

OPEXA THERAPEUTICS, INC.

FORM 8-K

(Current report filing)

Filed 05/15/09 for the Period Ending 05/14/09

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
CIK	0001069308
Symbol	OPXA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

**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): **May 14, 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)

76-0333165

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

**2635 N. Crescent Ridge Drive
The Woodlands, Texas**

(Address of Principal Executive Office)

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 1.01 Entry into a Material Definitive Agreement

The Company closed a second and final tranche of a private offering consisting of secured convertible notes and warrants on May 14, which together with the first tranche that closed on April 14, 2009, generated approximately \$1.3 million in gross proceeds. The notes mature in four years from the date of issue and accrue interest at a 10% rate, compounded annually. The interest is payable at maturity in either cash or common stock at the Company's option. The notes are secured by substantially all of the Company's assets and are convertible into common stock, at the option of the holders, at a price of \$0.50 per share. Additionally, subject to the satisfaction of certain conditions, the notes are mandatorily convertible into common stock, at the Company's option, during their term also at \$0.50 per share. The required conditions are: (1) the Company enters into an agreement that will fund a Phase IIb or Phase III clinical trial for the further development of the Company's product known as Tovaxin®, (2) the Company's common stock trades at a price greater than or equal to \$1.00 per share for twenty consecutive trading days, and (3) the Company has an effective registration statement on file with the Securities and Exchange Commission for the re-sale of the shares of common stock issuable upon conversion of the notes. The warrants have a four year term and are exercisable for 50% of the number of shares that the note is convertible into at an exercise price of \$0.75 per share. In connection with the offering, the Company has agreed to pay commissions equal to 10% of the Units sold and will issue broker warrants to acquire the number of shares of common stock equal to 7% of the aggregate number of broker warrant shares and shares of common stock issuable upon conversion of the broker notes. The Company will reimburse the broker for its costs associated with the placement of the Units. The financing agreements are identical to those previously filed for the initial tranche and filed as exhibits to the 8-k filed on April 14, 2009.

Item 2.02 Results of Operations and Financial Condition

The Company intends to use the net proceeds of this transaction for working capital purposes. Management believes that these proceeds will be sufficient to meet projected operating and capital expenditures into September 2009.

On May 15, 2009 Registrant filed its Quarterly Report on Form 10-Q for the quarter ended March 31, 2009. On May 15, 2009, Registrant announced its results of operations in a press release. A copy of the press release announcing the results is filed as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 3.02 Unregistered Sales of Equity Securities

As more fully described in Item 1.01, the Company issued a principal amount of \$1,294,000 of secured convertible notes and warrants to purchase 1,294,000 shares of Company common stock to an aggregate of 37 "accredited investors" as such term is defined in Rule 501 under the Securities Act of 1933 (the "Act"). Participating in the financing were existing shareholders, consisting of institutional investors, private individuals and members of Opexa's Board of Directors. The Company received gross proceeds of \$1,294,000 (net proceeds of \$1,240,600, after deducting sales commissions) from the private placement.

The offers and sales were made without registration under the Act, or the securities laws of certain states, in reliance on the exemptions provided by Section 4(2) of Act and Regulation D under the Act and in reliance on similar exemptions under applicable state laws. The issuance of the Company's secured convertible notes and the warrants did not involve any public offering; each investor made representations regarding its investment intent, experience and sophistication; each investor either received or had access to adequate information about us in order to make an informed investment decision; having received representations to this effect, we believe that each investor is an "accredited investor" as that term is defined under Rule 501(a) of Regulation D; and no advertising or general solicitation was made in connection with the sale and issuance of the Company's secured convertible notes and warrants.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

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 May 15, 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: May 14, 2009

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued May 15, 2009

Opexa Therapeutics Reports First Quarter 2009 Financial Results and Closes Private Financing

THE WOODLANDS, Texas--(BUSINESS WIRE)--May 15, 2009-- **Opexa Therapeutics, Inc.** (NASDAQ: OPXA), a company developing a novel T-cell therapy for multiple sclerosis (MS) and a stem cell therapy for diabetes, today reported financial results for the quarter ended March 31, 2009, and provided details on the final closing of its private offering of secured convertible notes.

Recent highlights include:

- Closing a private placement of \$1.3 million
- Presentation of Tovaxin® TERMS Phase IIb clinical data at the American Academy of Neurology (AAN) 61st annual meeting in Seattle, WA
- Publication of dose escalation clinical study in *Journal of Clinical Immunology*

“We have managed well in a difficult economic environment and being able to raise \$1.3 million in a private financing in these capital markets demonstrates the value our investors place on our novel technologies,” commented Neil K. Warma, president and chief executive officer of Opexa. “Gross proceeds from the financing should provide additional working capital into September 2009 and allow us to continue potential partnering discussions for both the stem cell and T-cell therapies.”

“It was evident at the recent AAN meeting that patients and physicians are still in need of new, safe and effective therapies for multiple sclerosis as side effects of many marketed therapies remain a serious concern and are resulting in patients choosing to discontinue treatment. We are also seeing similar side effect issues in MS drugs in clinical development. Based on the positive feedback we continue to receive from patients and physicians including at the AAN, we believe that Tovaxin, Opexa’s treatment for MS currently in Phase IIb development, has the potential to address many of these concerns as it has shown to be safe and effective in clinical studies to date,” added Mr. Warma.

The Company closed a second and final tranche of a private offering consisting of secured convertible notes and warrants on May 14, which together with the first tranche that closed on April 14, 2009, generated approximately \$1.3 million in gross proceeds. The notes mature in four years from the date of issue and accrue interest at a 10% rate, compounded annually. The interest is payable at maturity in either cash or common stock at the Company’s option. The notes are secured by substantially all of the Company’s assets and are convertible into common stock, at the option of the holders, at a price of \$0.50 per share. Additionally, subject to the satisfaction of certain conditions, the notes are mandatorily convertible into common stock, at the Company’s option, during their term also at \$0.50 per share. Opexa will use the proceeds from the financing to support the ongoing partnering discussions for both its Tovaxin T-cell program and its stem cell platform.

First Quarter Financial Results

Opexa recorded no revenues for the three months ended March 31, 2009 or in the comparable prior-year period.

Research and development expense was approximately \$0.7 million for the three months ended March 31, 2009, compared to approximately \$2.4 million for the three months ended March 31, 2008. The decrease in expenses was primarily due to the completion of the Phase IIb clinical trial in August 2008, closing the extension trial and a reduction in staff offset in part by an increase in non-cash stock compensation expense.

General and administrative expense was approximately \$0.4 million for the three months ended March 31, 2009, as compared to approximately \$0.7 million, for the three months ended March 31, 2008. The decrease in expenses is due to a decrease in non-cash stock compensation expense, overhead expenses, professional service fees, board compensation fees and a reduction in staff.

Opexa recognized a non-cash loss on derivative instruments of \$440,980 for the three months ended March 31, 2009. This loss is a result of the net unrealized change in the fair value of our derivative instrument liabilities related to warrants associated with the August 2008 financing which qualified for treatment under EITF 07-5.

Opexa reported a net loss for the three months ended March 31, 2009, of approximately \$1.6 million, or \$0.13 per share (basic and diluted), compared with a net loss of approximately \$3.1 million or \$0.37 per share (basic and diluted), for the three months ended March 31, 2008. The decrease in net loss is primarily due to the reduction of costs associated with the Phase IIb clinical trial of Tovaxin that was completed in 2008.

The Company had cash and cash equivalents of approximately \$0.4 million as of March 31, 2009, compared with approximately \$1.2 million as of December 31, 2008. The March 31, 2009 quarter-end cash balance does not include approximately \$1.3 million in gross proceeds from the private financing completed subsequent to the end of the quarter.

About Opexa Therapeutics

Opexa Therapeutics develops and commercializes cell therapies to treat autoimmune diseases such as multiple sclerosis 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.

OPEXA THERAPEUTICS, INC.
(a development stage company)

STATEMENTS OF EXPENSES

	Three Months Ended	
	March 31,	
	2009	2008
Research and development	\$ 737,778	\$ 2,373,936
General and administrative	396,315	709,517
Depreciation	57,378	58,277
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Operating loss	(1,191,471)	(3,141,730)
Interest income	1,109	37,709
Other income and expense, net	—	8,317
Loss on derivative liability	(440,980)	—
Interest expense	(5,627)	(6,326)
	<hr/>	<hr/>
Net loss	\$ (1,636,969)	\$ (3,102,030)
Basic and diluted loss per share	\$ (0.13)	\$ (0.37)
Weighted average shares outstanding	12,245,858	8,312,169

Selected Balance Sheet Data:

	March 31,	December 31,
	2009	2008
Cash, cash equivalents and investments	\$ 403,943	\$ 1,243,187
Other current assets	141,692	86,705
Fixed assets (net)	1,109,152	1,166,530
Total assets	1,654,787	2,496,422
Total current liabilities	1,580,017	906,247
Total long term liabilities	86,425	102,778
Total stockholders' equity	(11,655)	1,487,397

CONTACT:

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