



## Oramed Issues Letter to Shareholders with Updates on Oral Insulin and COVID-19 Vaccine

May 25, 2021

### - Phase 3 Studies of Oral Insulin Underway and on Schedule - Oral COVID-19 Vaccine Clinical Trials Through Oravax Medical to Begin H2 2021

NEW YORK, May 25, 2021 /PRNewswire/ -- Oramed Pharmaceuticals Inc. (Nasdaq: ORMP) (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,

I'm excited to share with you significant milestones we have achieved over the past few months. Our oral delivery platform technology could apply to a range of proteins and disease modalities, and we expect over time to have a range of programs. We are currently advancing our two primary programs: oral insulin for diabetes and an oral COVID vaccine. We believe these milestones create an inflection point in the value for our company.

#### **ORMD-0801 Positioned to be the World's First Oral Insulin Capsule**

We're pleased at the pace of our Phase 3 oral insulin studies. Under a U.S. FDA protocol, we are advancing two concurrent pivotal Phase 3 studies for ORMD-0801 in the treatment of type 2 diabetes (T2D). ORA-D-013-1 has recruited close to 300 of the planned 675 patients through 75 U.S. clinical sites, while ORA-D-013-2 has commenced enrollment. We look forward to keeping you updated on the progress of these studies.

We anticipate completing enrollment for the U.S. study, ORA-D-013-1, before the end of 2021 and announcing initial results from this study in 2022. Following results from both studies, we expect to submit a Biologics License Approval (BLA) filing to the FDA.

#### **Unlocking Value with Oravax Medical**

- **Oral COVID-19 Vaccine Clinical Trial through Oravax Medical to Begin H2 2021**
- **Oravax Expected to Bring Value to Oramed Shareholders, Potentially Through Dividend Shares of Oravax Medical Shares to Oramed Shareholders**

Our platform technology for the oral delivery of proteins has the potential to be transformative and is generating a lot of interest in the vaccine industry. Oravax Medical Inc., Oramed's venture that combines Oramed's proprietary POD™ oral delivery technology and Premas Biotech's novel vaccine technology, is preparing to begin clinical trials of an oral COVID-19 vaccine in H2 2021.

A single dose of Oravax Medical's oral vaccine produced a significant antibody response with long-retention in a preclinical *in-vivo* study. We believe that Oravax Medical's novel vaccine technology is a strong candidate for protection against COVID-19 and its variants due to triple antigen targeting, easier distribution, and ease of use. We are now in discussions with potential partners for pre-orders of Oravax Medical's vaccine candidate.

We believe there is tremendous value to be unlocked through Oravax Medical's development of a portfolio of oral vaccines for COVID-19 and other infectious diseases. Accordingly, we are exploring ways to ensure that Oramed's shareholders will benefit more directly from Oravax Medical's promise, including potentially issuing dividend shares of some of Oramed's shares in Oravax Medical to Oramed's shareholders, which would make Oravax Medical a publicly held company that may then apply for listing on Nasdaq if eligible. We look forward to updating you on developments.

#### **Strong Balance Sheet**

We are well positioned to capitalize on these market opportunities with a balance sheet that has over \$75 million in cash (as of April 13, 2021) with no

debt.

2021 has started with strong momentum for Oramed. We are working hard at delivering more clinical and corporate milestones and generating value for our shareholders through the rest of the year and beyond.

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 the United States and Israel, Oramed has developed a novel Protein Oral Delivery (POD™) technology. 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 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 recruitment and enrollment for our trials and studies, the expected timing of initiating and completing our and Oravax Medical's trials and studies, the potential for FDA approval of our oral insulin, our expectation that we have enough cash to move forward, expected updates regarding future milestones, the potential of Oravax Medical's novel vaccine technology to be a strong candidate for protection against COVID-19 and its variants, as well as other infectious diseases, the potential for partners for pre-orders of Oravax Medical's vaccine candidate, the potential benefits of Oravax Medical to bring value to our shareholders, a potential dividend of Oravax Medical shares to Oramed's shareholders, 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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