

OPEXA THERAPEUTICS, INC.

FORM 10-Q (Quarterly Report)

Filed 10/23/08 for the Period Ending 09/30/08

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

(Mark One)



QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Quarterly Period Ended September 30, 2008

or



TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Transition Period from _____ to _____

Commission File Number: 001-33004



Opexa Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Texas

(State or other jurisdiction of Incorporation or organization)

2635 North Crescent Ridge Drive
The Woodlands, Texas 77381

(Address of principal executive offices and zip code)

76-0333165

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

(281) 272-9331

Registrant's telephone number, including area code

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Accelerated filer ☐

Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 21, 2008, there were 12,263,558 shares of the issuer's Common Stock outstanding.

OPEXA THERAPEUTICS, INC.
(A development stage company)

For the Quarter Ended September 30, 2008

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

OPEXA THERAPEUTICS, INC. (a development stage company) BALANCE SHEETS (unaudited)

	September 30, 2008	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,044,082	\$ 2,645,482
Other current assets	180,240	355,266
Total current assets	4,224,322	3,000,748
Property & equipment, net of accumulated depreciation of \$789,766 and \$614,079 respectively	1,225,905	1,370,647
Total assets	<u>\$ 5,450,227</u>	<u>\$ 4,371,395</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 819,723	\$ 938,442
Accounts payable - related parties	134,597	54,091
Accrued expenses	1,050,480	1,022,461
Current maturity of loan payable	63,912	60,360
Total current liabilities	2,068,712	2,075,354
Long term liabilities:		
Loan payable	116,131	162,456
Total liabilities	<u>2,184,843</u>	<u>2,237,810</u>
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock, no par value, 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, \$0.50 par value, 100,000,000 shares authorized, 12,263,558 and 6,696,784 shares issued and outstanding	6,131,738	3,348,351
Additional paid in capital	84,713,562	76,498,054
Deficit accumulated during the development stage	(87,579,916)	(77,712,820)
Total stockholders' equity	3,265,384	2,133,585
Total liabilities and stockholders' equity	<u>\$ 5,450,227</u>	<u>\$ 4,371,395</u>

See accompanying notes to consolidated financial statements

OPEXA THERAPEUTICS, INC.
(a development stage company)
STATEMENTS OF EXPENSES
Three and nine months ended September 30, 2008 and 2007 and the
Period from January 22, 2003 (Inception) to September 30, 2008
(unaudited)

	Three Months Ended September 30, 2008	Three Months Ended September 30, 2007	Nine Months Ended September 30, 2008	Nine Months Ended September 30, 2007	Inception through September 30, 2008
Research and development	\$ 2,429,258	3,189,256	\$ 7,134,786	10,148,930	\$ 60,892,323
General and administrative	660,814	842,079	2,668,511	2,557,609	20,293,286
Depreciation and amortization	58,826	50,446	175,896	149,371	694,106
Loss on disposal of assets	-	-	116	4,034	495,617
Operating loss	(3,148,898)	(4,081,781)	(9,979,309)	(12,859,944)	(82,375,332)
Interest income	23,681	102,292	92,885	423,086	1,346,711
Other income	-	-	34,901	-	106,904
Gain on extinguishment of debt	-	1,612,440	-	1,612,440	1,612,440
Interest expense	(4,553)	(4,731)	(15,573)	(10,875)	(8,270,639)
Net loss	<u>\$ (3,129,770)</u>	<u>\$ (2,371,780)</u>	<u>\$ (9,867,096)</u>	<u>\$ (10,835,293)</u>	<u>\$ (87,579,916)</u>
Basic and diluted loss per share	\$ (0.28)	\$ (0.35)	\$ (0.99)	\$ (1.62)	N/A
Weighted average shares outstanding	11,370,527	6,696,784	9,977,831	6,696,784	N/A

See accompanying notes to consolidated financial statements

OPEXA THERAPEUTICS, INC.
(a development stage company)
STATEMENTS OF CASH FLOWS
Nine months ended September 30, 2008 and 2007 and the
Period from January 22, 2003 (Inception) to September 30, 2008
(unaudited)

	Nine Months Ended September 30,		Inception through September 30, 2008
	2008	2007	2008
Cash flows from operating activities			
Net loss	\$ (9,867,096)	\$ (10,835,293)	\$ (87,579,916)
Adjustments to reconcile net loss to net cash used in operating activities			
Stock payable for acquired research and development	-	-	112,440
Stock issued for acquired research and development	-	-	26,286,589
Stock issued for services	68,561	-	1,929,961
Stock issued for debt in excess of principal	-	-	109,070
Amortization of discount on notes payable due to warrants and beneficial conversion feature	-	-	6,313,205
Realized gain on marketable securities	-	25,912	-
Gain on extinguishment of debt	-	(1,612,440)	(1,612,440)
Depreciation	175,896	149,371	694,106
Debt financing costs	-	-	365,910
Option expense	1,675,891	2,086,911	13,700,814
Loss on disposition of fixed assets	116	4,034	495,617
Changes in:			
Marketable securities	-	2,926,184	-
Prepaid and other expenses	175,026	87,164	(596,913)
Accounts payable	(38,213)	358,018	504,679
Accrued expenses	28,019	656,065	923,826
Net cash used in operating activities	<u>(7,781,800)</u>	<u>(6,154,074)</u>	<u>(38,353,052)</u>
Cash flows from investing activities			
Purchase of property & equipment	(31,270)	(147,782)	(1,337,741)
Net cash used in investing activities	<u>(31,270)</u>	<u>(147,782)</u>	<u>(1,337,741)</u>
Cash flows from financing activities			
Common stock sold for cash, net of offering costs	9,254,443	-	35,764,180
Common stock repurchased and canceled	-	-	(325)
Proceeds from debt	-	137,286	8,102,199
Repayments on notes payable	(42,773)	(11,045)	(131,179)
Net cash provided by financing activities	<u>9,211,670</u>	<u>126,241</u>	<u>43,734,875</u>
Net change in cash and cash equivalents	1,398,600	(6,175,615)	4,044,082
Cash and cash equivalents at beginning of period	2,645,482	12,019,914	-
Cash and cash equivalents at end of period	<u>\$ 4,044,082</u>	<u>\$ 5,844,299</u>	<u>\$ 4,044,082</u>

Cash paid for:

Income tax	\$	-	\$	-	\$	-
Interest		15,573		16,103		42,714

NON-CASH TRANSACTIONS

Issuance of common stock to Sportan shareholders	-	-	147,733
Issuance of common stock for accrued interest	-	-	525,513
Conversion of notes payable to common stock	-	-	6,407,980
Conversion of accrued liabilities to common stock	-	-	197,176
Conversion of accounts payable to note payable	-	-	93,364
Discount on convertible notes relating to:			
- warrants	-	-	3,309,790
- beneficial conversion feature	-	-	1,715,973
- stock attached to notes	-	-	1,287,440
Reclassification of derivative liabilities	-	6,656,677	-

See accompanying notes to consolidated financial statements

OPEXA THERAPEUTICS, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS
(unaudited)

Note 1. Basis of Presentation

The accompanying unaudited interim financial statements of Opexa Therapeutics, Inc., a development stage company, have been prepared in accordance with accounting principles generally accepted in the United States of America and the rules of the Securities and Exchange Commission and should be read in conjunction with the audited financial statements and notes thereto contained in Opexa's latest Annual Report filed with the SEC on Form 10-K. In the opinion of management, all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of financial position and the results of operations for the interim periods presented have been reflected herein. The results of operations for interim periods are not necessarily indicative of the results to be expected for the full year. Notes to the financial statements that would substantially duplicate the disclosure contained in the audited financial statements for the most recent fiscal year as reported in Form 10-K, have been omitted.

Note 2. Going Concern

Opexa incurred a net loss of approximately \$9.9 million for the nine months ended September 30, 2008 and has an accumulated deficit of approximately \$87.6 million. The cash balance of approximately \$4.0 million as of September 30, 2008 is not sufficient to fund our operations for the next twelve months if we are to execute our operating plan including completing our analysis of our Phase IIb clinical trial of Tovaxin[®] for the treatment of multiple sclerosis ("MS"), conducting the open label extension of our Phase IIb clinical trial of Tovaxin and continuing with the development of Tovaxin. These conditions raise substantial doubt as to Opexa's ability to continue as a going concern. Management continues to seek means to raise additional capital through sales of equity and/or partnering arrangements related to our technology. The financial statements do not include any adjustments that might be necessary if Opexa is unable to continue as a going concern.

Note 3. Marketable Securities

Opexa considers all highly liquid investments with an original maturity of three months or less, when purchased, to be cash equivalents. Investments with maturities in excess of three months but less than one year are classified as short-term investments and are stated at fair market value.

At September 30, 2008, Opexa invested approximately \$4.0 million in a money market account with an average market yield of 2.8%. Interest income of \$92,885 was recognized for the nine months ended September 30, 2008 in the statements of expenses. As of September 30, 2008, the Company held no auction rate securities.

Note 4. Commitments and Contingencies

In September 2006, Opexa entered into an Individual Project Agreement (IPA) with PharmaNet, LLC (PharmaNet), a contract research organization focused on managing central nervous system clinical trials. Pursuant to such IPA, PharmaNet, LLC will provide Opexa with services in connection with its Phase IIb clinical trial. Under the terms of the IPA, Opexa is required to advance funds for investigator grants, professional fees and out of pocket expenses. In March 2008, PharmaNet agreed to waive the investigator grant advance requirement and in return Opexa will pay the invoice in full within 30 days of receipt. In June 2008, PharmaNet agreed to revise the professional fee advance to \$233,000 to be applied 1/8th per month to invoices for the months of May through December 2008. PharmaNet will continue to hold a \$60,000 advance for out-of-pocket expenses. At the conclusion of the program, advance balances remaining will be applied to outstanding invoices. These advances are treated as prepaid items and included in the other current assets section of the balance sheet. As of September 30, 2008, the advance balance to PharmaNet, LLC was \$114,568.

In July 2007, Opexa entered into a seconded amended and restated license agreement with the University of Chicago that requires Opexa to make milestone payments of up to \$1,350,000 if certain late stage clinical trial and FDA approval milestones are achieved. Opexa has determined that these payments are not probable at this time and thus no liability has been recorded as of September 30, 2008.

Note 5. Loan Payable

Loan payable consists of an equipment line of \$250,000 with Wells Fargo Bank of which \$180,042 was outstanding as of September 30, 2008. This loan has an interest rate of 7.61% per annum, matures in May 2011 and is secured by Opexa's furniture and equipment purchased with the loan proceeds. Payments are due and payable monthly on the same day of each month until maturity.

Note 6. Equity

In February, 2008, Opexa entered into an Underwriting Agreement with MDB Capital Group LLC, for itself and as representative of several underwriters, relating to the public offering of 3,500,000 shares of Opexa's common stock and 3,500,000 Series E warrants, each warrant to purchase one share of common stock at an exercise price of \$2.00 per share. Pursuant to the Underwriting Agreement, Opexa granted the underwriters a 30-day option to purchase up to an additional 525,000 shares of common stock and 525,000 warrants to cover over-allotments. The closing for the sale of shares of common stock and warrants took place in February 2008. The underwriters exercised their over-allotment option as to the warrants only, and Opexa sold an aggregate of 3,500,000 shares and 4,025,000 warrants.

The public offering price for each share was \$2.00, and the public offering price for each warrant was \$0.15. Each share and each warrant was sold to the underwriters at the public offering price of each security less an underwriting discount of 10%. The Company received approximately \$7.6 million in gross proceeds from the offering. The Company also paid the underwriters 1% of the gross proceeds of the offering (excluding the over-allotment option) as an expense allowance. The net proceeds to Opexa, after underwriter discounts, commissions and other expenses, was approximately \$6.4 million. As additional compensation, the Company issued warrants to the underwriter to purchase 350,000 shares of common stock at a price of \$2.40 per share and an option to acquire 350,000 Series E warrants at a price of \$0.18 per Series E warrant.

On August 11, 2008, Opexa closed a financing transaction in which Opexa issued 2,003,874 shares of its common stock and warrants to purchase 2,003,874 shares of Opexa's common stock (the "Unit") for gross proceeds of approximately \$3.0 million to certain institutional and accredited investors (the "Transaction"). The net proceeds to Opexa, after offering costs, was approximately \$2.9 million. The purchase price paid by non-affiliate investors was \$1.48 for each Unit and with regard to affiliate investors was \$1.655 for each Unit. The warrants expire in four years, are first exercisable after six months of the closing of the Transaction and are exercisable at \$1.78 per share. The shares are exercisable on a cashless basis. If Opexa fails to register, achieve effectiveness of registration or maintain effectiveness of registration of shares underlying the warrants and shares, they are required to make certain liquidated damage payments of 1% of the offering per month for every month in default with a maximum of 6%. 2,003,874 warrants were issued to investors in connection with the Transaction. Opexa evaluated the application of FASB Staff Positions FSP EITF 00-19-2 "Accounting for Registration Payment Arrangements", which addresses an issuer's accounting for registration payment arrangements, and determined that the warrants issued in the Transaction should be classified as equity. In addition, Opexa accounts for registration rights agreement penalties as contingent liabilities, applying the accounting guidance of Financial Accounting Standard No. 5, "Accounting for Contingencies" ("FAS 5"). This accounting is consistent with views established by the FASB Staff Positions FSP EITF 00-19-2. Accordingly, Opexa recognizes the damages when it becomes probable that they will be incurred and amounts are reasonably estimable. No liability has been recorded.

No commissions or fees to placement agents were paid in connection with the Transaction.

Note 7. Options

Share-based Compensation:

The June 2004 Compensatory Stock Option Plan authorizes the issuance of various forms of stock-based awards, including incentive and non-statutory stock options, stock purchase rights, stock appreciation rights, and restricted and unrestricted stock awards. A total of 2,300,000 shares are authorized to be issued under the Plan through June, 2014. At September 30, 2008, 1,674,475 shares were issued.

The Company accounts for share-based compensation, including options and nonvested shares, according to the provisions of SFAS No. 123R, "Share Based Payment". During the three and nine-month periods ended September 30, 2008, the Company recognized share-based compensation expense of approximately \$0.3 million and \$1.7 million respectively. Activity in options and restricted stock during the nine-month period ended September 30, 2008 and related balances outstanding as of that date are reflected below. The weighted average fair value per share of options granted to employees for the nine-month period ended September 30, 2008 was approximately \$0.92.

A summary of share-based compensation activity for the nine-month period ended September 30, 2008 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contract Term	Intrinsic Value
Outstanding at January 1, 2008	1,039,525	\$ 9.31		
Granted	703,300	1.12		
Exercised	-	-		
Forfeited or canceled	(68,350)	8.17		
Outstanding at September 30, 2008 ¹	1,674,475	\$ 5.92	7.73	-
Exercisable at September 30, 2008	1,017,861	\$ 8.21	6.73	-

Stock Option Activity:

Stock option awards issued by the Company have a ten year life and have various vesting dates that range from partial vesting upon date of grant to full vesting on a specified date, quarterly vesting on the anniversary date of hire and quarterly vesting on the anniversary date of grant. The Company estimates the fair value of stock options using the Black-Scholes option-pricing model and records the compensation expense ratably over the service period.

The fair values of stock options granted during the nine months ended September 30, 2008 and 2007 were estimated using the following assumptions:

	Nine Months Ended September 30, 2008	Nine Months Ended September 30, 2007
Expected Volatility	115.28% - 116.51%	95.36% - 103.91%
Expected term	6 years	5 - 6 years
Risk free rate	3.07% - 3.73%	4.20% - 5.07%
Expected dividends	0.00%	0.00%

Restricted Stock:

The Company grants restricted stock to employees and directors that entitle the holders to receive shares of the Company's common stock upon the fulfillment of certain service and/or performance conditions. The fair value of restricted stock is based on the market price of the Company's stock on the date of grant and is recorded as compensation expense ratably over the service period.

A summary of restricted stock activity for the nine months ended September 30, 2008 follows:

Restricted Stock	Number of Shares
Nonvested at January 1, 2008	-
Granted	62,900
Vested	(25,700)
Forfeited	-
Nonvested at September 30, 2008	37,200

Note 8. Warrants

In connection with the closing of our February 2008 public offering of common shares, the investors were issued five-year warrants to purchase up to an aggregate of 4,025,000 shares of our common stock, at an initial exercise price of \$2.00 per share and a market price of \$0.15 per warrant was used to assign fair value of the warrants for a total fair value of \$603,750.

As additional compensation, the Company issued warrants to the underwriter to purchase 350,000 shares of common stock at a price of \$2.40 per share and an option to acquire 350,000 Series E warrants at a price of \$0.18 per Series E warrant. The estimated fair value of the underwriter warrants was \$319,436 and was calculated using the Black-Scholes valuation model. The following assumptions were used: (i) no expected dividends, (ii) risk free interest rate of 2.93%, (iii) expected volatility of 97.67%, and (iv) expected life of 3 years.

The fair value of warrants granted in the first quarter of 2008 was included in additional paid-in capital along with the proceeds from issuance of common stock.

In connection with the closing of our August 2008 private financing of common shares, the investors were issued four-year warrants to purchase up to an aggregate of 2,003,874 shares of our common stock, at an initial exercise price of \$1.78 per share. The warrants expire in four years, are first exercisable after six months of the closing of the Transaction and are exercisable on a cashless basis. \$1,976,457 fair value was assigned to the Series F Warrants and was included in additional paid-in capital along with the proceeds from issuance of common stock.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read in conjunction with the accompanying financial statements and the related footnotes thereto.

Forward-Looking Statements

Some of the statements contained in this report discuss future expectations, contain projections of results of operations or financial condition, or state other "forward-looking" information. The words "believe," "intend," "plan," "expect," "anticipate," "estimate," "project," "goal" and similar expressions identify such statement was made. These statements are subject to known and unknown risks, uncertainties, and other factors that could cause the actual results to differ materially from those contemplated by the statements. The forward-looking information is based on various factors and is derived using numerous assumptions. Factors that might cause or contribute to such a discrepancy include, but are not limited to the risks discussed in this and our other SEC filings. We do not promise to update forward-looking information to reflect actual results or changes in assumptions or other factors that could affect those statements. Future events and actual results could differ materially from those expressed in, contemplated by, or underlying such forward-looking statements.

The following discussion and analysis of our financial condition is as of September 30, 2008. Our results of operations and cash flows should be read in conjunction with our unaudited financial statements and notes thereto included elsewhere in this report and the audited financial statements and the notes thereto included in our Form 10-K for the year ended December 31, 2007.

Business Overview

Unless otherwise indicated, we use "Opexa," "the Company," "we," "our" and "us" in this annual report to refer to the businesses of Opexa Therapeutics, Inc.

We are a biopharmaceutical company developing autologous cellular therapies to treat several major illnesses, including multiple sclerosis (MS) and diabetes. These therapies are based on our proprietary T-cell and adult stem cell technologies. The information discussed related to our product candidates is preliminary and investigative. Our product candidates are not approved by the Food and Drug Administration (FDA).

Our lead product, Tovaxin[®], is a T-cell based therapeutic vaccine for MS licensed from the Baylor College of Medicine, which offers a unique and personalized approach to treating the disease by inducing an immune response against the autoimmune myelin peptide-reactive T-cells (MRTCs), which are believed to be responsible for the initiation of the disease process.

T-Cell Therapy

We have an exclusive worldwide license from Baylor College of Medicine to an individualized T-cell therapeutic vaccine, Tovaxin, which has recently been studied in a United States (U.S.) FDA Phase IIb human clinical trial to evaluate its safety and effectiveness in treating MS.

MS is the result of a person's own T-cells attacking the myelin sheath that coats the nerve cells of the central nervous system. Tovaxin consists of attenuated patient-specific myelin reactive T-cells (MRTCs) against peptides from one or more of the primary proteins on the surface of the myelin sheath (myelin basic protein, proteolipid protein, and myelin oligodendrocyte glycoprotein). Patient-specific MRTCs are expanded in culture with specific peptides identified by our proprietary test of the patient's peripheral blood. The cells are then attenuated by gamma irradiation, and returned to the patient as a subcutaneous injection. Although further testing is necessary, results from our initial human trials appear to indicate that these attenuated T-cells cause an immune response directed at the autoreactive T-cells in the patient's body, resulting in a reduction in the level of harmful T-cells.

We believe that our initial human trials suggest that Tovaxin safely induces the depletion and regulation of MRTCs, possibly stabilizing the disease, reducing the annualized relapse rate, and potentially improving the disability scores of patients. Patients treated in a 10-subject, open-label Phase I/II dose escalation clinical trial with Tovaxin have experienced minimal side effects and the "per protocol" analysis of patients treated with Tovaxin achieved a 90% reduction ($p=0.0039$) in annualized relapse rate (ARR). The group treated with the mid dose ($30-45 \times 10^6$ attenuated T-cells) achieved a 100% reduction in ARR. The Phase IIb trial was conducted with the mid dose.

In a one-year, 8-subject extension clinical trial of relapsing remitting and secondary progressive multiple sclerosis subjects, the “per-protocol” analysis of Tovaxin therapy achieved a 92% (p=0.0078) reduction ARR in subjects who received two treatment doses of $30\text{--}45 \times 10^6$ attenuated T-cells eight weeks apart and were monitored for an additional 44 weeks. Subjects in the extension study had previously been treated an average of approximately 5 years earlier at Baylor College of Medicine under the direction of the inventor of Tovaxin Jingwu Zhang, M.D., Ph.D with an early version of the T-cell vaccine.

An analysis of the second year open-label clinical retreatment studies of the “intent to treat” population of 22 patients who participated in the Phase I/II studies showed that, as a group, 73% remained relapse free after two years and 86% demonstrated no worsening of disease (27% of these showed sustained improvement). Additionally, there was an overall decrease in the ARR of 82% (from 1.38 to 0.21 relapses/patient/year). Each of these endpoints was compared to the patient’s own baseline reading, taken prior to enrollment in the trials.

We recently completed a Phase IIb study in 150 patients in a multi-center, randomized, double blind, and placebo-controlled study in patients with relapsing remitting multiple sclerosis or clinically isolated syndrome. Top-line results from the study demonstrated a positive trend in the reduction in annualized relapse rate (ARR) for patients treated with Tovaxin as compared to placebo. However, this finding did not achieve statistical significance. In addition, the study did not achieve statistical significance with its primary endpoint, the cumulative number of gadolinium-enhanced brain lesions.

Top-line results from the study showed that Tovaxin-treated patients experienced an ARR of 0.214 as compared to 0.339 for placebo-treated patients. Despite the low relapse rate in the placebo arm, this still represented a 37 percent decrease in ARR for Tovaxin as compared to placebo in the general population. Additionally, in the group of patients who had an ARR > 1 in the one year prior to study entry, Tovaxin demonstrated a 55 percent reduction in ARR compared to placebo.

The study also 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. We believe that this favorable safety profile may be an important advantage as patient compliance represents a significant challenge due to serious side effects associated with many currently available MS treatments.

Stem Cell Therapy

We have developed a proprietary adult stem cell technology to produce monocyte-derived stem cells (MDSCs) from blood. These MDSCs can be derived from a patient’s monocytes, expanded in our laboratories, and then administered to the same patient. We believe that because this is an autologous therapy, there should be no immunological problems. Normally, allogenic cells trigger host immune responses and require the use of anti-rejection drugs.

Our multi-potent stem cell is derived from peripheral blood monocytes which when cultured under defined conditions are able to further differentiate into several cellular lineages. Molecular biology and cellular analysis studies have shown that these MDSCs have specific markers that distinguish them from other stem cells. In addition these studies have also shown a time-dependence for the expression of these markers during the growth and differentiation of MDSCs. *In vitro* experiments with MDSCs have shown their capacity to differentiate as hematopoietic, epithelial, endothelial, endocrine and neuronal cells. Our main focus is the further development of this monocyte-derived stem cell technology as a platform for the *in vitro* generation of highly specialized cells for potential application in autologous cell therapy for patients with diseases such as diabetes mellitus and cardiovascular disease.

Other Opportunities

We may conduct basic research to determine the potential use of stem cells and differentiated cells in other indications, such as macular degeneration, stroke, myocardial infarction, wound healing and Parkinson’s disease. We will attempt to partner or sublicense some of these indications if they are not pursued for internal development. For those indications where we believe we can participate commercially, we also desire to partner in key commercial markets outside of the U.S.

Critical Accounting Policies

General

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The Company’s significant accounting policies are disclosed in the Company’s Annual Report on Form 10-K for the year ended December 31, 2007. The Company has not materially changed its significant accounting policies.

Results of Operations and Financial Condition

Three Months Ended September 30, 2008 Compared with the Three Months Ended September 30, 2007

Net Sales. We recorded no sales for the three months ended September 30, 2008 and 2007.

Research and Development Expenses. Research and development expense was 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. We have made and expect to continue to make substantial investments in research and development in order to develop and market our technology. We expense research and development costs as incurred. Acquired research and development that has no alternative future use is expensed when acquired. Property, plant and equipment for research and development that has an alternative future use is capitalized and the related depreciation is expensed. We expect our research and development expense to increase as we continue to invest in the development of our technology.

General and Administrative Expenses. Our general and administrative expense was 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. We anticipate increases in general and administrative expenses as we continue to develop and expand our product platforms.

Interest Expense. Interest expense was \$4,553 for the three months ended September 30, 2008, compared to \$4,731 for the three months ended September 30, 2007

Interest Income. Interest income was \$23,681 for the three months ended September 30, 2008 compared to \$102,292 for the three months ended September 30, 2007. The decrease was due to the reduction in cash balances that were available for investment in cash equivalent investments and a reduction in interest rates.

Net loss. We had a net loss for the three months ended September 30, 2008, of approximately \$3.1 million, or \$0.28 per share (basic and diluted), compared with a net loss of approximately \$2.4 million or \$0.35 per share (basic and diluted), for the three months ended September 30, 2007.

Nine Months Ended September 30, 2008 Compared with the Nine Months Ended September 30, 2007

Net Sales. We recorded no sales for the nine months ended September 30, 2008 and 2007.

Research and Development Expenses. Research and development expense was 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. Our general and administrative expense was 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.

Interest Expense. Interest expense was \$15,573 for the nine months ended September 30, 2008, compared to \$10,875 for the nine months ended September 30, 2007

Interest Income. Interest income was \$92,885 for the nine months ended September 30, 2008 compared to \$423,086 for the nine months ended September 30, 2007. The decrease was due to the reduction in cash balances that were available for investment in cash equivalent investments and a reduction in interest rates.

Net loss. We had a net loss for the nine months ended September 30, 2008, of approximately \$9.9 million or \$0.99 per share (basic and diluted), compared with a net loss of approximately \$10.8 million or 1.62 per share (basic and diluted), for the nine months ended September 30, 2007.

Liquidity and Capital Resources

Changes in cash flow. Cash used in operations for the nine month period ended September 30, 2008 was approximately \$7.8 million as compared to cash used by operations of approximately \$6.2 million for the nine months ended September 30, 2007. The increase in cash used in operations is primarily due to the maturity of approximately \$2.9 million in marketable securities in 2007 and its reclassification to cash and cash equivalents. Cash used in investing activities for the nine month period ended September 30, 2008 was approximately \$31,000, as compared to approximately \$148,000 for the nine months ended September 30, 2007. The decrease was due to a decrease in equipment purchases. Cash provided from financing activities for the nine month period ended September 30, 2008 was approximately \$9.2 million,, as compared to approximately \$126,000 for the nine months ended September 30, 2007. The increase was due to the proceeds from the February 2008 public offering and the August 2008 private placement.

Liquidity . Historically, we have financed its operations primarily from the sale of its debt and equity securities. As of September 30, 2008, we had cash and cash equivalents of approximately \$4.0 million.

Our financing activities generated approximately \$9.3 million in net proceeds for the nine months ended September 30, 2008 and resulted from the a public offering in February 2008 of 3,500,000 shares of common stock at a price to the public of \$2.00 per share and 4,025,000 Series E warrants to purchase shares of common stock exercisable at \$2.00 per share at a price of \$0.15 per warrant; and a private placement in August 2008 in which 2,003,874 shares of common stock and warrants to purchase 2,003,874 shares of common stock (the "Unit") at an initial exercise price of \$1.78 per share were issued. The purchase price paid by non-affiliate investors was \$1.48 for each Unit and affiliate investors paid \$1.655 for each Unit.

Our current burn rate is approximately \$900,000 per month. Our capital resources at September 30, 2008, will support our operations at current levels through the fourth quarter of 2008. We will need to raise additional capital in the fourth quarter of 2008 to fund our business plan and support our operations beyond the beginning of the first quarter of 2009. As our prospects for funding, if any, develop during the next quarter, we will assess our business plan and make adjustments accordingly. We are actively seeking strategic partnership or collaboration arrangements with companies for our technologies. While we have successfully funded our operations to date by attracting additional investors in our equity, there is no assurance that our capital raising efforts will be able to attract additional necessary capital for our operations. If we are unable to obtain additional funding for operations at any time now or in the future, we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations.

Off-Balance Sheet Arrangements

As of September 30, 2008, we had no off-balance sheet arrangements.

Recent Accounting Pronouncements

For the period ended September 30, 2008, there were no other changes to our critical accounting policies as identified in our annual report of Form 10-K for the year ended December 31, 2007.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not Applicable.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit to the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified by the Securities and Exchange Commission's rules and forms, and that information is accumulated and communicated to our management, including our principal executive and principal financial officers (whom we refer to in this periodic report as our Certifying Officers), as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Certifying Officers, the effectiveness of our disclosure controls and procedures as of September 30, 2008, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of September 30, 2008, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting that occurred during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We will continue to evaluate the effectiveness of internal controls and procedures on an on-going basis.

PART II

OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

This Item 1A should be read in conjunction with "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

We will need additional capital to conduct our operations and develop our products and our ability to obtain the necessary funding is uncertain.

We need to obtain significant amounts of additional capital to develop our products and continue our business. The capital may come from many sources, including equity and/or debt financings, license arrangements, grants and/or strategic collaborative or partnership arrangements. As of September 30, 2008, we had cash and cash equivalents of approximately \$4.0 million. Our current burn rate is approximately \$900,000 per month. We will need to raise additional capital to fund our working capital needs beyond early first quarter of 2009. We must rely upon third-party debt, equity funding or collaboration or partnership arrangements and we can provide no assurance that we will be successful in any funding effort. The failure to raise such funds will necessitate the curtailment or ceasing of operations and impact the conduct of our clinical trials.

We do not have any committed sources of capital, although we have issued and outstanding warrants that, if exercised, would result in an equity capital raising transaction. Additional financing through strategic collaborations, public or private equity financings, capital lease transactions or other financing sources may not be available on acceptable terms, or at all. Additional equity financings could result in significant dilution to our stockholders. Further, if additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize ourselves. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse effect on our financial condition or business prospects.

We have a "going-concern qualification" which may make capital raising more difficult and may require us to scale back or cease operations.

The report of our independent auditors in respect of the 2007 fiscal year includes a going concern qualification which indicates an absence of obvious or reasonably assured sources of future funding that will be required by us to maintain ongoing operations. Although we have successfully funded Opexa, to date, by attracting additional investors in our equity, there is no assurance that our capital raising efforts will be able to attract the additional capital needed to sustain our operations. The going concern qualification from our auditors may make it more difficult for us to raise funds. If we are unable to obtain additional funding for operations, we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations. In such event, investors may lose a portion or all of their investment.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On August 11, 2008, Opexa closed a financing transaction in which Opexa issued 2,003,874 shares of its common stock and warrants to purchase 2,003,874 shares of Opexa's common stock for gross proceeds of approximately \$3.0 million (the "Unit") to certain institutional and accredited investors (the "Transaction"). The purchase price paid by non-affiliate investors was \$1.48 for each Unit and with regard to the Affiliate Investors was \$1.655 for each Unit. The warrants expire in four years, are first exercisable after nine months of the closing of the Transaction and are exercisable at \$1.78 per share. The shares are exercisable on a cashless basis. If Opexa fails to register, achieve effectiveness of registration or maintain effectiveness of registration of shares underlying the warrants and shares, they are required to make certain liquidated damage payments of 1% of the offering per month for every month in default with a maximum of 6%.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Submission of Matters to a Vote of Security Holders.

(a) Annual Meeting of Shareholders.

On September 26, 2008 the Company held its 2008 Annual Meeting of Shareholders and the shareholders approved several items detailed in the Proxy Statement previously filed with the Commission.

(b) Election of Board of Directors.

The following nominees were elected as directors by the shareholders at the 2008 Annual Meeting:

Gregory H. Bailey	Lorin J. Randall
David Hung	Michael S. Richman
David E. Jorden	Scott B. Seaman
David B. McWilliams	Neil K. Warma

(c) Proposals Voted Upon and Shareholder Vote.

The shareholders voted to (i) elect eight (8) Directors to the Company's Board of Directors to hold office until the next annual meeting of shareholders or until their respective successors are duly elected and qualified; (ii) amend the Company's June 2004 Compensatory Stock Option Plan to increase the number of shares of common stock authorized for issuance under the Plan from a total of 1,200,000 shares to a total of 2,300,000 shares; and (iii) ratify the selection by the Audit Committee of Malone & Bailey, PC as the independent auditors of the Company for the fiscal year ending December 31, 2008. A total of 8,057,096 shares were voted representing 65.7% of the outstanding shares. The votes cast for and against each of the above-described three proposals are listed in the tables below.

Proposal #1 - Election of Each of the Nominated Directors:

<u>Directors:</u>	<u>For</u>	<u>Against</u>	<u>Abstain</u>	<u>Totals</u>
Gregory H. Bailey	8,041,279	11,355	4,462	8,057,096
David Hung	8,041,541	11,213	4,342	8,057,096
David E. Jorden	8,045,466	7,158	4,472	8,057,096
David B. McWilliams	8,044,286	9,353	3,457	8,057,096
Lorin J. Randall	8,045,596	7,158	4,342	8,057,096
Michael S. Richman	8,045,596	7,016	4,484	8,057,096
Scott B. Seaman	8,041,421	11,213	4,462	8,057,096
Neil K. Warma	8,044,166	8,888	4,042	8,057,096

Proposal # 2 – Amendment to 2004 Compensatory Stock Option Plan:

For	Against	Abstain	Totals
7,698,239	344,705	14,152	8,057,096

Proposal #3 - Ratification of Appointment of Auditor:

For	Against	Abstain	Totals
8,041,647	828	14,621	8,057,096

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit 31.1*	Chief Executive Officer Certification Pursuant to Section 13a-14 of the Securities Exchange Act
Exhibit 31.2*	Chief Financial Officer Certification Pursuant to Section 13a-14 of the Securities Exchange Act
Exhibit 32.1*	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes- Oxley Act of 2002
Exhibit 32.2*	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes- Oxley Act of 2002

* Filed herewith

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

OPEXA THERAPEUTICS, INC.

Date: October 22, 2008

By: /s/ NEIL K. WARMA

Neil K. Warma

President and Chief Executive Officer

Date: October 22, 2008

By: /s/ LYNNE HOHLFELD

Lynne Hohlfeld

Chief Financial Officer and Principal Accounting Officer

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT**

I, Neil K. Warma, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Opexa Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 22, 2008

By: /s/Neil K. Warma

Neil K. Warma

President and Chief Executive Officer

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT**

I, Lynne Hohlfeld, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Opexa Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 22, 2008

By: /s/Lynne Hohlfeld

Lynne Hohlfeld

Chief Financial Officer and Principal Accounting Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Opexa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2008, (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Neil K. Warma, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 22, 2008

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

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Opexa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2008, (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Lynne Hohlfeld, Chief Financial Officer and Principal Accounting Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 22, 2008

By: /s/Lynne Hohlfeld

Lynne Hohlfeld

Chief Financial Officer and Principal Accounting Officer