

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 05/14/14 for the Period Ending 05/14/14

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
CIK	0001069308
Symbol	OPXA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

**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 14, 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 May 14, 2014, Opexa Therapeutics, Inc. (the “**Company**”) filed its Quarterly Report on Form 10-Q for the quarter ended March 31, 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 (253) 237-1170 or toll free at (877) 372-0867. Please reference conference ID # 44945084 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 7.01. Regulation FD Disclosure.

The slide presentation that will be used in connection with the teleconference disclosed in Item 2.02 above will be posted to the Investor Relations page of the Company’s website at www.opexatherapeutics.com. A copy of the slide presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The Company does not undertake to update this presentation.

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 14, 2014
99.2	Opexa Therapeutics, Inc. Earnings Update Teleconference Presentation dated May 14, 2014

The information in Items 2.02 and 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, 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 14, 2014

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

EXHIBIT INDEX

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

THE WOODLANDS, Texas--(BUSINESS WIRE)--May 14, 2014--Opexa Therapeutics, Inc. (NASDAQ: OPXA), a biotechnology company developing Tcelna[®] (imilecleucel-T), a novel T-cell immunotherapy for the treatment of Multiple Sclerosis (MS), today reported financial results for the first quarter ended March 31, 2014 and provided an overview of the Company's recent corporate developments.

Recent highlights include:

- **Clinical**
 - As of May 13, 2014, Opexa reached the targeted enrollment of 180 patients in the Phase IIb "Abili-T" clinical study of Tcelna (imilecleucel-T) in patients with Secondary Progressive Multiple Sclerosis. The Abili-T clinical trial is a randomized, double-blind, placebo-controlled study at approximately 35 leading clinical sites in the U.S. and Canada.
 - The Company will also allow patients who are currently in the screening process to enroll in the Abili-T clinical study should they meet the trial's entry criteria. The Company expects to report the top-line results of the Abili-T clinical study in mid-2016.
- **Operations**
 - In March, Opexa appointed two highly experienced individuals to join the Company's Board of Directors - Hans-Peter Hartung, M.D., Ph.D., FRCP, a world leading clinician and expert in the treatment of Multiple Sclerosis and other neurological diseases, and Timothy Barabe, a proven CFO with global operational and financial expertise.
- **Financial**
 - Reported cash and cash equivalents of \$19,659,525 as of March 31, 2014.
 - Opexa believes it has sufficient liquidity to support its current clinical activities for the Abili-T trial and general operations to sustain the Company and support such trial into the fourth quarter of 2015.

"Reaching our clinical trial enrollment target of 180 patients in the Phase IIb Abili-T trial in Secondary Progressive Multiple Sclerosis represents an important milestone in the development of our personalized immunotherapy for this unmet medical need," said Neil K. Warma, Opexa's President and Chief Executive Officer. "MS patients are in dire need of a product to treat the progressive form of the disease. With so few treatment options for Secondary Progressive MS patients, we remain committed in our efforts to develop Tcelna for this patient group."

During the first quarter of 2014, Hans-Peter Hartung and Tim Barabe joined Opexa's Board of Directors. They bring with them deep experience in the areas of clinical development, neurology, finance and operations.

As of March 31, 2014, Opexa's cash and cash equivalents totaled approximately \$19.7 million and our monthly burn rate for the three months ending March 2014 was approximately \$1.3 million. Based on the cash position, the Company believes it has sufficient liquidity to support its current clinical activities for the Abili-T trial and general operations to sustain itself into the fourth quarter of 2015.

First Quarter Financial Results

Opexa reported revenue of \$348,837 for the three months ended March 31, 2014, compared to \$220,100 for the three months ended March 31, 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 \$2,811,139 for the three months ended March 31, 2014, compared with \$1,621,366 for the three months ended March 31, 2013. The increase in expenses is primarily due to increased costs in connection with the enrollment of patients for the ongoing clinical trial of Tcelna in Secondary Progressive Multiple Sclerosis, the procurement and use of supplies for product manufacturing and development, the number of employees to support the ongoing clinical trial and stock compensation expense.

General and administrative expenses for the three months ended March 31, 2014 were \$1,102,880, compared with \$1,102,435 for the three months ended March 31, 2013. The increase in expense is due to increases in employee compensation and stock compensation expenses, and was partially offset by decreases in legal and professional fees.

Depreciation and amortization expenses for the three months ended March 31, 2014 were \$95,586, compared with \$78,311 for the three months ended March 31, 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.

Interest expense of \$1,635,254 for the three months ended March 31, 2013 was primarily related to the amortized debt discount and interest on both the July 25, 2012 convertible secured promissory notes and the January 23, 2013 convertible promissory notes and the amortization of the financing fees over the life of the notes. No interest expense was recorded for the three months ended March 31, 2014.

Opexa reported a net loss for the three months ended March 31, 2014 of approximately \$3.7 million, or \$0.13 loss per share (basic and diluted), compared with a net loss of approximately \$4.2 million or \$0.58 loss per share (basic and diluted) for the three months ended March 31, 2013. The decrease in net loss is primarily due to a decrease in interest expense and an increase in revenue, and was partially offset by increases in research and development, general and administrative and depreciation costs.

Cash and cash equivalents were \$19,659,525 as of March 31, 2014, compared to \$23,644,542 as of December 31, 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 (253) 237-1170 or toll free at (877) 372-0867. Please reference conference ID 44945084 or the Opexa Therapeutics Earnings Call.

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

About Opexa

Opexa's mission is to lead the field of Precision Immunotherapy™ by aligning the interests of patients, employees and shareholders. 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.

About Multiple Sclerosis (MS)

Multiple Sclerosis is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that approximately two million people have MS worldwide.

While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common. The Secondary Progressive form of MS represents about a third of the MS patient population.

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.

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

This earnings release contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements contained in this release, other than statements of historical fact, constitute “forward-looking statements.” The words “expects,” “believes,” “potential,” “possibly,” “estimates,” “may,” “could” and “intends,” as well as similar expressions, are intended to identify forward-looking statements. These forward-looking statements do not constitute guarantees of future performance. Investors are cautioned that statements which are not strictly historical statements, including, without limitation, statements regarding plans and objectives for product development (including for Tcelna (imilecleucel T)), constitute forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated. These risks and uncertainties include, without limitation, risks associated with the following: market conditions; our capital position; our ability to compete with larger, better financed pharmaceutical and biotechnology companies; new approaches to the treatment of our targeted diseases such as MS; our expectation of incurring continued losses; our uncertainty of developing a marketable product; our ability to raise additional capital to continue our development programs (including to undertake and complete any ongoing or further clinical studies for Tcelna or clinical studies related to our T-cell platform); our ability to maintain compliance with NASDAQ listing standards; the success of our clinical trials (including the Phase IIb trial for Tcelna in secondary progressive MS which, depending upon results, may determine whether Ares Trading SA (Merck), a wholly owned subsidiary of Merck Serono S.A., elects to exercise its option (Option) to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna program for the treatment of MS); whether Merck exercises its Option and, if so, whether we receive any development or commercialization milestone payments or royalties from Merck pursuant to the Option; our dependence (if Merck exercises its Option) on the resources and abilities of Merck for the further development of Tcelna; the efficacy of Tcelna for any particular indication, such as for Relapsing Remitting MS or Secondary Progressive MS; our ability to develop and commercialize products; our ability to obtain required regulatory approvals; our compliance with all Food and Drug Administration regulations; our ability to obtain, maintain and protect intellectual property rights (including for Tcelna and future pipeline candidates); the risk of litigation regarding our intellectual property rights or the rights of third parties; the success of third party development and commercialization efforts with respect to products covered by intellectual property rights that we may license or transfer; our limited manufacturing capabilities; our dependence on third-party suppliers and manufacturers; our ability to hire and retain skilled personnel; our volatile stock price; and other risks detailed in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update or revise any forward-looking statements contained herein to reflect any changes in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the SEC.

OPEXA THERAPEUTICS, INC.
(a development stage company)

Statements of Operations Data:

	Three Months Ended March 31,	
	2014	2013
Option revenue	\$ 348,837	\$ 220,100
Research and development	2,811,139	1,621,366
General and administrative	1,102,880	1,102,435
Depreciation and amortization	95,586	78,311
Operating loss	(3,660,768)	(2,582,012)
Interest income	5,194	1,874
Other income and expense, net	-	37,910
Interest expense	-	(1,635,254)
Net loss	\$ (3,655,574)	\$ (4,177,482)
Basic and diluted loss per share	\$ (0.13)	\$ (0.58)
Weighted average shares outstanding	27,584,615	7,239,102

Selected Balance Sheet Data:

	March 31, 2014	December 31, 2013
Cash and cash equivalents	\$ 19,659,525	\$ 23,644,542
Other current assets	1,565,648	1,122,576
Fixed assets, net	1,289,623	1,295,024
Other long-term assets	166,649	177,666
Total assets	22,681,445	26,239,808
Total current liabilities	3,339,334	3,324,493
Deferred revenue, net of current portion	1,989,204	2,338,041
Total stockholders' equity	17,352,907	20,577,274

CONTACT:

Company Contact:

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Opexa Therapeutics, Inc.
Chief Financial Officer
281-775-0600

or

Investor Relations:

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OPEXA THERAPEUTICS



Precision Immunotherapy™

Opexa Therapeutics, Inc.

*May 14, 2014
Q1 2014 Earnings Call*



Forward-Looking Statements

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Opexa's Mission

To lead the field of
Precision Immunotherapy™ by
aligning the interests of
patients, employees and
shareholders.



Abili-T : Phase IIb clinical trial

Enrollment Target Reached

- **FDA Fast Track Designation**
- **Secondary Progressive MS patients only**
- **Status**
 - **Enrolment target reached: 180 patients**
 - Patients currently in screening process still eligible to enroll
- **Design**
 - Double-blind, 1:1 randomized, placebo-controlled
 - Trial fully enrolled at 180 patients
 - Approximately 35 clinical sites in USA and Canada
 - Two annual courses of personalized therapy
- **Key Endpoints**
 - Whole-brain atrophy
 - Sustained progression measured by EDSS
 - Time to sustained progression
- **Timing**
 - Top-line data expected mid-2016



Income Statement

	Q1 2014	Q1 2013
Option Revenue	\$0.35 MM	\$0.22 MM
Research & Development	\$2.8 MM	\$1.6 MM
General & Administrative	\$1.1 MM	\$1.1 MM
Depreciation & Amortization	\$0.1 MM	\$0.1 MM
Operating Loss	\$3.7 MM	\$2.6 MM
Interest Expense	-	\$1.6 MM
Net Loss	\$3.7 MM	\$4.2 MM
Basic and Diluted Loss per Share	\$(0.13)	\$(0.58)



Balance Sheet Highlights

	Mar 31, 2014	Dec 31, 2013
Assets:		
Cash & Cash Equivalents	\$19.7 MM	\$23.6MM
Prepays & Other Current Assets	\$ 1.6 MM	\$ 1.1 MM
Property Plant & Equipment	\$ 1.3 MM	\$ 1.3 MM
Other Long Term Assets	\$ 0.2 MM	\$ 0.2 MM
Liabilities & Shareholders' Equity:		
Accounts Payable	\$ 0.7 MM	\$ 0.7 MM
Accrued Expenses	\$ 1.2 MM	\$ 1.2 MM
Deferred Revenue, current & long-term	\$ 3.4 MM	\$ 3.7 MM
Shareholders' equity	\$17.4MM	\$20.6MM



Investment Thesis

- T-cell platform company with Fast Track designation in SPMS
- Strong Intellectual property with 50 issued patents (domestic and international)
- Esteemed Scientific Advisory Board
- Precision Immunotherapy potentially optimizes benefit-risk profile
- Targeting an unmet medical need in a potentially substantial market
- Option Agreement with Merck Serono, a strong potential commercial partner
- Replacement value of Company is multiples of present market cap
- Attractive potential risk-reward profile for long term/value investors
- Goal-oriented management team focused on value creation