OPEXA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 08/13/13 for the Period Ending 08/13/13

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): August 13, 2013

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 8.01. Other Events.

On August 13, 2013, Opexa Therapeutics, Inc. (the " **Company** ") issued a press release entitled "Opexa Therapeutics, Inc. Announces Closing of Secondary Offering of Common Stock," a copy of which is hereby filed as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated August 13, 2013.

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: August 13, 2013

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma
Neil K. Warma
President & Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated August 13, 2013.

Exhibit 99.1

Opexa Therapeutics, Inc. Announces Closing of Public Offering of Common Stock

THE WOODLANDS, Texas--(BUSINESS WIRE)--August 13, 2013-- **Opexa Therapeutics, Inc.** (NASDAQ: OPXA), a biotechnology company developing Tcelna®, a patient-specific T-cell immunotherapy for the treatment of multiple sclerosis (MS), today announced the closing of the previously announced underwritten public offering of 12,000,000 shares of its common stock at a price to the public of $1.50 per share. The gross proceeds to Opexa from this offering were $18 million, before deducting underwriting discounts and commissions and other estimated offering expenses. All of the shares in the offering were sold by Opexa. Opexa has also granted the underwriters a 30-day option to purchase up to an additional 1,800,000 shares of common stock to cover over-allotments, if any.

Opexa intends to use the net proceeds from the offering to fund further clinical development of Tcelna in an ongoing Phase IIb clinical study of patients with Secondary Progressive MS as well as the expenses of its operations during such development and for general corporate purposes. Opexa may also use a portion of the net proceeds to repay all or a portion of its outstanding convertible secured promissory notes.

Aegis Capital Corp. acted as sole book-running manager for the offering.

A registration statement relating to these securities was declared effective by the Securities and Exchange Commission on August 7, 2013. The offering was made only by means of a prospectus. Copies of the prospectus relating to the offering are available on the SEC's website at http://www.sec.gov . Copies of the prospectus may also be obtained from the offices of Aegis Capital Corp., Prospectus Department, 810 Seventh Avenue, 18 th Floor, New York, NY, 10019, via telephone at (212) 813-1010, or via email at prospectus@aegiscap.com .

This press release does not constitute an offer to sell or the solicitation of an offer to buy these securities, nor will there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale is not permitted.

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 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 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," "anticipates," "estimates," "may," "could," "intends," 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 report which are not strictly historical statements, including, without limitation, statements regarding the intention to use a portion of the net proceeds to repay outstanding convertible secured promissory notes and the development of the Company's product candidate, 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, but are not limited to, risks associated with: market conditions; our capital position; the rights and preferences provided to the Series A convertible preferred stock and investors in the convertible secured notes we issued in July 2012 (including a secured interest in all of our assets); 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), including in this regard our ability to satisfy various conditions required to access the financing potentially available under the purchase agreements with Lincoln Park Capital Fund, LLC (“Lincoln Park”) (such as the minimum closing price for our common stock and the requirement for an ongoing trading market for our stock); our ability to raise additional capital through the sale of shares of our common stock under the purchase agreements with Lincoln Park or under our at-the-market (ATM) facility; 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”) elects to exercise its option for an exclusive license to Tcelna for the treatment of MS (the “Option”)); 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); 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 manufacturers; our ability to hire and retain skilled personnel; our volatile stock price; and other risks detailed in our filings with the SEC. 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 Registration Statement on Form S-1 declared effective by the SEC on August 7, 2013, as well as 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.

CONTACT:

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