

**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): May 12, 2016

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 May 12, 2016, Opexa Therapeutics, Inc. (the “Company”) filed its Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 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 and provide a corporate update. Interested individuals desiring to participate in the teleconference may dial in before the scheduled 4:30 P.M. ET call to (201) 689-8040 or toll free at (877) 407-8133. Please reference conference ID # 13636799 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 Investor Relations page of the Company’s website (www.opexatherapeutics.com). An archive of the webcast will be available on the Company’s website until August 12, 2016.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Opexa Therapeutics, Inc. on May 12, 2016 regarding quarterly earnings.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibits 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: May 12, 2016

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma
President, Chief Executive Officer and
Acting Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Opexa Therapeutics, Inc. on May 12, 2016 regarding quarterly earnings.



Opexa Therapeutics Reports First Quarter 2016 Financial Results and Provides Corporate Update

Conference Call Scheduled Today at 4:30 PM ET

THE WOODLANDS, Texas (May 12, 2016) - **Opexa Therapeutics, Inc.** (NASDAQ: OPXA), a biopharmaceutical company developing personalized immunotherapies for autoimmune disorders, including Tcelna[®] for multiple sclerosis (MS) and OPX-212 for neuromyelitis optica (NMO), today reported financial results for the quarter ended March 31, 2016, and provided an update on the Company's recent corporate developments.

"We are pleased to be coming off a productive quarter and progressing further towards the completion of our Phase 2b Abili-T trial in secondary progressive MS," stated Neil K. Warma, President and Chief Executive Officer of Opexa. "Approximately 98% of all patient visits in the Abili-T trial have been completed, and we are excited to be approaching the release of our top-line data expected in early fourth quarter of this year. The trial is being conducted in over 180 patients and is coupled with a comprehensive immune monitoring, biomarker study. We believe this is the first clinical trial that is delivering a personalized T-cell immunotherapy to patients with secondary progressive MS and we are hopeful that we may be the first to commercialize a safe and effective therapy for these individuals. There are currently no treatments for patients with secondary progressive MS so the unmet medical need is significant and the market for this indication could be significant. As Tcelna has been partnered, through an option and license agreement, with Merck Serono, Opexa hopes to be able to leverage our combined expertise to move into a Phase III clinical trial should the Phase 2b data be positive."

"We were also pleased that Opexa was invited to present at the Third International Conference on the Progress of Regenerative Medicine and its Cultural Impact, in Vatican City, and to participate in the important discussions surrounding the potential of immunotherapies to transform the treatment of diseases with serious unmet medical need, such as secondary progressive MS and neuromyelitis optica. We are continuing to advance OPX-212 through preclinical development for NMO and are pleased with the progress demonstrated on this program during this quarter," added Mr. Warma.

Business Highlights

Clinical and Preclinical Efforts

- The Phase 2b clinical trial of Tcelna[®] (*imilecleucel-T*) in secondary progressive multiple sclerosis (SPMS) (Abili-T trial) continued to advance towards completion. Top line data is expected in early fourth quarter of 2016. The final dose was administered to the last patient in the last week of February 2016 and approximately 98% of all patient visits have now been completed. The Abili-T clinical trial is a randomized, double-blind, placebo-controlled study being conducted at approximately 35 leading clinical sites in the U.S. and Canada. Opexa has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for Tcelna in SPMS.
- In February 2016, a regularly scheduled meeting of the independent Data Safety Monitoring Board (DSMB) took place. The DSMB recommendation was to continue the Abili-T study as per protocol. The DSMB also stated that because dosing has been completed and no concerns over safety had been noted, no further DSMB meetings would be required for the Abili-T study.

Corporate Activities

- In April 2016, Neil K. Warma, Opexa's President and Chief Executive Officer, was invited to present at *Cellular Horizons: The Third International Conference on the Progress of Regenerative Medicine and its Cultural Impact*, in Vatican City. Mr. Warma was among the world's leading cell therapy scientists, physicians, patients, ethicists and leaders of faith, government and philanthropists discussing the latest cellular therapy breakthroughs and the hope they provide for the future treatment of disease. Mr. Warma's presentation was entitled, "Can T-cells be Used to Treat Neuromyelitis Optica (NMO) and Other Autoimmune Disorders?"

Financial Results for the Quarter Ended March 31, 2016

- **Cash position:** Cash and cash equivalents were \$9,955,449 as of March 31, 2016, compared to \$12,583,764 as of December 31, 2015.
 - **R & D Expense :** Research and development expenses were \$1,829,062 for the quarter ended March 31, 2016, compared to \$2,636,999 for the quarter ended March 31, 2015. The decrease in expenses is primarily due to a decrease in the costs in connection with the ongoing clinical trial of Tcelna in SPMS, a decrease in the procurement and use of supplies for product manufacturing and development, a decrease in employee and stock-based compensation expense as well as a reduction in the facility cost.
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- **G & A Expense:** General and administrative expenses were \$987,248 for the quarter ended March 31, 2016, compared to \$1,006,130 for the quarter ended March 31, 2015. The decrease in expenses is primarily due to the reduction in employee stock-based compensation expense and a decline in consulting services. This is offset by an increase in employee compensation including severance payments and severance accruals due to the March 2016 restructuring initiative.
- **Net loss:** Net loss reported for the quarter ended March 31, 2016 was \$2,160,394, or \$.31 per share (basic and diluted), compared with a net loss of \$3,350,880, or \$.95 per share (basic and diluted), for the quarter ended March 31, 2015. The decreased net loss is primarily related to the decrease in research and development expenses, specifically site payments relating to the ongoing Abili-T clinical trial and related lab supplies. The decreased net loss is also due to the increase in revenue of \$348,838 recognized in connection with the additional \$3.0 million in funding from Merck Serono for Phase III planning which was received in March 2015. General and administrative expenses, specifically a reduction in the Black Sholes and consulting expenses, also reduced our net loss for the three months ended March 31, 2016.

Financial Guidance

- Based on the current activities of the Company and projected burn, Opexa believes it has sufficient liquidity to support its current clinical activities for the Abili-T trial of Tcelna in SPMS, to continue planned preclinical development activities for OPX-212 in NMO, and for general operations to sustain the Company and support such activities through the first quarter of 2017. Opexa expects top-line data for the Abili-T trial to be available early in the fourth quarter of 2016, and thus believes it has sufficient resources to complete such trial.

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

Conference Call and Webcast Details

To listen to the 4:30 P.M. ET conference call, dial 201-689-8040 or toll free 877-407-8133. The conference ID number is 13636799.

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). An archive of the webcast will be available on the Company's website until August 12, 2016 .

There will be a brief Question & Answer session following management commentary.

About Opexa

Opexa is a biopharmaceutical company developing a personalized immunotherapy 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 2b clinical development program (the Abili-T trial) for the treatment of secondary progressive MS. Tcelna consists of myelin-reactive T-cells, which are expanded ex vivo from the patient's peripheral blood and reintroduced into the patient in an attenuated form via subcutaneous injections. This process triggers a potent immune response against specific subsets of autoreactive T-cells known to attack myelin for each individual patient.

For more information, visit the Opexa Therapeutics website at www.opexatherapeutics.com or follow company news on [Twitter](#) via [@OpexaCEO](#).

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 as well as the sufficiency of our resources, 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 and OPX-212, our ability to obtain, maintain and protect intellectual property rights (including for Tcelna and 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, 2015 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.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenue:		
Option revenue	\$ 726,291	\$ 377,453
Expenses:		
Research and development	1,829,062	2,636,999
General and administrative	987,248	1,006,130
Depreciation and amortization	72,589	96,982
Operating loss	(2,162,608)	(3,362,658)
Interest income, net	108	731
Other income, net	2,106	11,047
Net loss	<u>\$ (2,160,394)</u>	<u>\$ (3,350,880)</u>
Basic and diluted loss per share	\$ (.31)	\$ (.95)
Weighted average shares outstanding - Basic and diluted	6,982,909	3,529,344

Selected Balance Sheet Data:

	March 31,	December 31,
	2016	2015
Cash and cash equivalents	\$ 9,955,449	\$ 12,583,764
Other current assets	932,409	995,067
Property and equipment, net	765,763	837,867
Total assets	11,653,621	14,416,698
Total current liabilities	4,044,900	4,801,436
Total stockholders' equity	7,608,721	9,615,262
Total liabilities and stockholders' equity	<u>\$ 11,653,621</u>	<u>\$ 14,416,698</u>

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