

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 11/04/11 for the Period Ending 11/04/11

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): November 4, 2011

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 Technology Forest Blvd., 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 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))
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Item 2.02 Results of Operations and Financial Condition

On November 4, 2011, Opexa Therapeutics, Inc. filed its Quarterly Report on Form 10-Q for the quarter ended September 30, 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

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press Release by Opexa Therapeutics, Inc. on November 4, 2011.
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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: November 4, 2011

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 November 4, 2011.

Opexa Therapeutics Reports Third Quarter 2011 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--November 4, 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 quarter ended September 30, 2011 and provided an overview of recent corporate developments.

Recent highlights include:

- Electing Gail J. Maderis, a seasoned pharmaceutical executive with a strong track record of leading biopharma companies through the clinical development stage, to Opexa's Board of Directors, thereby strengthening the Company's oversight to execute on its key strategic initiatives;
- Appointing Mark Freedman, M.D., a leading worldwide expert in MS, to Opexa's highly esteemed Scientific Advisory Board; and
- Advancing the clinical plans for Tovaxin and defining a clinical trial protocol for Secondary Progressive MS.

"Much progress was made in further advancing our plans and discussions in the area of Secondary Progressive MS," commented Neil K. Warma, President and Chief Executive Officer of Opexa. "We know that this population of MS patients is greatly underserved with only one drug currently approved by the FDA specifically for Secondary Progressive MS. Our focus has been on further clarifying Tovaxin's potential in SPMS through discussions with key opinion leaders, patients and pharmaceutical companies. We have treated numerous patients with Secondary Progressive MS in previous clinical trials. The data appears encouraging and safety is superb, as it has been for all Tovaxin clinical trials, and the unmet need remains significant. Consequently, this disease area remains a high priority for Opexa."

"To prepare for the next clinical trial with Tovaxin, we have remained on schedule with respect to the implementation of manufacturing and clinical priorities. Hiring of key staff has proceeded according to plan and we have appointed very strong individuals in the areas of Manufacturing, Quality Control and Quality Assurance. I am very pleased with this progress."

"In addition to augmenting our staff with excellent individuals, we have significantly strengthened our Scientific Advisory Board through the appointment of Dr. Mark Freedman, M.D. and our Board of Directors with the appointment of Gail Maderis. Dr. Freedman is one of the world's leading experts in MS and will be invaluable as we move into the next clinical trial with Tovaxin. Ms. Maderis spent years as a senior pharmaceutical executive previously at Genzyme and also developed strong expertise in the industry as a biotech entrepreneur and CEO and brings a wealth of experience to the Board. We are grateful for their support and guidance."

"As of September 30, 2011, our cash and cash equivalents totaled approximately \$8.6 million and our current monthly burn rate was approximately \$450,000," continued Mr. Warma. "At the current burn rate, we should have sufficient capital to support our operations at their current level through 2012. Moving forward, we expect to maintain our focus on implementing operational steps in anticipation of continuing the clinical study of Tovaxin and working to secure the necessary resources to support such a study."

Third Quarter Financial Results

Opexa reported no commercial revenues in the three and nine months ended September 30, 2011 or in the comparable prior-year periods.

Research and development expenses were \$654,772 and \$2,194,141 for the three and nine months ended September 30, 2011, respectively, compared with \$625,282 and \$2,193,919 for the three and nine months ended September 30, 2010, respectively. The increase for the three months ended September 30, 2011 compared to the three months ended September 30, 2010 was due to increased staff associated with development activities and an increase in associated laboratory costs and supplies, and was partially offset by a decrease in the engagement of consultants.

General and administrative expenses for the three and nine months ended September 30, 2011 were \$584,794 and \$1,737,686, respectively, compared with \$626,697 and \$1,706,546 for the three and nine months ended September 30, 2010, respectively. The decrease for the three months ended September 30, 2011 compared to the three months ended September 30, 2010 was due to a decrease in compensation expense, and was partially offset by an increase in business development expenses. The increase for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 was due to an increase in costs related to business development expenses, increased investor relations outreach costs and an increase in stock compensation expense, and was partially offset by a decrease in legal costs.

Depreciation and amortization expense for the three and nine months ended September 30, 2011 was \$56,888 and \$157,254, respectively, compared with \$37,647 and \$136,022 for the three and nine months ended September 30, 2010, respectively. The increase was due to an increase in depreciation for facility buildout 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 to replace and upgrade obsolete equipment.

Interest expense for the three and nine months ended September 30, 2011 was \$638 and \$2,643, respectively, compared with \$2,004 and \$499,200 for the three and nine months ended September 30, 2010, respectively. The decrease in expense for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 was primarily related to the amortized interest incurred during the first half of 2010 and the amortization of the remaining discount and deferred financing fees in conjunction with the June 23, 2010 conversion of the 10% Convertible Promissory Notes.

Opexa reported a net loss for the three months ended September 30, 2011 of \$1.30 million, or (\$0.06) per share, and a net loss for the nine months ended September 30, 2011 of \$4.09 million, or (\$0.18) per share. For the same three month and nine month periods ending September 30, 2010, Opexa reported a net loss of \$1.29 million, or (\$0.07) per share, and \$4.53 million, or (\$0.27) per share, respectively.

Cash and cash equivalents were \$8,639,856 as of September 30, 2011 compared to \$4,733,445 as of September 30, 2010.

Further details can be found in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.

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 therapy, Tovaxin®, is a personalized cellular immunotherapy treatment that is in late stage clinical development for 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.

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 RRMS or SPMS, 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 September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Research and development	\$ 654,772	\$ 625,282	\$ 2,194,141	2,193,919
General and administrative	584,794	626,697	1,737,686	1,706,546
Depreciation and amortization	56,888	37,647	157,254	136,022
Loss on disposal of assets	413	-	413	-
Operating loss	(1,296,867)	(1,289,626)	(4,089,494)	(4,036,487)
Interest income	227	815	698	1,395
Interest expense	(638)	(2,004)	(2,643)	(499,200)
Net gain/(loss)	<u>\$ (1,297,278)</u>	<u>\$ (1,290,815)</u>	<u>\$ (4,091,439)</u>	<u>\$ (4,534,292)</u>
Net income (loss) per share				
Basic and Diluted	\$ (0.06)	\$ (0.07)	\$ (0.18)	\$ (0.27)
Weighted average shares outstanding				
Basic and Diluted	23,048,488	18,421,600	22,358,611	16,601,503

Selected Balance Sheet Data:

	September 30, 2011	December 31, 2010
Cash and cash equivalents	\$ 8,639,856	\$ 3,812,535
Other current assets	105,645	85,525
Fixed assets, net	953,219	815,958
Total assets	9,698,720	4,714,018
Total current liabilities	730,450	745,305
Total long term liabilities	-	-
Total stockholders' equity	8,968,270	3,968,713

CONTACT:

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