## Edgar Filing: ORAMED PHARMACEUTICALS INC. - Form 8-K

ORAMED PHARMACEUTICALS INC. Form 8-K January 26, 2011

# 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): January 26, 2011

### ORAMED PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Nevada (State or other jurisdiction of incorporation) 000-50298 (Commission File Number) 98-0376008 (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))

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#### ITEM 7.01 REGULATION FD DISCLOSURE

On January 26, 2011, Oramed Pharmaceuticals Inc. (the "Corporation") made presentations to various investors that included the following material information about the Corporation:

- The Corporation intends to file an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration (the "FDA") for Phase 2 clinical studies of its orally ingested insulin during the third quarter of 2011. If the Corporation does not receive comments from the FDA on its IND application within 30 days from submission, it intends to immediately commence an FDA approved Phase 2 study to evaluate the safety, tolerability and efficacy of its oral insulin capsule (ORMD 0801) on type 2 diabetic volunteers.
- The Corporation expects to have expenditures in the approximate aggregate amount of \$11.1 million for the 24 month period following January 1, 2011, of which \$8.9 million (net of governmental grants received by the Corporation from the Israeli Office of the Chief Scientist) is expected to be expended on clinical trials.

This Current Report on Form 8-K contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates' 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 as denoted in this Current Report on Form 8-K. Additionally, statements concerning future matters are forward-looking statements. Although forward-looking statements in this Current Report on Form 8-K reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under "Item 1A - Risk Factors" in our Annual Report on Form 10-K for the year ended August 31, 2010, and filed with the Securities and Exchange Commission (the "SEC" or the "Commission") on November 29, 2010, as well as those discussed elsewhere in our annual report. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Current Report on Form 8-K. We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Current Report on Form 8-K. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this Current Report on Form 8-K which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

The information in this Current Report on Form 8-K furnished pursuant to Item 7.01 shall not be deemed "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 7.01 of this report.

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## **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 26, 2011

By: /s/ Nadav Kidron

Nadav Kidron

President, CEO and Director