

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 11/14/12 for the Period Ending 11/14/12

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): November 14, 2012

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 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 November 14, 2012, Opexa Therapeutics, Inc. filed its Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 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 issued by Opexa Therapeutics, Inc. on November 14, 2012.
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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 14, 2012

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 14, 2012.

Opexa Therapeutics Reports Third Quarter 2012 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--November 14, 2012--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a company developing Tcelna™, a novel T-cell therapy for multiple sclerosis (MS), today reported financial results for the quarter ended September 30, 2012 and provided an overview of recent corporate developments.

Third quarter and recent highlights include:

- Commenced the Abili-T clinical study, a Phase IIb clinical trial of Tcelna in patients with Secondary Progressive Multiple Sclerosis (SPMS);
- Closed a \$4,085,000 convertible secured note financing;
- Entered into two purchase agreements in which Opexa has the right to sell, over a 30-month period, up to \$16.5 million in shares of its common stock to an institutional investor, subject to certain conditions and limitations; and
- Received approval from Health Canada enabling expansion of the Abili-T clinical trial into Canada.

“After extensive preparations up through August of this year, including the enhancement of our Tcelna manufacturing process and the optimization of our clinical development strategy, we successfully returned to the clinic in September and initiated the Abili-T clinical study, a Phase IIb clinical trial in patients with SPMS,” commented Neil K. Warma, President and Chief Executive Officer of Opexa. “The enthusiastic response by physicians and patients alike to the Abili-T study has resulted in good initial enrollment. The two-year trial is expected to enroll a total of 180 SPMS patients in 30 sites in the U.S. and Canada. Currently, we have secured contracts with over half of the clinical sites and continue to progress in discussions with additional sites that have expressed a desire to participate in the study. We have enrolled approximately ten percent of the patients to date in the clinical study and expect enrollment to expand as more sites become activated and begin to screen potential patients. We are also pleased to have received approval by Health Canada, the Canadian equivalent of the U.S. Food and Drug Administration, to expand the trial with Canadian sites. Given Tcelna’s previously demonstrated strong safety profile, along with very limited treatment options currently available in SPMS, we expect enrollment of the Abili-T study to progress well.”

“Earlier this month, we entered into two purchase agreements with Lincoln Park Capital Fund, LLC whereby we have the right to sell to Lincoln Park an aggregate of up to \$16.5 million in shares of our common stock over a 30-month period, subject to certain conditions and limitations,” commented Mr. Warma. “Additionally, we implemented an at-the-market (ATM) facility in September in which we can sell up to four million shares of our common stock from time to time depending on market demand. Meanwhile we continue to explore opportunities to properly resource the Company from a capital standpoint to be able to fully support ongoing clinical development. These opportunities may result in additional capital raises, a strategic partnership or both.”

“As of September 30, 2012, our cash and cash equivalents totaled approximately \$2.2 million. Our monthly burn rate for the nine months ending September 2012 was approximately \$885,000, inclusive of the cost of preparations to commence the Phase IIb clinical study,” continued Mr. Warma. “We believe we have sufficient liquidity to support our current clinical trial activities into December 2012. Moving forward, we are continuing to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to continue and complete the Phase IIb study and to support ongoing operations during the pendency of such study.”

Second Quarter Financial Results

Opexa reported no commercial revenues in the three and nine months ended September 30, 2012 or in the comparable prior-year periods.

Research and development expenses were \$1,455,938 and \$4,504,243 for the three and nine months ended September 30, 2012, respectively, compared with \$654,772 and \$2,194,141 for the three and nine months ended September 30, 2011, respectively. The increases were primarily due to increases in the procurement and use of supplies for both our laboratory and our product manufacturing operations, the engagement of consultants for further clinical development, stock compensation expense and facilities costs.

General and administrative expenses for the three and nine months ended September 30, 2012 were \$532,474 and \$1,878,236, respectively, compared with \$584,794 and \$1,737,686 for the three and nine months ended September 30, 2011, respectively. The decrease for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 was primarily due to a decrease in business development expenses and was partially offset by increases in stock compensation expense and investor outreach activities. The increase for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was primarily due to increases in employee compensation expense, legal expenses, investor outreach and capital financing activities, and was partially offset by a decrease in business development expenses.

Depreciation and amortization expense for the three and nine months ended September 30, 2012 was \$81,514 and \$225,365, respectively, compared with \$56,888 and \$157,254 for the three and nine months ended September 30, 2011, respectively. The increase in expense is primarily due to increases in depreciation for facility build-out costs, and increases in depreciation for laboratory, manufacturing and information technology equipment acquired during 2011 and 2012.

Interest expense for the three and nine months ended September 30, 2012 was \$151,029 and \$152,002, respectively, compared with \$638 and \$2,643 for the three and nine months ended September 30, 2011, respectively. The increase in interest expense was primarily related to the amortized debt discount and interest on the July 25, 2012 convertible notes and the amortization of the financing fees over the life of the notes.

Opexa reported a net loss for the three months ended September 30, 2012 of \$2.36 million, or (\$0.10) per share, and a net loss for the nine months ended September 30, 2012 of \$6.90 million, or (\$0.20) per share. For the three month and nine month periods ending September 30, 2011, Opexa reported a net loss of \$1.30 million, or (\$0.06) per share, and \$4.09 million, or (\$0.18) per share, respectively.

Cash and cash equivalents were \$2,237,618 as of September 30, 2012 compared to \$8,639,856 as of September 30, 2011.

Further details can be found in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.

About Opexa

Opexa Therapeutics, Inc. is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases such as MS. The Company's leading therapy, Tcelna™, is a personalized cellular immunotherapy treatment that is in late stage clinical development for MS. Tcelna 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," "hopes," "anticipates," "estimates," "may," "could," "intends," "exploring," "enable," "enhance," "evaluating," "progressing," "proceeding" 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, Tcelna, 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 rights and preferences provided to the Series A Convertible Preferred Stock and investors in the convertible secured notes issued by the Company in July 2012 (including a secured interest in all of our assets), the ability of the Company to enter into and benefit from a partnering arrangement for the Company's product candidate, Tcelna, on reasonably satisfactory terms (if at all), our dependence (if partnered) on the resources and abilities of any partner for the further development of Tcelna, 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 development programs (including to undertake and complete any ongoing or further clinical studies for Tcelna) including in this regard our ability to satisfy various conditions required to access the financing potentially available under the purchase agreements with Lincoln Park (such as the minimum closing price for our common stock, the registration of the underlying shares of common stock under the Securities Act of 1933, as amended, and the requirement for an ongoing trading market for our stock), the success of our clinical trials, the efficacy of Tcelna 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 Tcelna), the risk of litigation regarding our intellectual property rights or the rights of third parties, 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, 2011.

OPEXA THERAPEUTICS, INC.
(a development stage company)

Statements of Expenses Data (unaudited):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Research and development	\$ 1,455,938	\$ 654,772	\$ 4,504,243	\$ 2,194,141
General and administrative	532,474	584,794	1,878,236	1,737,686
Depreciation and amortization	81,514	56,888	225,365	157,254
Loss on disposal of assets	-	413	-	413
Operating loss	(2,069,926)	(1,296,867)	(6,607,844)	(4,089,494)
Interest income	61	227	256	698
Gain (loss) on derivative instruments	(136,889)	-	(136,889)	-
Interest expense	(151,029)	(638)	(152,002)	(2,643)
Net loss	<u>\$ (2,357,783)</u>	<u>\$ (1,297,278)</u>	<u>\$ (6,896,479)</u>	<u>\$ (4,091,439)</u>
Basic and diluted loss per share	\$ (0.10)	\$ (0.06)	\$ (0.30)	\$ (0.18)
Weighted average shares outstanding	23,048,488	23,048,488	23,048,488	22,358,611

Selected Balance Sheet Data:

	September 30, 2012 (unaudited)	December 31, 2011
Cash and cash equivalents	\$ 2,237,618	\$ 7,109,215
Other current assets	1,188,237	124,773
Fixed assets, net	1,327,649	1,029,236
Other long term assets	1,245,408	-
Total assets	5,998,912	8,263,224
Total current liabilities	3,352,295	1,067,860
Total long term liabilities	307,332	-
Total stockholders' equity	2,339,285	7,195,364

CONTACT:

Opexa Therapeutics, Inc.

Neil K. Warma

President & CEO

281.775.0600

nwarma@opexatherapeutics.com