OPEXA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 08/10/09 for the Period Ending 08/07/09

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 7, 2009**

Opexa Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Texas	
(State or Other Jurisdiction of Incorporation)	
001-33004	**76-0333165**
(Commission File Number)	(I.R.S. Employer Identification No.)
2635 N. Crescent Ridge Drive **The Woodlands, Texas**	**77381**
(Address of Principal Executive Office)	(Zip Code)

Registrant's telephone number, including area code: **(281) 272-9331**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions (see General Instruction A.2 below) :

☐ 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 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; transfer of Listing.

On August 7, 2009, the Company received notice that the Listing Qualifications Staff of The NASDAQ Stock Market LLC ("NASDSAQ") has determined that the Company has regained compliance with the continued listing requirements and shall remain listed on the NASDAQ Capital Market. This follows last week's announcement of Opexa's agreement with Novartis, a leading global pharmaceutical company, whereby Novartis acquired Opexa's stem cell technology in a deal potentially valued at over $50 million.

Opexa had received a letter from NASDAQ on August 4, 2009, stating that the company had not regained compliance with the NASDAQ stockholders' equity requirement, as set forth in Listing Rule 5550(b)(1), by the previously established NASDAQ deadline. Subsequent to this letter, Opexa was able to finalize the agreement with Novartis on the stem cell technology, as announced on August 7, 2009. As a result, on August 7, 2009, NASDAQ notified Opexa that it has been deemed in compliance.

A copy of this press release is furnished as Exhibit 99.1 to this Current Report.

Item 9.01 Exhibits

(c) Exhibit 99.1

The following exhibit is to be filed as part of this 8-K:

Exhibit No.	Description
99.1	Press release issued August 10, 2009

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 hereunto duly authorized.

OPEXA THERAPEUTICS, INC.

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

DATE: August 10, 2009

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued August 10, 2009

Exhibit 99.1

Opexa Regains NASDAQ Compliance Following Stem Cell Agreement

Stem Cell Transaction Potentially Valued at Over $50 Million Was Key to Compliance

THE WOODLANDS, Texas--(BUSINESS WIRE)--August 10, 2009-- **Opexa Therapeutics, Inc** . (NASDAQ:OPXA), a company developing a novel T-cell immunotherapy for multiple sclerosis (MS), today announced that on August 7, 2009, the Company received notice that the Listing Qualifications Staff of The NASDAQ Stock Market LLC ("NASDAQ") has determined that Opexa has regained compliance with the continued listing requirements and shall remain listed on The NASDAQ Capital Market. This follows last week's announcement of Opexa's agreement with Novartis, a leading global pharmaceutical company, whereby Novartis acquired Opexa's stem cell technology in a deal potentially valued at over $50 million.

"We are very pleased that NASDAQ has determined that we have regained compliance with the applicable listing requirements as this reflects positively on the underlying strength of our company," commented Neil K. Warma, Opexa's president and chief executive officer. "Regaining compliance and receiving immediate and near term payments totaling $4 million from the stem cell transaction enables us to continue to aggressively pursue the clinical development of Tovaxin®, our lead clinical asset, which is in Phase IIb development for Relapsing Remitting Multiple Sclerosis (RRMS). We have been firmly focused on three key elements of Tovaxin development over the past several months - the preparation and planning of the next clinical study, securing a long term strategic partnership and the continued analysis of the Phase IIb data. All three are progressing well and strengthening our financial position and securing compliance with the NASDAQ requirements will allow us to maintain our focus on developing this very safe and effective treatment for MS. Additionally, we are also pleased that our SEC Form 10-Q for the period ended June 30, 2009, which will be filed later this week, will no longer include a reference to a going concern qualification from our independent public accountants as a further consequence of the announced stem cell transaction."

Opexa had received a letter from NASDAQ on August 4, 2009, stating that the company had not regained compliance with the NASDAQ stockholders' equity requirement, as set forth in Listing Rule 5550(b)(1), by the previously established NASDAQ deadline. Subsequent to this letter, Opexa was able to finalize the agreement with Novartis on the stem cell technology, as announced on August 7, 2009. As a result, on August 7, 2009, NASDAQ notified Opexa that it has been deemed in compliance.

About Opexa

Opexa Therapeutics, Inc. is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases. The Company's leading therapy, Tovaxin ®, is an individualized cellular immunotherapy treatment in Phase IIb clinical development for Multiple Sclerosis (MS). Tovaxin 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. Data from the first Phase IIb clinical study showed compelling evidence that Relapsing Remitting MS patients treated with Tovaxin saw overall clinical, MRI, and immunological benefits over the placebo group, including statistical significance for decrease in the Annualized Relapse Rate (ARR), improvement in disability score (EDSS), and improvement in quality of life measures (MSQLI), as well as an excellent safety profile with no serious adverse events related to Tovaxin treatment.

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 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 current or future financial payments, returns, royalties, performance and position, management's strategy, plans and objectives for future operations, plans and objectives for product development, plans and objectives for present and future clinical trials and results of such trials, plans and objectives for regulatory approval, litigation, intellectual property, product development, manufacturing plans and performance, 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: the success of third party development and commercialization efforts with respect to products covered by intellectual property rights transferred by the Company, the success of third party patent prosecution efforts with respect to such products, the ability of the Company to enter into and benefit from a partnering arrangement for the Company's product candidate, Tovaxin, on reasonably satisfactory terms (if at all), and our dependence (if partnered) on the resources and abilities of any partner for the further development of Tovaxin, 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 treatment development programs, the success of our clinical trials, 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 for our products, the risk of litigation regarding our intellectual property rights, our limited manufacturing capabilities, our dependence on third-party manufacturers and value added resellers, 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. We assume no obligation to update any forward-looking information contained in this press release or with respect to the announcements described herein.

CONTACT:
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