Oramed wanted to provide our shareholders and other constituents with an update on our business. Over the past weeks, we have closely followed the guidance of governments and leading public health institutes to ensure the safety of our employees. Additionally, we have conducted a business review to assess the potential impact of COVID-19. At this time, we continue to move ahead with all strategic initiatives and anticipate limited long-term impact from COVID-19. As our platform technology could be effective for protein-based vaccines, we are closely monitoring developments on the efforts to find a vaccine for COVID-19 and any potential partnerships on this front.

### Oral Insulin (ORMD-0801)

We are moving ahead with the planning for our oral insulin (ORMD-0801) Phase 3 clinical studies and have accomplished several key milestones to this end. In February, Oramed conducted its initial End-of-Phase 2 (EoP2) meeting with the U.S. Food and Drug Administration (FDA) to discuss Chemistry Manufacturing and Control (CMC) of ORMD-0801 ([Press Release dated March 19, 2020](#)). The meeting followed the successful completion of Oramed's Phase 2b study of ORMD-0801 for the treatment of type 2 diabetes ([Press Release dated November 12, 2019](#)), which achieved its primary endpoint. During the meeting, the FDA provided feedback on key issues relating to Drug Product manufacturing. We are also looking forward to the second of the EoP2 meetings with FDA. This meeting will include a discussion of the results from the Phase 2 study and the design of the Phase 3 clinical studies proposed to support a license application for a Type 2 diabetes indication if the Phase 3 studies are successfully completed. During this meeting, we anticipate receiving the FDA's guidance on the Phase 3 study design in order to take the next step of submitting the protocols and initiate planning for the Phase 3 program at multiple clinical sites in the U.S. and Europe. We have also requested a meeting with the European Medicines Agency (EMA) regarding our Phase 3 study design, as we intend to utilize clinical sites and file for marketing approval in Europe.

### NASH Exploratory Clinical Study



Our NASH exploratory clinical study of oral insulin for the treatment of chronic liver disease assesses the efficacy of ORMD-0801 in reducing liver fat content, inflammation, and fibrosis. We intend to present data on the early patient cohort in the near future. We are expanding the trial to 30 patients and will shortly be adding additional sites in Israel, Europe and potentially the U.S.

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

We previously communicated our expectation of initiating and completing a Leptin proof-of-concept single dose study, evaluating the pharmacokinetic and pharmacodynamics of our oral Leptin drug candidate in 10 type 1 adult diabetic patients, during the first quarter of 2020. Due to the COVID-19 pandemic, enrollment has been delayed. The trial, however, is ready to resume once the health crisis is contained.

#### **Chinese Clinical Trial**

Due to COVID-19 our Chinese partner's (HTIT) development progress was understandably slowed over the past few months. HTIT has confirmed that they are now fully back to work and in contact with the Chinese regulatory agency (NMPA) on moving forward to the next trials.

#### **Cash Runway**

Following our recent financing of \$21 million in March 2020 ([Press Release dated February 27, 2020](#)), Oramed is well funded with a cash position of roughly \$50 million, which will allow us to progress smoothly into later-stage clinical trials. Our balance sheet remains flexible and strong with zero debt.

**We will continue to assess the evolving COVID-19 situation and provide our constituents appropriate updates when possible. We are very optimistic in our business and believe that 2020 will be a very productive and event driven year for Oramed. We look forward to continuing the advancement of our clinical programs, particularly the initiation this year of a U.S. 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.**

**Wishing you and yours good health,**

Sincerely,

Nadav Kidron  
Chief Executive Officer

#### **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 strategic initiatives and our belief that there will be limited long-term impact from COVID-19, future meetings with the FDA and EMA and the expected outcome thereof, expansion of our NASH clinical study and additional sites, the timing of our Leptin proof-of-concept study, HTIT's future progress, the adequacy of our cash position and balance sheet flexibility, the potential use of our oral delivery technology in a future COVID-19 vaccine, 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.

#### **Company Contact**

Estee Yaari  
+1-844-9-ORAMED  
[estee@oramed.com](mailto:estee@oramed.com)