

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 09/12/12 for the Period Ending 09/12/12

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): September 12, 2012

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 7.01. Regulation FD Disclosure.

On September 12, 2012, Opexa Therapeutics, Inc. issued a press release announcing the initiation of a Phase IIb clinical trial of Tcelna™ in patients with secondary progressive multiple sclerosis.

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

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
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5.1	Opinion of Pillsbury Winthrop Shaw Pittman LLP.
23.1	Consent of Pillsbury Winthrop Shaw Pittman LLP (included in Exhibit 5.1).
99.1	Press Release issued by Opexa Therapeutics, Inc. on September 12, 2012.

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.

Dated: September 12, 2012

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President & Chief Executive Officer

EXHIBIT INDEX

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September 12, 2012

Opexa Therapeutics, Inc.
2635 Technology Forest Blvd.
The Woodlands, Texas 77381

Ladies and Gentlemen:

We are acting as counsel for Opexa Therapeutics, Inc., a Texas corporation (the “**Company**”), in connection with the issuance and sale of up to 4,000,000 shares (the “**Shares**”) of common stock, \$0.01 par value (the “**Common Stock**”), of the Company, all of which are authorized but heretofore unissued shares to be offered and sold by the Company pursuant to the Registration Statement on Form S-3 (Registration No. 333-163108) (the “**Registration Statement**”) filed by the Company with the Securities and Exchange Commission (the “**Commission**”) under the Securities Act of 1933 (the “**Act**”) and related prospectus dated November 23, 2009, as supplemented by the prospectus supplement dated September 12, 2012 relating to the offer and sale of the Shares (as so supplemented, the “**Prospectus**”).

We have reviewed and are familiar with such documents, corporate proceedings and other matters as we have considered relevant or necessary as a basis for the opinions in this letter. Based on the foregoing, we are of the opinion that the Shares have been duly authorized and, when issued and sold by the Company in the manner described in the Registration Statement and the Prospectus and in accordance with the resolutions adopted by the Board of Directors of the Company, will be validly issued, fully paid and nonassessable.

The opinions set forth in this letter are limited to the Business Organizations Code of the State of Texas, as in effect on the date hereof.

We hereby consent to the filing of this opinion letter as Exhibit 5.1 to the Company’s Current Report on Form 8-K filed by the Company with the Commission on the date hereof and the incorporation thereof in the Registration Statement and to the use of our name under the caption “Legal Matters” in the Prospectus. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission promulgated thereunder.

Very truly yours,

/s/ Pillsbury Winthrop Shaw Pittman LLP

Opexa Initiates Late Stage Clinical Study of Tcelna in Patients with Secondary Progressive Multiple Sclerosis (SPMS)

First Ever Personalized Immunotherapy for MS Being Studied in Phase IIb Abili-T Trial; Tcelna Has Fast Track Designation in Significantly Underserved SPMS Patient Population

THE WOODLANDS, Texas--(BUSINESS WIRE)--September 12, 2012--Opexa Therapeutics, Inc. (NASDAQ:OPXA), a company developing Tcelna™, a novel T-cell therapy for multiple sclerosis (MS), today announced the initiation of a Phase IIb clinical trial of Tcelna in patients with Secondary Progressive Multiple Sclerosis (SPMS). Several patients have already been enrolled in the study and enrollment is expected to increase rapidly as additional sites begin screening and enrolling patients in the coming weeks. Tcelna is the first ever personalized T-cell therapy for MS patients and has received Fast Track Designation from the United States Food and Drug Administration (FDA) for the treatment of SPMS. The therapy is specifically tailored to each patient's individual disease profile and has demonstrated superior safety and encouraging indications of efficacy in previous clinical studies in MS that included the treatment of SPMS patients. There is currently only one FDA-approved treatment for SPMS but safety warnings have severely restricted its use.

The newly initiated trial, named Abili-T, is a randomized, double-blind, placebo-controlled clinical study in SPMS patients who demonstrate evidence of disease progression without associated relapses. The trial is expected to enroll 180 patients at approximately 30 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 study will assess a number of clinical endpoints to evaluate the efficacy and safety of Tcelna in patients with SPMS. The primary efficacy outcome of the trial 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 (ARR) and changes in disability as measured by EDSS and the Multiple Sclerosis Functional Composite (MSFC).

In multiple previously conducted clinical trials for the treatment of patients with MS, Tcelna has demonstrated one of the safest side effect profiles of any marketed or development-stage MS therapy, as well as encouraging efficacy signals indicating Opexa's therapy may have the potential to be both safe and effective for the treatment of both SPMS and RRMS patients. In Phase I/II studies involving SPMS patients treated with Tcelna (n=36), 80 percent of the patients treated with Tcelna showed no evidence of disease progression at 24 months (a 50% improvement, with respect to patients showing evidence of disease progression, over historical controls). Following two years of treatment, a subset of these patients (n=10) reported no worsening of their physical or psychological condition. Additionally, in 21 years of cumulative follow up in the same SPMS patients treated with Tcelna, the annualized relapse rate for this same subset of patients was reduced significantly compared to baseline and only one patient experienced a relapse during this time.

"To witness the initiation of this clinical study following the extensive preparations that were required is a tremendous testament to the dedication and talent of the entire Opexa team. We believe this is a critical milestone for not just our Company, but for all of those SPMS patients who desperately need and deserve a better, safer and more effective treatment option," said Neil K. Warma, President and Chief Executive Officer of Opexa. "We return to the clinic with an enhanced manufacturing process, an optimized clinical development strategy, Fast Track designation from the FDA and the belief that Tcelna is the most promising MS treatment in development today."

The initiation of this trial follows a number of key enhancements to the Tcelna clinical development program. First, Opexa has optimized its Chemistry, Manufacturing and Control (CMC) process for the therapy in order to improve efficiency, reduce overall costs and bring it further in line with commercial stage requirements. Following completion of these manufacturing and logistical enhancements, the Company submitted an updated CMC application which has been fully reviewed by the FDA. In addition, the Company has modified its clinical development strategy for Tcelna to focus current efforts on the SPMS patient population in order to address the severe lack of treatment options currently available or in development for these patients. Finally, to reflect its work in optimizing the overall manufacturing process and clinical development strategy for the program, Opexa's lead product candidate, formerly known as Tovaxin, has been rebranded as Tcelna.

"It is very gratifying to see Opexa's novel T-cell therapy return to the clinic and I am excited to be part of the ongoing investigation of a potential MS treatment that possesses such an impressive early safety profile. This is an exceedingly important study for the entire MS community as it will go a long way toward demonstrating how effective the therapy may be for the most in need and underserved progressive MS patient population," stated Mark Freedman, M.D., director of the Multiple Sclerosis Research Unit at the Ottawa Hospital, member of Opexa's Scientific Advisory Board, and an investigator for the Abili-T trial. "While a positive trial outcome will certainly be good news for SPMS patients, it is also not difficult to envision that it could position Tcelna as a promising treatment for the larger RRMS patient population as well."

"The initiation of this clinical trial is a very important milestone in the area of MS research, particularly in light of the significant need for new and effective treatments for these patients," commented Hans-Peter Hartung, M.D., chairman of the department of neurology at Heinrich-Heine University, Dusseldorf and member of Opexa's Scientific Advisory Board. "As a personalized immunotherapy, Tcelna's unique mechanism strongly differentiates it from other development stage MS treatments. This combined with a safety profile that is unmatched by other MS therapies currently available or in development positions Tcelna as a potentially very interesting therapy for a large, underserved patient population. Currently, there is no satisfactory treatment available for SPMS patients."

While its current clinical trial targets SPMS patients, Opexa also intends to continue the development of Tcelna as a treatment for RRMS patients. Opexa has successfully completed End of Phase II meetings with the FDA and believes it is positioned to initiate Phase III pivotal trials

in RRMS patients. Importantly, the results of the ongoing Abili-T trial should further enhance the Company’s future efforts in the RRMS indication. The primary focus at present, however, is the ongoing Phase IIb SPMS Abili-T trial and on securing the necessary capital required for the completion of that trial.

About SPMS

SPMS is a progressive phase of MS which is characterized by a steady progression of clinical neurological damage with or without relapses. After ten years of disease characterized by relapse events and remitting disability (RRMS), approximately 50 percent of patients will have progressed to SPMS. In SPMS, relapses dissipate over time and subjects experience general progression and increasing disability. It is believed that the resulting neurological damage cannot be reversed.

About Tcelna

Tcelna is a personalized therapy that is 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 believes the potential combination of efficacy, superior safety, excellent tolerability and administration may position Tcelna as the MS treatment of choice as compared to existing therapeutics.

About Opexa

Opexa Therapeutics, Inc. is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases such as MS. The Company's leading therapy, Tcelna™, is a personalized cellular immunotherapy treatment that is in late stage clinical development for MS. Tcelna is derived from T-cells isolated from 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 and, thereby, reduces the risk of relapse over time.

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. The words "expects," "believes," "hopes," "anticipates," "estimates," "may," "could," "intends," "exploring," "evaluating," "progressing," "proceeding" and similar expressions are intended to identify forward-looking statements. The forward-looking statements in this release do not constitute guarantees of future performance. Investors are cautioned that statements in this press release which are not strictly historical statements, including, without limitation, statements regarding the development of the Company's product candidate, Tcelna, 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, including, without limitation, risks associated with: our capital position, the rights and preferences provided to the Series A Convertible Preferred Stock and investors in the convertible secured notes issued by the Company in July 2012 (including a secured interest in all of our assets), the ability of the Company to enter into and benefit from a partnering arrangement for the Company's product candidate, Tcelna, on reasonably satisfactory terms (if at all), our dependence (if partnered) on the resources and abilities of any partner for the further development of Tcelna, our ability to compete with larger, better financed pharmaceutical and biotechnology companies, new approaches to the treatment of our targeted diseases, 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), the success of our clinical trials, 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), 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 the Company may license or transfer, our limited manufacturing capabilities, our dependence on third-party 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 any forward-looking statements to reflect any changes in 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 reports filed with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2011.

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