
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): October 28, 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 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.

On October 28, 2016, Opexa Therapeutics, Inc. (the “**Company**”) announced the top-line results from its Phase 2b “Abili-T” clinical trial designed to evaluate the efficacy and safety of Tcelna (imilecleucel-T) in patients with secondary progressive multiple sclerosis. Tcelna did not meet the 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.

A copy of the press release is furnished as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
--------------------	--------------------

<u>99.1</u>	Press release issued by Opexa Therapeutics, Inc. on October 28, 2016.
-----------------------------	---

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.

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.

OPEXA THERAPEUTICS, INC.

Dated: October 28, 2016

By: /s/ Neil K. Warma

Neil K. Warma
President, Chief Executive Officer and Acting Chief
Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
<u>99.1</u>	Press release issued by Opexa Therapeutics, Inc. on October 28, 2016.

Opexa Therapeutics Announces Phase 2b Abili-T Trial of Tcelna® (*imilecleucel-T*) in Secondary Progressive Multiple Sclerosis Did Not Meet Primary Endpoint

THE WOODLANDS, TX, October 28, 2016 – Opexa Therapeutics (Nasdaq:OPXA), a biopharmaceutical company developing personalized immunotherapies for autoimmune disorders, today 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.

“We are disappointed that Tcelna did not meet the predefined endpoints in the Abili-T trial,” said Neil K. Warma, President and Chief Executive Officer of Opexa. “We will evaluate the full data set over the coming weeks and review cash preservation options while we consider the best path forward for the company.”

Abili-T is a 183-patient, randomized, double-blind, placebo-controlled Phase 2b study (ClinicalTrials.gov Identifier: NCT01684761) that was conducted at 35 clinical trial sites in the U.S. and Canada. Patients in the Tcelna arm of the study received two annual courses of Tcelna treatment consisting of five subcutaneous injections per year.

“We would like to express our sincere thanks to the patients in the Abili-T trial, as well as to the principal investigators and study coordinators, for their contributions to the study,” said Mr. Warma.

About Opexa Therapeutics

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, please visit 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 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.

###

Contact:

Opexa Therapeutics, Inc.
Camilla Zuckero
281.775.0600
czuckero@opexatherapeutics.com