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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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CURRENT REPORT

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

Date of Report (Date of earliest event reported): September 9, 2008

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**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**

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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):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - 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 September 9, 2008, Oramed Pharmaceuticals Inc. (“Oramed”) issued a press release announcing that it has entered into an agreement with ETI Karle Clinical Pvt. Ltd., a clinical research organization in India to conduct Phase 2B clinical trials on its oral insulin capsules. A copy of the press release is being furnished with this report as [Exhibit 99.1](#) and is incorporated herein by reference.

As previously disclosed, Oramed, in conjunction with the Diabetes Unit, Hadassah University Hospital, was selected to display its abstract, entitled "Open Label Study to Assess the Safety, Pharmacokinetics (PK) and Pharmacodynamics (PD) of Five Oral Insulin Formulations in Healthy Subjects," at the 44th Annual Meeting of the European Association for the Study of Diabetes (EASD) held on September 9, 2008 in Rome, Italy. A copy of the abstract is being furnished with this report as [Exhibit 99.2](#) and is incorporated herein by reference.

Pursuant to the rules of the Securities and Exchange Commission, the information contained in this report (including the exhibits) shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and will not be incorporated by reference into any filing by Oramed under such Act or the Securities Act of 1933, as amended.

**ITEM 9.01                    FINANCIAL STATEMENTS AND EXHIBITS.**

(d) Exhibits

[99.1](#) Press Release dated September 9, 2008

[99.2](#) Oramed Pharmaceuticals Inc. Abstract Entitled “Open Label Study to Assess the Safety, Pharmacokinetics (PK) and Pharmacodynamics (PD) of Five Oral Insulin Formulations in Healthy Subjects.”

**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.

Dated: September 9, 2008

**ORAMED PHARMACEUTICALS INC.**

By: /s/ Nadav Kidron

Nadav Kidron

President, CEO and Director



**Oramed Pharmaceuticals Partners with ETI Karle Clinical to Conduct  
Phase 2B Trials on Its Oral Insulin Capsule, ORMD 0801**

ORMD 0801 to be tested on Type 2 Diabetic Volunteers

JERUSALEM, Israel - September 9, 2008 - Oramed Pharmaceuticals, Inc. (OTCBB: ORMP.OB; [www.oramed.com](http://www.oramed.com)), a developer of oral delivery systems, announced today the signing of an agreement with ETI Karle Clinical Pvt. Ltd. ([www.etiklinical.com](http://www.etiklinical.com)), a clinical research organization (CRO) located in India, to conduct Phase 2B clinical trials on its oral insulin capsules.

The study is intended to evaluate the safety, tolerability and efficacy of ORMD 0801, Oramed's oral insulin capsule, on diabetic type 2 patients.

It is anticipated that the Phase 2B study will be conducted over several months starting in the first quarter of 2009, with approximately 60 subjects participating in the trial.

"Oramed has been able to demonstrate that ORMD 0801 has a good safety profile and effective on a small group of diabetes patients. This trial is intended to affirm that ORMD 0801 will perform to our expectation on a large group of type 2 diabetes patients," said Nadav Kidron, CEO of Oramed.

ETI Karle Clinical Pvt. Ltd is a Pan-Asian CRO, headquartered in Bangalore with a network of 60 clinical trial sites across all therapeutic areas, with access to 2 million patients, and 120 researchers.

**About Oramed Pharmaceuticals**

Oramed Pharmaceuticals is a technology pioneer in the field of oral delivery solutions for drugs and vaccines presently delivered via injection. Oramed is seeking to revolutionize the treatment of diabetes through its patented flagship product, an orally ingestible insulin capsule currently in phase 2 clinical trials. Established in 2006, Oramed's technology is based on over 25 years of research by top research scientists at Jerusalem's Hadassah Medical Center. The Company's corporate and R&D headquarters are based in Jerusalem.

*For more information, please visit [www.oramed.com](http://www.oramed.com)*

**Forward-looking statements**

Some of the statements contained in this press release are forward-looking statements which involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such 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 for our product candidates; competition from other pharmaceutical or biotechnology companies; and the company's ability to obtain additional funding required to conduct its research, development and commercialization activities. Please refer to the company's filings with the Securities and Exchange Commission for a comprehensive list of risk factors that could cause actual results, performance or achievements of the company to differ materially from those expressed or implied in such forward looking statements. The company undertakes no obligation to update or revise any forward-looking statements.

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# Open Label Study to Assess the Safety, Pharmacokinetics (PK) and Pharmacodynamics (PD) of Five Oral Insulin Formulations in Healthy Subjects

Miriam Kidron, Itamar Raz, \*Micha Wolfensberger, \* Katrin Kessler \* Herve Schwob \* Christian Schrufer  
Diabetes Unit, Hadassah University Hospital, and Oramed Pharmaceuticals Jerusalem Israel \* Swiss Caps, Kirchberg Switzerland

EASD Rome 2008  
Poster # 1006



## Introduction:

An estimated 246 million people worldwide are affected by diabetes (T2DM). With a further 7 million people developing diabetes each year, that number is expected to reach 380 million by 2025. Despite the availability of many different types of medications to treat T2DM, less than one half of patients reach target glycosylated hemoglobin (HbA<sub>1c</sub>) levels. Because of this high prevalence and the difficulty patients experience reaching targets for glycemic control, research of new agents to improve the management of T2DM are actively pursued. Over the past few years, a number of new medications have been approved for clinical use. With the exception of the DPP-IV inhibitors, none of the recently approved diabetes medications are administered orally.

Oramed is developing an oral dosage form of insulin based on its proprietary drug delivery technology, which facilitates the absorption of peptides and proteins across biological membranes. Preclinical studies in dogs and clinical studies in healthy volunteers have shown that when insulin given orally in a prototypical formulation, and combined with Oramed's drug delivery agents is absorbed, reduces glucose levels and decreases c-peptide levels. The objective of this study, part of a formulation optimization study, was to assess the safety, pharmacokinetic (PK) and pharmacodynamic (PD) profiles of five oral insulin formulations in healthy subjects. The formulations consisted of 1 capsule containing 8 mg of insulin and 5 different concentration of Oramed's absorption enhancing agents.

## Methods:

Eight healthy male volunteers (mean age 26 years, BMI 24 kg/m<sup>2</sup>) participated in this 5-period, cross-over study. Subjects were dosed after an overnight fast and each consecutive visit was separated by a 72 to 96 hours washout period. The formulations consisted of 1 capsule containing 8 mg of insulin and 5 different concentration of Oramed's absorption enhancing agents. Individual blood samples (29 totals) for PK/PD analysis were collected up to 5 hours post-dose. Pharmacodynamic effects were assessed by measuring the effects of the formulation on glucose, insulin and c-peptide.

## Results:

Administration of an oral form of insulin in the fasted state demonstrated a significant decrease in c-peptide levels in all formulations (16%-92%) as well as reduction in blood glucose (7%-32%). All of the formulations were well tolerated by the volunteers, and no serious adverse events have been reported. A lead formulation was identified.

## Discussion:

Oral delivery of proteins and peptide drugs remains a major challenge because of their unique physico-chemical and biologic properties. Oramed's proprietary technology has been demonstrated to effectively deliver these molecules in preclinical and early clinical studies. In the current study 5 different formulations were assessed, and all were found to be safe and showed a salutary PD profile. The most apparent effects observed were on c-peptide and glucose. C-peptide co-secreted in equimolar concentration with insulin from the  $\beta$ -cell is not metabolized by the liver and thus reflects accurately

the effects of exogenous insulin administration. The pharmacokinetics and pharmacodynamics of this specific enteric coated formulation are characterized by a delayed absorption and onset of action and effect (Figs 3,4).

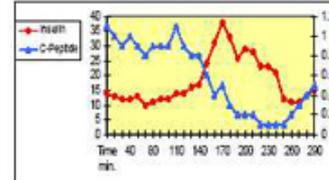


Fig 1. Representative case: Demonstrates an inverse correlation of insulin and C-peptide.

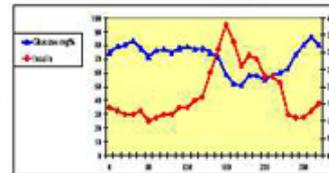


Fig 2. Same case as above: Demonstrates an inverse correlation of insulin and glucose.

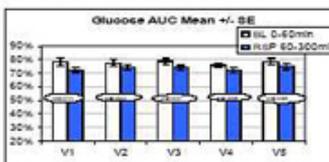


Fig 3. Mean glucose AUC. Delayed reduction observed across the five formulations.

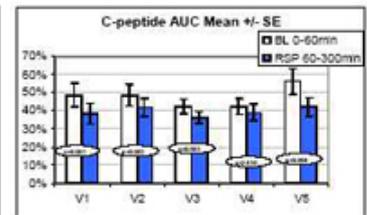


Fig 4. Mean C-peptide AUC. Reduction (delayed) observed across the five formulations.

## Conclusions:

The results of this study in healthy volunteers showed that insulin combined with Oramed's drug delivery enhancers and formulated in a capsule dosage form is absorbed and results in plasma glucose reduction, c-peptide decrease and insulin increase. The PK and PD of the current formulation suggests a potential clinical utility in IGT and early stage T2DM as a supplement to endogenous insulin. Supplementing endogenous insulin is likely to reduce the burden of the "overtaxed"  $\beta$ -cells as suggested by the observed consistent reduction in c-peptide in this study, and allow for  $\beta$ -cell "sparing".

## Acknowledgments:

Authors would like to thank Tara Horn for her assistance.

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