

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 03/17/09 for the Period Ending 03/17/09

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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Symbol	OPXA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
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**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): **March 17, 2009**



Opexa Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Texas

(State or Other Jurisdiction of Incorporation)

001-33004

(Commission File Number)

2635 N. Crescent Ridge Drive

The Woodlands, Texas

(Address of Principal Executive Office)

76-0333165

(I.R.S. Employer Identification No.)

77381

(Zip Code)

Registrant's telephone number, including area code: **(281) 272-9331**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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 8.01 Other Event.

On March 17, 2009, the Company announced new preclinical data to support its autologous stem cell therapy program and provided an update of its ongoing stem cell therapy for diabetes. A copy of this press release is furnished as Exhibit 99.1 to this Current Report.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibit 99.1

The following exhibit is to be filed as part of this 8-K:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued March 17, 2009

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.

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma
Neil K. Warma
President and Chief Executive Officer

DATE: March 17, 2009

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued March 17, 2009

Opexa's Stem Cell Therapy for Diabetes Shows Progress

Peripheral blood cells demonstrate ability to differentiate into insulin producing pancreatic-like cells

THE WOODLANDS, Texas--(BUSINESS WIRE)--March 17, 2009--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a company dedicated to the development of stem cell therapies for diabetes today announced new preclinical data to support its autologous stem cell therapy program. Opexa completed confirmatory studies within its c-GMP facility showing that cells obtained from peripheral blood have the ability to differentiate into stem cells and ultimately into pancreatic-like cells. Opexa's proprietary technology has shown that peripheral blood mononuclear cells obtained from the blood of healthy and diabetic patients can differentiate into pancreatic islet-like cells, demonstrating many of the expected characteristics of true pancreatic islet cells including the ability to secrete insulin, glucagon and somatostatin. Additional studies recently completed by Opexa's scientists also support these findings showing high levels of C-peptide, a by-product of insulin synthesis, within these islet-like cells, as well as many key stem cell and pancreatic biomarkers.

Opexa is currently completing preclinical development and advancing toward a Phase I clinical trial for the use of its proprietary autologous stem cell therapy derived from a patient's own blood for the treatment of diabetes. Preclinical data obtained in animal and *in vitro* studies to date have been encouraging and have yielded the following results:

- Opexa has derived multipotent stem cells from peripheral blood mononuclear cells obtained from the blood of both healthy and diabetic subjects. These stem cells have been differentiated into insulin-producing islet-like clusters.
- These islet-like clusters express a variety of endocrine specific markers, are composed of the key pancreatic cell types (α , β , δ), and are able to synthesize and secrete insulin in a glucose-responsive manner *in vitro*.
- *In vivo* studies involving the subcapsular kidney transplantation of these islet-like clusters into diabetic NOD/SCID mice resulted in a reduction in the blood glucose levels for prolonged periods of time.

Additional preclinical studies are planned to examine optimal dosing, delivery and route of administration of the islet-like clusters, and toxicology. Following a preliminary meeting with the FDA and through consultations with its Clinical Advisory Board, Opexa has designed a Phase I clinical study protocol. Primary endpoints are proposed to be safety of monocyte derived pancreatic-like islet cell transplantation and insulin independence or reduction in exogenous insulin requirements at one year post initial infusion.

"I am pleased to see important advances with our stem cell therapy as this technology could offer benefits not only for the treatment of diabetes but also in other disease areas," remarked Neil K. Warma, president and chief executive officer. "We are also hopeful to be able to derive one course of treatment from a single blood draw from a diabetic patient which, ideally, would lead to a readily available source of patient-specific β -cells suitable for autologous cell transplantation."

“We have developed a manufacturing process based on a small-scale, bag-based system which we believe should yield significant cost savings over typical embryonic stem cell and cadaveric cell manufacturing processes,” commented Donna Rill, senior vice president, Operations. “We have extensive experience with cell therapy technology having just completed a 150 patient Phase IIb clinical study with our T-cell therapy and have applied many of the same principles to our stem cell manufacturing process. Much work still remains but we are encouraged with these data.”

About Opexa

Opexa Therapeutics develops and commercializes cell therapies to treat autoimmune diseases such as multiple sclerosis, rheumatoid arthritis and diabetes. The Company is focused on autologous cellular therapy applications of its proprietary T-cell and stem cell therapies. The Company's lead product is Tovaxin, a T-cell therapy for multiple sclerosis that recently completed Phase IIb trials. The Company holds the exclusive worldwide license for adult multipotent stem cells derived from mononuclear cells of peripheral blood. The technology allows large quantities of monocyte-derived stem cells to be produced efficiently for use in autologous therapy, thus circumventing the threat of rejection. The Company is in preclinical development for diabetes mellitus. For more information visit the Opexa Therapeutics website at www.opexatherapeutics.com.

Cautionary Statement Relating to Forward - Looking Information for the Purpose of "Safe Harbor" Provisions of the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements in this release do not constitute guarantees of future performance. Investors are cautioned that statements in this press release which are not strictly historical statements, including, without limitation, statements regarding current or future financial performance and position, management's strategy, plans and objectives for future operations, plans and objectives for product development, plans and objectives for present and future clinical trials and results of such trials, plans and objectives for regulatory approval, litigation, intellectual property, product development, manufacturing plans and performance, constitute forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated, including, without limitation, risks associated with: the success of collaborative relationships, our ability to compete with larger, better financed pharmaceutical and biotechnology companies, new approaches to the treatment of our targeted diseases, our expectation of incurring continued losses, our uncertainty of developing a marketable product, our ability to raise additional capital to continue our treatment development programs, the success of our clinical trials, our ability to develop and commercialize products, our ability to obtain required regulatory approvals, our compliance with all Food and Drug Administration regulations, our ability to obtain, maintain and protect intellectual property rights for our products, the risk of litigation regarding our intellectual property rights, our limited manufacturing capabilities, our dependence on third-party manufacturers and value added resellers, our ability to hire and retain skilled personnel, our volatile stock price, and other risks detailed in our filings with the Securities and Exchange Commission. We assume no obligation to update any forward-looking information contained in this press release or with respect to the announcements described herein.

CONTACT:

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