

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

February 4, 2014

Via E-mail
Yifat Zommer
Chief Financial Officer
Oramed Pharmaceuticals, Inc.
Hi-Tech Park 2/4 Givat Ram
PO Box 39098
Jerusalem, Israel 91390

**Re:** Oramed Pharmaceuticals, Inc.

Form 10-K for the Fiscal Year Ended August 31, 2013

Filed November 27, 2013

File No. 001-35813

Dear Ms. Zommer:

We have reviewed your filing and have the following comments. In our comments, we ask you to provide us with information so we may better understand your disclosures.

Please respond to this letter within 10 business days by providing us the requested information or by advising us when you will provide the requested response. If you do not believe a comment applies to your facts and circumstances, please tell us why in your response. Please furnish us a letter on EDGAR under the form type label CORRESP that keys your responses to our comments.

After reviewing the information provided, we may raise additional comments and/or request that you amend your filing.

## <u>Item 1. Business</u> Orally Ingestible Insulin, page 4

- 1. We note your disclosure regarding your communications with the FDA over development of ORMD-0801 and the FDA's request that you conduct a Phase 2a sub study before proceeding to your planned Phase 2b study. In this regard, we note the following:
  - your disclosure on page 29 that you initially filed an IND application with the FDA in December of 2012;
  - the press release from May 17, 2013, included on your website, that the FDA had "cleared" the IND for ORMD-0801;
  - your press release from November 12, 2013, announcing the end stage of the Phase 2a clinical trial and noting that the delay in the Phase 2b trial related to the FDA's concerns about safety of the product candidate.

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Please revise your disclosure to clarify whether there is currently an active IND on file with the FDA for ORMD-0801 and the related indication. Please further revise to include all material details of your communications with the FDA regarding this matter, including but not limited to the reasons for the FDA's request for further trials before a Phase 2b trial could commence, including any adverse events experienced. Finally, please expand to disclose the intended design of your Phase 2b trial, including the intended location, design and goals for Phase 2b testing and the specific results from your Phase 2a trial that lead you to the conclusion that advancement to Phase 2b is warranted.

## Patents and Licenses, page 6

2. Please clarify in disclosure, if true, that you currently hold 8 issued patents worldwide. Please further provide the expiration dates for each of the 8 issued patents along with the relevant jurisdiction and type of protection offered (e.g., composition of matter, method of use, etc.).

## Item 9A. Controls and Procedures, page 39

- 3. We note that you conduct substantially all of your operations outside of the United States. In order to enhance our understanding of how you prepare your financial statements and assess your internal control over financial reporting, we ask that you provide us with information that will help us understand more about the background of the people who are primarily responsible for preparing and supervising the preparation of your financial statements and evaluating the effectiveness of your internal control over financial reporting and their knowledge of U.S. GAAP and SEC rules and regulations. Do not identify people by name, but for each person, please tell us:
  - What role he or she takes in preparing your financial statements and evaluating the effectiveness of your internal control;
  - What relevant education and ongoing training he or she has had relating to U.S. GAAP:
  - The nature of his or her contractual or other relationship to you;
  - Whether he or she holds and maintains any professional designations such as Certified Public Accountant (U.S.) or Certified Management Accountant; and
  - About his or her professional experience, including experience in preparing and/or auditing financial statements prepared in accordance with U.S. GAAP and evaluating effectiveness of internal control over financial reporting.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Exchange Act of 1934 and all applicable Exchange Act rules require. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

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In responding to our comments, please provide a written statement from the company acknowledging that:

- the company is responsible for the adequacy and accuracy of the disclosure in the filing;
- staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- the company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

You may contact Vanessa Robertson, Staff Accountant, at (202) 551-3649 or Mary Mast, Senior Staff Accountant, at (202) 551-3613 if you have questions regarding the processing of your response as well as any questions regarding comments on the financial statements and related matters. You may contact Austin Stephenson, Staff Attorney, at (202) 551-3192 or John Krug, Senior Counsel, at (202) 551-3862 with questions on any of the other comments. In this regard, do not hesitate to contact me at (202) 551-3679.

Sincerely,

/s/ Jim B. Rosenberg

Jim B. Rosenberg Senior Assistant Chief Accountant