OPEXA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 02/27/12 for the Period Ending 02/27/12

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): February 27, 2012

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 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))

Item 2.02 Results of Operations and Financial Condition

On February 27, 2012, Opexa Therapeutics, Inc. filed its Annual Report on Form 10-K for the fiscal year ended December 31, 2011 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 February 27, 2012.

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: February 27, 2012

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 February 27, 2012.

Exhibit 99.1

Opexa Therapeutics Reports Year End 2011 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--February 27, 2012--Opexa Therapeutics, Inc. (NASDAQ:OPXA), a biotechnology company developing a novel T-cell therapy for multiple sclerosis (MS), today reported financial results for the year ended December 31, 2011 and provided an overview of corporate developments during the last year.

2011 highlights include:

- **Clinical and Regulatory**
  - Granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for Tovaxin® for the treatment of patients with Secondary Progressive Multiple Sclerosis (SPMS);
  - Published the results of the Company's prior Phase IIb TERMS clinical trial of Tovaxin in a leading peer-reviewed publication, *Multiple Sclerosis Journal* ;
  - Executed strategic agreements with the American Red Cross and the Blood Group Alliance, Inc. to streamline blood procurement for future clinical trials; and
  - Met with Health Canada's Biologics and Genetics Therapies Directorate as part of the process to secure approval for Opexa to conduct a portion of future clinical development in Canada.
- **Operational**
  - Optimized the manufacturing process through the implementation of a functionally closed system and single cycle cGMP process;
  - Advanced overall clinical plans for Tovaxin and clearly defined the study protocol for the planned Phase IIb clinical trial in SPMS;
  - Increased employee headcount thereby strengthening our overall cell therapy expertise in preparation for the planned clinical trial in SPMS; and
  - Designed and implemented a proprietary Web-based system to manage patient and product flow throughout future clinical studies.
- **Financial**
  - Closed a financing of $8.5 million in gross proceeds through an underwritten public offering in February 2011.

"2011 was a very productive year for Opexa as we remained clearly focused on the preparations for our next clinical trial with Tovaxin," commented Neil K. Warma, President and Chief Executive Officer of Opexa. "We made a firm decision, based on numerous conversations with key MS opinion leaders, clinicians, pharmaceutical companies, and the FDA to target Secondary Progressive MS. We remain on track to initiate the Phase IIb clinical trial in SPMS within a period of several months subject to securing the necessary resources. We are most pleased with our recruiting efforts as we have been able to hire numerous experts in cell therapy in the areas of manufacturing, quality assurance, quality control and R&D. It is our belief that Tovaxin could be the therapy of choice for many MS patients; and if we are able to demonstrate success, especially in SPMS patients, we will change the course of how MS is treated and will have built significant value in the company."

“We ended the year with approximately $7.1 million in cash and cash equivalents. Our monthly cash burn during 2011 was approximately $470,000. As we prepare for and proceed toward the initiation of a Phase IIb clinical study in North America, we expect substantial increases in our monthly cash burn. Moving forward, in order to initiate the trial we will need to secure additional financing either through a potential partnership or additional capital raise, and this will be an important focus for us over the coming months,” commented Mr. Warma.

Year Ended December 31, 2011 Financial Results

Opexa reported no commercial revenues in the year ended December 31, 2011 or in the comparable prior-year period.

Research and development expenses were $3,340,038 for 2011, compared with $2,584,734 for 2010. The increase in expenses was primarily due to an increase in personnel, an increase in development fees, an increase in facilities costs and the initiation of key experiments in preparation for our next clinical trial, and was partially offset by a decrease in the engagement of consultants and a decrease in stock compensation expense. The increase in expenses compared to the prior year was also due in part to a one-time $244,479 credit received from the Internal Revenue Service during 2010 for the Qualifying Therapeutic Discovery Grant for qualifying 2009 research and development expenses.

General and administrative expenses for 2011 were $2,406,269 compared with $2,216,043 for 2010. The increase in expense is due to an increase in business development costs, an increase in investor relations outreach, an increase in stock compensation expense and an increase in facilities costs, and was partially offset by a reduction in professional service fees.

Depreciation and amortization expenses for 2011 were $210,252 compared with $168,843 for 2010. The increase in expense is due to an increase in depreciation for facility build out costs incurred during 2011, an increase in depreciation for laboratory and manufacturing equipment acquired during 2011 and an increase in depreciation for information technology equipment acquired during 2011.

Interest expense was $3,135 for 2011, compared with $500,648 for 2010. The decrease 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.

Opexa reported a net loss for the year ended December 31, 2011 of $5,968,448, or $0.26 per share, compared with a net loss for the year ended December 31, 2010 of $5,469,067, or $0.32 per share. The increase in net loss is primarily due to the increases in research and development, general and administrative, and depreciation expenses, and was partially offset by a decrease in interest expense.

Cash and cash equivalents were $7,109,215 as of December 31, 2011 compared to $3,812,535 as of December 31, 2010.

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 such as multiple sclerosis (MS). The Company's leading T-cell therapy is a personalized cellular immunotherapy treatment that is in late stage clinical development targeting both Secondary Progressive and Relapsing Remitting MS. The T-cell therapy 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.

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,” “exploring,” “evaluating” 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 the development of the Company’s product candidate, Tovaxin, 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: 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), 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 any further clinical studies for Tovaxin, the success of our clinical trials, the efficacy of Tovaxin for any particular indication, such as for relapsing remitting MS or secondary progressive MS, 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 that the Company may license or transfer, 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:

	Twelve Months Ended December 31,	
	2011	**2010**
Research and development	$ 3,340,038	$ 2,584,734
General and administrative	2,406,269	2,216,043
Depreciation and amortization	210,252	168,843
Loss on disposal of assets	9,686	459
Operating loss	(5,966,245)	(4,970,079)
Interest income	932	1,660
Interest expense	(3,135)	(500,648)
Net loss	$ (5,968,448)	$ (5,469,067)
Basic and diluted loss per share	$ (0.26)	$ (0.32)
Weighted average shares outstanding	22,532,498	17,071,691

Selected Balance Sheet Data:

	2011	**2010**
Cash and cash equivalents	$ 7,109,215	$ 3,812,535
Other current assets	124,773	85,525
Fixed assets, net	1,029,236	815,958
Total assets	8,263,224	4,714,018
Total current liabilities	1,067,860	745,305
Total long term liabilities	-	-
Total stockholders' equity	7,195,364	3,968,713

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