Oramed Issues Shareholder Update on Pivotal Phase 3 Oral Insulin Studies: Protocols Submitted to FDA

- 1,125 patients combined in both studies
- Efficacy data available after the 6-month dosing

NEW YORK, October 16, 2020 – Oramed Pharmaceuticals Inc. (Nasdaq/TASE: ORMP) (www.oramed.com), a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, is pleased to provide the following Shareholder Update from Chief Executive Officer Nadav Kidron.

Dear Shareholders,

We are pleased to announce that based on guidance received from the U.S. Food and Drug Administration (FDA) as part of the End-of-Phase 2 meeting process for our oral insulin candidate, ORMD-0801, we have submitted to the FDA the protocols for our upcoming pivotal Phase 3 studies. In line with the FDA's expectations and recommendations, we intend to conduct two Phase 3 studies concurrently in patients with type 2 diabetes (T2D). These studies involve about 1,125 patients to provide evidence of ORMD-0801's safety and efficacy in T2D patients over a treatment period of 6 to 12 months. A geographically diverse patient population will be recruited from multiple sites throughout the U.S., European Union countries, and Israel.

As agreed with the FDA, our ORA-D-013-1 study will treat T2D patients with inadequate glycemic control who are currently on 1, 2 or 3 oral glucose-lowering agents. This U.S. study will recruit 675 patients from 75 clinical sites located throughout the U.S. Patients will be randomized 1:1:1 in this double-dummy study into cohorts of: 8 mg ORMD-0801 once-daily at night and placebo 45 mins before breakfast; 8 mg ORMD-0801 twice-daily, at night and 45 mins before breakfast; and placebo twice-daily, at night and 45 mins before breakfast. The primary endpoint of the study is to evaluate the efficacy of ORMD-0801 compared to placebo in improving glycemic control as assessed by A1c, with a secondary efficacy endpoint of assessing the change from baseline in fasting plasma glucose at 26 weeks.

The ORA-D-013-2 study will include T2D patients with inadequate glycemic control who are managing their condition with either diet alone or with diet and metformin monotherapy. A total of 450 patients will be recruited through 36 sites in the U.S. and 25 sites in Western Europe and Israel. Patients will be randomized 1:1 into two cohorts dosed with: 8 mg ORMD-0801 at night; and placebo at night. The primary endpoint is to evaluate the efficacy of ORMD-0801 compared to placebo in improving glycemic control as assessed by A1c over a 26-week treatment period, with a secondary efficacy endpoint of assessing the change from baseline in fasting plasma glucose at 26 weeks.

We plan to commence patient enrollment for both studies this quarter and expect efficacy data to be available after all patients have completed the 6-month treatment period. If we successfully complete the pivotal studies, we expect to conduct a pre-BLA (Biologics License Application) meeting to finalize the plans and data for the BLA submission. After BLA submission and review, if the BLA is approved, a full 12 years of marketing exclusivity would be granted. Oramed is committed to advancing the science and clinical

development of oral insulin, as we believe it can deliver meaningful benefits to patients' quality of life and significantly enhance 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. 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 2 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.

Forward-looking statements: This press release contains forward-looking statements. For example, we are using forward-looking statements when we discuss the potential safety and efficacy of ORMD-801, the validation of preliminary findings in future trials, the potential timing of enrollment for our studies and release of related data, the potential benefits of ORMD-0801, 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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