OPEXA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 05/13/14 for the Period Ending 05/13/14

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 13, 2014

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

Texas	**001-33004**	**76-0333165**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2635 Technology Forest Blvd., The Woodlands, Texas	**77381**
(Address of principal executive offices)	(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))

Item 7.01. Regulation FD Disclosure.

Neil K. Warma, President and Chief Executive Officer of Opexa Therapeutics, Inc. (the " **Company** "), will discuss the Company's financial results for the quarter ended March 31, 2014 and the status of the Company's Abili-T clinical trial progress during the Company's first quarter earnings call on Wednesday, May 14, 2014 at 5:00 p.m. EDT. To listen to 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).

A copy of the press release issued by the Company on May 13, 2014 is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in Item 7.01 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.

Item 8.01. Other Events.

On May 13, 2014, the Company announced that it has reached the targeted enrollment in its Phase IIb clinical trial in Secondary Progressive Multiple Sclerosis (" **SPMS** "). As of such date, 180 patients with SPMS have been randomized in the Company's Phase IIb "Abili-T" clinical study of Tcelna (imilecleucel-T), a novel T-cell immunotherapy for the treatment of Multiple Sclerosis (" **MS** "). The Company will allow patients who are currently in the screening process at the time of full enrollment and who meet the trial's entry criteria to also be enrolled.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Opexa Therapeutics, Inc. on May 13, 2014.

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 13, 2014

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 May 13, 2014.

Exhibit 99.1

Opexa Reaches Enrollment Target in Phase IIb Trial of Personalized Immunotherapy for Secondary Progressive Multiple Sclerosis

THE WOODLANDS, Texas--(BUSINESS WIRE)--May 13, 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 it has reached the targeted enrollment in its Phase IIb clinical trial in Secondary Progressive Multiple Sclerosis. As of today, 180 patients with Secondary Progressive MS have been randomized in the Phase IIb "Abili-T" clinical study of Tcelna. The Company will also allow patients who are currently in the screening process at the time of full enrollment and who meet the trial's entry criteria to also be enrolled in the trial.

"Interest from physicians and patients to participate in the study was high, underscoring the need for innovative treatments for Secondary Progressive MS, an area of high unmet medical need," said Neil K. Warma, President and Chief Executive Officer of Opexa. "This is an important milestone for Opexa as we continue to work towards developing patient-specific immunotherapies for the treatment of Multiple Sclerosis."

Mr. Warma credited the outstanding support of the clinical trial sites across the United States and Canada for helping the Company achieve its targeted enrollment. Even though the Company has reached the full 180-patient enrollment it sought for the Abili-T trial, the Company will continue to support those patients currently in the screening process. This likely means that the Abili-T trial will complete enrollment with a modest number of patients in excess of the 180 targeted as the Company believes it is important to support patients that had already started the enrollment process.

Edward Fox, M.D., Ph.D., one of the enrolling neurologists in the Abili-T trial, noted that there are few treatment options for patients with Secondary Progressive MS. "Achieving this significant milestone provides hope for this group and all individuals with MS."

The Abili-T trial is a Phase IIb study of Tcelna in patients with Secondary Progressive MS in 35 leading clinical sites in the U.S. and Canada. Each patient is 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. Top line data is expected in mid-2016. Opexa has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for Tcelna in Secondary Progressive Multiple Sclerosis. Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions, as well as fill an unmet medical need and get important new drugs to patients earlier.

In February 2013, Opexa entered into an option and license agreement for Tcelna with Merck Serono, one of the leading multinational companies focused on the treatment of MS. Merck Serono's option is exercisable prior to or upon completion of the Abili-T trial. Under the agreement, Opexa could be eligible to receive up to $220 million in milestone payments, as well as 8 to 15 percent in royalties.

Mr. Warma will discuss the Abili-T trial progress during Opexa's Q1 earnings call on Wednesday, May 14 th at 5:00 P.M. EDT. To listen to 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 here or 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 a patient's peripheral blood, expanded ex vivo, and reintroduced into the patient 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)

MS 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 press 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 the reports we file with the SEC.

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