

March 4, 2014

## **VIA EDGAR**

Mr. Jim B. Rosenberg Senior Assistant Chief Accountant United States Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549

Re: Oramed Pharmaceuticals Inc. (the "Company")
Form 10-K for the Fiscal Year Ended August 31, 2013
Filed November 27, 2013 (the "Filing")
File No. 001-35813

Dear Mr. Rosenberg:

The Company is writing in response to your letter dated February 4, 2014. For your convenience, each of your original comments appears below in italicized text and is followed by the Company's response.

## Item 1. Business, 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.

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.

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**Company Response:** In future periodic reports under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Company will revise its disclosure to include the following:

"We currently have an active Investigational New Drug, or IND, application on file with the Federal Drug Administration, or FDA, for our oral insulin capsule, ORMD-0801, for improved glycemic control in patients with type 1 or type 2 diabetes. We originally filed an IND with the FDA in December 2012 for clearance to begin a Phase 2 clinical trial of ORMD-0801, in order to evaluate the safety, tolerability and efficacy of our oral insulin capsule on type 2 diabetic volunteers. Because the identical formulation of ORMD-0801 had not yet been studied in humans at bedtime, in February 2013 the FDA noted concerns about mitigating potential risks of severe hypoglycemia and requested that Oramed perform a sub-study in a controlled in-patient setting for a one-week period prior to beginning the larger multi-centered Phase 2 trial. As a result, we withdrew the original IND and, in April 2013, we submitted a new IND for the Phase 2a sub-study. Following the FDA's clearance to proceed in May 2013, we began the Phase 2a sub-study in July 2013. As we announced in January 2014, the Phase 2a sub-study met all primary and secondary endpoints. Specifically, the Phase 2a study evaluated the pharmacodynamic effects of ORMD-0801 on mean nighttime glucose (determined using a continuous glucose monitor). The results show that the ORMD-0801, has exhibited a sound safety profile, led to reduced mean daytime and nighttime glucose readings, when compared to placebo and lowered fasting blood glucose concentrations, when compared to placebo. In addition, no serious adverse events occurred during the Phase 2a study, and the only adverse events that occurred during the study were not drug related. In light of these results, we believe that we should move forward with the Phase 2b clinical trial, which we anticipate beginning in the third quarter of calendar year 2014. This clinical trial will be designed to assess the safety and efficacy of ORMD-0801 and its structure is still under design by the Company."

## 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.).

**Company Response:** The Company hereby confirms that it currently holds eight issued patents. Further, the expiration dates for each of the eight issued patents, along with the relevant jurisdiction and type of protection offered (e.g., composition of matter, method of use, etc.), are shown on Exhibit A hereto.

Also, the Company will revise its disclosure in future Exchange Act periodic reports to include the following:

"We hold eight patents worldwide, including patents issued by the Australian, Chinese, Israeli, Japanese, New Zealand and South African patent offices that cover a part of our technology which allows for the oral delivery of proteins and patents issued by the New Zealand and South African patent offices that cover part of our technology for the oral delivery of exenatide."

## 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.

**Company Response:** The Company's Chief Financial Officer ("CFO"), supported by the Company's bookkeeper ("Bookkeeper"), is primarily responsible for preparing the Company's financial statements and, together with the Company's Chief Executive Officer ("CEO"), evaluating the effectiveness of the Company's internal control over financial reporting. As the Company is relatively small and in the development stage, it does not face complex accounting issues. Additionally, the CEO and the Audit Committee review both the financial reports provided by the Company to the SEC, as well as the Company's internal financial and accounting controls.

The roles of each of the CFO and Bookkeeper, their relevant education and ongoing training in U.S. GAAP, the nature of their relationship to the Company, their professional designations and professional experience are described below.

#### A. Chief Financial Officer

i. Role in preparing financial statements and evaluating the effectiveness of the Company's internal control – The CFO's role is to supervise the Bookkeeper; review and sign off on the trial balances of the Company and its subsidiary, prepared by the Bookkeeper; prepare consolidating entries according to the Company policies and guidelines; prepare the consolidated financial statements; sign off confirming that all procedures on the quarterly or year-end checklist were performed; and take ultimate responsibility over financial reporting and, together with the CEO, the effectiveness of the Company's internal control over financial reporting. The nature of the consolidating entries performed by the CFO are simple in nature, given that the Company has only two subsidiaries. These entries are not reviewed on an individual basis but rather reviewed by the Audit Committee and the CEO as part of their review of the financial results of the Company each quarter or year-end. As such, while reviewing of specific journal entries is not performed, the entity level control review process is deemed sufficient given the Company's current intercompany structure and the consolidating reporting that is reported to the CEO and the Audit Committee. Please note that as the Company continues to grow, the journal entries will be prepared by the Bookkeeper and will be reviewed by the CFO during the normal close process.

- ii. Relevant education and ongoing training relating to U.S. GAAP The CFO holds a Bachelor of Accounting and Economics degree from the Hebrew University (1998), a Master's of Business Administration degree (MBA) from Tel-Aviv University (2004) and a master's degree in Law (LL.M.) from Bar-Ilan University, Israel (2012). The CFO participates in annual conferences held by Kesselman & Kesselman, the Company's independent auditing firm and a member firm of PricewaterhouseCoopers International Limited ("PwC"), regarding updates and developments in U.S. GAAP and SEC financial reporting rules and regulations through professional reading of accounting, finance and legal updates, including updates published by the FASB and SEC, as well as by accounting and law firms.
- iii. Nature of the Relationship to the Company The CFO is a full-time employee of the Company.
- iv. <u>Professional designations</u> –Although she does not have any U.S. professional designations, the CFO has been a Certified Public Accountant in Israel since 1999.
- v. <u>Professional experience</u> The CFO has approximately 13 years of experience in U.S. GAAP, commencing with her time spent at PwC, from January 2001 to April 2006. Prior to joining the Company, the CFO served as the CFO of Witech Communications Ltd., a subsidiary of IIS Intelligence Information Systems Ltd., which was a foreign private issuer, from April 2007 through October 2008, where she supervised the preparation of the financial statements under U.S. GAAP, and as the CFO of CTWARE Ltd., an Israeli private company where she supervised the preparation of the financial statements under Israeli GAAP from April 2006 to April 2007.

#### B. Bookkeeper

- i. Role in preparing financial statements and evaluating the effectiveness of the Company's internal control The Bookkeeper is in charge of the day-to-day accounting and financial function of the Company. The Bookkeeper completes the quarterly and year-end procedures in accordance with the Company's accounting policies and guidelines, including preparation of the trial balances and signing off confirming that all procedures on the quarterly or year-end checklist were performed.
- ii. Relevant education and ongoing training relating to U.S. GAAP The Bookkeeper holds a bookkeeping (level 2) degree from the Jerusalem College.

- iii. Nature of the Relationship to the Company The Bookkeeper is a full-time employee of the Company and reports to the CFO.
- vi. <u>Professional designations</u> The Bookkeeper has held an Israeli bookkeeping certificate (level 2) since 2000 and an Israeli salary controller certificate since 1998.
- vii. <u>Professional experience</u> The Bookkeeper has been acting in her current capacity since August 2013. Prior to that time she worked as a bookkeeper at several Israeli companies and an accounting firm. The Bookkeeper has approximately eleven years of experience in bookkeeping.

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#### The Company acknowledges 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.

The Company appreciates your comments and welcomes the opportunity to discuss with you the responses provided above. Please call me at +972 (0)72 221 8906 if you have any questions or require additional information.

Sincerely,

Oramed Pharmaceuticals Inc.

By: <u>/s/ Yifat Zommer</u> Yifat Zommer Chief Financial Officer

## Exhibit A

# **Patent Information**

	COUNTRY	APPLICATION NO.	PATENT NO.	EXPIRATION DATE*	TYPE OF PROTECTION
	Patent name:	METHODS AND COMPOSITIONS FOR ORAL ADMINISTRATION OF PROTEINS			
1	China	200980118673.40	ZL20098011	2/26/2029	composition of matter
2	New Zealand	588603	588603	2/26/2029	composition of matter and method of use
3	South Africa	2010/07522	2010/07522	2/26/2029	composition of matter and method of use
	Patent name:	METHODS AND COMPOSITIONS FOR ORAL ADMINISTRATION OF PROTEINS			
4	Australia	2006288703	2006288703	8/31/2026	composition of matter and method of use
5	Israel	189956	189956	8/31/2026	composition of matter and method of use
6	Japan	2008-529778	5222727	8/31/2026	composition of matter and method of use
	Patent name:	METHODS AND COMPOSITIONS FOR ORAL ADMINISTRATION OF EXENATIDE			
7	New Zealand	589390.00	589390	5/3/2029	composition of matter and method of use
8	South Africa	2010/08090	2010/08090	5/3/2029	composition of matter and method of use

st All expiration dates assume no patent term extension or adjustment.