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, 2011

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	**2635 Technology Forest Blvd.**	**76-0333165**
(State or other jurisdiction of Incorporation or organization)	**The Woodlands, Texas 77381** (Address of principal executive offices and zip code)	(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 October 31, 2011, there were 23,048,488 shares of the issuer's Common Stock outstanding.

OPEXA THERAPEUTICS, INC.
(a development stage company)
For the Quarter Ended September 30, 2011

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 8,639,856	$ 3,812,535
Other current assets	105,645	85,525
Total current assets	8,745,501	3,898,060
Property & equipment, net of accumulated depreciation of $1,222,758 and $1,109,558, respectively	953,219	815,958
Total assets	$ 9,698,720	$ 4,714,018
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 429,565	$ 358,837
Accounts payable - related parties	15,000	15,000
Accrued expenses	285,885	335,861
Current maturity of loan payable	-	35,607
Total current liabilities	730,450	745,305
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, 23,048,488 and 18,466,924 shares issued and outstanding	230,485	184,670
Additional paid in capital	107,541,563	98,496,382
Deficit accumulated during the development stage	(98,803,778)	(94,712,339)
Total stockholders' equity	8,968,270	3,968,713
Total liabilities and stockholders' equity	$ 9,698,720	$ 4,714,018

See accompanying notes to unaudited financial statements

OPEXA THERAPEUTICS, INC.
(a development stage company)
STATEMENTS OF EXPENSES
(unaudited)

	Three Months Ended September 30, 2011	Three Months Ended September 30, 2010	Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010	Inception through September 30, 2011
Research and development	$ 654,772	$ 625,282	$ 2,194,141	$ 2,193,919	$ 69,032,978
General and administrative	584,794	626,697	1,737,686	1,706,546	26,940,492
Depreciation and amortization	56,888	37,647	157,254	136,022	1,293,483
Loss on disposal of assets	413	-	413	-	500,975
Operating loss	(1,296,867)	- (1,289,626)	(4,089,494)	(4,036,487)	(97,767,928)
Interest income	227	815	698	1,395	1,358,183
Other income and expense, net	-	-	-	-	661,146
Gain on extinguishment of debt	-	-	-	-	1,612,440
Gain (loss) on derivative instruments	-	-	-	-	1,388,848
Gain on sale of technology	-	-	-	-	3,000,000
Interest expense	(638)	(2,004)	(2,643)	(499,200)	(9,056,467)
Net loss	$ (1,297,278)	$ (1,290,815)	$ (4,091,439)	$ (4,534,292)	$ (98,803,778)
Basic and diluted loss per share	$ (0.06)	$ (0.07)	$ (0.18)	$ (0.27)	N/A
Weighted average shares outstanding	23,048,488	18,421,600	22,358,611	16,601,503	N/A

See accompanying notes to unaudited financial statements

OPEXA THERAPEUTICS, INC.
(a development stage company)
STATEMENTS OF CASH FLOWS
(unaudited)

	Nine Months Ended September 30,		Inception through September 30, 2011
	2011	2010	
Cash flows from operating activities			
Net loss	$ (4,091,439)	$ (4,534,292)	$ (98,803,778)
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	87,028	64,350	2,061,743
Stock issued for debt in excess of principal	-	-	109,070
Amortization of discount on notes payable due to warrants and beneficial conversion feature	-	314,749	6,752,698
Gain on extinguishment of debt	-	-	(1,612,440)
Depreciation	157,254	136,022	1,293,483
Amortization of debt financing costs	-	108,117	524,378
Option expense	385,811	414,753	15,471,104
Gain on derivative instruments	-	-	(1,388,848)
Loss on disposition of fixed assets	413	-	500,975
Changes in:			
Other current assets	(20,120)	33,498	(522,318)
Accounts payable - third parties and related parties	59,817	(140,280)	(16,396)
Accrued expenses	(49,976)	95,316	237,321
Net cash used in operating activities	(3,471,212)	(3,507,767)	(48,993,979)
Cash flows from investing activities			
Purchase of property & equipment	(284,017)	-	(1,658,878)
Net cash used in investing activities	(284,017)	-	(1,658,878)
Cash flows from financing activities			
Common stock and warrants sold for cash, net of offering costs	8,618,157	-	49,072,488
Common stock repurchased and canceled	-	-	(325)
Proceeds from exercise of warrants and options	-	109,641	1,248,588
Proceeds from debt	-	-	9,283,184
Repayments on notes payable	(35,607)	(50,011)	(311,222)
Net cash provided by financing activities	8,582,550	59,630	59,292,713
Net change in cash and cash equivalents	4,827,321	(3,448,137)	8,639,856
Cash and cash equivalents at beginning of period	3,812,535	8,181,582	-
Cash and cash equivalents at end of period	$ 8,639,856	$ 4,733,445	$ 8,639,856

Cash paid for:			
Income tax	$ -	$ -	$ -
Interest	2,643	85,043	152,671
NON-CASH TRANSACTIONS			
Issuance of common stock to Sportan shareholders	-	-	147,733
Issuance of common stock for accrued interest	-	78,091	603,604
Issuance of warrants to placement agent	-	-	37,453
Conversion of notes payable to common stock	-	1,302,000	7,709,980
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
Unpaid additions to property and equipment	10,911	-	10,911

See accompanying notes to unaudited 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. ("Opexa"), 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 on Form 10-K filed with the SEC. 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.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that are adopted by Opexa as of the specified effective date. Unless otherwise discussed, Opexa believes that the impact of recently issued accounting pronouncements that are not yet effective will not have a material impact on their financial position or results of operations upon adoption.

Note 2. Cash and Cash Equivalents

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, 2011, Opexa invested approximately $8.2 million in a money market fund investing exclusively in high-quality, short-term money market instruments consisting of U.S. government obligations and repurchase agreements collateralized by the U.S. Government. While this fund seeks current income while preserving capital and liquidity, the fund is subject to risk, including U.S. government obligations risk, and is not federally insured or guaranteed by or obligations of the Federal Deposit Insurance Corporation or any other agency. For the nine months ended September 30, 2011, the money market fund recognized an average market yield of 0.01%. Interest income of $227 and $698 was recognized for the three and nine months ended September 30, 2011, respectively, in the statements of expenses.

Note 3. Commitments and Contingencies

Stem Cell Technology Agreement

In 2009, Novartis Pharmaceuticals acquired Opexa's stem cell technology platform, which had been in early preclinical development, and took over all future responsibilities and opportunities for this technology, although Opexa retained an option on certain manufacturing rights. As part of the transaction, Opexa was paid an upfront fee of $3 million and a milestone payment of $500,000 for certain technology transfer activities. Opexa remained eligible to receive a second technology transfer milestone fee in addition to potential clinical and commercial milestones and royalty payments from the sale of any products resulting from the use of the technology.

As further described below in Note 6 (Subsequent Events), on November 2, 2011, Opexa re-acquired the stem cell assets transferred to Novartis in exchange for a release with respect to any further payment obligations owed to Opexa by Novartis, including the remaining $500,000 technology transfer milestone payment. A related license agreement with the University of Chicago was also assigned back to Opexa.

Note 4. Equity

In January 2011, Opexa sold an aggregate of 384,759 shares of common stock under the Continuous Offering Program Agreement dated May 14, 2010 (the "ATM Agreement") for net proceeds of $1,033,994. Opexa paid compensation and fees totaling $10,826 to the placement agent with respect to the shares sold. The ATM Agreement was subsequently terminated by Opexa on February 7, 2011.

In February 2011, Opexa sold an aggregate of 4,146,500 units in a public offering, with each unit consisting of one share of common stock and a warrant to purchase four-tenths (0.40) of a share of common stock, at a price to the public of $2.05 per unit, for gross proceeds of $8,500,325. The shares of common stock and warrants were immediately separable and were issued separately such that no units were issued. The warrants were exercisable immediately upon issuance, having a five-year term and an exercise price of $2.61 per share. The warrants have a fair value of $3,236,584 that was calculated using the Black-Scholes valuation model with the following assumptions: (1) discount rate of 2.38%, (2) term of 5 years, (3) expected volatility of 197.60% and (4) zero expected dividends. The net proceeds to Opexa from this offering were approximately $7,584,163, after deducting underwriting discounts and commissions and other offering expenses. The offering closed on February 11, 2011.

Note 5. Stock-Based Compensation

Restricted Shares

Pursuant to an agreement with a consultant for professional services, Opexa granted 50,305 restricted shares of common stock which were accounted for on March 19, 2011 pursuant to the relevant accounting rules. These shares vested immediately and were issued on April 8, 2011 and have a fair value of $87,028 based on the share price at the grant date, which was recognized as share-based compensation expense for the nine months ended September 30, 2011.

Stock Options

The 2010 Stock Incentive Plan (the “2010 Plan”) provides for the grant of equity incentive awards to employees, directors and consultants of Opexa in the form of incentive stock options or nonqualified stock options, as well as restricted stock, stock appreciation rights, restricted stock units and performance awards that may be settled in cash, stock or other property. The 2010 Plan is the successor to and continuation of Opexa’s June 2004 Compensatory Stock Option Plan (the “2004 Plan”). A total of 2,500,000 shares of common stock are authorized to be issued for awards made under the 2010 Plan through September 2020, plus (i) the number of shares subject to stock options outstanding under the 2004 Plan that are forfeited or terminate prior to exercise and would otherwise be returned to the share reserves under the 2004 Plan and (ii) any reserved shares under the 2004 Plan that were not issued or subject to outstanding grants. In addition, shares subject to awards granted under the 2010 Plan that terminate or expire before being exercised or settled will become available for grant under the 2010 Plan. As of September 30, 2011, options to purchase an aggregate of 1,739,072 shares were issued and outstanding.

Opexa accounts for share-based compensation, including options and nonvested shares, according to the provisions of FASB Accounting Standards Codification (“ASC”) 718, "Share Based Payment.” During the nine months ended September 30, 2011, Opexa recognized option expense of $385,811. Unamortized stock compensation expense as of September 30, 2011 amounted to $457,009.

Stock Option Activity

A summary of stock option activity for the nine months ended September 30, 2011 is presented below:

	Number of Shares	Wtd. Avg. Exercise Price	Wtd. Avg. Remaining Contract Term (# years)	Intrinsic Value
Outstanding at January 1, 2011	1,542,072	$ 2.15		
Granted	272,000	1.64		
Exercised	-	-		
Forfeited and canceled	(75,000)	5.00		
Outstanding at September 30, 2011	1,739,072	$ 1.94	7.4	$ 324,513
Exercisable at September 30, 2011	1,419,739	$ 1.98	7.0	$ 324,513

Option awards are granted with an exercise price equal to the market price of Opexa’s stock at the date of issuance, generally have a ten-year life, and have various vesting dates that range from no vesting or 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.

Employee Options

During the nine months ended September 30, 2011, options to purchase an aggregate of 175,000 shares were granted to employees, based on 2010 performance objectives, at an exercise price of $1.56. These options have terms of 10 years and have a vesting schedule of three years. Fair value of $268,451 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for the options issued during the nine month period ended September 30, 2011 include (1) discount rate of 3.36%, (2) expected term of 6 years, (3) expected volatility of 192.44% and (4) zero expected dividends.

Non-Employee Options

During the nine months ended September 30, 2011, options to purchase an aggregate of 82,000 shares were granted to non-employee directors for service on Opexa's Board at an exercise price of $1.78. Options to purchase an aggregate of 40,000 shares have terms of 10 years, with 50% of the shares vesting immediately and 50% vesting in one year from the date of grant. Options to purchase the remaining 42,000 shares will expire on the earlier of 10 years or a change in control of the Company, with 50% of the shares vesting immediately and 50% vesting on December 31, 2011. Fair value of $142,877 was calculated using the Black-Scholes option-pricing model.

During the nine months ended September 30, 2011, an option to purchase 15,000 shares was granted to a consultant at an exercise price of $1.78. This option has a term of 10 years, with 50% of the shares vesting immediately and 50% vesting on December 31, 2011. Fair value of $26,136 was calculated using the Black-Scholes option-pricing model.

Variables used in the Black-Scholes option-pricing model for the non-employee options issued during the nine months ended September 30, 2011 include (1) discount rate of 3.50%, (2) expected term of 5.3 years, (3) expected volatility of 198.22% and (4) zero expected dividends.

Warrant Activity

A summary of warrant activity for the nine months ended September 30, 2011 is presented below:

	Number of Shares	Wtd. Avg. Exercise Price	Wtd. Avg. Remaining Contract Term (# years)	Intrinsic Value
Outstanding at January 1, 2011	11,459,576	$ 2.75		
Granted	1,658,600	2.61		
Exercised	-	-		
Forfeited and canceled	(2,687,890)	5.93		
Outstanding at September 30, 2011	10,430,286	$ 1.90	2.0	$ 733,987
Exercisable at September 30, 2011	10,430,286	$ 1.90	2.0	$ 733,987

In connection with Opexa's February 2011 public offering, as disclosed in Note 4, Opexa issued warrants to purchase an aggregate of 1,658,600 shares of common stock to the investors at an exercise price of $2.61 per share. These warrants have a term of five years and are immediately exercisable.

Note 6. Subsequent Events

On October 27, 2011, Opexa granted ten-year options to a non-employee director to purchase an aggregate of 23,423 shares of common stock at an exercise price of $1.05. Of such options, 20,000 shares vest one-third immediately and the remaining two-thirds on the first and second anniversary of the grant date, and 1,667 shares vest one-half immediately and one-half on April 5, 2011. The remaining 1,756 option shares vest one-half immediately and one-half on December 31, 2011, and the options expire on the earlier of ten years or a change in control of the Company.

On November 2, 2011, Opexa entered into an Assignment Agreement and General Release with Novartis by which Opexa re-acquired certain novel stem cell technology assets previously transferred to Novartis pursuant to an Asset Purchase

Agreement dated August 6, 2009. Novartis recently advised Opexa that the advancement of the stem cell program was not a priority for Novartis, and that Novartis was willing to transfer the assets back to Opexa in exchange for a release with respect to any further payment obligations owed to Opexa by Novartis, including the remaining $500,000 technology transfer milestone payment. In connection with the re-acquisition of the stem cell assets from Novartis, a related license agreement with the University of Chicago was assigned back to Opexa.

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 September 30, 2011. 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, 2010.

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. Statements contained in this report, other than statements of historical fact, constitute "forward-looking statements." The words "expects," "believes," "anticipates," "estimates," "may," "could," "intends," and similar expressions are intended to identify forward-looking statements. In particular, these forward-looking statements may be found, among other places, under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." These forward-looking statements do not constitute guarantees of future performance. Investors are cautioned that statements which are not strictly historical statements, including, without limitation, statements regarding current or future financial payments, returns, royalties, performance and position, management's strategy, plans and objectives for future operations, plans and objectives for product development, plans and objectives for present and future clinical trials and results of such trials, plans and objectives for regulatory approval, litigation, intellectual property, product development, manufacturing plans and performance, and management's initiatives and strategies, constitute forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated. These risks and uncertainties include, but are not limited to, those risks discussed in "Risk Factors," as well as, without limitation, risks associated with: 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 program and to undertake and complete any further clinical studies of Tovaxin; the success of our clinical trials; the efficacy of Tovaxin for any particular indication, such as for RR-MS or SP-MS; 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 us; 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 detailed in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this report. We assume no obligation or undertaking to update any forward-looking statements contained herein 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 late-stage clinical development for the treatment of MS.

T-Cell Therapy

Tovaxin® is a novel T-cell immunotherapy in clinical development for the treatment of patients with relapsing remitting MS (RR-MS) and secondary progressive MS (SP-MS). It is a personalized therapy that is specifically tailored to each patient's disease profile. Tovaxin is manufactured using our proprietary method for the production of a patient-specific T-cell immunotherapy, which encompasses the collection of blood from the MS patient, isolation of peripheral blood

mononuclear cells, generation of an autologous pool of myelin-reactive T-cells (MRTCs) raised against selected peptides from myelin basic protein (MBP), myelin oligodendrocyte glycoprotein (MOG) and proteolipid protein (PLP), and the return of these expanded, irradiated T-cells back to the patient. These attenuated T-cells are reintroduced into the patient via subcutaneous injection to trigger a therapeutic immune system response.

Summary of TERMS Phase IIb Clinical Trial Data

Tovaxin for Early Relapsing Multiple Sclerosis (TERMS) was a Phase IIb clinical study of Tovaxin in RR-MS patients. Although the study did not show statistical significance in its primary endpoint (the cumulative number of gadolinium-enhanced brain lesions using MRI scans summed at various points in the study), the study showed compelling evidence of efficacy in various clinical and other MRI endpoints.

The TERMS study was a multi-center, randomized, double blind, placebo-controlled trial in 150 patients with RR-MS or high risk Clinically Isolated Syndrome. Patients received a total of five subcutaneous injections at weeks 0, 4, 8, 12 and 24. Key results from the TERMS trial include:

- In the modified intent to treat patient population (n=142), the 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;
- In a prospective group of patients with more active disease (ARR>1, n=50), Tovaxin demonstrated a 55% reduction in ARR as compared to placebo, and a 73% 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; and
- In a retrospective analysis in patients naïve to previous disease modifying treatment (*i.e.*, patients who had not previously used any drugs other than steroids to treat their disease), the results showed that patients, when treated with Tovaxin, had a 64% reduction in ARR versus placebo (p=0.046, n=70).

Tovaxin has demonstrated a favorable side effect profile throughout the clinical development program. In four clinical trials to date, including the Phase IIb TERMS trial, there have been no serious adverse events associated with Tovaxin treatment. The most common side effect is mild to moderate irritation at the site of injection, which is typically resolved in 24 hours. We believe the favorable safety profile of Tovaxin is a key differentiator when compared to marketed or other developmental MS drugs.

T-Cell Therapy Regulatory and Development Status

During 2010, we continued to analyze the data from the 2008 TERMS Phase IIb study and we evaluated options for the further clinical development of Tovaxin. In late 2010, we completed face-to-face discussions with the FDA regarding our planned development program for Tovaxin. Based on positive feedback from the FDA, we believe that we are now positioned from a regulatory perspective to advance with a pivotal Phase III clinical study of Tovaxin in RR-MS, subject to securing the appropriate financing to conduct such a study.

Our late-2010 discussions with the FDA consisted of two separate meetings to review both the complete Tovaxin manufacturing process as well as the prospective clinical trial plan for Tovaxin. The first meeting focused on the improvements and modifications we have incorporated into Tovaxin's manufacturing and CMC (chemistry, manufacturing and control) process in an effort to improve efficiency, reduce overall costs and implement commercial stage requirements. As part of this meeting, we presented data and details supporting an optimized manufacturing process, including a transition to fewer process steps, comparability plans and complete reagent profiles. The FDA agreed that the optimized Tovaxin manufacturing process would meet the requirements for a pivotal Phase III clinical trial, although additional supporting data is expected to be submitted to the FDA prior to initiating such a study.

The second meeting was an "end of Phase II" clinical meeting in which we presented our rationale and trial design for a Phase III pivotal study with Tovaxin in RR-MS patients. The FDA concurred in general with our proposed clinical trial protocol, including the patient population, end points, patient numbers and overall trial design. The FDA also offered several recommendations to further enhance such a Phase III trial.

We are currently advancing with necessary preparations to be able to initiate pivotal trials in RR-MS and are exploring trial designs for a potential Phase II clinical study in SP-MS. As there remain very limited treatment options for patients with progressive forms of MS, the substantial unmet medical need has increased the urgency to develop new treatments for these patients and, subsequently, our interest in advancing Tovaxin in SP-MS. We believe Tovaxin is well positioned in both RR-MS and SP-MS indications, with demonstrated safety and promising clinical efficacy across a broad spectrum of MS patients. Prior to initiating any clinical study, however, we will need to secure additional resources. Unless we are able to secure at least a substantial portion of the resources necessary to complete a clinical study and support our operations during the pendency of such study, or we are reasonably confident that such resources will be secured, we will likely not proceed with the initiation of any such study.

Given our need for substantial amounts of capital to conduct a clinical study, we are continuing to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to fund such a study and to support our operations during the pendency of such study. In addition to one or more additional financings, these opportunities and alternatives may include a partnering arrangement with a large biotech or pharmaceutical company. There can be no assurance that any such financing or partnering arrangement can be consummated on acceptable terms, if at all.

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 2009, Novartis Pharmaceuticals acquired our stem cell technology platform, which had been in early preclinical development, and took over all future responsibilities and opportunities for this technology, although we retained an option on certain manufacturing rights. As part of the transaction, we were paid an upfront fee of $3 million and a milestone payment of $500,000 for certain technology transfer activities. We remained eligible to receive a second technology transfer milestone fee in addition to potential clinical and commercial milestones and royalty payments from the sale of any products resulting from the use of the technology.

On November 2, 2011, we entered into an Assignment Agreement and General Release with Novartis by which we re-acquired certain novel stem cell technology assets previously transferred to Novartis pursuant to an Asset Purchase Agreement dated August 6, 2009. Novartis recently advised us that the advancement of the stem cell program was not a priority for Novartis, and that Novartis was willing to transfer the assets back to us in exchange for a release with respect to any further payment obligations owed to us by Novartis, including the remaining $500,000 technology transfer milestone payment. In connection with the re-acquisition of the stem cell assets from Novartis, a related license agreement with the University of Chicago was assigned back to us. Opexa and the University of Chicago entered into a Fourth Amended and Restated License Agreement in connection with such assignment to Opexa.

Preliminary data for this technology, which had been in early preclinical development at Opexa prior to the 2009 sale, showed the potential to generate monocyte derived islet cells from peripheral blood mononuclear cells.

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 of options as 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 September 30, 2011 with the Three Months Ended September 30, 2010

Net Sales. We recorded no commercial revenues for the three months ended September 30, 2011 and 2010.

Research and Development Expenses. Research and development expenses were $654,772 for the three months ended September 30, 2011, compared with $625,282 for the three months ended September 30, 2010. The increase in expenses is primarily related to an increase of staff to conduct increased development activities, an increase in the procurement and use of supplies used in our laboratory and an increase in maintenance and utilities costs due to increased activity in our laboratory, and was partially offset by a decrease in the engagement of consultants and a write-off of certain legal fees related to intellectual property matters.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2011 were $584,794, compared with $626,697 for the three months ended September 30, 2010. The decrease in expense is due to a decrease in compensation expense, and was partially offset by an increase in business development expenses.

Depreciation and Amortization Expenses. Depreciation and amortization expenses for the three months ended September 30, 2011 were $56,888, compared with $37,647 for the three months ended September 30, 2010. The increase in expense is due to an increase in depreciation for facility build-out costs incurred during the first half of 2011, an increase in depreciation for laboratory and manufacturing equipment acquired during 2011 to support increased development activities and an increase in depreciation for information technology equipment to replace and upgrade obsolete equipment.

Interest Expense. Interest expense was $638 for the three months ended September 30, 2011, compared to $2,004 for the three months ended September 30, 2010.

Interest Income. Interest income was $227 for the three months ended September 30, 2011, compared to $815 for the three months ended September 30, 2010.

Net loss. We had a net loss for the three months ended September 30, 2011 of approximately $1.30 million, or $0.06 per share (basic and diluted), compared with a net loss of approximately $1.29 million or $0.07 per share (basic and diluted) for the three months ended September 30, 2010. The increase in net loss is primarily due to an increase of staff, lab supplies and maintenance and utilities costs to support increased development activities, an increase in business development expenses, and an increase in depreciation for facility build-out costs and lab, manufacturing and information technology equipment, which was partially offset by a decrease in the engagement of consultants, a write-off of certain legal fees and a decrease in compensation expense.

Comparison of the Nine Months Ended September 30, 2011 with the Nine Months Ended September 30, 2010

Net Sales. We recorded no commercial revenues for the nine months ended September 30, 2011 and 2010.

Research and Development Expenses. Research and development expenses were $2,194,141 for the nine months ended September 30, 2011, compared with $2,193,919 for the nine months ended September 30, 2010. The increase in expenses is primarily related to an increase of staff to conduct increased development activities and an increase in maintenance and utilities costs due to increased activity in our laboratory, and was partially offset by a decrease in the engagement of consultants.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2011 were $1,737,686, compared with $1,706,546 for the nine months ended September 30, 2010. The increase in expense is due to costs associated with increased investor relations outreach, an increase in business development costs and an increase in stock compensation expense, and was partially offset by a decrease in legal costs.

Depreciation and Amortization Expenses. Depreciation and amortization expenses for the nine months ended September 30, 2011 were $157,254, compared with $136,022 for the nine months ended September 30, 2010. The increase in expense is due to an increase in depreciation for facility build-out costs incurred during the first half of 2011, an increase in depreciation for laboratory and manufacturing equipment acquired during 2011 to support increased development activities and an increase in depreciation for information technology equipment to replace and upgrade obsolete equipment.

Interest Expense. Interest expense was $2,643 for the nine months ended September 30, 2011, compared to $499,200 for the nine months ended September 30, 2010. The decrease in interest expense is primarily related to the amortized interest incurred during the first half of 2010 and the amortization of the remaining discount and deferred financing fees in

conjunction with the June 23, 2010 conversion of the 10% Convertible Promissory Notes (these notes were converted to common stock in June 2010). Interest expense for the nine months ended September 30, 2011 related solely to the financing costs on insurance policies and the loan payable on an equipment line.

Interest Income. Interest income was $698 for the nine months ended September 30, 2011, compared to $1,395 for the nine months ended September 30, 2010.

Net loss. We had a net loss for the nine months ended September 30, 2011 of approximately $4.09 million, or $0.18 per share (basic and diluted), compared with a net loss of approximately $4.53 million, or $0.27 per share (basic and diluted), for the nine months ended September 30, 2010. The decrease in net loss is primarily due to a decrease in interest expense, a decrease in professional fees, and was partially offset by an increase in staff, maintenance, and utilities costs for increased development activities, an increase in business development and investor outreach activity costs, an increase in stock compensation expense and an increase in depreciation expense.

Liquidity and Capital Resources

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of September 30, 2011, we had cash and cash equivalents of approximately $8.6 million. Our financing activities generated $8.6 million for the nine months ended September 30, 2011, compared to $59,630 for the same period of 2010. The cash generated in the first nine months of 2011 was proceeds from the sale of our securities in two separate offerings. During January 2011, we sold an aggregate of 384,759 shares of our common stock for net proceeds of $1,033,994 under an “at the market” continuous offering program pursuant to a prospectus supplement dated May 17, 2010. During February 2011, we raised net proceeds of $7,584,163 through a public offering of common stock and warrants pursuant to a prospectus supplement dated February 8, 2011.

Our current burn rate, which is in the absence of any clinical trial but includes some preparation for initiation of a trial, is approximately $450,000 per month. While we believe we have sufficient liquidity to support our operations through 2012, we will need to raise additional capital in the future to fund our current business plan and support our operations.

We are currently advancing with necessary preparations to be able to initiate pivotal trials in RR-MS and are exploring trial designs for a potential Phase II clinical study in SP-MS. As there remain very limited treatment options for patients with progressive forms of MS, the substantial unmet medical need has increased the urgency to develop new treatments for these patients and, subsequently, our interest in advancing Tovaxin in SP-MS. We believe Tovaxin is well positioned in both RR-MS and SP-MS indications, with demonstrated safety and promising clinical efficacy across a broad spectrum of MS patients. Prior to initiating any clinical study, however, we will need to secure additional resources. Unless we are able to secure at least a substantial portion of the resources necessary to complete a clinical study and support our operations during the pendency of such study, or we are reasonably confident that such resources will be secured, we will likely not proceed with the initiation of any such study. Given our need for substantial amounts of capital to conduct a clinical study, we are continuing to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to fund such a study and to support our operations during the pendency of such study. In addition to one or more additional financings, these opportunities and alternatives may include a partnering arrangement with a large biotech or pharmaceutical company. There can be no assurance that any such financing or partnering arrangement can be consummated on acceptable terms, if at all.

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, 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 and debt securities, 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 nine months ended September, 2011, 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 4. 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 September 30, 2011, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officer concluded that, as of September 30, 2011, 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, 2010 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.
- We will be required to raise significant additional capital, or secure a development partner, in the near-term, and our ability to obtain funding is uncertain. If sufficient capital is not available, we may not be able to continue our operations as proposed (including any clinical trial for Tovaxin), which may require us to modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws.
- 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, holders 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.
- We may issue debt and equity securities or securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquidation, which could negatively affect the value of our common stock.
- Our management has significant flexibility in using the net proceeds of the February 2011 public offering.

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. [Removed and Reserved]

Item 5. Other Information.

On November 2, 2011, we entered into an Assignment Agreement and General Release with Novartis by which we re-acquired certain novel stem cell technology assets previously transferred to Novartis pursuant to an Asset Purchase Agreement dated August 6, 2009. Preliminary data for this technology, which had been in early preclinical development at Opexa prior to the 2009 sale, showed the potential to generate monocyte derived islet cells from peripheral blood mononuclear cells. Under the terms of the 2009 agreement with Novartis: (i) Novartis acquired the stem cell technology platform from us and took over all future responsibilities and opportunities for this technology, although we retained an option on certain manufacturing rights; (ii) we were paid an upfront fee of $3 million and a milestone payment of $500,000 for certain technology transfer activities; and (iii) we remained eligible to receive a second technology transfer milestone fee in addition to potential clinical and commercial milestones and royalty payments from the sale of any products resulting from the use of the technology.

Novartis recently advised us that the advancement of the stem cell program was not a priority for Novartis, and that Novartis was willing to transfer the assets back to us in exchange for a release with respect to any further payment obligations owed to us by Novartis, including the remaining $500,000 technology transfer milestone payment. In connection with the re-acquisition of the stem cell assets, a related license agreement with the University of Chicago was assigned back to us. Opexa and the University of Chicago entered into a Fourth Amended and Restated License Agreement in connection with such assignment to Opexa.

The foregoing description is qualified in its entirety by reference to the terms and conditions of the (i) Assignment Agreement and General Release and (ii) Fourth Amended and Restated License Agreement, copies of which are filed as exhibits hereto and incorporated herein by reference.

Item 6. Exhibits.

Exhibit No.	Description
10.1*	Assignment Agreement and General Release, dated November 2, 2011, by and between Opexa Therapeutics, Inc. and Novartis Institutes for BioMedical Research, Inc.
10.2*	Fourth Amended and Restated License Agreement, dated November 2, 2011, by and between Opexa Therapeutics, Inc. and the University of Chicago.
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.
101+	Financial statements from the Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2011, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets; (ii) Statements of Expenses; (iii) Statements of Cash Flows; and (iv) Notes to Financial Statements.

* Filed herewith

\+ In accordance with Rule 406T under Regulation S-T, the XBRL-related information in Exhibit 101 shall be deemed to be “furnished” and not “filed.”

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: November 4, 2011

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

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* Filed herewith

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EXHIBIT 10.1

[ASSIGNMENT AGREEMENT AND GENERAL RELEASE]

EXHIBIT 10.2

[FOURTH AMENDED AND RESTATED LICENSE AGREEMENT]

EXHIBIT 31.1

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: November 4, 2011

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

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

In connection with the Quarterly Report of Opexa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2011 (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: November 4, 2011

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)