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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): August 11, 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 August 11, 2016, Opexa Therapeutics, Inc. (the “Company”) filed its Quarterly Report on Form 10-Q for the quarter ended June 30, 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 # 13642247 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 November 11, 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 August 11, 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: August 11, 2016

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma  
Neil K. Warma  
President, Chief Executive Officer and  
Acting Chief Financial Officer

**EXHIBIT INDEX**

Exhibit No. Description

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# OPEXA THERAPEUTICS

## Opexa Therapeutics Reports Second Quarter 2016 Financial Results and Provides Corporate Update

### *Abili-T Trial in Secondary Progressive MS On-Schedule With Top-line Results Expected in Early Q4*

*Conference Call Scheduled Today at 4:30 PM ET*

**THE WOODLANDS, Texas (August 11, 2016) - Opexa Therapeutics, Inc.** (NASDAQ: OPXA), a biopharmaceutical company developing personalized immunotherapies for autoimmune disorders, including Tcelna<sup>®</sup> for multiple sclerosis (MS) and OPX-212 for neuromyelitis optica (NMO), today reported financial results for the quarter ended June 30, 2016, and provided an update on the Company's clinical development and corporate activities.

"During the second quarter we continued to advance our Phase 2b Abili-T trial in secondary progressive multiple sclerosis towards completion and we are excited to approach this significant milestone in the development of our personalized immunotherapy, Tcelna," stated Neil K. Warma, President and Chief Executive Officer of Opexa. "There are only a few scheduled patient visits remaining in the study and top-line results are expected early in the fourth quarter of this year. The entire Company is working diligently to complete the remaining activities and close out the study. We believe the Abili-T trial results could significantly impact the lives of those suffering with multiple sclerosis. Secondary progressive MS is a serious disease for which currently, there are no treatment options. We believe Tcelna has the potential to become the first safe and effective treatment for secondary progressive MS patients."

"If Tcelna is proven safe and effective, we believe it could become the therapy of choice for patients with the progressive form of multiple sclerosis and, possibly, enable us to enter what we estimate to be a roughly \$7 billion overall market," continued Warma. "Additionally, with positive results in the Abili-T study, we could be positioned for a streamlined path to a Phase III pivotal trial in secondary progressive MS. This would involve working closely with Merck Serono, our potential partner for Tcelna. In 2013, we signed an option and license agreement with Merck Serono, one of the top MS companies in the world. With positive Phase II data, we believe Merck Serono would exercise their option and advance Tcelna into a Phase III trial and through clinical development in MS."

## Business Highlights

### Clinical Efforts

- The Phase 2b Abili-T trial of Tcelna<sup>®</sup> ( *imilecleucel-T*) in secondary progressive multiple sclerosis (SPMS) continued to advance in the second quarter. Approximately 99% of all patient visits have now been completed and top-line data is expected in early fourth quarter of 2016. The Abili-T clinical trial is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Tcelna in subjects with SPMS and is 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.

### Corporate Activities

- In April, 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?"
- In May, Neil K. Warma, Opexa's President and Chief Executive Officer, was an invited speaker at the U.S. China Innovation and Investment Summit in Houston, Texas. The summit was organized in part by the Ministry of Science and Technology of the People's Republic of China, the State of Texas Governor's Office and the City of Houston Mayor's Office.

### Financial Results for the Quarter Ended June 30, 2016

- **Cash position:** Cash and cash equivalents were \$7,847,360 as of June 30, 2016, compared to \$12,583,764 as of December 31, 2015.
- **R & D Expense :** Research and development expenses were \$1,814,940 for the three months ended June 30, 2016, compared to \$2,795,858 for the three months ended June 30, 2015. The decrease in expenses is primarily due to cost reductions in connection with the winding down of the clinical trial of Tcelna in SPMS, especially a reduction in milestone payments to Opexa's contract research organization as well as a reduction in site expenses. There was also a decrease in the procurement and use of supplies for product manufacturing and development which was partially offset by an increase in supplies and legal expenses related to the NMO study development.
- **G & A Expense:** General and administrative expenses were \$953,582 for the three months ended June 30, 2016, compared with \$1,345,624 for the three months ended June 30, 2015.
- **Net loss:** Net loss reported for the three months ended June 30, 2016 was approximately \$2.1 million, or \$0.30 loss per share (basic and diluted), compared with a net loss of approximately \$3.5 million or \$0.56 loss per share (basic and diluted) for the three months ended June 30, 2015.

## **Financial Guidance**

- Based on the current activities of the Company and projected burn, Opexa believes it has sufficient liquidity to support our 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 into 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 the trial.

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

## **Conference Call and Webcast Details**

The Company will host a conference call and webcast today at 4:30 p.m. ET to provide an update on the Company and discuss second quarter 2016 financial results. To access the conference call, please dial 201-689-8040 or toll free 877-407-8133 five minutes prior to the start time. The conference ID number is 13642247 .

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](http://www.opexatherapeutics.com)). An archive of the webcast will be available on the Company's website until November 11, 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. Top-line results from the Abili-T trial are expected in early 4<sup>th</sup> quarter of 2016.

For more information, visit the Opexa Therapeutics website at [www.opexatherapeutics.com](http://www.opexatherapeutics.com) or follow company news on Twitter via [@OpexaCEO](https://twitter.com/OpexaCEO) or [LinkedIn](https://www.linkedin.com/company/opexa) .

**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), the ability of any of our potential products (such as Tcelna), assuming approval by applicable regulatory authorities (such as the Food and Drug Administration), to achieve commercial success, 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue:				
Option revenue	\$ 726,291	\$ 726,292	\$ 1,452,582	\$ 1,103,745
Research and development	1,814,940	2,795,858	3,644,002	5,432,857
General and administrative	953,582	1,345,624	1,940,830	2,351,754
Depreciation and amortization	65,653	94,002	138,242	190,984
Operating loss	(2,107,884	(3,509,192	(4,270,492	(6,871,850
Interest income, net	) 414	) 2,337	) 522	) 3,068
Other income, net	2,749	9,974	4,855	21,021
Net loss	\$ (2,104,721	\$ (3,496,881	\$ (4,265,115	\$ (6,847,761
Basic and diluted loss per share	) (0.30	) (0.56	) (0.61	) (1.40
Weighted average shares outstanding - Basic and diluted	6,995,686	6,221,152	6,989,298	4,882,680

**Selected Balance Sheet Data:**

	June 30, 2016	December 31, 2015
	(unaudited)	
Cash and cash equivalents	\$ 7,847,360	\$ 12,583,764
Other current assets	339,782	498,798
Property and equipment, net	700,846	837,867
Other long term assets	489,517	496,269
Total assets	9,435,490	14,416,698
Total current liabilities	3,523,011	4,801,436
Total stockholders' equity	5,912,479	9,615,262
Total liabilities stockholders' equity	9,435,490	14,416,698

**Company Contact:**

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