

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 11/06/14 for the Period Ending 11/06/14

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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Industry	Biotechnology & Drugs
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**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 6, 2014

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 6, 2014, Opexa Therapeutics, Inc. (the “ **Company** ”) filed its Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 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.

On the same day, members of the Company’s management will hold a teleconference to discuss the financial results. Interested individuals desiring to participate in the teleconference may dial in approximately ten minutes before the scheduled 5:00 P.M. ET call to (201) 689-8040 or toll free at (877) 407-8133. Please reference conference ID # 13594378 or the Opexa Therapeutics Earnings Call when dialing into the call. A live webcast of the call can also be accessed via the webcast link on the Company’s website (www.opexatherapeutics.com).

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 6, 2014
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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 6, 2014

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President and Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Opexa Therapeutics, Inc. on November 6, 2014

Opexa Therapeutics Reports Third Quarter 2014 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--November 6, 2014--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biopharmaceutical company developing personalized immunotherapies for autoimmune disorders, including multiple sclerosis (MS) and Neuromyelitis Optica (NMO), today reported financial results for the third quarter ended September 30, 2014 and provided an overview of the Company's recent corporate developments.

Recent highlights include:

Operational Highlights:

- Opexa announced it had initiated early development in a second autoimmune disease, Neuromyelitis Optica (NMO), a rare neurological disease; preclinical development is on-going; and an IND for OPX-212, Opexa's product candidate in NMO, is expected to be submitted by mid-2015;
- Opexa highlighted its NMO development plan and progress during an analyst event at the 2014 Joint ACTRIMS/ECTRIMS meeting in Boston;
- Opexa announced the issuance of its 98th patent (US and international) covering its T-cell technology;
- Opexa held an R&D update for analysts and investors in New York highlighting progress on its pipeline candidates including the Phase IIb Abili-T trial currently on-going in Secondary Progressive Multiple Sclerosis (SPMS) and the preclinical development program for OPX-212 in NMO;
- Opexa was selected to present at the 12th Annual Cleveland Clinic Medical Innovation Summit; and
- At a recent and regularly scheduled meeting of the Data Safety and Monitoring Board (DSMB), the independent board overseeing Opexa's Phase IIb Abili-T trial, the DSMB recommended the trial be continued as planned.

Financial Highlights

- Reported cash and cash equivalents of \$13,637,419 as of September 30, 2014.
 - Based on the current activities, Opexa believes it has sufficient capital to support its clinical activities for the Abili-T trial, as well as preclinical development activities for OPX-212 in NMO (with an expected IND submission by mid-2015) and general operations of the Company, into the fourth quarter of 2015.
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“Opexa is coming off a productive quarter,” said Neil K. Warma, Opexa’s President and Chief Executive Officer. “Importantly, our Phase IIb clinical trial in Secondary Progressive MS, Abili-T, is advancing on schedule, and on October 8th, the DSMB recommended continuing the study as planned. The trial is fully enrolled and we expect top-line data in the second half of 2016. Merck Serono, one of the leaders in MS, secured the option to license the MS program in 2013 and we continue to interact with them through the Joint Steering Committee that was first convened in July of this year.”

“We were especially pleased to report on the launch of the second disease off our proprietary T-cell platform. In September, we announced the initiation of early development activities for Neuromyelitis Optica, a rare disease that attacks the optic nerve and spinal cord. NMO is a rare or orphan disease for which there is no approved treatment, giving rise to a significant unmet medical need,” said Mr. Warma. “With this announcement, we believe we have demonstrated our ability to leverage our platform to be able to generate additional drug candidates, including those for orphan diseases. Our target for NMO is to submit an IND by the middle of next year and move into clinical development thereafter, once the FDA has reviewed and accepted the submission and once we have raised the necessary capital.”

As of September 30, 2014, Opexa’s cash and cash equivalents totaled approximately \$13,637,419 and the Company’s monthly burn rate for the nine months ending September 2014 was approximately \$1.1 million. Based on the current activities, Opexa believes it has sufficient liquidity to support its clinical activities for the Abili-T trial as well as preclinical development activities for OPX-212 in NMO (with an expected IND submission by mid-2015) and general operations of the Company into the fourth quarter of 2015.

Third Quarter Financial Results

Opexa reported revenue of \$307,686 for the three months ended September 30, 2014, compared to \$348,837 for the three months ended September 30, 2013. The revenue is related to the recognized portion of the \$5 million upfront payment received from Merck Serono in conjunction with the Option and License Agreement entered into between Opexa and Merck Serono during February 2013.

Research and development expenses were \$3,173,538 for the three months ended September 30, 2014, compared with \$2,494,463 for the three months ended September 30, 2013. The increase in expenses is primarily due to an increase in the costs in connection with the increased enrollment of patients for the ongoing clinical trial of Tcelna in SPMS, an increase in the procurement and use of supplies for product manufacturing and development, and increases in the number of employees to support the ongoing clinical trial, employee compensation expense and stock compensation expense.

General and administrative expenses for the three months ended September 30, 2014 were \$917,335 compared with \$626,668 for the three months ended September 30, 2013. The increase in expense is due to increases in capital financing expenses which was brought about by the reversal of accrued banker’s fees for \$118,000 in the third quarter of 2013 due to a settlement and increases in stock compensation expenses, and was partially offset by decreases in legal fees.

Depreciation and amortization expenses for the three months ended September 30, 2014 were \$97,364, compared with \$90,935 for the three months ended September 30, 2013. The increase in expense is due to increases in depreciation for laboratory, manufacturing and computer equipment acquired during 2013 and 2014 and leasehold improvements during 2013 and 2014 to support increased development activities.

Opexa reported a net loss for the three months ended September 30, 2014 of \$3,878,053, or \$0.14 loss per share (basic and diluted), compared with a net loss of \$5,723,932 or \$0.39 loss per share (basic and diluted) for the three months ended September 30, 2013. The decreased net loss is primarily related to the recording of a \$2.5 million loss on extinguishment of debt in 2013 and interest expense related to promissory notes in 2013 partially offset by a decrease in revenue, an increase in research and development expenses, higher general and administrative expenses and higher depreciation expenses for the quarter ending September 30, 2014.

Cash and cash equivalents were \$13,637,419 as of September 30, 2014, compared to \$20,172,485 as of September 30, 2013.

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

Conference Call and Webcast Details

Opexa will conduct a conference call and webcast to provide a corporate update and discuss the financial results at 5:00 p.m. Eastern Time today. To participate in the conference call, dial in approximately ten minutes before the scheduled 5:00 p.m. time to 201-689-8040 or toll free at 877-407-8133. Please reference conference ID 13594378 or the Opexa Therapeutics Earnings Call.

A live webcast of the call can also be accessed here or via the webcast link on the Investor Relations page of Opexa's website (www.opexatherapeutics.com).

About Opexa

Opexa is a biopharmaceutical company developing personalized immunotherapies with the potential to treat major illnesses, including multiple sclerosis (MS) as well as other autoimmune diseases, such as neuromyelitis optica (NMO). These therapies are based on Opexa's proprietary T-cell technology. The Company's leading therapy candidate, Tcelna[®], is a personalized T-cell immunotherapy that is in a Phase IIb clinical development program (the Abili-T trial) for the treatment of Secondary Progressive MS. Tcelna is derived from T-cells isolated from the patient's 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. Opexa's mission is to lead the field of Precision Immunotherapy[®] by aligning the interests of patients, employees and shareholders.

About Tcelna

Tcelna[®] is a potential personalized therapy that is under development to be specifically tailored to each patient's disease profile. Tcelna is manufactured using ImmPath[®], Opexa's proprietary method for the production of a patient-specific T-cell immunotherapy, which encompasses the collection of blood from the MS patient, isolation of peripheral blood mononuclear cells, generation of an autologous pool of myelin-reactive T-cells (MRTCs) raised against selected peptides from myelin basic protein (MBP), myelin oligodendrocyte glycoprotein (MOG) and proteolipid protein (PLP), and the return of these expanded, irradiated T-cells back to the patient. These attenuated T-cells are reintroduced into the patient via subcutaneous injection to trigger a therapeutic immune system response.

Opexa is currently conducting a Phase IIb study of Tcelna. Named "Abili-T," the trial is a randomized, double-blind, placebo-controlled clinical study in patients who demonstrate evidence of disease progression with or without associated relapses. The trial is being conducted at approximately 35 leading clinical sites in the U.S. and Canada with each patient receiving two annual courses of Tcelna treatment consisting of five subcutaneous injections per year. The trial's primary efficacy outcome is the percentage of brain volume change (atrophy) at 24 months. Study investigators will also measure several important secondary outcomes commonly associated with MS, including disease progression as measured by the Expanded Disability Status Scale (EDSS), annualized relapse rate and changes in disability as measured by EDSS and the MS Functional Composite.

About Neuromyelitis Optica (NMO)

NMO is a rare autoimmune disorder in which immune system cells and antibodies mistakenly attack and destroy myelin cells in the optic nerves and the spinal cord. The damage to the optic nerves produces swelling and inflammation that cause pain and loss of vision; the damage to the spinal cord causes weakness or paralysis in the legs or arms, loss of sensation, and problems with bladder and bowel function. NMO affects approximately 4,800 people in the U.S. and the worldwide estimated prevalence is 1-2 people per 100,000 population. There is no cure for NMO and there are no FDA-approved therapies, other than to treat an attack while it is happening, to reduce symptoms and to prevent relapses.

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

Statements contained in this release, other than statements of historical fact, constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The words "expects," "believes," "may," "intends," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements do not constitute guarantees of future performance. Investors are cautioned that forward-looking statements, including without limitation statements regarding the safety, efficacy and projected development timeline of drug candidates such as Tcelna® and OPX-212 constitute forward-looking statements. These forward-looking statements are based upon our current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include without limitation our ability to raise additional capital to continue our development programs, our ability to successfully develop potential products such as Tcelna, our ability to obtain, maintain and protect intellectual property rights (including for Tcelna and future pipeline candidates such as OPX-212), as well as other risks associated with the process of discovering, developing and commercializing drug candidates that are safe and effective for use as human therapeutics. These and other risks are described in detail in our SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2013 and our Quarterly Reports on Form 10-Q. All forward-looking statements contained in this release speak only as of the date on which they were first made by us, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after such date.

OPEXA THERAPEUTICS, INC.

Statement of Operations Data:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue:				
Option revenue	\$307,686	\$348,837	\$964,209	\$917,774
Research and development	3,173,538	2,494,463	9,393,887	6,338,859
General and administrative	917,335	626,668	2,987,582	2,479,708
Depreciation and amortization	97,364	90,935	291,608	258,144
Operating loss	<u>(3,880,551)</u>	<u>(2,863,229)</u>	<u>(11,708,868)</u>	<u>(8,158,937)</u>
Interest income	3,456	4,448	12,940	9,388
Other income, net	-	-	-	37,910
(Loss) on extinguishment of debt	-	(2,518,912)	-	(2,518,912)
Interest expense	<u>(958)</u>	<u>(346,239)</u>	<u>(958)</u>	<u>(2,267,293)</u>
Net loss	<u><u>\$(3,878,053)</u></u>	<u><u>\$(5,723,932)</u></u>	<u><u>\$(11,696,886)</u></u>	<u><u>\$(12,897,844)</u></u>
Basic and diluted loss per share	\$ (0.14)	\$ (0.39)	\$ (0.42)	\$ (1.29)
Weighted average shares outstanding - Basic and diluted	27,826,615	14,721,474	27,691,855	10,011,453

Selected Balance Sheet Data:

	September 30,		December 31,	
	2014		2013	
	(unaudited)			
Cash and cash equivalents	\$ 13,637,419		\$ 23,644,542	
Other current assets	727,830		1,122,576	
Fixed assets, net	1,152,603		1,295,024	
Other long term assets	48,674		177,666	
Total assets	15,566,526		26,239,808	
Total current liabilities	3,457,228		3,324,493	
Deferred revenue	1,538,434		2,338,041	
Total stockholders' equity	10,570,864		20,577,274	

CONTACT:

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Chief Financial Officer