

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

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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): March 5, 2010

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

(IRS Employer Identification
No.)

2635 N. Crescent Ridge Drive, The Woodlands, Texas

(Address of principal executive offices)

77381

(Zip Code)

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

N/A

(Former name or former address, if changed since last report)

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:

- ☐ 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 2.02 Results of Operations and Financial Condition.

On March 5, 2010, Opexa Therapeutics, Inc. filed its Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and announced its results of operations in a press release. A copy of the press release announcing the results is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Opexa Therapeutics, Inc. on March 5, 2010.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities under that Section, nor be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933.

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, thereunto duly authorized.

Dated: March 5, 2010

OPEXA THERAPEUTICS, INC.

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Opexa Therapeutics, Inc. on March 5, 2010.

Opexa Therapeutics Reports Year End 2009 Financial Results

THE WOODLANDS, Texas--(BUSINESS WIRE)--March 5, 2010--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a company developing Tovaxin®, a novel T-cell therapy for multiple sclerosis (MS), today reported financial results for the year ended December 31, 2009 and provided an update on its progress.

2009 highlights include:

- Closing a Stem Cell agreement with Novartis Pharmaceuticals for an upfront payment of \$3 million and potential technology transfer milestone payments totaling another \$1 million (with total potential payments from the deal that could exceed \$50 million);
- Securing the first milestone payment from Novartis related to the stem cell transaction of \$0.5 million;
- Strengthening the management team, including the hiring of a highly qualified Senior VP of Clinical Development & Regulatory Affairs;
- Completing the TERMS Phase IIb clinical study analysis, which demonstrated that Tovaxin is safe and well tolerated with promising efficacy across key clinical endpoints including Annualized Relapse Rate and disability (EDSS);
- Closing two financings: \$5.1 million in gross proceeds from a registered direct offering and \$1.3 million in gross proceeds from a private placement of secured notes; and
- Presentation of Tovaxin® TERMS Phase IIb clinical data at the American Academy of Neurology (AAN) 61st annual meeting in Seattle, WA.

“I am pleased with the results and success we demonstrated on a number of fronts this past year despite operating in a very challenging economic climate,” commented Neil K. Warma, President and Chief Executive Officer of Opexa. “The company showed resolve and commitment throughout 2009 and finished the year competitively having strengthened its balance sheet and having positioned Tovaxin as perhaps one of the more promising treatments in development for MS. The pivotal point in the year was the completion of the stem cell transaction with Novartis. This alone contributed an immediate \$3 million upfront payment and positioned us as eligible for future clinical and sales milestone payments in addition to future royalties on net sales of products developed from the use of the technology.”

“We finished the year with approximately \$8.2 million in cash and cash equivalents which, at the current level of monthly burn of approximately \$300,000, provides us with sufficient capital beyond 2010. Our focus over the next 6-12 months will be preparing for Tovaxin’s next clinical study, advancing regulatory and manufacturing activities and continuing our ongoing discussions with potential strategic partners regarding the further development of Tovaxin. Strengthening the Opexa team in 2009 through key internal hires and the addition of world class consultants was an important step in positioning Tovaxin for continued clinical development,” added Mr. Warma.

Year Ended December 31, 2009 Financial Results

Opexa reported no revenues in the year ended December 31, 2009 or in the comparable prior-year period.

Research and development expenses were \$2,107,833 for 2009, compared with \$8,388,734 for 2008. The decrease in expenses was primarily due to a decrease in activities related to the Phase IIb clinical trial for Tovaxin which was completed in 2008, closing the extension trial, a reduction in staff and a reduction in stock compensation expense.

General and administrative expenses for 2009 were \$2,020,572 compared with \$3,341,415 for 2008. The decrease in expense is due to a reduction in staff and a decrease in stock compensation expense, overhead expenses, professional service fees and board compensation fees.

Interest expense was \$278,127 for 2009, compared with \$19,983 for 2008. Interest expense for 2009 was primarily related to accrued interest on the convertible notes, amortized interest on the convertible notes and the (non-cash) amortization of the financing fees over the life of the notes. Interest expense for 2008 was solely related to the equipment line loan payable.

Interest income was \$1,764 for 2009, compared with \$100,235 for 2008. The decrease was due to the reduction in cash balances that were available for investment in cash equivalent investments and a reduction in interest rates.

Gain on sale of assets was \$3 million for the year ended December 31, 2009, compared with \$-0- for 2008. The gain is attributable to the sale of our stem cell technology program to Novartis for an upfront payment of \$3 million.

Other income for the year ended December 31, 2009 was \$554,242, compared with \$34,901 for 2008. The increase in other income is primarily attributable to the receipt of an initial \$500,000 technology transfer fee milestone payment pursuant to the terms of the stem cell technology acquisition agreement with Novartis.

Opexa reported a net loss for the year ended December 31, 2009 of \$1,433,922, or (\$0.11) per share, compared with a net loss for the year ended December 31, 2008 of \$11,852,152, or (\$1.12) per share.

Cash and cash equivalents and investments in marketable securities were \$8,181,582 as of December 31, 2009 compared to \$1,243,187 as of December 31, 2008.

About Opexa

Opexa Therapeutics, Inc. is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases. The Company's leading therapy, Tovaxin®, is an individualized cellular immunotherapy treatment in Phase IIb clinical development for multiple sclerosis (MS). Tovaxin is derived from T-cells isolated from peripheral blood, expanded ex vivo, and reintroduced into the patients via subcutaneous injections. This process triggers a potent immune response against specific subsets of autoreactive T-cells known to attack myelin, believed to be a primary cause of MS attacks and nervous system damage.

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 payments, returns, royalties, 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: market conditions, our capital position, the success of third party development and commercialization efforts with respect to products covered by intellectual property rights transferred by the Company, the success of third party patent prosecution efforts with respect to such products, the ability of the Company to enter into and benefit from a partnering arrangement for the Company's product candidate, Tovaxin, on reasonably satisfactory terms (if at all), and our dependence (if partnered) on the resources and abilities of any partner for the further development of Tovaxin, 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 Data:

	Twelve Months Ended December 31,	
	2009	2008
Research and development	\$ 2,107,833	\$ 8,388,734
General and administrative	2,020,572	3,341,415
Depreciation and amortization	214,851	234,325
Loss on disposal of assets	1,771	2,831
Operating loss	(4,345,027)	(11,967,305)
Interest income	1,764	100,235
Other income and expense, net	554,242	34,901
Loss on derivative instruments	(366,774)	-
Gain on sale of technology	3,000,000	-
Interest expense	(278,127)	(19,983)
Net loss	<u>\$ (1,433,922)</u>	<u>\$ (11,852,152)</u>
Basic and diluted loss per share	\$ (0.11)	\$ (1.12)
Weighted average shares outstanding	12,556,056	10,551,321

Selected Balance Sheet Data:

	2009	2008
Cash and cash equivalents	\$ 8,181,582	\$ 1,243,187
Other current assets	187,306	86,705
Fixed assets, net	949,910	1,166,530
Total assets	9,318,798	2,496,422
Total current liabilities	833,974	906,247
Total long term liabilities	1,109,676	102,778
Total stockholders' equity	7,375,148	1,487,397

CONTACT:

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