ORAMED PHARMACEUTICALS INC.
Form 8-K
January 02, 2013

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 31, 2012

ORAMED PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

| Delaware | 000-50298 | 98-0376008 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

Hi-Tech Park 2/5 Givat Ram
PO Box 39098
Jerusalem, Israel 91390
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: 972-2-566-0001

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 7.01. REGULATION FD DISCLOSURE.

On December 31, 2012, the CEO of Oramed Pharmaceuticals Inc., or Oramed, sent a letter to the persons listed in Oramed's mailing list. A copy of the letter is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

ITEM 8.01. OTHER EVENTS.

On December 31, 2012, Oramed filed an Investigational New Drug, or IND, application with the U.S. Food and Drug Administration, or FDA, to begin a Phase 2 clinical trial of its orally ingested insulin candidate, ORMD-0801. The trial is to include 147 type 2 diabetic patients in multiple centers across the United States. Oramed plans to initiate the trial following FDA approval of the IND. If Oramed does not receive comments from the FDA on the IND application within 30 days from filing, Oramed intends to immediately commence the trial to evaluate the safety, tolerability and efficacy of its oral insulin capsule on type 2 diabetic volunteers. The IND application was mailed to the FDA on December 28, 2012, and was received by the FDA on December 31, 2012.

Warning Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements. Statements preceded by, followed by, or that otherwise include the words "expects," "anticipates," "intends," "plans," "planned expenditures," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements. Additionally, statements concerning future matters are forward-looking statements. For example, statements related to the projected commencement of Oramed's upcoming clinical trials, the amount of patients to be included in the trials, additional patents being approved in the coming year, or the prospect of being listed on Nasdaq. 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 Oramed's ability to obtain the additional funding required to conduct its 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 Oramed's clinical trials; changes in legislation; inability to timely develop and introduce new technologies, products and applications; lack of validation of Oramed's technology as it progresses further and lack of acceptance of its methods by the scientific community; inability to retain or attract key employees whose knowledge is essential to the development of Oramed's products; unforeseen scientific difficulties that may develop with Oramed's 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; Oramed's patents may not be sufficient; and 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.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

99.1 CEO Letter, dated December 31, 2012.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ORAMED PHARMACEUTICALS INC.

Dated: January 2, 2013

By: /s/ Nadav Kidron
Nadav Kidron
President, CEO and a Director

Exhibit Index

| Exhibit Number | Description |
| --- | --- |
| 99.1 | CEO Letter, dated December 31, 2012. |