

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 12/02/09 for the Period Ending 12/02/09

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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**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): **December 2, 2009**



Opexa Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Texas

(State or Other Jurisdiction of Incorporation)

001-33004

(Commission File Number)

**2635 N. Crescent Ridge Drive
The Woodlands, Texas**

(Address of Principal Executive Office)

76-0333165

(I.R.S. Employer Identification No.)

77381

(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))
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Item 8.01. Other Events.

On December 2, 2009, Opexa Therapeutics, Inc. (the “Company”) issued a press release announcing that Jaye Thompson, Ph.D. has been hired to lead the Company’s efforts to further the clinical development of Tovaxin[®], Opexa’s flagship therapy for multiple sclerosis and Dawn McGuire, M.D., Opexa’s expert clinical advisor and member of the Company’s Clinical Advisory Board has agreed to further increase her advisory role in the Company and to represent Opexa as its acting Chief Medical Officer.

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

The following exhibit is filed as part of this Current Report on Form 8-K:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued December 2, 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: December 2, 2009

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued December 2, 2009

Seasoned Clinical Development Expert Joins Opexa to Lead Tovaxin[®] Development in Multiple Sclerosis

Strengthening of Clinical Team Demonstrates Strong Commitment to Tovaxin and Positions Company for Future Development

THE WOODLANDS, Texas--(BUSINESS WIRE)--December 2, 2009-- **Opexa Therapeutics, Inc.** (NASDAQ:OPXA), a company developing a novel T-cell therapy for multiple sclerosis (MS), today announced that Jaye Thompson, Ph.D. has been hired to lead the Company's efforts to further the clinical development of Tovaxin[®], Opexa's flagship therapy for MS. Additionally, Dawn McGuire, M.D., Opexa's expert clinical advisor and member of the Company's Clinical Advisory Board has agreed to further increase her advisory role in the Company and to represent Opexa as its acting Chief Medical Officer.

Jaye Thompson adds considerable strength to Opexa's management team as the Senior Vice President of Clinical Development and Regulatory Affairs. Dr. Thompson has significant experience in clinical development having been the president and founder of SYNERGOS, Inc., a full service contract research organization which she managed and successfully grew until its acquisition by inVentiv Health (NASDAQ:VTIV) in 2006. She has advised a number of leading life science companies on strategic and regulatory planning as well as clinical product development. She has directed and managed statistical analysis, data management, report writing and the conduct of clinical trials for a wide variety of indications including MS. Dr. Thompson has been actively involved in over 200 clinical trials for drugs and has been associated with numerous FDA regulatory submissions. Dr. Thompson has a Bachelor's degree in Applied Mathematics and a Ph.D. in Biostatistics.

"It is a tremendous pleasure joining Opexa at this stage of its development as we prepare for the next clinical milestone for Tovaxin," stated Dr. Thompson. "There is much potential in Tovaxin and its safety and efficacy are apparent at a time when there is a pressing need for new therapies in this area. I am pleased to be leading the clinical development efforts for Opexa and we have a focused effort within the Company to advance toward the next clinical study with Tovaxin. The first set of priorities is advancing the clinical development program, progressing discussions with the regulatory agencies and supporting our on-going partnering discussions and I look forward to working with Opexa's already strong management team to deliver on these targets."

Dr. McGuire, who has been advising Opexa as a consultant and who has substantial expertise in the clinical management of MS, is also strengthening her role with the Company. She is a board certified neurologist and served as development leader of Tysabri[®] as Vice President of Clinical Research and Medical Affairs at Elan Pharmaceuticals. Dr. McGuire has agreed to deepen her involvement with the Company as its acting Chief Medical Officer and will work closely with Dr. Thompson to guide the Company's efforts to further the clinical development of Tovaxin.

"I am pleased to increase my role in helping advance Tovaxin effectively through clinical development," commented Dr. McGuire. "The analysis of the Phase IIb data has been very encouraging, and safety and efficacy data strongly support the continued development of Tovaxin. Roughly half of MS patients are not on any therapy, and Tovaxin has the potential to be a compelling treatment option across patient groups, including the newly diagnosed. Early data suggest that Tovaxin may be neuroprotective, as indicated radiographically by reduction in brain atrophy and clinically by stability or improvement in disability. Among patients with frequent MS exacerbations, Tovaxin appears to reduce the relapse rate substantially. I look forward to working with Dr. Thompson and the entire Opexa team in their efforts to advance Tovaxin through clinical development."

"I couldn't be more pleased with the clinical team that is now in place to move Tovaxin forward," commented Neil K. Warma, Opexa's President and CEO. "The combination of Jaye's substantial hands-on experience in clinical development and regulatory affairs and Dawn's MS drug development expertise positions us very well to advance the clinical development of Tovaxin. Finalizing the clinical development plan will continue in parallel with on-going partnering discussions. We had a constructive third quarter marked not only by the TERMS data analysis of Tovaxin efficacy, but also by the stem cell agreement with Novartis, which booked revenue for the first time in Opexa's history and strengthened the Company's balance sheet. This has allowed us to remain focused on Tovaxin and to assemble a world-class management team. We are making clear progress in our efforts to bring one of the more promising MS treatments to the patients in need."

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, believed to be a primary cause of MS attacks and nervous system damage.

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, and management's initiatives and strategies, 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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