

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 11/04/09 for the Period Ending 11/04/09

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): **November 4, 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 2.02 Results of Operations and Financial Condition

On November 4, 2009 Registrant filed its Quarterly Report on Form 10-Q for the quarter ended September 30, 2009. On November 4, 2009, Registrant 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 9.01. Financial Statements and Exhibits

(c) Exhibits

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 November 4, 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: November 3, 2009

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued November 4, 2009

Opexa Therapeutics Reports Third Quarter 2009 Financial Results and Corporate Update

THE WOODLANDS, Texas--(BUSINESS WIRE)--November 4, 2009-- **Opexa Therapeutics, Inc.** (NASDAQ: OPXA), a company developing a novel T-cell therapy for multiple sclerosis (MS), today reported financial results for the quarter ended September 30, 2009, and provided details on further developments.

Recent highlights include:

- 3rd quarter net income of \$2.2 million as a consequence of the gain on the sale of the Company's stem cell technology;
- Closing of sale of early stage adult stem cell technology to Novartis and achievement of first technology transfer milestone; and
- Receipt of approximately \$1.2 million in additional cash from warrant exercises before and after quarter end.

"As we move forward during the fourth quarter and look ahead to 2010, we are quite pleased with our overall situation, especially in comparison to our circumstances last year at this time," stated Neil K. Warma, president and chief executive officer of Opexa. "The Novartis stem cell transaction bolstered our financial resources and consequently leaves us with \$4.1 million in cash as of the end of October. The terms of the agreement allow Opexa to benefit considerably from progress in the stem cell technology's clinical development and potential commercial success in Novartis' capable hands. We have a very novel, late stage clinical asset in Tovaxin®, our autologous cellular immunotherapy treatment for MS – a current \$9 billion market with a still significant unmet medical need and currently served by several approved drug therapies. Our enthusiasm for Tovaxin comes not only from its attractive clinical efficacy but also from its very compelling risk/benefit relationship, an aspect of the regulatory approval pathway that is gaining increasing importance."

"In the weeks ahead, our primary focus will continue to be on advancing our ongoing partnership discussions around Tovaxin. At the same time, our strengthened financial position has provided us with the opportunity to become more aggressive and invest back into Tovaxin's clinical development as we prepare for the next clinical trial. Supporting this is the on-going analysis from the TERMS trial which has recently focused on the vast array of immunological data which is providing valuable insight into and support of Tovaxin's potential mechanism of action," continued Mr. Warma.

"2010 promises to be an exciting year for Opexa and we look forward to sharing developments with our various stakeholders as the year unfolds. We will continue our undeterred focus on what we believe to be one of the most promising therapies in development for MS. At our current burn rate, today's cash resources are sufficient to fund the company's operations through the 2010 calendar year," added Mr. Warma.

Third Quarter Financial Results

Opexa recorded no sales for the three months ended September 30, 2009 or in the comparable prior-year period.

Research and development expense was approximately \$0.5 million for the three months ended September 30, 2009, compared to approximately \$2.4 million for the three months ended September 30, 2008. The decrease in expenses was primarily due to the completion of the Phase IIb clinical trial in August 2008, closing the extension trial, a reduction in staff and a decrease in non-cash stock compensation expense.

General and administrative expense was approximately \$666,000 for the three months ended September 30, 2009, as compared to approximately \$661,000, for the three months ended September 30, 2008. The increase in expenses was due to a senior management bonus accrual and increased legal fees which were largely offset by a decrease in non-cash stock compensation expense, overhead expenses, board compensation fees and a reduction in staff.

Opexa recognized a gain on the sale of assets of \$3 million for the three months ended September 30, 2009. The gain is attributable to the sale of the Company's stem cell technology program to Novartis for an upfront payment of \$3 million.

Opexa recognized other income of \$0.5 million for the three months ended September 30, 2009 attributable to the completion of the initial \$0.5 million technology transfer fee milestone and pursuant to the terms of the stem cell technology acquisition agreement with Novartis. Payment was received subsequent to quarter end.

Opexa reported net income for the three months ended September 30, 2009, of approximately \$2.2 million, or \$0.18 per basic share and \$0.14 per diluted share, compared with a net loss of approximately \$3.1 million or \$0.28 per share (basic and diluted), for the three months ended September 30, 2008. The income in 2009 is attributable to the sale of the Company's stem cell technology program to Novartis for an upfront payment of \$3 million and a reduction of costs associated with the Phase IIb clinical trial of Tovaxin that was completed in 2008, a reduction in staff and a decrease in non-cash stock compensation expense.

The Company had cash and cash equivalents of approximately \$4 million as of September 30, 2009, compared with approximately \$1.2 million as of December 31, 2008. The September 30, 2009 quarter-end cash balance includes initial proceeds of \$3 million for the sale of the Company's stem cell technology program to Novartis but does not include a \$0.5 million payment from Novartis received subsequent to the end of the quarter for completing the first of two technology transfer milestones.

Year-to-Date Financial Results

Opexa recorded no sales in the nine months ended September 30, 2009 or in the comparable prior-year period.

Research and development expense was approximately \$1.7 million for the nine months ended September 30, 2009, compared to approximately \$7.1 million for the nine months ended September 30, 2008. The decrease in expenses was primarily due to the completion of the Phase IIb clinical trial in August 2008, closing the extension trial, a reduction in staff and a decrease in non-cash stock compensation expense.

General and administrative expense was approximately \$1.5 million for the nine months ended September 30, 2009, as compared to approximately \$2.7 million, for the nine months ended September 30, 2008. The decrease in expenses is due to a decrease in non-cash stock compensation expense, overhead expenses, professional service fees, board compensation fees and a reduction in staff.

Opexa recognized a gain on the sale of assets of \$3 million for the nine months ended September 30, 2009. The gain is attributable to the sale of the Company's stem cell technology program to Novartis for an upfront payment of \$3 million.

Opexa recognized other income of \$0.5 million for the nine months ended September 30, 2009 attributable to the completion of the initial \$0.5 million technology transfer fee milestone pursuant to the terms of the stem cell technology acquisition agreement with Novartis. Payment of \$0.5 million was received subsequent to quarter end.

Opexa recognized a non-cash loss on derivative instruments of \$366,774 for the nine months ended September 30, 2009. This loss is a result of the net unrealized (non-cash) change in the fair value of our derivative instrument liabilities related to warrants associated with the August 2008 financing which had been accounted for under FASB ASC 815 and which accounting treatment was discontinued on June 1, 2009.

Opexa reported a net loss for the nine months ended September 30, 2009, of approximately \$0.3 million, or \$0.02 per share (basic and diluted), compared with a net loss of approximately \$9.9 million or \$0.99 per share (basic and diluted), for the nine months ended September 30, 2008. The decrease in net loss is primarily due to the \$3 million gain on sale of technology, a reduction of costs associated with the Phase IIb clinical trial of Tovaxin that was completed in 2008, a reduction in staff and a decrease in non-cash stock compensation expense.

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 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, 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.

OPEXA THERAPEUTICS, INC.
(a development stage company)

Statements of Expenses Data:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Research and development	\$ 490,273	\$ 2,429,258	\$ 1,653,755	7,134,786
General and administrative	665,649	660,814	1,473,639	2,668,511
Depreciation and amortization	52,055	58,826	163,139	175,896
Loss on disposal of assets	1,771	-	1,771	116
Operating loss	(1,209,748)	(3,148,898)	(3,292,304)	(9,979,309)
Interest income	131	23,681	1,625	92,885
Other income and expense, net	500,000	-	500,000	34,901
Gain on extinguishment of debt	-	-	-	-
Gain (loss) on derivative instruments	-	-	(366,774)	-
Gain on sale of technology	3,000,000	-	3,000,000	-
Interest expense	(69,901)	(4,553)	(122,529)	(15,573)
Net gain/(loss)	<u>\$ 2,220,482</u>	<u>\$ (3,129,770)</u>	<u>\$ (279,982)</u>	<u>\$ (9,867,096)</u>
Net income (loss) per share				
Basic	\$ 0.18	\$ (0.28)	\$ (0.02)	\$ (0.99)
Diluted	\$ 0.14	\$ (0.28)	\$ (0.02)	\$ (0.99)
Weighted average shares outstanding				
Basic	12,354,942	11,370,527	12,282,619	9,977,831
Diluted	16,723,005	11,370,527	12,282,619	9,977,831

Selected Balance Sheet Data:

	September 30, 2009	December 31, 2008
Cash and cash equivalents	\$ 3,952,224	\$ 1,243,187
Accounts receivable	500,000	-
Other current assets	147,880	86,705
Fixed assets, net	1,001,621	1,166,530
Total assets	5,601,725	2,496,422
Total current liabilities	1,086,646	906,247
Total long term liabilities	992,788	102,778
Total stockholders' equity	3,522,291	1,487,397

CONTACT:

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