

**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, 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
(State or other jurisdiction of
Incorporation or organization)

**2635 Technology Forest Blvd.
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 1, 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 March 31, 2011

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

| | March 31, | December 31, |
|---|----------------------|---------------------|
| | 2011 | 2010 |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 11,427,985 | \$ 3,812,535 |
| Other current assets | 113,774 | 85,525 |
| Total current assets | 11,541,759 | 3,898,060 |
| Property & equipment, net of accumulated depreciation of \$1,139,191 and \$1,109,558, respectively | 980,358 | 815,958 |
| Total assets | <u>\$ 12,522,117</u> | <u>\$ 4,714,018</u> |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 652,870 | \$ 358,837 |
| Accounts payable - related parties | 15,000 | 15,000 |
| Accrued expenses | 374,686 | 335,861 |
| Current maturity of loan payable | 17,970 | 35,607 |
| Total current liabilities | 1,060,526 | 745,305 |
| Total liabilities | 1,060,526 | 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 | 107,251,222 | 98,496,382 |
| Deficit accumulated during the development stage | (96,020,116) | (94,712,339) |
| Total stockholders' equity | 11,461,591 | 3,968,713 |
| Total liabilities and stockholders' equity | <u>\$ 12,522,117</u> | <u>\$ 4,714,018</u> |

See accompanying notes to financial statements

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

| | | Three Months Ended | | Inception |
|---------------------------------------|----------------|---------------------------|-----------------------|------------------------|
| | | March 31, | | through |
| | | 2011 | 2010 | March 31, 2011 |
| Research and development | | \$ 685,161 | \$ 783,534 | \$ 67,523,998 |
| General and administrative | | 592,058 | 484,425 | 25,794,864 |
| Depreciation and amortization | | 29,634 | 49,646 | 1,165,863 |
| Loss on disposal of assets | | - | - | 500,562 |
| | Operating loss | (1,306,853) | (1,317,605) | (94,985,287) |
| Interest income | | 211 | 185 | 1,357,696 |
| Other income and expense, net | | - | - | 661,146 |
| Gain (loss) 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 | | (1,135) | (105,075) | (9,054,959) |
| | Net loss | <u>\$ (1,307,777)</u> | <u>\$ (1,422,495)</u> | <u>\$ (96,020,116)</u> |
| Basic and diluted loss per share | | \$ (0.06) | \$ (0.09) | |
| Weighted average shares outstanding | | 20,955,860 | 15,523,710 | |

See accompanying notes to financial statements

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

| | Three Months Ended | | Inception through March 31, 2011 |
|---|--------------------|----------------|--|
| | March 31, | | |
| | 2011 | 2010 | |
| Cash flows from operating activities | | | |
| Net loss | \$ (1,307,777) | \$ (1,422,495) | \$ (96,020,116) |
| 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 | - | 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 | - | 51,166 | 6,752,698 |
| Loss (Gain) on extinguishment of debt | - | - | (1,612,440) |
| Depreciation | 29,634 | 49,646 | 1,165,863 |
| Amortization of debt financing costs | - | 19,173 | 524,378 |
| Option expense | 95,470 | 105,358 | 15,180,763 |
| Loss on derivative instruments | - | - | (1,388,848) |
| Loss on disposition of fixed assets | - | - | 500,562 |
| Changes in: | | | |
| Other current assets | (28,249) | (30,984) | (530,447) |
| Accounts payable - third parties and related parties | 294,033 | (121,286) | 217,820 |
| Accrued expenses | 38,825 | 219,262 | 326,122 |
| Net cash used in operating activities | (791,036) | (1,130,160) | (46,313,803) |
| Cash flows from investing activities | | | |
| Purchase of property & equipment | (194,034) | - | (1,568,895) |
| Net cash used in investing activities | (194,034) | - | (1,568,895) |
| 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 | - | 56,966 | 1,248,588 |
| Proceeds from debt | - | - | 9,283,184 |
| Repayments on notes payable | (17,637) | (16,352) | (293,252) |
| Net cash provided by financing activities | 8,600,520 | 40,614 | 59,310,683 |
| Net change in cash and cash equivalents | 7,615,450 | (1,089,546) | 11,427,985 |
| Cash and cash equivalents at beginning of period | 3,812,535 | 8,181,582 | - |
| Cash and cash equivalents at end of period | \$ 11,427,985 | \$ 7,092,036 | \$ 11,427,985 |

| | | | | | | | |
|---|--|----|-------|----|-------|----|-----------|
| Cash paid for: | | | | | | | |
| Income tax | | \$ | - | \$ | - | \$ | - |
| Interest | | | 1,135 | \$ | 2,632 | | 151,163 |
| NON-CASH TRANSACTIONS | | | | | | | |
| Issuance of common stock to Sportan shareholders | | | - | | - | | 147,733 |
| Issuance of common stock for accrued interest | | | - | | - | | 603,604 |
| Issuance of warrants to placement agent | | | - | | - | | 37,453 |
| Conversion of notes payable to common stock | | | - | | - | | 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 |

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. (“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 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. 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 March 31, 2011, Opexa invested approximately \$11.3 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. For the three months ended March 31, 2011, the money market fund recognized an average market yield of 0.01%. Interest income of \$211 was recognized for the three months ended March 31, 2011 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 retains 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 remains 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. However, 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 credit line of \$250,000 with Wells Fargo Bank of which \$17,970 was outstanding as of March 31, 2011. 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. 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. Under the ATM Agreement, prior to its termination as noted below, Opexa may sell an aggregate of up to 2,000,000 shares of common stock from time to time through the placement agent. The placement agent may sell the common stock by any method permitted by law, including sales deemed to be an “at the market” offering defined in Rule 415 of the Securities Act of 1933. Sales may be made directly on the NASDAQ Stock Market or to or through a market maker. The placement agent may also sell the common stock in privately negotiated transactions, subject to Opexa’s prior approval. Opexa will pay the placement agent a commission equal to 1% of the gross proceeds from the sale of common stock by it as agent under the ATM Agreement. The ATM Agreement may be terminated by either party at any time (without affecting any pending sale by the agent on

behalf of Opexa). 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 are immediately separable and were issued separately such that no units were issued. The warrants are 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 using 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 6. 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 three months ended March 31, 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 either 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 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 any reserved shares 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 plan. As of March 31, 2011, options to purchase an aggregate of 1,717,072 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, 2011, Opexa recognized share-based compensation expense of \$95,470. Unamortized stock compensation expense as of March 31, 2011 amounted to \$587,408.

Stock Option Activity

A summary of stock option activity for the three months ended March 31, 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 | 175,000 | 1.56 | | |
| Exercised | - | - | | |
| Forfeited and canceled | - | - | | |
| Outstanding at March 31, 2011 | 1,717,072 | \$ 2.09 | 7.4 | \$ 770,385 |
| Exercisable at March 31, 2011 | 1,331,739 | \$ 2.18 | 6.9 | \$ 734,802 |

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 three months ended March 31, 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 three month period ended March 31, 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.

Warrant Activity

A summary of warrant activity for the three months ended March 31, 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 | - | - | | |
| | | | | |
| Outstanding at March 31, 2011 | 13,118,176 | \$ 2.73 | 2.0 | \$ 1,661,327 |
| | | | | |
| Exercisable at March 31, 2011 | 13,118,176 | \$ 2.73 | 2.0 | \$ 1,661,327 |

In connection with Opexa's February 2011 public offering, as disclosed in Note 5, 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.

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, 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 a pivotal Phase III study in the United States for Tovaxin in RR-MS; 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 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 positioned to enter Phase III clinical development for the treatment of relapsing remitting MS (RR-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. We are in the process of completing necessary preparations to be able to initiate such a study.

Our recent 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 currently intend to use the net proceeds of approximately \$7.6 million from our February 2011 public offering for general corporate purposes (including working capital and operational purposes) and to prepare for and proceed toward the initiation of a pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, although the proceeds from such offering together with our existing resources are not adequate to permit us to proceed materially beyond the initiation of such a study (*i.e.*, the dosing of the first patient) or to complete such study or any significant portion of it. A pivotal Phase III clinical study in the United States of Tovaxin in RR-MS is expected to involve 240 patients and take approximately two and one-half years to complete. If we are able to commence such a study in the second half of 2011, the costs of such study as well as the ongoing expenses of our operations through the expected completion date of such study are estimated at

approximately \$35 million. Unless we secure at least a substantial portion of the additional resources that will be necessary to complete the planned Phase III study and support our operations during the pendency of such study, or we are reasonably confident that such resources will be secured, we would likely not proceed with the initiation of such study.

Given our need for substantial amounts of capital to undertake a pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to complete the planned Phase III 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 financings or partnering arrangement can be consummated on acceptable terms, if at all.

Assuming we are able to achieve financing which is sufficient to support the planned Phase III study in the United States and to support our operations during the pendency of such study, we are also preparing for a second pivotal Phase III clinical study in Europe. Any such second study would also depend upon the availability of sufficient resources.

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 retain 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 remain 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. However, 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 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 March 31, 2011 with the Three Months Ended March 31, 2010

Net Sales. We recorded no commercial revenues for the three months ended March 31, 2011 and 2010.

Research and Development Expenses. Research and development expenses were \$685,161 for the three months ended March 31, 2011, compared with \$783,534 for the three months ended March 31, 2010. The decrease in expenses was primarily related to a decrease in the engagement of consultants, a decrease in the procurement and use of supplies in our laboratory, a reduction of stock compensation expense, and the reduction of expenses to recruit employees, and was partially offset by an increase of staff in preparation for increased development activities.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2011 were \$592,058, compared with \$484,425 for the three months ended March 31, 2010. The increase in expense is due to an increase in stock compensation expense to employees and an increase in business development activities, and was partially offset by a decrease in legal expense costs.

Interest Expense. Interest expense was \$1,135 for the three months ended March 31, 2011, compared to \$105,075 for the three months ended March 31, 2010. The decrease in interest expense was primarily related to the amortized interest on the April and May 2009 convertible notes incurred in the first quarter of 2010 (these notes were converted to common stock in June 2010). Interest expense for the three months ended March 31, 2011 related solely to the financing costs on insurance policies and the loan payable on the equipment line.

Interest Income. Interest income was \$211 for the three months ended March 31, 2011, compared to \$185 for the three months ended March 31, 2010.

Net loss. We had a net loss for the three months ended March 31, 2011 of approximately \$1.31 million, or \$0.06 per share (basic and diluted), compared with a net loss of approximately \$1.42 million or \$0.09 per share (basic and diluted) for the three months ended March 31, 2010. The decrease in net loss is primarily due to a decrease in professional fees and a decrease in the procurement and use of supplies in our laboratory, and was partially offset by an increase in stock compensation expense, an increase in business development activities, and an increase of staff in preparation for increased development activities.

Liquidity and Capital Resources

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of March 31, 2011, we had cash and cash equivalents of approximately \$11.4 million. Our financing activities generated \$8.6 million for the three months ended March 31, 2011, compared to \$40,614 for the same period of 2010. The cash generated in the first quarter 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 approximately \$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 \$425,000 per month. While we believe we have sufficient liquidity to support our operations through 2011, we will need to raise additional capital in the future to fund our current business plan and support our operations.

We currently intend to use the proceeds from the February 2011 public offering for general corporate purposes (including working capital and operational purposes) and to prepare for and proceed toward the initiation of a pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, although the proceeds from such offering together with our existing resources would not be adequate to permit us to proceed materially beyond the initiation of such a study (i.e., the dosing of the first patient) or to complete such study or any significant portion of it. A pivotal Phase III clinical study in the United States of Tovaxin in RR-MS is expected to involve 240 patients and take approximately two and one-half years to complete. If we are able to commence such a study in the second half of 2011, the costs of such study as well as the ongoing expenses of our operations through the expected completion date of such study are estimated at approximately \$35 million. Unless we secure at least a substantial portion of the additional resources that will be necessary to complete the planned

Phase III study and support our operations during the pendency of such study, or we are reasonably confident that such resources will be secured, we would likely not proceed with the initiation of such study.

Given our need for substantial amounts of capital, in addition to the proceeds from the February 2011 offering, to undertake a pivotal Phase III clinical study in the United States of Tovaxin in RR-MS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to complete the planned Phase III study and to support the operations of the Company 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 financings or partnering arrangement can be consummated on acceptable terms, if at all.

Assuming we are able to achieve financing which is sufficient to support the planned Phase III study in the United States and to support our operations during the pendency of such study, we are also preparing for a second pivotal Phase III clinical study in Europe. Any such second study would also depend upon the availability of sufficient resources.

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 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 three months ended March 31, 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 March 31, 2011, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officer concluded that, as of March 31, 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.

None.

Item 6. Exhibits.

Exhibit

| <u>No.</u> | <u>Description</u> |
|------------|--|
| 4.1 | Form of Series H Warrant issued by the Company on February 11, 2011 (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed February 8, 2011). |
| 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 5, 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

Exhibit

No. **Description**

- | | |
|-------|--|
| 4.17 | Form of Series H Warrant issued by the Company on February 11, 2011 (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed February 8, 2011). |
| 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

**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 5, 2011

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, 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: May 5, 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)