
**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, 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 November 14, 2016, Opexa Therapeutics, Inc. (the “Company”) filed its Quarterly Report on Form 10-Q for the quarter ended September 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.

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, 2016 regarding quarterly earnings.
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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, 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

[99.1](#) Press release issued by Opexa Therapeutics, Inc. on November 14, 2016 regarding quarterly earnings.



**Opexa Therapeutics Reports Third Quarter 2016 Financial Results and
Provides Corporate Update**

THE WOODLANDS, Texas (November 14, 2016) - Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biopharmaceutical company developing personalized immunotherapies for autoimmune disorders, today reported financial results for the quarter ended September 30, 2016, and provided an update on the Company's clinical development and corporate activities.

"Over the past several years, Opexa has dedicated itself to developing therapies to treat patients with high unmet medical needs, such as those with secondary progressive multiple sclerosis," stated Neil K. Warma, President and Chief Executive Officer of Opexa. "We are extremely disappointed that the Abili-T trial did not meet the predefined endpoints, and we are evaluating strategic alternatives for the Company in order to determine the best path forward."

Clinical Activities

- On October 28, 2016, Opexa announced that the Phase 2b Abili-T clinical trial designed to evaluate the efficacy and safety of Tcelna (*imilecleucel-T*) in patients with secondary progressive multiple sclerosis (SPMS) did not meet its primary endpoint of reduction in brain volume change (atrophy), nor did it meet the secondary endpoint of reduction of the rate of sustained disease progression. Tcelna did show a favorable safety and tolerability profile. Further details surrounding the Abili-T trial results can be found in Opexa's 3rd Quarter Form 10-Q, filed this morning with the Securities and Exchange Commission.
 - Opexa is currently analyzing the complete data set from the Abili-T trial. However, based on the top-line results, it is unlikely that the Company will continue with further development of Tcelna.
 - The Company is conducting a review of its other research and development programs, including the preclinical program for OPX-212 in neuromyelitis optica (NMO), to assess the viability of continuing to pursue one or more of these programs.
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Corporate Activities

- On November 2, 2016, Opexa announced a reduction in workforce of 40% of the Company's then 20 full-time employees while the Company evaluates its programs and various strategic alternatives in light of the disappointing Abili-T study data. The Company estimates that it will incur incremental aggregate cash charges of approximately \$95,000 associated with workforce reduction. The Company expects that additional restructuring will occur by year-end.
- On November 2, 2016, Opexa announced that the Company had accepted the resignations of Ms. Donna Rill, Opexa's Chief Development Officer, and Mr. Scott Seaman, a member of Opexa's Board of Directors.

Financial Results for the Quarter Ended September 30, 2016

- **Cash position:** Cash and cash equivalents were \$5,814,300 as of September 30, 2016, compared to \$12,583,764 as of December 31, 2015. As of September 30, 2016, the Company had accounts payable and accrued expenses of \$2,121,043.
 - **R & D Expense :** Research and development expenses were \$2,165,728 for the three months ended September 30, 2016, compared with \$2,420,220 for the three months ended September 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, including site expenses as well as additional expense reduction due to a pause in NMO study development cost. Additionally, there was a decrease in legal patent protection expenses, and the March 2016 workforce reduction further reduced third quarter expenses. These reductions were almost completely offset by the increase in monthly expenses to Pharmaceutical Research Associates, Inc. (PRA), as well as an execution payment and additional milestone payments relating to an amendment entered into for a change order relating to the clinical trials management services agreement for the Abili-T study.
 - **G & A Expense:** General and administrative expenses were \$512,727 for the three months ended September 30, 2016, compared with \$1,023,848 for the three months ended September 30, 2015.
 - **Net loss:** Net loss reported for the three months ended September 30, 2016 was approximately \$2.0 million, or \$0.28 loss per share (basic and diluted), compared with a net loss of approximately \$2.8 million or \$0.42 loss per share (basic and diluted) for the three months ended September 30, 2015.
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Financial Guidance

- Based on the current activities of the Company and projected burn, Opexa believes it has sufficient liquidity to support current activities in winding down the Abili-T trial and for general operations to sustain the Company and support such activities into the first quarter of 2017.

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

About Opexa

Opexa Therapeutics is a biopharmaceutical company developing personalized immunotherapies based on ImmPath®, its proprietary T-cell technology, with the potential to treat autoimmune diseases. Opexa's staff of cell therapy experts operates in a stand-alone facility located on one acre in the Woodlands, Texas. The facility is comprised of over 10,000 sq. ft. of state of the art space for cGMP manufacturing suites, a quality control laboratory, a research and development laboratory, quality assurance, specialized flow cytometry, a microscopy lab and clinical and regulatory affairs, as well as warehouse space for materials management. Opexa's patent estate is currently comprised of over 160 issued patents (domestic and international).

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

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 report, 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," "should," 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 continued development of Tcelna or NMO or any other drug candidate and the Company's evaluation of its research and development programs, the Company's evaluation of various strategic alternatives, the anticipation of additional workforce restructuring, the anticipated current and future reduction in operating expenses and cash conservation benefits associated therewith, and the future charges expected to be incurred, and the sufficiency of the Company's resources, constitute forward-looking statements. These forward-looking statements are based upon the Company's 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 risks and uncertainties associated with the Company's ability to raise additional capital to continue any of its development programs and support its operations, whether the Company continues development of Tcelna, OPX-212 or any of its other research and development programs, possible changes in the magnitude or timing of the planned workforce reduction, including as a result of changes that may occur in the Company's operations or operating plan, or other reasons or events, possible changes in the amount of charges and cash payments associated with the workforce reduction, including the possibility that the Company may incur unanticipated charges or make cash payments that are not currently contemplated, the Company's ability to reduce its operating expenses and conserve cash on a net basis as a result of the workforce reduction or any other cost-cutting measures that are implemented, the 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 the Company's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2015 and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2016. All forward-looking statements contained in this report speak only as of the date on which they were first made by the Company, and the Company undertakes 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Option revenue	\$ 726,291	\$ 726,291	\$ 2,178,873	\$ 1,830,036
Research and development	2,165,728	2,420,220	5,809,730	7,853,076
General and administrative	512,727	1,023,848	2,453,557	3,375,602
Loss on disposition of assets	---	1,167	---	1,167
Depreciation and amortization	52,045	89,018	190,287	280,003
Operating loss	(2,004,209))	(2,807,962))	(6,274,701))	(9,679,812))
Interest income, net	686	2,222	1,208	5,290
Other income (expense), net	(2,381))	11,760)	2,474)	32,781)
Net loss	<u>\$ (2,005,904)</u>)	<u>\$ (2,793,980)</u>)	<u>\$ (6,271,019)</u>)	<u>\$ (9,641,741)</u>)
Basic and diluted loss per share	\$ (0.28))	\$ (0.42))	\$ (0.89))	\$ (1.75))
Weighted average shares outstanding - Basic and diluted	7,073,703	6,709,251	7,017,638	5,498,228
Cash and cash equivalents	\$ 5,814,300		\$ 12,583,764	
Other current assets	224,806		498,798	
Property and equipment, net	648,801		837,867	
Other long term assets	489,517		496,269	
Total assets	7,177,424		14,416,698	
Total current liabilities	2,847,335		4,801,436	
Total stockholders' equity	4,330,089		9,615,262	
Total liabilities stockholders' equity	7,177,424		14,416,698	

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