
**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 12, 2015

OPEXA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

<u>Texas</u> (State or other jurisdiction of incorporation)	<u>001-33004</u> (Commission File Number)	<u>76-0333165</u> (IRS Employer Identification No.)
<u>2635 Technology Forest Blvd., The Woodlands, Texas</u> (Address of principal executive offices)		<u>77381</u> (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 12, 2015, Opexa Therapeutics, Inc. (the “Company”) filed its Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 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 # 13614871 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 12, 2015.

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 August 12, 2015.
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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: August 12, 2015

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

EXHIBIT INDEX

Exhibit No.

Description

[99.1](#) Press release issued by Opexa Therapeutics, Inc. on August 12, 2015.



Opexa Therapeutics Reports Second Quarter 2015 Financial Results and Provides Corporate Update

THE WOODLANDS, Texas (August 12, 2015) - 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 three months ended June 30, 2015 and provided an update on the Company's recent corporate developments.

Recent highlights include:

Clinical and Operational Highlights

- The Phase 2b clinical trial of Tcelna[®] (*imilecleucel-T*) in Secondary Progressive Multiple Sclerosis (SPMS) (Abili-T trial) continued to advance in the second quarter. Top line data is expected in the second half of 2016. The two year trial is fully enrolled and to date, approximately 86% of the total patient visits have 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 continued to advance the Company's second therapy candidate toward the clinic. OPX-212 is being developed for the treatment of Neuromyelitis Optica (NMO). During the second quarter of 2015, Opexa continued with IND-enabling activities as well as process development and manufacturing activities to support OPX-212 preclinical development. An IND is expected to be filed by the end of 2015.
- Opexa was invited to present novel biomarker data in two poster presentations at the American Academy of Neurology (AAN) 2015 annual meeting, which included support for the proposed mechanism of action of OPX-212 in NMO.

Financial Highlights

- In April 2015, Opexa completed a rights offering and raised \$13,804,140 in gross proceeds, before expenses, through subscriptions for 25,098,437 units, including the exercise of over-subscription privileges. Each unit consisted of one share of common stock and a warrant to purchase an additional share of common stock. Net proceeds, after deduction of fees and expenses, were approximately \$12 million.
 - Based on the current activities of the Company and projected burn, Opexa believes it has sufficient liquidity to continue its current operations into the fourth quarter of 2016. The Company expects this will support the completion and reporting of top line results for the Phase 2b Abili-T study of Tcelna in SPMS patients and the completion of the preclinical activities for OPX-212 in NMO, as well as supporting general operations of the Company.
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“The second quarter of 2015 progressed well as we advanced closer toward our key Phase 2b clinical trial milestone and raised significant capital to support the trial,” said Neil Warma, President and Chief Executive Officer of Opexa. “The Phase 2b clinical study in Secondary Progressive MS is expected to deliver top line results in the second half of 2016, and we have now completed 86% of all patient visits. There are very limited treatment options for patients with SPMS and we remain focused on completing this trial as Tcelna would, if successful, mark a significant contribution for patients with the progressive form of MS. Importantly, with the completion of a significant rights offering in April, Opexa is now fully funded to data for the Abili-T Phase 2b clinical trial. This was an important milestone for the Company. With the exercise of over-subscription rights, we managed to secure over 85% subscription in the rights offering, which was encouraging. We were especially pleased with the \$3 million payment we received at the end of the first quarter from Merck-Serono, our potential partner in MS. This payment was outside the original agreement that was signed in 2013, and supports Tcelna and the on-going Abili-T clinical trial.”

“Progress was made in our orphan program, OPX-212 in NMO during the second quarter. We are continuing with IND-enabling studies and process development steps that should prepare us for the submission of our IND by the end of this year. As a result of our R & D studies, which showed evidence of persistent inflammation in NMO patients despite receiving B-cell depleting therapy, we were invited to present our data at this year’s AAN Annual Meeting. Both programs progressed during the second quarter and we remain committed to maintaining a leadership position in the development of personalized T-cell immunotherapies in autoimmune diseases,” added Mr. Warma.

Second Quarter Financial Results

Opexa reported revenue of \$726,292 and \$307,686 for the three months ended June 30, 2015 and 2014, respectively. 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 and the \$3 million payment from Merck Serono in connection with the March 2015 amendment.

Research and development expenses were \$2,795,858 for the three months ended June 30, 2015, compared with \$3,409,210 for the three months ended June 30, 2014. The decrease in expenses is primarily due to a decrease in the investigator costs associated with the ongoing clinical trial of Tcelna in SPMS, a decrease in the procurement and use of supplies for product manufacturing and development, partially offset by increases in intellectual property legal fees and employee compensation expense.

General and administrative expenses for the three months ended June 30, 2015 were \$1,345,624, compared with \$967,367 for the three months ended June 30, 2014. The increase in expense is due to the expensing of \$238,154 of previously deferred costs related to financing agreements with Lincoln Park and increases in employee cash compensation partially offset by decreased stock compensation expense.

Depreciation and amortization expenses for the three months ended June 30, 2015 were \$94,002, compared with \$98,658 for the three months ended June 30, 2014. The decrease in expense is due to some assets being fully amortized which was partially offset by increases in depreciation for laboratory, manufacturing and computer equipment acquired during 2014 and 2015.

Interest income net of interest expense was \$2,337 for the three months ended June 30, 2015, compared to \$4,290 for the three months ended June 30, 2014.

Other income was \$9,974 for the three months ended June 30, 2015, compared to \$0 in the three months ending June 30, 2014. This was primarily driven by a gain on exchange rate, which was related to two clinical sites located in Canada and the difference between the Canadian dollar and the US dollar on payments to these clinical sites. Payments to these sites began in December 2014.

Net loss reported for the three months ended June 30, 2015 was approximately \$3.5 million, or \$0.07 loss per share (basic and diluted), compared with a net loss of approximately \$4.2 million, or \$0.15 loss per share (basic and diluted), for the three months ended June 30, 2014. The decreased net loss for the quarter is primarily related to the increase in revenue due to the March 2015 amendment to our Option and License Agreement with Merck Serono and a decrease in research and development expenses, which was partially offset by the increase in general and administrative expenses.

Cash and cash equivalents were \$18,283,560 as of June 30, 2015, compared to \$9,906,373 as of December 31, 2014.

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. ET 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 13614871 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). An archive of the webcast will be available on the Company's website until November 12, 2015 .

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 IIb 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 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, 2014 and our Quarterly Reports on Form 10-Q for the quarter ended June 30, 2015. 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

**OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenue:				
Option revenue	\$ 726,292	\$ 307,686	\$ 1,103,745	\$ 656,523
Research and development	2,795,858	3,409,210	5,432,857	6,220,349
General and administrative	1,345,624	967,367	2,351,754	2,070,247
Depreciation and amortization	94,002	98,658	190,984	194,244
Operating loss	(3,509,192)	(4,167,549)	(6,871,850)	(7,828,317)
Interest income, net	2,337	4,290	3,068	9,484
Other income, net	9,974	-	21,021	-
Net loss	<u>\$ (3,496,881)</u>	<u>\$ (4,163,259)</u>	<u>\$ (6,847,761)</u>	<u>\$ (7,818,833)</u>
Basic and diluted loss per share	\$ (0.07)	\$ (0.15)	\$ (0.18)	\$ (0.28)
Weighted average shares outstanding - Basic and diluted	49,769,294	27,661,675	39,061,510	27,623,358

Selected Balance Sheet Data:

	June 30, 2015	December 31, 2014
	(unaudited)	
Cash and cash equivalents	\$ 18,283,560	\$ 9,906,373
Other current assets	403,634	758,943
Fixed assets, net	918,899	1,098,104
Other long term assets	19,469	38,939
Total assets	19,625,562	11,802,359
Total current liabilities	4,954,385	3,132,424
Total long-term liabilities	1,452,584	1,230,748
Total stockholders' equity	13,218,593	7,439,187

Source: Opexa Therapeutics, Inc.
Company Contact:
Karthik Radhakrishnan
Opexa Therapeutics, Inc .
Chief Financial Officer
281-775-0600
