OPEXA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 03/08/11 for the Period Ending 03/08/11

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 8, 2011

OPEXA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Texas	**001-33004**	**76-0333165**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2635 Technology Forest Blvd., The Woodlands, Texas	**77381**
(Address of principal executive offices)	(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 obligations 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))

Item 2.02 Results of Operations and Financial Condition

On March 8, 2011, Opexa Therapeutics, Inc. filed its Annual Report on Form 10-K for the fiscal year ended December 31, 2010 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

Exhibit No.	Description
99.1	Press Release issued by Opexa Therapeutics, Inc. on March 8, 2011.

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 8, 2011

OPEXA THERAPEUTICS, INC.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Opexa Therapeutics, Inc. on March 8, 2011.

Exhibit 99.1

Opexa Therapeutics Reports Year End 2010 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--March 8, 2011--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, 2010 and provided an update on its progress.

2010 and recent 2011 highlights include:

- Clinical and Regulatory
  - December 2010: Completed two successful meetings with the FDA, positioning Opexa to pursue a Phase III clinical study for Tovaxin® in relapsing-remitting MS (RR-MS);
  - July 2010: Enlisted the support of worldwide thought leaders in MS, neurology, and immunology for newly reconstituted Scientific Advisory Board;
  - April 2010: Presentation of key immunological data at the 62nd annual American Academy of Neurology (AAN) conference supporting Tovaxin mechanism of action;
- Financial
  - January 2011: Closed a financing of $8.5 million in gross proceeds through an underwritten public offering;
  - June 2010: Prepayment of $1.3 million in principal amount of 10% convertible notes to eliminate debt and interest payments and remove security interest on Opexa assets;
- Operational
  - Optimized Tovaxin manufacturing process to reduce costs and labor to prepare for a pivotal Phase III clinical trial;
  - April 2010: Strengthened management team with the hiring of an experienced cell therapy immunologist as V.P. of Scientific Development to lead R&D efforts of Tovaxin development; and
  - Strengthened the Tovaxin patent estate through issuance of key patents.

“2010 was a very productive year for us as we accomplished numerous key milestones,” commented Neil K. Warma, President and Chief Executive Officer of Opexa. “Foremost, we were able to complete two key meetings with the FDA, the first which focused on the optimized manufacturing process for Tovaxin and the second which focused on the clinical trial protocol. The meetings concluded successfully and now position Opexa to proceed to Phase III clinical trials with Tovaxin for the treatment of RR-MS. In advance of the meetings and critical for their success, we spent the better part of the year optimizing our manufacturing process and clinical trial design to be able to meet the requirements set out by the FDA. In doing so, our manufacturing process has become much more streamlined and cost effective as we reduced the overall process time in half. Not only are we prepared for pivotal Phase III studies, we have also implemented numerous steps to the process to allow for an eventual smooth transition to commercial production. Having a clear clinical direction for Tovaxin from the FDA was a critical step and enables us, we believe, to advance toward the initiation of the next clinical trial. We are using the proceeds from our recent financing to ramp up our efforts in preparation for the trial. The funds will be directed, in part, over the next several months to increasing our headcount to an appropriate level to manage future studies and completing our engineering runs in advance of initiating the trial. I am very pleased with our progress over the past year as we finished 2010 in a strong position and started 2011 competitively as we are now positioned to advance toward Phase III studies with what we believe to be one of the most novel, safe and effective treatments for MS,” added Mr. Warma.

“We ended the year with approximately $3.8 million in cash and cash equivalents and supplemented our cash balance in January and February 2011 with approximately $1.1 million raised under an at-the-market (ATM) offering and another $7.6 million in net proceeds through an underwritten public offering. Our monthly cash burn during 2010 was approximately $380,000, and as we prepare for and proceed toward the initiation of a pivotal Phase III clinical study in the United States, we expect to increase our monthly cash burn during 2011. We believe we have sufficient cash on hand to fund our expanding operations through 2011. Moving forward, as we target the second half of the year to initiate the trial, we will need to secure additional financing either through a potential Tovaxin partnership or additional capital raise, and this will be an additional focus for us over the coming months,” commented Mr. Warma.

Year Ended December 31, 2010 Financial Results

Opexa reported no commercial revenues in the year ended December 31, 2010 or in the comparable prior-year period.

Research and development expenses were $2,584,734 for 2010, compared with $2,107,833 for 2009. The increase in expenses was primarily due to an increase in personnel, an increase in professional service fees and the initiation of key experiments in preparation for our next clinical trial, partially offset by a $244,479 credit received from the Internal Revenue Service in payment for our application for the Qualifying Therapeutic Discovery Grant for qualifying 2009 research and development expenses.

General and administrative expenses for 2010 were $2,216,043 compared with $2,020,572 for 2009. The increase in expense is due to an increase in professional service fees as well as an increase in executive compensation costs, and was partially offset by a decrease in stock and bonus compensation expense.

Interest expense was $500,648 for 2010, compared with $278,127 for 2009. The increase in interest expense was primarily related to the non-cash amortization of the remaining discount and deferred financing fees in connection with the June 23, 2010 conversion to common stock of $1,250,000 in principal amount of convertible promissory notes.

Interest income was $1,660 for 2010, compared with $1,764 for 2009.

Gain on sale of assets was $-0- for the year ended December 31, 2010, compared with $3 million for 2009. This gain is attributable to the sale of our stem cell technology program to Novartis for an upfront payment of $3 million. As there was no cost basis associated with the stem cell assets on the financial statements, the entire upfront payment was recognized as a gain on sale of technology.

Other income for the year ended December 31, 2010 was $-0-, compared with $554,242 for 2009. During 2009, we received 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, 2010 of $5,469,067, or $0.32 per share, compared with a net loss for the year ended December 31, 2009 of $1,433,922, or $0.11 per share. The increase in net loss is primarily due to the absence of the $3 million gain on technology sale and $500,000 technology transfer fee milestone in the year ended December 31, 2010, as well as increases in research and development, general and administrative, and interest expenses.

Cash and cash equivalents and investments in marketable securities were $3,812,535 as of December 31, 2010 compared to $8,181,582 as of December 31, 2009.

For additional information please see Opexa's Annual Report on Form 10-K filed today with the SEC.

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 a personalized cellular immunotherapy treatment that is in 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, and, thereby, reduces the risk of relapse over time.

Opexa has completed a Phase IIb clinical study with Tovaxin in 150 patients with MS. Data from this clinical study show evidence that relapsing-remitting MS (RR-MS) patients treated with Tovaxin saw overall clinical and disability benefits over the placebo group, including a clinically relevant decrease in the Annualized Relapse Rate (ARR), and improvement in disability score (EDSS), as well as an excellent safety profile with no serious adverse events related to Tovaxin treatment.

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 words "expects," "believes," "anticipates," "estimates," "may," "could," "intends," and similar expressions are intended to identify forward-looking statements. 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 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 and to undertake and complete a pivotal Phase III study in the United States for Tovaxin in RR-MS, 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 (including for Tovaxin), the risk of litigation regarding our intellectual property rights, the success of third party development and commercialization efforts with respect to products covered by intellectual property rights transferred by the Company, our limited manufacturing capabilities, our dependence on third-party manufacturers, 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. These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update any forward-looking statements to reflect any changes in expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in our reports filed with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2010.

OPEXA THERAPEUTICS, INC.
(a development stage company)

Statements of Expenses Data:

	Three Months Ended December 31,	
	2010	**2009**
Research and development	$ 2,584,734	$ 2,107,833
General and administrative	2,216,043	2,020,572
Depreciation and amortization	168,843	214,851
Loss on disposal of assets	459	1,771
Operating loss	(4,970,079)	(4,345,027)
Interest income	1,660	1,764
Other income and expense, net	-	554,242
Loss on derivative instruments	-	(366,774)
Gain on sale of technology	-	3,000,000
Interest expense	(500,648)	(278,127)
Net loss	$ (5,469,067)	$ (1,433,922)
Basic and diluted loss per share	$ (0.32)	$ (0.11)
Weighted average shares outstanding	17,071,691	12,556,056

Selected Balance Sheet Data:

	December 31, 2010	**December 31, 2009**
Cash and cash equivalents	$ 3,812,535	$ 8,181,582
Other current assets	85,525	187,306
Fixed assets, net	815,958	949,910
Total assets	4,714,018	9,318,798
Total current liabilities	745,305	833,974
Total long term liabilities	-	1,109,676
Total stockholders' equity	3,968,713	7,375,148

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