

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 09/16/14 for the Period Ending 09/16/14

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): September 16, 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 8.01. Other Events.

On September 16, 2014, Opexa Therapeutics, Inc. issued a press release entitled “Opexa Therapeutics, Inc. Announces Termination of Public Offering of Common Stock,” a copy of which is hereby filed as Exhibit 99.1 and is incorporated herein by reference. The termination results from an assessment by Opexa’s management that current market conditions are not conducive for an offering on terms that would be in the best interests of Opexa’s stockholders. As a result of such termination, no shares will be sold pursuant to the offering.

Item 9.01. Financial Statements and Exhibits.

(d)

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press Release issued by Opexa Therapeutics, Inc. on September 16, 2014.
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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 16, 2014

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma

President and Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press Release issued by Opexa Therapeutics, Inc. on September 16, 2014.
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Opexa Therapeutics, Inc. Announces Termination of Public Offering of Common Stock

THE WOODLANDS, Texas--(BUSINESS WIRE)--September 16, 2014-- **Opexa Therapeutics, Inc.** (NASDAQ:OPXA), a company developing a novel T-cell therapy for multiple sclerosis (MS), today announced that it has terminated the public offering of shares of its common stock previously announced on Monday, September 15, 2014. The termination results from an assessment by Opexa's management that current market conditions are not conducive for an offering on terms that would be in the best interests of Opexa's stockholders. As a result of such termination, no shares will be sold pursuant to the offering.

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 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.

About Neuromyelitis Optica (NMO)

NMO is a rare autoimmune disorder in which immune system cells and antibodies mistakenly attack and destroy myelin cells in the optic nerves and the spinal cord. The damage to the optic nerves produces swelling and inflammation that cause pain and loss of vision; the damage to the spinal cord causes weakness or paralysis in the legs or arms, loss of sensation, and problems with bladder and bowel function. NMO affects approximately 4,800 people in the U.S., and the worldwide estimated prevalence is 1-2 people per 100,000 population. There is no cure for NMO and there are no FDA-approved therapies, other than to treat an attack while it is happening, to reduce symptoms and to prevent relapses.

For more information, visit the Opexa Therapeutics website at www.opexatherapeutics.com.

CONTACT:

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