

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

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Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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Symbol	OPXA
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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): **October 23, 2008**



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

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

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

(Address of Principal Executive Office)

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 2.02. Results of Operations and Financial Condition.

On October 23, 2008 the Company filed its Quarterly Report on Form 10-Q for the quarter ended September 30, 2008. On October 23, 2008, the Company announced its results of operations in a press release. A copy of the press release announcing the results is filed as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 8.01. Other Event.

On October 23, 2008, the Company announced additional positive data from the company's Phase Iib TERMS clinical trial (Tovaxin® for Early Relapsing Multiple Sclerosis). A copy of the press release is attached as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

- (c) Exhibit 99.1
Exhibit 99.2

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued October 23, 2008
99.2	Press release issued October 23, 2008

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/ Lynne Hohlfeld
Lynne Hohlfeld
Chief Financial Officer

DATE: October 23, 2008

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued October 23, 2008
99.2	Press release issued October 23, 2008

Opexa Therapeutics Reports Third Quarter 2008 Financial Results

THE WOODLANDS, Texas--(BUSINESS WIRE)--October 23, 2008--Opexa Therapeutics, Inc. (NASDAQ:OPXA), a company dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases such as multiple sclerosis (MS) and diabetes, today reported financial results for the quarter ended September 30, 2008, and provided an update on its recent accomplishments.

Recent Highlights:

- Completed first-in-class Phase IIb TERMS (Tovaxin(R) for Early Relapsing Multiple Sclerosis) clinical study evaluating Tovaxin, a novel patient-specific treatment for MS. Top-line findings, which were reported in September 2008 at the World Congress on Treatment and Research in Multiple Sclerosis include:
 - Annualized relapse rate (ARR) of 0.214 for patients treated with Tovaxin, which compares favorably to the lowest ARR reported in studies of any MS therapy on the market or in development.
 - Excellent safety with no serious adverse events attributed to Tovaxin.
 - Additional data analysis, which focused on patients with the most active disease (prospectively defined ARR>1 population) provided the following findings:
 - Tovaxin-treated patients experienced a statistically significant improvement in disability as measured by the Expanded Disability Status Scale (EDSS) ($p=0.045$) as compared to placebo.
 - Tovaxin-treated patients experienced an improvement in brain atrophy and in the number of Gadolinium enhanced (Gd) lesions as well as in T-2 lesion volumes, as compared to patients receiving placebo.
 - Tovaxin-treated patients had less T-cell reactivity and experienced fewer relapses as compared to patients on placebo suggesting that Tovaxin may lower the risk of relapse for patients in this population.
 - Completed enrollment of one-year open label extension study of Tovaxin. Approximately 90 percent of patients in the Phase IIb TERMS study elected to participate.
 - Completed a private placement financing with gross proceeds of approximately \$3 million.
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“Opexa’s Phase IIb TERMS study provided important data which highlighted Tovaxin’s potential therapeutic benefit to those patients suffering with more active disease and most in need of treatment,” commented Neil K. Warma, president and chief executive officer of Opexa. “Earlier today, we were pleased to report Tovaxin’s positive results with the prospectively defined ARR>1 population as evidenced by a statistically significant reduction in disability, improvements with respect to brain atrophy and lesions, and an important reduction in T-cell reactivity. Previously, we reported that Tovaxin demonstrated a reduction in ARR to levels on par with the most efficacious currently available MS treatments, as well as an impressive safety and tolerability profile. We are aggressively pursuing the ongoing interest of potential strategic partners to further advance this innovative therapy.”

Third Quarter Financial Results

Opexa recorded no revenues for the three months ended September 30, 2008 or in the comparable prior-year period.

Research and development expenses were approximately \$2.4 million for the three months ended September 30, 2008, compared to approximately \$3.2 million for the three months ended September 30, 2007. The decrease in expenses was primarily due to a wind down of costs of conducting the Phase IIb clinical trial for Tovaxin recorded in 2008 offset in part by costs associated with enrollment of the one-year Phase IIb extension study of Tovaxin.

General and administrative expenses were approximately \$0.7 million for the three months ended September 30, 2008, as compared to approximately \$0.8 million for the three months ended September 30, 2007. The decrease in expenses is primarily due to a decrease in stock compensation expense in the current period.

Opexa reported a net loss for the three months ended September 30, 2008, of approximately \$3.1 million, or \$0.28 per share, compared with a net loss of approximately \$2.4 million, or \$0.35 per share, for the three months ended September 30, 2007.

The company had cash and cash equivalents of approximately \$4.0 million as of September 30, 2008, compared with approximately \$2.6 million as of December 31, 2007.

Year-to-Date Financial Results

Opexa reported no revenues in the nine months ended September 30, 2008, or in the comparable prior-year period.

Research and development expenses were approximately \$7.1 million for the nine months ended September 30, 2008, compared to approximately \$10.1 million for the nine months ended September 30, 2007. The decrease in expenses was primarily due to a decrease in activities related to the Phase IIb clinical trial for Tovaxin in 2008 as compared to 2007 and a reduction in stock compensation expense recorded in 2008.

General and administrative expenses were approximately \$2.7 million for the nine months ended September 30, 2008, as compared to approximately \$2.6 million for the nine months ended September 30, 2007. The increase in expenses is primarily due to an increase in stock compensation expense during the current period.

Opexa reported a net loss for the nine months ended September 30, 2008, of approximately \$9.9 million, or \$0.99 per share, compared with a net loss of approximately \$10.8 million, or \$1.62 per share, for the nine months ended September 30, 2007.

Conference Call Information

Opexa will host a conference call on Thursday, October 23, 2008, at 8:30 a.m. Eastern Time to discuss the company's third quarter results and recent clinical developments.

The conference call can be accessed by dialing (800) 230-1092 from the U.S. and (651) 291-0618 internationally. Additionally a live webcast of the call will be available on Opexa's web site at www.opexatherapeutics.com. The webcast will be archived until November 22, 2008.

Additionally, a replay of the conference call can be accessed until October 30, 2008, at 11:59 p.m., by dialing (800) 475-6701 from the U.S. and (320) 365-3844 internationally, and entering the following access code: 965022.

About Opexa Therapeutics

Opexa Therapeutics is a biotechnology company dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases. The company's leading therapies currently in development have the potential to address significant unmet medical needs in several large patient populations including multiple sclerosis (MS) and diabetes. The company's lead product is Tovaxin, a T-cell therapy for MS which recently completed a Phase IIb trial. The company also holds an exclusive worldwide license for adult multi-potent stem cells derived from mononuclear cells of peripheral blood. The technology provides means to differentiate these stem cells into other tissue types such as pancreatic islets. By using an individual's own cells, this approach may minimize threat of treatment rejection. This technology serves as the basis for Opexa's preclinical diabetes program, which is focused on the generation of insulin-secreting pancreatic-like cells. 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 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 collaborative relationships, 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.

OPEXA THERAPEUTICS, INC.

(a development stage company)

Financial Highlights

(Unaudited)

Statements of Expenses Data:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Research & development	\$ 2,429,258	\$ 3,189,256	\$ 7,134,786	\$ 10,148,930
General and Administrative	660,814	842,079	2,668,511	2,557,609
Depreciation	58,826	50,446	175,896	149,371
Loss on disposal of assets	—	—	116	4,034
Operating loss	(3,148,898)	(4,081,781)	(9,979,309)	(12,859,944)
Interest Income	23,681	102,292	92,885	423,086
Other income and expense, net	—	1,612,440	34,901	1,612,440
Interest expense	(4,553)	(4,731)	(15,573)	(10,875)
Net loss	<u>\$ (3,129,770)</u>	<u>\$ (2,371,780)</u>	<u>\$ (9,867,096)</u>	<u>\$ (10,835,293)</u>
Basic and diluted loss per share	\$ (0.28)	\$ (0.35)	\$ (0.99)	\$ (1.62)
Weighted average shares outstanding	11,370,527	6,696,784	9,977,831	6,696,784

Selected Balance Sheet Data:

	September 30, 2008	December 31, 2007
Cash and cash equivalents	\$ 4,044,082	\$ 2,645,482
Other current assets	180,240	355,266
Fixed assets (net)	1,225,905	1,370,647
Total assets	5,450,227	4,371,395
Total current liabilities	2,068,712	2,075,354
Total long term liabilities	116,131	162,456
Total stockholders' equity	3,265,384	2,133,585

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Tim Brons, 415-675-7400 (Media)

tbrons@vidacommunication.com

Opexa Provides Additional Promising Data Including Statistically Significant Reduction in Disability With Tovaxin[®] for the Treatment of Multiple Sclerosis

Tovaxin Also Demonstrates Reduction in Relapse Risk and Myelin T-cell Reactivity in Patients With More Active Disease

THE WOODLANDS, Texas--(BUSINESS WIRE)--October 23, 2008--Opexa Therapeutics, Inc. (NASDAQ:OPXA), a company dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases such as multiple sclerosis (MS) and diabetes, today announced additional positive data from the company's Phase IIb TERMS clinical trial (Tovaxin[®] for Early Relapsing Multiple Sclerosis). The latest analysis focused on a prospective group of patients (n=50) with an annualized relapse rate (ARR) of greater than 1 at study entry which is comparable to ARR baselines of patients in previous Tovaxin studies. These findings demonstrate a statistically significant improvement in disability as measured by the Expanded Disability Status Scale (EDSS) (p=0.045) for patients treated with Tovaxin as compared to those receiving placebo. In this group, 28.1 percent of patients treated with Tovaxin showed an improvement in EDSS as compared to only 5.6 percent in the placebo group. Additionally, there was an 88 percent reduction in the level of brain atrophy and a more than 20 percent reduction in the number of gadolinium (Gd) lesions progressing to black holes in the Tovaxin group, which may suggest a beneficial neuroprotective effect. Overall, the analysis shows that patients treated with Tovaxin demonstrated a benefit across all clinical and magnetic resonance imaging (MRI) endpoints (primary, secondary and tertiary) in this patient population. Immunology data also appears to support Tovaxin's mechanism of action, indicating that patients with less myelin T-cell reactivity have a lower risk of relapse. Additional quality of life measurements, such as the Timed 25 foot Walk, also showed a benefit for Tovaxin over placebo (0.14 vs. -0.02, as measured by respective Z scores).

The data shows that these patients when treated with Tovaxin demonstrate an ARR of 0.28 which represents a 55 percent reduction compared to those patients on placebo. This relapse rate is on par with the lowest relapse rates observed with currently available MS treatments which range from 0.2 to 0.9. Study findings also show Tovaxin possesses an impressive safety and tolerability profile. Opexa expects to conduct a Phase II close-out meeting with the United States Food and Drug Administration during the first half of 2009 to discuss next steps for the further clinical development of Tovaxin. Opexa is actively engaged in discussions with potential strategic partners for the Tovaxin program.

The TERMS study provided Opexa the opportunity to create a comprehensive database of clinical immunology and epitope data in MS patients that may significantly advance the understanding and treatment of the disease. This type of information is particularly important for Opexa as Tovaxin's dual mechanism of action involves the depletion of myelin-reactive T-cells in the peripheral blood and the regulation of anti-inflammatory T-cells to rebalance an MS patient's immune system. Previous studies show that if the myelin-peptide reactivity in a patient's peripheral blood is reduced, the clinical symptoms associated with MS will also be reduced. The initial analysis of the study's immunology and epitope database has shown that patients treated with Tovaxin appeared to have less myelin-peptide reactivity over the course of the study than those on placebo. This was measured using Opexa's proprietary Epitope Analysis Assay (EAA) which assessed reactivity across all three key myelin proteins at several time points throughout the 52-week study. Additionally, over the full course of treatment, more patients on Tovaxin remained in the lower quartile of peptide reactivity (56 percent) than those on placebo (39 percent). This epitope data appears to correlate with the study's MRI and clinical endpoints which, among other findings, showed that following the full course of treatment (weeks 28-52), the ARR in the Tovaxin group dropped to 0.065 (0.749 for placebo).

The pattern emerging from the analysis of the immunology and epitope database suggests that those patients exhibiting a higher T-cell reactivity often demonstrated a worsening of at least one MRI endpoint (Gd lesion, Gd volume, new T2 count or progression to black holes) and one clinical endpoint (either relapse or EDSS). The converse also appears true with less T-cell reactivity implying less or no worsening of certain MRI and clinical endpoints.

Additionally, the immunology data shows that reactivity to all three of the key myelin proteins (MOG, PLP and MBP) was broadly present in study patients, which may be an important finding for the future treatment of MS. Opexa is also assessing which specific peptides from each of the proteins may provide the most relevant targets for the company to enhance its manufacturing process and further strengthen its intellectual property portfolio.

“Tovaxin seems to be demonstrating a benefit to these patients as indicated by immunology, MRI and clinical parameters,” stated Dr. Clyde Markowitz, associate professor of neurology and director of the MS center at the University of Pennsylvania School of Medicine. “This is interesting data and additional trials are certainly warranted to further explore the potential of this novel treatment.”

Previously reported top-line results from the TERMS study demonstrated that Tovaxin was safe and well tolerated with no serious adverse events related to treatment. The most common adverse event related to Tovaxin was mild injection site reaction. Continued analysis of safety and tolerability data has confirmed these top-line results with no serious adverse events observed in any Tovaxin-treated patients during the entire study.

“This landmark first-in-class study has yielded impressive results for Tovaxin in MS patients with high disease burden, including a marked reduction in disability, relapse risk and levels of T-cell reactivity. These findings are very encouraging and we are eager to continue the clinical development of this novel therapeutic,” commented Neil K. Warma, president and chief executive officer of Opexa Therapeutics. “There remains a tremendous unmet medical need for MS patients, and we believe a safe and effective patient-specific treatment may generate considerable interest among regulatory authorities, patients, physicians and potential strategic partners. With this in mind, we remain committed to aggressively pursuing our two primary objectives: the continued development of Tovaxin towards a pivotal Phase III trial and a high-value partnership for the Tovaxin program. With the MS market exceeding \$6 billion and growing, we believe Tovaxin is very competitively positioned from a safety, efficacy and patient compliance perspective.”

About Tovaxin

Tovaxin is an individualized T-cell therapeutic vaccine that consists of attenuated patient-specific myelin-reactive T-cells (MRTCs) against peptides of proteins from Myelin basic protein (MBP), Myelin oligodendrocyte glycoprotein (MOG) and Proteolipid protein (PLP) or combinations thereof. Tovaxin’s dual mechanism of action combats the demyelination of the nerve fibers in the central nervous system, the underlying cause of MS. Clinical results have demonstrated that Tovaxin produces the following therapeutic effects:

- Anti-idiotypic effect – Induces an immune response that depletes and regulates the circulating pathogenic myelin-reactive T-cells that attack the myelin sheath of nerve fibers.
- Anti-ergotypic effect – Rebalances the overall immune system by causing a shift from pathogenic inflammatory T-cells to anti-inflammatory T-cells.

Tovaxin is manufactured in Opexa’s in-house cGMP facility.

About the TERMS Study

The TERMS study was a Phase IIb multi-center, randomized, double blind, placebo-controlled trial in 150 patients with Relapsing-Remitting Multiple Sclerosis or high risk Clinically Isolated Syndrome (CIS). The study involved 2:1 randomization with 100 patients receiving Tovaxin and 50 receiving placebo. According to the study protocol, patients received a total of five subcutaneous injections at weeks 0, 4, 8, 12 and 24. The primary efficacy endpoint of the TERMS trial was the cumulative number of gadolinium-enhanced brain lesions (CELs) using MRI scans summed over weeks 28, 36, 44 and 52. The trial's secondary efficacy endpoints included annualized relapse rate (ARR), new CELs at weeks 28 through 52 and T2-weighted lesion volume compared to baseline.

Conference Call Information

Opexa will host a conference call on Thursday, October 23, 2008, at 8:30 a.m. Eastern Time to discuss this additional data from the TERMS study as well as the company's third quarter results.

The conference call can be accessed by dialing (800) 230-1092 from the U.S. and (651) 291-0618 internationally. Additionally a live webcast of the call will be available on Opexa's web site at www.opexatherapeutics.com. The webcast will be archived until November 22, 2008.

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About Opexa

Opexa Therapeutics develops and commercializes cell therapies to treat autoimmune diseases such as multiple sclerosis, rheumatoid arthritis and diabetes. The Company is focused on autologous cellular therapy applications of its proprietary T-cell and stem cell therapies. The Company's lead product is Tovaxin, a T-cell therapy for multiple sclerosis is in Phase IIb trials. The Company holds the exclusive worldwide license for adult multipotent stem cells derived from mononuclear cells of peripheral blood. The technology allows large quantities of monocyte-derived stem cells to be produced efficiently for use in autologous therapy, thus circumventing the threat of rejection. The Company is in preclinical development for diabetes mellitus. 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 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 collaborative relationships, 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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