

OPEXA THERAPEUTICS, INC.

FORM 10-Q (Quarterly Report)

Filed 05/13/10 for the Period Ending 03/31/10

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
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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 March 31, 2010

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☐ 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 ☐

Accelerated filer ☐

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

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 May 10, 2010, there were 15,618,823 shares of the issuer's Common Stock outstanding.

OPEXA THERAPEUTICS, INC.
(A development stage company)

For the Quarter Ended March 31, 2010

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	March 31, 2010	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,092,036	\$ 8,181,582
Other current assets	199,117	187,306
Total current assets	7,291,153	8,368,888
Property & equipment, net of accumulated depreciation of \$1,078,887 and \$1,029,241, respectively	900,264	949,910
Total assets	<u>\$ 8,191,417</u>	<u>\$ 9,318,798</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 489,316	\$ 593,011
Accounts payable - related parties	15,000	32,591
Accrued expenses	328,223	141,065
Current maturity of loan payable	68,619	67,307
Total current liabilities	901,158	833,974
Long term liabilities:		
Convertible promissory notes, net of discount of \$263,583 and \$314,749 respectively	1,038,417	987,251
Loan payable	17,961	35,625
Accrued interest	118,904	86,800
Total liabilities	<u>2,076,440</u>	<u>1,943,650</u>
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock, no par value, 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, \$0.01 par value, 100,000,000 shares authorized, 15,588,823 and 15,476,222 shares issued and outstanding	155,888	154,762
Additional paid in capital	96,624,856	96,463,658
Deficit accumulated during the development stage	(90,665,767)	(89,243,272)
Total stockholders' equity	6,114,977	7,375,148
Total liabilities and stockholders' equity	<u>\$ 8,191,417</u>	<u>\$ 9,318,798</u>

See accompanying notes to financial statements

OPEXA THERAPEUTICS, INC.
(a development stage company)
STATEMENTS OF EXPENSES
Three months ended March 31, 2010 and 2009 and the
Period from January 22, 2003 (Inception) to March 31, 2010
(unaudited)

	Three Months Ended March 31,		Inception through March 31, 2010
	2010	2009	
Research and development	\$ 783,534	\$ 737,778	\$ 65,037,638
General and administrative	484,425	396,315	23,471,187
Depreciation and amortization	49,646	57,378	1,017,032
Loss on disposal of assets	-	-	500,103
Operating loss	(1,317,605)	(1,191,471)	(90,025,960)
Interest income	185	1,109	1,356,010
Other income and expense, net	-	-	661,146
Gain on extinguishment of debt	-	-	1,612,440
Gain (loss) on derivative instruments	-	(440,980)	1,388,848
Gain on sale of technology	-	-	3,000,000
Interest expense	(105,075)	(5,627)	(8,658,251)
Net loss	<u>\$ (1,422,495)</u>	<u>\$ (1,636,969)</u>	<u>\$ (90,665,767)</u>
Basic and diluted loss per share	\$ (0.09)	\$ (0.13)	
Weighted average shares outstanding	15,523,710	12,245,858	

See accompanying notes to financial statements

OPEXA THERAPEUTICS, INC.
(a development stage company)
STATEMENTS OF CASH FLOWS
Three months ended March 31, 2010 and 2009 and the
Period from January 22, 2003 (Inception) to March 31, 2010
(unaudited)

	Three Months Ended March 31,		Inception through March 31, 2010
	2010	2009	
Cash flows from operating activities			
Net loss	\$ (1,422,495)	\$ (1,636,969)	\$ (90,665,767)
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	-	-	1,910,365
Stock issued for debt in excess of principal	-	-	109,070
Amortization of discount on notes payable due to warrants and beneficial conversion feature	51,166	-	6,489,115
Gain on extinguishment of debt	-	-	(1,612,440)
Depreciation	49,646	57,378	1,017,032
Amortization of debt financing costs	19,173	-	435,434
Option expense	105,358	358,752	14,682,101
Loss on derivative instruments	-	440,980	(1,388,848)
Loss on disposition of fixed assets	-	-	500,103
Changes in:			
Prepaid and other expenses	(30,984)	(54,987)	(526,846)
Accounts payable	(121,286)	(10,464)	54,266
Accrued expenses	219,262	21,224	320,472
Net cash provided by (used in) operating activities	<u>(1,130,160)</u>	<u>(824,086)</u>	<u>(42,276,914)</u>
Cash flows from investing activities			
Purchase of property & equipment	-	-	(1,339,511)
Net cash provided by (used in) investing activities	<u>-</u>	<u>-</u>	<u>(1,339,511)</u>
Cash flows from financing activities			
Common stock and warrants sold for cash, net of offering costs	-	-	40,454,331
Common stock repurchased and canceled	-	-	(325)
Proceeds from exercise of warrants and options	56,966	-	1,195,913
Proceeds from debt	-	-	9,283,184
Repayments on notes payable	(16,352)	(15,158)	(224,642)
Net cash provided by financing activities	<u>40,614</u>	<u>(15,158)</u>	<u>50,708,461</u>
Net change in cash and cash equivalents	(1,089,546)	(839,244)	7,092,036
Cash and cash equivalents at beginning of period	8,181,582	1,243,187	-
Cash and cash equivalents at end of period	<u>\$ 7,092,036</u>	<u>\$ 403,943</u>	<u>\$ 7,092,036</u>
Cash paid for:			
Income tax	\$ -	\$ -	\$ -
Interest	2,632	5,627	65,989
NON-CASH TRANSACTIONS			
Issuance of common stock to Sportan shareholders	-	-	147,733
Issuance of common stock for accrued interest	-	-	525,513
Issuance of warrants to placement agent	-	-	37,453
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	-	-	3,659,737
Beneficial conversion feature	-	-	1,805,519
Stock attached to notes	-	-	1,287,440

Fair value of derivative instrument	-	-	4,680,220
Derivative reclassified to equity	-	-	587,609

See accompanying notes to 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. 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 March 31, 2010, Opexa invested approximately \$6.9 million in a money market account with an average market yield of 0.01%. Interest income of \$185 was recognized for the three months ended March 31, 2010 in the statements of expenses. As of March 31, 2010, the Company held no auction rate securities.

Note 3. Commitments and Contingencies

Office Lease

In October 2005, Opexa entered into a ten-year lease for its office and research facilities. The facility including the property is leased for a term of ten years with two options for an additional five years each at the then prevailing market rate. Future minimum lease payments under the non-cancellable operating lease are \$110,655 for 2010, \$147,540 for 2011, \$150,129 for 2012 and a total of \$434,221 for years 2013 to 2015.

Stem Cell Technology Agreement

Effective August 6, 2009, Opexa entered into an exclusive agreement with Novartis for the further development of the Company's novel stem cell technology. This technology, which has generated preliminary data showing the potential to generate monocyte derived islet cells from peripheral blood mononuclear cells, was in early preclinical development at Opexa. Pursuant to this agreement, Novartis acquired the stem cell technology from Opexa and Novartis will have full responsibility for funding and carrying out all research, development and commercial activities. Novartis has to date paid Opexa \$3.5 million (\$3 million as an upfront payment and \$0.5 million upon the completion of the first of two technology transfer milestones). Opexa remains eligible to receive an additional \$0.5 million technology transfer fee upon the completion of a second technology transfer milestone. As part of ongoing technology transfer activities, Novartis has requested that Opexa perform supplemental activities as part of the second technology transfer milestone, and Opexa is willing to do so assuming agreement between the parties regarding the scope of such activities. Although the timing of completion of the second technology transfer milestone is dependent upon resolution between the parties as to a mutually acceptable scope and thereafter as to the pace and outcome of these activities, Opexa currently expects that the related milestone fee will be paid in 2010. Opexa is also eligible to receive certain clinical and commercial milestone payments as well as royalty payments from the sale of any products resulting from the use of the technology and Opexa retains an option on certain manufacturing rights. Notwithstanding the forgoing, there can be no assurance that Opexa will receive any future payments in respect of the stem cell technology.

Note 4. Loan Payable

Loan payable consists of an equipment line of \$250,000 with Wells Fargo Bank of which \$86,580 was outstanding as of March 31, 2010. This loan has an interest rate of 7.61% per annum, matures in May 2011 and is secured by furniture and equipment purchased with the loan proceeds. Payments are due and payable monthly until maturity.

Note 5. Options and Warrants

Stock Options

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 of common stock are authorized to be issued for awards made under the Plan through June 2014. In addition, shares subject to options granted under the plan that terminate or expire without being exercised will become available for grant under the plan. As of March 31, 2010, options to purchase an aggregate of 1,723,608 shares were issued and outstanding.

Opexa accounts for share-based compensation, including options and nonvested shares, according to the provisions of FASB ASC 718, "Share Based Payment". During the three months ended March 31, 2010, Opexa recognized share-based compensation expense of \$105,358. Unamortized stock compensation expense as of March 31, 2010 amounted to \$514,824.

Stock Option Activity

A summary of stock option activity for the three month period ended March 31, 2010 is presented below:

	Number of Shares	Wtd. Avg. Exercise Price	Wtd. Avg. Remaining Contract Term (# years)	Intrinsic Value
Outstanding at January 1, 2010	1,923,376	\$ 3.70		
Granted	-	-		
Exercised	(78,226)	0.72		
Forfeited and canceled	(121,542)	10.61		
Outstanding at March 31, 2010	1,723,608	\$ 3.09	7.7	\$ 1,193,877
Exercisable at March 31, 2010	1,388,443	\$ 3.38	7.3	\$ 1,066,677

The plan permits the granting of stock options to employees, officers, consultants and directors of Opexa. Option awards are generally granted with an exercise price equal to the market price of Opexa's stock at the date of issuance. Stock option awards issued by Opexa 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. Opexa estimates the fair value of stock options using the Black-Scholes option-pricing model and records the compensation expense ratably over the service period.

No stock option awards were issued during the three months ended March 31, 2010.

Warrant Activity

A summary of warrant activity for the three month period ended March 31, 2010 is presented below:

	Number of Shares	Wtd. Avg. Exercise Price	Wtd. Avg. Remaining Contract Term (# years)	Intrinsic Value
Outstanding at January 1, 2010	12,676,761	\$ 6.93		
Granted	7,867	2.00		
Exercised	(68,411)	2.10		
Forfeited and canceled	-	-		
Outstanding at March 31, 2010	12,616,217	\$ 5.19	2.4	\$ 3,300,427
Exercisable at March 31, 2010	11,251,959	\$ 5.51	2.2	\$ 3,300,427

Note 6. Subsequent Events

In April 2010, Opexa received approximately \$36,000 from the exercise of stock options and issued 30,000 shares of its common stock.

Opexa evaluated all subsequent events through the date of this filing.

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

The following discussion and analysis of our financial condition is as of March 31, 2010. 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, 2009.

Forward-Looking Statements

This Quarterly Report on Form 10-Q 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. Many statements, other than statements of historical facts, included or incorporated into this report are forward-looking statements. In particular, these statements may be found under the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" sections, among other places. The words "expects," "believes," "anticipates," "estimates," "may," "could," "intends," and similar expressions are intended to identify forward-looking statements. The forward-looking statements in this report do not constitute guarantees of future performance. Investors are cautioned that statements in this report 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: market conditions, our capital position, our ability to enter into and benefit from a partnering arrangement for our 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 (including for Tovaxin), the risk of litigation regarding our intellectual property rights, the success of third party development and commercialization efforts with respect to products covered by intellectual property rights transferred by the Company, our limited manufacturing capabilities, our dependence on third-party manufacturers, our ability to hire and retain skilled personnel, our volatile stock price, and other risks described below under "Risk Factors" and detailed in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update any forward-looking statements to reflect any changes in expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in the reports we file with the Securities and Exchange Commission.

Business Overview

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

We are a biopharmaceutical company developing personalized cellular therapies with the potential to treat major illnesses, including multiple sclerosis (MS). These therapies are based on our proprietary T-cell technology. 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 candidate, Tovaxin[®], is a personalized T-cell therapeutic vaccine licensed from Baylor College of Medicine, which is in clinical development for the treatment of MS.

T-Cell Therapy

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 (CNS). 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 (MBP), proteolipid protein (PLP) and myelin oligodendrocyte glycoprotein (MOG)). Patient-specific MRTCs are expanded in culture with specific peptides identified by our proprietary assay of the patient's peripheral blood. The cells are then attenuated, or weakened, 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. In 2008, we completed an FDA cleared Phase IIb clinical trial of Tovaxin which enrolled 150-patients. The trial was entitled, A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Subcutaneous Tovaxin in Subjects with Clinically Isolated Syndrome or Relapsing Remitting Multiple Sclerosis (Tovaxin for Early Relapsing-Remitting MS, "TERMS").

The TERMS study was a Phase IIb multi-center, randomized, double blind, placebo-controlled trial in 150 patients with Relapsing-Remitting Multiple Sclerosis (RRMS) 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. Top-line data from the TERMS trial is as follows:

- Annualized relapse rate (ARR) for Tovaxin-treated patients was 0.214 as compared to 0.339 for placebo-treated patients, which represented a 37% decrease in ARR for Tovaxin as compared to placebo in the general population.
- For patients who had more active disease as indicated by a prospective subgroup of patients with an ARR>1 in the year prior to the study, Tovaxin demonstrated a 55% reduction in ARR as compared to placebo; and an 87% reduction in relapse rate was observed in Tovaxin patients in this population compared to placebo during the 24 week period following the administration of the full course of treatment (p=0.039).
- Patients who had an ARR>1 at study entry demonstrated a statistically significant improvement in disability score as measured by the Expanded Disability Status Scale (EDSS) (p =0.045) for patients treated with Tovaxin as compared to those receiving placebo. The EDSS score is a measure of disability ranging from 0-10. In addition, 28.1% of the Tovaxin patients showed an improvement in EDSS of at least one point as compared to 5.6% in the placebo group.
- Patients who had an ARR>1 at study entry and were treated with Tovaxin experienced an 88% reduction in brain atrophy and a 59% reduction in absolute T-2 lesion volume as compared to placebo.
- Tovaxin was safe and well tolerated with no serious adverse events related to Tovaxin treatment. The most common adverse event was injection site irritation which was generally mild and transient.

Further analysis of the TERMS clinical study of 150 patients with RRMS evaluated those patients with an annualized relapse rate of greater than or equal to one at study entry (ARR $\geq$ 1). More than 83% of the Tovaxin-treated group (n=85) remained relapse free at one year and the annualized relapse rate after treatment decreased to 0.20, a 42% reduction compared to placebo. The results of this expanded analysis confirm those found in the previously-reported per-protocol analysis of patients in the TERMS study with ARR>1. This *post-hoc* analysis, which represents 86% of the total patient population in the TERMS study, was conducted to evaluate Tovaxin treatment among study patients with the same baseline disease activity that is being targeted for inclusion in future clinical studies. Along with a marked reduction in relapses, 73% of the Tovaxin-treated patients with ARR $\geq$ 1 showed stabilization or improvement in MS disability, including 16.5% with a sustained improvement in their EDSS score of at least one full point. On MRI, the Tovaxin-treated group also demonstrated a reduction in brain atrophy and fewer inflammatory brain lesions that progressed to “black holes,” as compared to the placebo-treated group. Treatment with Tovaxin was well tolerated, with no serious adverse events reported in any Tovaxin-treated patient.

Tovaxin is a personalized T-cell vaccine based on a patient’s individual immunologic profile. Detailed immunology data analysis from the TERMS trial indicate that Tovaxin can successfully induce changes in T-cell reactivity to all three targeted myelin antigens implicated in the autoimmune attacks causing neurologic damage in MS. These changes appear epitope-specific, are sustained for six months or more, and match each patient’s Tovaxin formulation. Tovaxin is not broadly immunosuppressive, an important feature of its favorable safety profile.

Other Opportunities

Our proprietary T-cell technology has enabled us to develop intellectual property and a comprehensive sample database that may enable discovery of novel biomarkers and other relevant peptides to be used to treat MS patients.

Stem Cell Therapy

In August 2009, we entered into an exclusive agreement with Novartis for the further development of our novel stem cell technology. This technology, which has generated preliminary data showing the potential to generate monocyte derived islet cells from peripheral blood mononuclear cells, was in early preclinical development at Opexa. Pursuant to this agreement, Novartis acquired our stem cell technology and Novartis will have full responsibility for funding and carrying out all research, development and commercial activities. Novartis has to date paid us \$3.5 million (\$3 million as an upfront payment and \$0.5 million upon the completion of the first of two technology transfer milestones). We remain eligible to receive an additional \$0.5 million technology transfer fee upon the completion of a second technology transfer milestone. As part of ongoing technology transfer activities, Novartis has requested that we perform supplemental activities as part of the second technology transfer milestone, and we are willing to do so assuming agreement between the parties regarding the scope of such activities. Although the timing of completion of the second technology transfer milestone is dependent upon resolution between the parties as to a mutually acceptable scope and thereafter as to the pace and outcome of these activities, we currently expect that the related milestone fee will be paid in 2010. We are also eligible to receive certain clinical and commercial milestone payments as well as royalty payments from the sale of any products resulting from the use of the technology and we retain an option on certain manufacturing rights. Notwithstanding the foregoing, there can be no assurance that we will receive any future payments in respect of the stem cell technology.

Critical Accounting Policies

General. Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these 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. We believe the following critical accounting policies affect our most significant judgments and estimates used in preparation of our financial statements.

Stock-Based Compensation. We adopted the provisions of FASB ASC 718 which establishes accounting for equity instruments exchanged for employee service. We utilize the Black-Scholes option pricing model to estimate the fair value of employee stock based compensation at the date of grant, which requires the input of highly subjective assumptions, including expected volatility and expected life. Changes in these inputs and assumptions can materially affect the measure of estimated fair value of our share-based compensation. These assumptions are subjective and generally require significant analysis and judgment to develop. When estimating fair value, some of the assumptions will be based on, or determined from, external data and other assumptions may be derived from our historical experience with stock-based payment arrangements. The appropriate weight to place on historical experience is a matter of judgment, based on relevant facts and circumstances.

We estimated volatility by considering historical stock volatility. We have opted to use the simplified method for estimating expected term equal to the midpoint between the vesting period and the contractual term.

Research and Development. The costs of materials and equipment or facilities that are acquired or constructed for research and development activities and that have alternative future uses are capitalized as tangible assets when acquired or constructed. The cost of such materials consumed in research and development activities and the depreciation of such equipment or facilities used in those activities are research and development costs. However, the costs of materials, equipment, or facilities acquired or constructed for research and development activities that have no alternative future uses are considered research and development costs and are expensed at the time the costs are incurred.

Results of Operations and Financial Condition

Comparison of the Three Months Ended March 31, 2010 with the Three Months Ended March 31, 2009

Net Sales. We recorded no commercial revenues for the three months ended March 31, 2010 and 2009.

Research and Development Expenses. Research and development expenses were \$783,534 for the three months ended March 31, 2010, compared with \$737,778 for the three months ended March 31, 2009. The increase in expenses was primarily related to a slight increase in personnel and the initiation of key experiments, and was partially offset by a decrease in stock compensation expense.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2010 were \$484,425 compared with \$396,315 for the three months ended March 31, 2009. The increase in expense is due to an increase in professional service fees and partially offset by a decrease in stock compensation expense.

Gain/(Loss) on Derivative Instruments. Gain/(loss) on derivative instruments was zero for the three months ended March 31, 2010 compared to a loss of \$440,980 for the three months ended March 31, 2009. The accounting treatment was changed effective June 1, 2009; consequently, no further derivative gain/loss is recognized.

Interest Expense. Interest expense was \$105,075 for the three months ended March 31, 2010, compared to \$5,627 for the three months ended March 31, 2009. The increase in interest expense was primarily related to the amortized interest on the convertible notes and the amortization of the financing fees over the life of the note with the balance related to interest on the equipment line loan payable. Interest expense for the three months ended March 31, 2009 related solely to the loan payable on the equipment line.

Interest Income. Interest income was \$185 for the three months ended March 31, 2010 compared to \$1,109 for the three months ended March 31, 2009. The decrease was due to the reduction in interest rates.

Net loss. We had a net loss for the three months ended March 31, 2010 of approximately \$1.42 million, or \$0.09 per share (basic and diluted), compared with a net loss of approximately \$1.6 million or \$0.13 per share (basic and diluted) for the three months ended March 31, 2009. The decrease in net loss is primarily due to the absence of any loss from derivative instruments and partially offset by increases in research and development expenses, general and administrative expenses, and interest expense.

Liquidity and Capital Resources

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of March 31, 2010, we had cash and cash equivalents of approximately \$7.1 million.

Our current burn rate is approximately \$350,000 per month. We believe that while we have sufficient liquidity to support our operations, at current levels, beyond December 2010, we will need to raise additional capital in the future to fund our current business plan and support our operations. We do not maintain any external lines of credit, or have commitments for equity funds, and should we need any additional capital in the future, management will be reliant upon “best efforts” debt or equity financings. As our prospects for funding, if any, develop during the fiscal year, we will assess our business plan and make adjustments accordingly. Although 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 in the future. If we are unable to obtain additional funding for operations 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

None.

Recent Accounting Pronouncements

For the period ended March 31, 2010, there were no accounting standards or interpretations issued that are expected to have a material impact on our financial position, operations or cash flows.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not Applicable.

Item 4T. Controls and Procedures.

Evaluation of 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 officer (whom we refer to in this periodic report as our Certifying Officer), as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Certifying Officer, the effectiveness of our disclosure controls and procedures as of March 31, 2010, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officer concluded that, as of March 31, 2010, 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.

PART II

OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors.

Reference is made to “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Forward-Looking Statements” in Part I, Item 2 of this report. This Item 1A should be read in conjunction with Part I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009 filed with the Securities and Exchange Commission, which is incorporated herein by reference. Although we believe that the expectations reflected in any forward-looking statements we make are reasonable, we caution you that these expectations or predictions may not prove to be correct or we may not achieve the financial or operations results or other benefits anticipated in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, which could cause our actual results to vary materially from those suggested by the forward-looking statements, such as:

- Our business is at an early stage of development. We are largely dependent on the success of our lead product candidate, Tovaxin, and we cannot be certain that Tovaxin will receive regulatory approval or be successfully commercialized.
- We have a history of operating losses and do not expect to be profitable in the near future.
- Our ability to obtain necessary funding is uncertain.
- Our independent auditor’s report in respect of our 2008 fiscal year expressed substantial doubt about our ability to continue as a going concern, which may make raising capital more difficult.
- We will depend on strategic collaborations with third parties to develop and commercialize product candidates, such as Tovaxin, and we may not have control over a number of key elements relating to the development and commercialization of any such product candidate.
- We will need regulatory approvals for any product candidate, including Tovaxin, prior to introduction to the market, which will require successful testing in clinical trials. Clinical trials are subject to extensive regulatory requirements, and are very expensive, time-consuming and difficult to design and implement. Any product candidate, such as Tovaxin, may fail to achieve necessary safety and efficacy endpoints during clinical trials in which case we will be unable to generate revenue from the commercialization and sale of our products.
- We will rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that may hamper our ability to successfully develop and commercialize any product candidate, including Tovaxin.
- If we fail to identify and license or acquire other product candidates, we will not be able to expand our business over the long term.
- We are dependent upon our management team and a small number of employees.
- If we fail to meet our obligations under our license agreements, we may lose our rights to key technologies on which our business depends.
- Our current research and manufacturing facility is not large enough to manufacture product candidates, such as Tovaxin, for clinical trials or, if such clinical trials are successful, commercial applications.
- If any product we may eventually have is not accepted by the market or if users of any such product are unable to obtain adequate coverage of and reimbursement for such product from government and other third-party payors, our revenues and profitability will suffer.

- Any product candidate that we develop, such as Tovaxin, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.
- We have incurred, and expect to continue to incur, increased costs and risks as a result of being a public company.
- Patents obtained by other persons may result in infringement claims against us that are costly to defend and which may limit our ability to use the disputed technologies and prevent us from pursuing research and development or commercialization of potential products, such as Tovaxin.
- If we are unable to obtain patent protection and other proprietary rights, our operations will be significantly harmed.
- Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.
- A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.
- We are subject to stringent regulation of our product candidates, such as Tovaxin, which could delay development and commercialization.
- We may need to change our business practices to comply with health care fraud and abuse regulations, and our failure to comply with such laws could adversely affect our business, financial condition and results of operations.
- If our competitors develop and market products that are more effective than our product candidates, they may reduce or eliminate our commercial opportunities.
- Rapid technological change could make our products obsolete.
- Consumers may sue us for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.
- Health care reform measures could adversely affect our business.
- There is currently a limited market for our securities, and any trading market that exists in our securities may be highly illiquid and may not reflect the underlying value of our net assets or business prospects.
- Our stock may be delisted from NASDAQ, which could affect its market price and liquidity.
- As our share price is volatile, and you may not be able to resell our shares at a profit or at all.
- We may be or become the target of securities litigation, which is costly and time-consuming to defend.
- Our “blank check” preferred stock could be issued to prevent a business combination not desired by management or our current majority stockholders.
- Future sales of our common stock in the public market could lower our stock price.
- We presently do not intend to pay cash dividends on our common stock.
- Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock.

The risks described in this report and in our Annual Report on Form 10-K are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Other Information.

None.

Item 5. Exhibits.

Exhibit

No. Description

- 4.1* Form of First Amendment to Promissory Note and Security Agreement effective as of June 19, 2009 by and between Opexa Therapeutics, Inc. and the investors signatory thereto.
- 4.2* Form of Second Amendment to Security Agreement effective as of July 31, 2009, by and between Opexa Therapeutics, Inc. and the investors signatory thereto.
- 10.1 Amended and Restated Employment Agreement entered into on April 21, 2010 between Opexa Therapeutics, Inc. and Donna R. Rill (incorporated by reference to the Company's Current Report on Form 8-K filed on April 27, 2010).
- 31.1* Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1* Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith

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 thereunto duly authorized.

OPEXA THERAPEUTICS, INC.

Date: May 13, 2010

By: /s/ Neil K. Warma

Neil K. Warma
President and Chief Executive Officer
(Principal Executive Officer)
Acting Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit	
<u>No.</u>	<u>Description</u>
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4.2*	Form of Second Amendment to Security Agreement effective as of July 31, 2009, by and between Opexa Therapeutics, Inc. and the investors signatory thereto.
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31.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith

FIRST AMENDMENT
TO
PROMISSORY NOTE AND SECURITY AGREEMENT

THIS FIRST AMENDMENT TO PROMISSORY NOTE AND SECURITY AGREEMENT (“**Agreement**”), is effective as of June 19, 2009 (this “**Agreement**”), between Opexa Therapeutics, Inc., a Texas corporation (the “**Company**”), and the Investors on the signature pages hereto, and their respective successors and assigns (the “**Investors**”).

RECITALS

WHEREAS, the parties entered into 10% Convertible Promissory Notes (collectively the “**Notes**”) and Security Agreements (collectively the “**Security Agreement**”) effective, according to their terms, as of April 14, 2009 or May 14, 2009;

WHEREAS, the parties desire to clarify that all of the Notes rank *pari passu* and desire that such Notes and Security Agreements to be consolidated with respect to their rights;

WHEREAS, the parties now desire to amend the Notes and the Security Agreements as provided herein;

NOW, THEREFORE, in consideration of the premises and the mutual covenants herein, the parties hereto agree as follows:

1. Amendment of Notes. The first sentence of Section 3 of each of the Notes is hereby amended to read in its entirety as follows:

“This Note is one of several convertible promissory notes of the Company issued on and dated effective as of April 14, 2009 and May 14, 2009 (collectively, the “**April 2009 Notes**”) evidencing indebtedness incurred by the Company for interim financing provided to the Company.”

2. Amendment to Section 1 of the Security Agreement. The first sentence of Section 1 of each of the Security Agreements is hereby amended to read in its entirety as follows:

“This Agreement is granted by the Company in favor of the Investors under the Unit Purchase Agreements, dated effective as of April 14, 2009 or May 14, 2009, as the case may be, (collectively, the “**Purchase Agreement**”), and the convertible secured promissory notes issued to Investors by the Company under the Purchase Agreement (as may be amended, restated, modified or replaced from time to time, collectively, the “**Notes**”).”

3. Amendment of Section 12 of the Security Agreement. The fifth paragraph of Section 12 of each of the Security Agreements is hereby amended by deleting the sentence “This Agreement may be amended or supplemented only by a writing signed on behalf of both parties.” And inserting in lieu thereof the following:
-

“Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of the Company and Investors holding Notes representing a majority of the aggregate outstanding principal balance of the Notes. Any amendment or waiver effected in accordance with this paragraph shall be binding upon each Investor whether or not such Investor signs such amendment or waiver.”

4. No Other Amendments. This Amendment shall be construed as part of the Notes and the Security Agreements. Except as specifically amended herein, the Notes and the Security Agreements shall remain in full force and effect.

[Signature page follows.]

The parties have executed this Agreement effective as of the date first written above.

COMPANY:

OPEXA THERAPEUTICS, INC.

By: / s/ Neil K. Warma

Name: Neil K. Warma

Title: President and Chief Executive Officer

THE INVESTORS:

If Investor is a corporation, partnership, trust or other entity, enter the exact name as listed in the 10% Convertible Promissory Note:

By:	
	(Signature)
Print Name:	
Title:	
Date:	

**SECOND AMENDMENT
TO
SECURITY AGREEMENTS**

THIS SECOND AMENDMENT TO SECURITY AGREEMENTS (this “**Agreement**”), is effective as of July 31, 2009, between Opexa Therapeutics, Inc., a Texas corporation (the “**Company**”), and the Investors on the signature pages hereto, and their respective successors and assigns (the “**Investors**”).

RECITALS

WHEREAS, the Company and certain of the Investors entered into that certain Security Agreement dated as of April 14, 2009 and the Company and certain Investors entered into that certain Security Agreement dated as of May 14, 2009 (each, a “**Security Agreement**” and collectively, the “**Security Agreements**”);

WHEREAS, the parties entered into a First Amendment to Promissory Note and Security Agreement dated June 19, 2009, pursuant to which each Security Agreement was amended as set forth therein, including providing that each of the Security Agreements may be amended by the written consent of the Company and Investors holding Notes representing a majority of the aggregate outstanding principal balance of the Notes related to such Security Agreement;

WHEREAS, the Company and the Investors now desire to further amend each of the Security Agreements as provided herein;

NOW, THEREFORE, in consideration of the premises and the mutual covenants herein, the parties hereto agree as follows:

1. Amendment of Section 3.8 of each Security Agreement. Section 3.8 of each Security Agreement is hereby amended to read in its entirety as follows:

3.8 Exceptions. Notwithstanding the foregoing, Collateral shall not include (i) any equipment or fixtures subject to a lien in favor of Wells Fargo Bank, N.A. existing as of the date hereof and any equipment or fixtures acquired in the future and subject to a purchase lien, so long as such other liens are in effect, and (ii) the property described in Exhibit A hereto.

2. Addition of Exhibit A to each Security Agreement. A new “Exhibit A” is hereby added to and made a part of each Security Agreement to read in its entirety the same as Exhibit A to this Agreement.

3. Amendment of UCC Filing. Company (or any assignee of Company) may file any necessary documentation to amend any financing statement or other documents on file in any jurisdiction in connection with either Security Agreement and the security interests granted thereunder to reflect the exceptions referenced in Section 3.8 of the applicable Security Agreement (as amended hereby).

4. No Other Amendments . This Amendment shall be construed as part of each Security Agreement. Except as specifically amended herein, each Security Agreement shall remain in full force and effect.

5. Acknowledgment . The Investors party hereto agree and acknowledge that this Amendment operates to release certain collateral from the scope of the security interests granted under each of the Security Agreements, and further agree that no further security interest in such released collateral shall be retained by such Investors.

[Remainder of page intentionally blank]

The parties have executed this Agreement effective as of the date first written above.

COMPANY:

OPEXA THERAPEUTICS, INC.

By: / s/ Neil K. Warma

Name: Neil K. Warma

Title: President and Chief Executive Officer

THE INVESTORS:

If Investor is a corporation, partnership, trust or other entity,
enter the exact name as listed in the 10% Convertible Promissory Note:

By: _____
(Signature)
Print
Name: _____
Title: _____
Date: _____

**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: May 13, 2010

By: /s/ Neil K. Warma

Neil K. Warma
President, Chief Executive Officer and
Acting Chief Financial 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 March 31, 2010, (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Neil K. Warma, President, Chief Executive Officer and Acting Chief Financial 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: May 13, 2010

By: /s/ Neil K. Warma

Neil K. Warma
President and Chief Executive Officer
(Principal Executive Officer)
Acting Chief Financial Officer
(Principal Financial and Accounting Officer)