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, 2012

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 April 30, 2012, 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, 2012

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	March 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 4,677,956	$ 7,109,215
Other current assets	1,005,756	124,773
Total current assets	5,683,712	7,233,988
Property & equipment, net of accumulated depreciation of $1,260,334 and $1,193,601, respectively	1,390,674	1,029,236
Total assets	$ 7,074,386	$ 8,263,224
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,681,799	$ 476,315
Accounts payable - related parties	15,000	15,000
Accrued expenses	350,802	576,545
Total current liabilities	2,047,601	1,067,860
Total liabilities	2,047,601	1,067,860
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 shares issued and outstanding	230,485	230,485
Additional paid in capital	107,851,086	107,645,666
Deficit accumulated during the development stage	(103,054,786)	(100,680,787)
Total stockholders' equity	5,026,785	7,195,364
Total liabilities and stockholders' equity	$ 7,074,386	$ 8,263,224

See accompanying notes to unaudited financial statements

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

	Three Months Ended March 31,		Inception through
	2012	2011	March 31, 2012
Research and development	$ 1,490,097	$ 685,161	$ 71,668,972
General and administrative	816,196	592,058	28,425,271
Depreciation and amortization	67,355	29,634	1,413,836
Loss on disposal of assets	-	-	510,248
Operating loss	(2,373,648)	(1,306,853)	(102,018,327)
Interest income	136	211	1,358,553
Other income, net	-	-	661,146
Gain on extinguishment of debt	-	-	1,612,440
Gain on derivative instruments	-	-	1,388,848
Gain on sale of technology	-	-	3,000,000
Interest expense	(487)	(1,135)	(9,057,446)
Net loss	$ (2,373,999)	$ (1,307,777)	$ (103,054,786)
Basic and diluted loss per share	$ (0.10)	$ (0.06)	
Weighted average shares outstanding	23,048,488	20,955,860	

See accompanying notes to unaudited financial statements

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

	Three Months Ended March 31,		Inception through
	2012	2011	March 31, 2012
Cash flows from operating activities			
Net loss	$ (2,373,999)	$ (1,307,777)	$ (103,054,786)
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	-	-	6,752,698
Gain on extinguishment of debt	-	-	(1,612,440)
Depreciation	67,355	29,634	1,413,836
Amortization of debt financing costs	-	-	524,378
Option expense	205,420	95,470	15,780,627
Gain on derivative instruments	-	-	(1,388,848)
Loss on disposition of fixed assets	-	-	510,248
Changes in:			
Other current assets	(880,983)	(28,249)	(1,422,429)
Accounts payable - third parties and related parties	1,022,532	294,033	933,291
Accrued expenses	(225,743)	38,825	296,477
Net cash used in operating activities	(2,185,418)	(791,036)	(52,697,106)
Cash flows from investing activities			
Purchase of property & equipment	(245,841)	(194,034)	(1,917,651)
Net cash used in investing activities	(245,841)	(194,034)	(1,917,651)
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	-	-	1,248,588
Proceeds from debt	-	-	9,283,184
Repayments on notes payable	-	(17,637)	(311,222)
Net cash provided by financing activities	-	8,600,520	59,292,713
Net change in cash and cash equivalents	(2,431,259)	7,615,450	4,677,956
Cash and cash equivalents at beginning of period	7,109,215	3,812,535	-
Cash and cash equivalents at end of period	$ 4,677,956	$ 11,427,985	$ 4,677,956

Cash paid for:			
Income tax	$ -	$ -	$ -
Interest	487	1,135	153,650
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
Unpaid additions to property and equipment	182,952	136,266	182,952

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 interim unaudited 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.

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, 2012, Opexa invested approximately $4.5 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 three months ended March 31, 2012, the money market fund recognized an average market yield of 0.01%. Interest income of $136 was recognized for the three months ended March 31, 2012 in the statements of expenses.

Note 3. Other Current Assets

Other current assets at March 31, 2012 include prepaid reagents and supplies amounting to $796,154 that will be used in the Company's planned clinical study. Opexa expects to amortize these prepaid reagents and supplies to research and development costs upon initiation of the planned clinical study.

Note 4. Stock-Based Compensation

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 March 31, 2012, options to purchase an aggregate of 3,227,222 shares were issued and outstanding.

Opexa accounts for share-based compensation, including options and nonvested shares, according to the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 718, "Share Based Payment." During the three months ended March 31, 2012, Opexa recognized option expense of $205,420 which includes the related expense for the options that are expected to vest based on achievement of their related performance conditions (see below). Unamortized stock compensation expense as of March 31, 2012 amounted to $1,000,739.

Stock Option Activity

A summary of stock option activity for the three months ended March 31, 2012 is presented below:

	Number of Shares	Wtd. Avg. Exercise Price	Wtd. Avg. Remaining Contract Term (# years)	Intrinsic Value
Outstanding at January 1, 2012	1,771,705	$ 1.93		
Granted	1,541,767	0.95		
Exercised	-	-		
Forfeited and canceled	(86,250)	3.50		
Outstanding at March 31, 2012	3,227,222	$ 1.42	8.2	$ 157,807
Exercisable at March 31, 2012	1,520,822	$ 1.83	6.7	$ 157,807

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.

During the three months ended March 31, 2012, options to purchase an aggregate of 375,331 shares were granted to employees, based on 2011 performance objectives, at an exercise price of $0.95. These options have terms of ten years and have a vesting schedule of three years. Fair value of $344,309 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for the options issued to employees during the three months ended March 31, 2012 include (1) discount rate of 1.98%, (2) expected term of 5.25 years, (3) expected volatility of 183% and (4) zero expected dividends.

During the three months ended March 31, 2012, options to purchase an aggregate of 1,019,036 shares were granted to senior management, based on the achievement of future performance-based, strategic milestone objectives, at an exercise price of $0.95. These options have terms of ten years and have vesting schedules of three years commencing after the two specific milestone objectives have been met. Fair value of $964,715 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for the options issued to senior management during the three months ended March 31, 2012 include (1) discount rate of 1.98%, (2) expected term of ten years, (3) expected volatility of 183% and (4) zero expected dividends.

During the three months ended March 31, 2012, options to purchase an aggregate of 25,000 shares were granted to recently hired employees at exercise prices ranging from $0.92 to $0.95. These options have terms of ten years and have a vesting schedule of three years commencing after the one-year anniversary of the individual employee's date of hire. Fair value of $23,103 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for the options issued to recently hired employees during the three months ended March 31, 2012 include (1) discount rate of 1.40%, (2) expected term of seven years, (3) expected volatility of 183% and (4) zero expected dividends.

During the three months ended March 31, 2012, options to purchase an aggregate of 122,400 shares were granted to directors for service on Opexa's Board at an exercise price of $0.94. 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 82,400 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, 2012. Fair value of $111,428 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for the options issued to directors during the three months ended March 31, 2012 include (1) discount rate of 2.03%, (2) expected term of 5.25 years, (3) expected volatility of 186% and (4) zero expected dividends.

Warrant Activity

A summary of warrant activity for the three months ended March 31, 2012 is presented below:

	Number of Shares	Wtd. Avg. Exercise Price	Wtd. Avg. Remaining Contract Term (# years)	Intrinsic Value
Outstanding at January 1, 2012	10,430,286	$ 1.90		
Granted	-	-		
Exercised	-	-		
Forfeited and canceled	-	-		
Outstanding at March 31, 2012	10,430,286	$ 1.90	1.5	$ 137,840
Exercisable at March 31, 2012	10,430,286	$ 1.90	1.5	$ 137,840

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, 2012. 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, 2011.

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 for 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 that we may license or transfer; 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 IIb clinical development for the treatment of patients with secondary progressive MS (SP-MS) as well as Phase III clinical development for the treatment of patients with 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

In late 2010, we conducted formal End of Phase II meetings with the FDA regarding our planned development program for Tovaxin. These 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.

During the second meeting we presented our rationale and trial design for a Phase III pivotal study of 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 in RR-MS.

In 2011, we submitted our data, rationale and additional background information to support the SP-MS indication. Upon review of the dossier, the FDA granted us Fast Track designation for Tovaxin in SP-MS. The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical need. SP-MS is characterized by a steady accrual of irreversible disability, despite, in some cases, reversible relapses, remissions or clinical plateau. Only one product is currently approved in the United States specifically for the indication of SP-MS, and we believe that a significant unmet need exists for the safe and effective treatment of SP-MS.

Based on this positive FDA milestone, our encouraging data in SP-MS and supportive discussions with key opinion leaders, clinicians and patients, we have accelerated our plans for SP-MS and are currently planning to initiate a Phase IIb clinical trial of Tovaxin in SP-MS patients, subject to securing the necessary resources to conduct such a trial. We also remain committed to further advancing Tovaxin in RR-MS at a later date. For Opexa, moving forward in progressive MS, an area which we believe represents a higher unmet medical need, could further differentiate the Company and Tovaxin from other MS treatments.

A Phase IIb clinical study in North America of Tovaxin in SP-MS is expected to involve 180 patients and take approximately three years to complete. If we are able to commence such a study in mid-2012, 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 $32 million. 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. Unless we secure at least a substantial portion of the additional resources that will be necessary to complete the planned Phase IIb 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 Phase IIb clinical study in North America of Tovaxin in SP-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 IIb study and to support ongoing 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.

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.

We have developed a proprietary adult stem cell technology to produce monocyte-derived stem cells (MDSC) from blood. These MDSC can be derived from a patient's monocytes, expanded *ex vivo*, and then administered to the same patient. Our initial focus is the further development of this monocyte-derived stem cell technology as a platform for the *in vitro* generation of highly specialized cells for potential application in autologous cell therapy for patients with diabetes mellitus. The diabetes program is in an early (pre-clinical) development stage.

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, 2012 with the Three Months Ended March 31, 2011

Net Sales. We recorded no commercial revenues for the three months ended March 31, 2012 and 2011.

Research and Development Expenses. Research and development expenses were $1,490,097 for the three months ended March 31, 2012, compared with $685,161 for the three months ended March 31, 2011. The increase in expenses was primarily related to an increase in the procurement and use of laboratory reagents and supplies, an increase in professional service fees including initial costs incurred in conjunction with the engagement of a contract research organization to manage the clinical sites during the planned clinical study, an increase in personnel to conduct increased development activities as well as prepare for and conduct the clinical trial, an increase in facility costs relating to expanded operations and an increase of stock compensation expense to employees.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2012 were $816,196, compared with $592,058 for the three months ended March 31, 2011. The increase in expense is due to an increase in business development activities, an increase in legal expense costs, an increase in compensation expense to employees and an increase in stock compensation expense for stock options granted.

Depreciation and Amortization Expenses. Depreciation and amortization expenses were $67,355 for the three months ended March 31, 2012, compared to $29,634 for the three months ended March 31, 2011. 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 and 2012 to support increased development activities and an increase in depreciation for information technology equipment acquired during 2011 and 2012 to replace and upgrade obsolete equipment.

Interest Expense. Interest expense was $487 for the three months ended March 31, 2012, compared to $1,135 for the three months ended March 31, 2011.

Interest Income. Interest income was $136 for the three months ended March 31, 2012, compared to $211 for the three months ended March 31, 2011.

Net Loss. We had a net loss for the three months ended March 31, 2012 of approximately $2.37 million, or $0.10 per share (basic and diluted), compared with a net loss of approximately $1.31 million, or $0.06 per share (basic and diluted), for the three months ended March 31, 2011. The increase in net loss is primarily due to the increase in the procurement of key laboratory reagents and supplies, and increases in professional service fees, employee compensation expense, stock compensation expense, facility costs and depreciation expense.

Liquidity and Capital Resources

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of March 31, 2012, we had cash and cash equivalents of approximately $4.7 million.

Our burn rate during the first quarter of 2012, which is in the absence of any clinical trial but includes preparation for initiation of a trial, was approximately $810,000 per month. While we will need to raise additional capital to fund our current business plan and support our operations, we believe we would have sufficient liquidity to support our business operations through 2012 if we defer the preparations and commencement of our clinical trial accordingly.

We currently intend to continue to use our available cash to fund general corporate purposes (including working capital and operational purposes) and to prepare for and proceed toward the initiation of a Phase IIb clinical study of Tovaxin in SP-MS, subject to securing the necessary resources to conduct such a study. We also remain committed to further advancing Tovaxin in RR-MS at a later date (also subject to securing the necessary resources to do so). Significant activities in preparation for, and the conduct of, a clinical trial will result in substantial increases in our monthly cash burn. A Phase IIb clinical study in North America of Tovaxin is expected to involve 180 patients and take approximately three years to complete. If we are able to commence such a study in mid-2012, 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 $32 million. 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. Unless we secure at least a substantial portion of

the additional resources that will be necessary to complete the planned Phase IIb 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 Phase IIb clinical study in North America of Tovaxin in SP-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 IIb study and to support ongoing 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 IIb study in North America and to support our operations during the pendency of such study, we are also preparing for pivotal Phase III clinical studies in RR-MS in North America and Europe. Any such RR-MS studies 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, 2012, 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, 2012, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officer concluded that, as of March 31, 2012, 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 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, 2011 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 our current available cash.

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 6. Exhibits.

Exhibit No.	Description
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 March 31, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Expenses; (iii) Consolidated Statements of Cash Flows; and (iv) Notes to Consolidated Financial Statements.

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* 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: May 11, 2012

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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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: May 11, 2012

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 March 31, 2012 (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 11, 2012

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)