

---

**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): November 14, 2008

---

**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):

- 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))
-

**ITEM 7.01 REGULATION FD DISCLOSURE**

On November 14, 2008, Oramed Pharmaceuticals Inc. (the "Company") issued a press release announcing the presentation of the results of its exploratory study entitled "Enteral Administration of Exenatide-4; Proof of Concept Pharmacodynamic Study in Dogs" which was presented at the Diabetes Technology Society's Conference in Bethesda, Maryland.

A copy of the press release and an abstract of the presentation materials are attached to this Current Report on Form 8-K as [Exhibit 99.1](#) and [99.2](#) respectively and are incorporated herein by reference.

**ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.**

(d) Exhibits

[99.1](#) Press Release dated November 14, 2008

[99.2](#) Presentation Materials

---

**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: November 14, 2008

**ORAMED PHARMACEUTICALS INC.**

By: /s/ Nadav Kidron

Nadav Kidron  
President, CEO and Director

---



## **Oramed Pharmaceuticals Presents Results of Oral Administration of Exenatide-4; Proof of Concept Pharmacodynamic Study in Dogs**

The study suggests that the GLP-1 analog exenatide -4 when combined with Oramed's absorption promoters is absorbed through the gastrointestinal tract and retains its biological activity

JERUSALEM, Israel - November 14, 2008- Oramed Pharmaceuticals, Inc. (OTCBB: ORMP.OB; [www.oramed.com](http://www.oramed.com)), a developer of proprietary drug delivery systems, presented the results today of its exploratory study entitled "Enteral Administration of Exenatide-4; Proof of Concept Pharmacodynamic Study in Dogs" at the Diabetes Technology Society's Conference in Bethesda, Maryland.

Oramed's drug delivery technology is being utilized for the oral delivery of polypeptides and proteins. The Company previously demonstrated that using its proprietary technology enables the delivery of insulin when administered orally.

Exenatide -4 is a GLP-1 analog belonging to a new family of drugs referred to as the incretin mimetics. In addition to exenatide-4, incretin mimetics include liraglutide and a number of other GLP-1 analogs under development. Incretins are produced in the intestines and are released in response to meals. Incretins stimulate insulin secretions from the pancreas as well as delay gastric emptying. This has the effect of reducing blood glucose, which is central in the management of diabetes. Incretins have also been associated with reduction in appetite and may bring about gradual weight loss. Further, incretins appear to promote beta-cell regeneration and survival.

The study was conducted in dogs and the absorption of exenatide was assessed by measuring the effect of exenatide-4 on glucose absorption after oral glucose administration. Control experiments consisted of oral administration of the same amount of glucose but without exenatide-4. Two doses of exenatide -4 were tested and the drug was administered 30 minutes prior to the oral glucose load. The study suggested that exenatide-4 when combined with Oramed's absorption promoters significantly reduces glucose absorption and does so in a dose proportional manner.

Currently, exenatide-4 and all other GLP1 analogs are only available as injections. An oral dosage form such as a tablet or capsule that would replace the injection is likely to broaden the use of these important drugs and foster compliance and adherence among patients. Furthermore, it is plausible that the oral route of administration may convey physiological advantages for exenatide-4 and other analogs as it replicates the physiological route of incretin absorption, from the gut and conveyed to the portal vein and liver.

### **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.

**Company and Investor Relation Contacts:**

Oramed Pharmaceuticals  
Eric Rosenberg  
Cell: + 972-54-566-7713  
Office: + 972-2-566-0001  
Email: [eric@oramed.com](mailto:eric@oramed.com)

**Media Contacts:**

Ruder Finn Israel for Oramed  
Matthew Krieger  
Cell: + 972-54-467-6950  
Office: + 972-2-589-2003  
Email: [matthew@oramed.com](mailto:matthew@oramed.com)

---

# Enteral Administration of Exenatide-4; Proof of Concept Pharmacodynamic Study in Dogs

Miriam Kidron PhD(1, 3), Yael Shushlav DVM(3), Oded Ovadia MSc(2), Ehud Arbit MD(3)

(1)Diabetes Unit, Hadassah University Hospital, (2)School of Pharmacy Hebrew University and (3)Oramed Pharmaceuticals Jerusalem Israel

Diabetes Technology Meeting November 2008



## Introduction:

Exenatide is a synthetic version of exendin-4, a GLP-1 analogue or mimetic and a functional agonist of the GLP-1 receptor. The antihyperglycemic effects of Exenatide are due to its insulinotropic effect as it stimulates glucose-dependent insulin release from the pancreatic islets and its effects of slowing gastric emptying, inhibiting inappropriate glucagon release, stimulating  $\beta$ -cell proliferation and differentiation, and improving satiety. In clinical trials in patients with T2DM Exenatide when given in combination with metformin and/or sulfonylureas resulted in a hemoglobinA1c (HbA1c) reduction of 1.0% compared with placebo treatment, with the predominant effect on lowering postprandial glucose with less prominent reduction in fasting glucose. Exenatide as well as all other GLP-1 analogues are administered as subcutaneous injections. Exenatide is typically injected twice daily in doses of 5 to 10  $\mu$ g. A non-parenteral route to administer GLP-1 analogues including Exenatide will have significant therapeutic benefits, being more convenient it will foster compliance and adherence. Oramed is developing an oral dosage form of Exenatide based on its proprietary drug delivery technology, which facilitates the absorption of peptides and proteins across biological membranes. The objective of this study was to establish a dose response to escalating doses of Exenatide in dogs.

## Methods:

Study was conducted in 4 beagle dogs with an average weight of 10 kg. All the dogs had a cannula residing in the jejunum through which the drug was administered. After an overnight fast, the dogs were given different doses of oral GLP-1 analogue or sc injection of the analogue. Absorption of the GLP-1 analogue was assessed by measuring the effect on glucose excursion following an oral glucose load. Control experiment consisted of oral dosing without administration of GLP-1 analogue. The interval between oral administration and the oral glucose load was 30 minutes. The primary efficacy end point was the glucose excursion above the pre-OGTT glucose level over a 150 min interval (incremental area under the curve (AUC) 0-150 min.)

## Results:

Direct jejunal instillation of GLP-1 analogue significantly (ss) curbed glucose excursion, post glucose load (both in comparison to placebo and among the separate groups)

Table 1:

OGTT - Glucose AUC <sub>0-150 min</sub> Mean $\pm$ SD	
Placebo	8906 $\pm$ 1508
GLP-1 2.5 $\mu$ g sc	3656 $\pm$ 510
GLP-1 75 $\mu$ g PO	6292 $\pm$ 1043
GLP-1 100 $\mu$ g PO	5085 $\pm$ 931

## Discussion:

Oral delivery of proteins and peptide drugs remains a major challenge because of their unique physico-chemical and biologic properties. We have demonstrated in preclinical and clinical studies that our proprietary technology can effectively and reliably transport macromolecules including polypeptides and proteins across biological membranes. Moreover, the native compounds retain their biological activity on reaching the systemic circulation. Clinical studies in healthy volunteers and in people with type 1 and type 2 diabetes have shown that Oramed's oral insulin is absorbed and is effective in lowering blood glucose and decrease c-peptide levels.

In the current study in dogs we have clearly demonstrated that an oral GLP-1 analogue, exenatide, when administered before a meal can blunt meal induced glycemic excursion by about 40% as compared to parenteral exenatide 50% blunting capacity. Pd effects are commonly used in a semi-quantitative way to establish GLP-1 levels in studies assessing DPP IV inhibition. In this study we have demonstrated that the GLP-1 analogue exenatide can be created in an oral dosage form and that it could be ingested by the patient shortly before a meal. These two qualities in a drug significantly facilitate its acceptance among patients and foster higher compliance and adherence to the medication.

## Acknowledgments:

Authors would like to thank Tara Horn for her assistance.

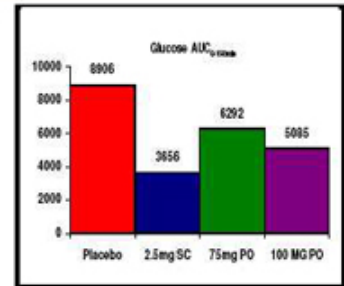


Fig 1 Glucose AUC

## Conclusions:

The results of this study in dogs showed that GLP-1 analogue exenatide when combined with Oramed's drug delivery enhancers and formulated in a capsule is absorbed and results in significant blunting of glucose excursion after an oral OGTT. The Pharmacodynamic response to oral exenatide ingestion was robust and reproducible and the short interval between capsule ingestion and meal suggests that a practical and patient friendly oral dosage form can be created. As of now the only incretin mimetics available as oral medication are the DPP IV inhibitors. An oral dosage form of GLP-1 analogues will broaden the choice of available drugs from this important class of antihyperglycemic medication.

## For More Information:

Eric Rosenberg  
Tel:1-646-240-4193  
info@oramed.com  
www.oramed.com

