UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Quarterly Period Ended September 30, 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 November 2, 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 September 30, 2012

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 2,237,618	$ 7,109,215
Other current assets	1,188,237	124,773
Total current assets	3,425,855	7,233,988
Property & equipment, net of accumulated depreciation		
of $1,418,344 and $1,193,601, respectively	1,327,649	1,029,236
Restricted cash	1,000,000	-
Deferred financing costs, net of amortization		
of $24,710 and $0, respectively	245,408	-
Total assets	$ 5,998,912	$ 8,263,224
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 534,368	$ 476,315
Accounts payable - related parties	8,333	15,000
Accrued expenses	358,070	576,545
Warrant derivative liabilities	2,451,524	-
Total current liabilities	3,352,295	1,067,860
Long term liabilities:		
Convertible debt, net of unamortized discount		
of $3,195,066 and $0, respectively	259,934	-
Convertible debt - related parties, net of unamortized discount		
of $582,602 and $0, respectively	47,398	-
Total liabilities	3,659,627	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	109,686,066	107,645,666
Deficit accumulated during the development stage	(107,577,266)	(100,680,787)
Total stockholders' equity	2,339,285	7,195,364
Total liabilities and stockholders' equity	$ 5,998,912	$ 8,263,224

See accompanying notes to unaudited consolidated financial statements

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

	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Inception through September 30, 2012
Research and development	$ 1,455,938	$ 654,772	$ 4,504,243	$ 2,194,141	$ 74,683,118
General and administrative	532,474	584,794	1,878,236	1,737,686	29,487,311
Depreciation and amortization	81,514	56,888	225,365	157,254	1,571,846
Loss on disposal of assets	-	413	-	413	510,248
Operating loss	(2,069,926)	- (1,296,867)	(6,607,844)	(4,089,494)	(106,252,523)
Interest income	61	227	256	698	1,358,673
Other income, net	-	-	-	-	661,146
Gain on extinguishment of debt	-	-	-	-	1,612,440
Gain (loss) on derivative instruments	(136,889)	-	(136,889)	-	1,251,959
Gain on sale of technology	-	-	-	-	3,000,000
Interest expense	(151,029)	(638)	(152,002)	(2,643)	(9,208,961)
Net loss	$ (2,357,783)	$ (1,297,278)	$ (6,896,479)	$ (4,091,439)	$ (107,577,266)
Basic and diluted loss per share	$ (0.10)	$ (0.06)	$ (0.30)	$ (0.18)	N/A
Weighted average shares outstanding	23,048,488	23,048,488	23,048,488	22,358,611	N/A

See accompanying notes to unaudited consolidated financial statements

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

	Nine Months Ended September 30,		Inception through
	2012	**2011**	**September 30, 2012**
Cash flows from operating activities			
Net loss	$ (6,896,479)	$ (4,091,439)	$ (107,577,266)
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	34,600	-	6,787,298
Gain on extinguishment of debt	-	-	(1,612,440)
Depreciation	225,365	157,254	1,571,846
Amortization of debt financing costs	24,710	-	549,088
Option expense	542,766	385,811	16,117,973
Gain on derivative instruments	136,889	-	(1,251,959)
Loss on disposition of fixed assets	-	413	510,248
Changes in:			
Other current assets	(1,025,807)	(20,120)	(1,567,253)
Accounts payable - third parties and related parties	(130,278)	59,817	(219,519)
Accrued expenses	(219,372)	(49,976)	302,848
Net cash used in operating activities	(7,307,606)	(3,471,212)	(57,819,294)
Cash flows from investing activities			
Purchase of property & equipment	(512,048)	(284,017)	(2,183,858)
Restricted cash	(1,000,000)	-	(1,000,000)
Net cash used in investing activities	(1,512,048)	(284,017)	(3,183,858)
Cash flows from financing activities			
Common stock and warrants sold for cash, net of offering costs	-	8,618,157	49,072,488
Convertible promissory notes and warrants sold for cash, net of offering costs	-	-	-
Common stock repurchased and canceled	-	-	(325)
Proceeds from exercise of warrants and options	-	-	1,248,588
Proceeds from third party debt	3,455,000	-	12,738,184
Proceeds from related party debt	630,000	-	630,000
Debt financing costs	(136,943)	-	(136,943)
Repayments on notes payable	-	(35,607)	(311,222)
Net cash provided by financing activities	3,948,057	8,582,550	63,240,770
Net change in cash and cash equivalents	(4,871,597)	4,827,321	2,237,618
Cash and cash equivalents at beginning of period	7,109,215	3,812,535	-
Cash and cash equivalents at end of period	$ 2,237,618	$ 8,639,856	$ 2,237,618

Cash paid for:			
Income tax	$ -	$ -	$ -
Interest	1,460	2,643	154,623
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	2,314,635	-	5,974,372
Beneficial conversion feature	1,497,634	-	3,303,153
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	11,730	10,911	11,730
Unpaid additions to deferred financing costs	170,831	-	170,831

See accompanying notes to unaudited consolidated financial statements

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

Note 1. Basis of Presentation and Principles of Consolidation

The accompanying interim unaudited consolidated financial statements of Opexa Therapeutics, Inc. ("Opexa" or the "Company"), 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 ("SEC") 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.

The accompanying unaudited consolidated financial statements for the nine months ended September 30, 2012 and 2011 have been prepared assuming that the Company will continue as a going concern, meaning the Company will continue in operation for the foreseeable future and will be able to realize assets and discharge liabilities in the ordinary course of operations. The Company does not currently generate commercial revenues and its burn rate during the nine months ended September 30, 2012, inclusive of the cost of preparations to commence the Phase IIb clinical study, was approximately $885,000 per month, thereby creating substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company continues to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to complete the ongoing Phase IIb study and to support ongoing operations during the pendency of such study. However, there can be no assurance that the Company will be able to secure additional funds and that if such funds are available, whether the terms or conditions would be acceptable to the Company. The consolidated financial statements contain no adjustment for this uncertainty.

The accompanying consolidated financial statements include the accounts of Opexa and any subsidiaries. All intercompany balances and transactions have been eliminated in the consolidation.

Note 2. Cash and Cash Equivalents

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

At September 30, 2012, Opexa had $2,237,618 in cash and cash equivalents with approximately $2.0 million of this invested in a money market fund investing exclusively in high-quality, short-term money market instruments consisting of U.S. government obligations and repurchase agreements collateralized by the U.S. Government. While this fund seeks current income while preserving capital and liquidity, the fund is subject to risk, including U.S. government obligations risk, and is not federally insured or guaranteed by or obligations of the Federal Deposit Insurance Corporation or any other agency. For the nine months ended September 30, 2012, the money market fund recognized an average market yield of 0.01%. Interest income of $256 was recognized for the nine months ended September 30, 2012 in the statement of expenses.

Note 3. Other Current Assets

Other current assets at September 30, 2012 include prepaid reagents and supplies amounting to $719,879 that will be used in Opexa's recently commenced clinical study. Opexa expects to amortize these prepaid reagents and supplies to research and development costs over the course of the clinical study.

Other current assets at September 30, 2012 also include costs incurred from third parties in connection with the implementation of an at-the-market program ("ATM Agreement") pursuant to which Opexa may sell shares of its common stock from time to time depending upon market demand through a sales agent in transactions deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933. As of September 30, 2012, the costs of $47,657 in connection with the implementation of the

ATM Agreement were capitalized and are included in other current assets. Upon the sales of any shares of common stock under the ATM Agreement, the capitalized costs will be offset against the proceeds of such sales of shares of common stock.

Note 4. Restricted Cash

Opexa issued a total of $4,085,000 in principal amount of convertible secured promissory notes to related parties and third parties on July 25, 2012 (see Note 6). As part of the security interest granted by Opexa to the investors, $1,000,000 of the proceeds are required to be maintained in an account subject to a deposit account control agreement while the Notes are outstanding. As of September 30, 2012, the $1,000,000 balance in the controlled account is reported as restricted cash in the consolidated balance sheets.

Note 5. Deferred Financing Costs

Deferred financing costs at September 30, 2012 consist of costs incurred from third parties in conjunction with the debt financing which closed on July 25, 2012 (See Note 6). The costs in connection with the debt financing were capitalized and are amortized to interest expense over the term of the related debt. As of September 30, 2012, the unamortized deferred financing costs totaling $245,408 are reported as deferred financing costs in the consolidated balance sheets. During the quarter ended September 30, 2012, Opexa amortized $24,710 of deferred financing costs as interest expense.

Note 6. Convertible Secured Promissory Notes

On July 25, 2012, Opexa issued a total of $4,085,000 in principal amount of secured convertible promissory notes ("Notes") to third parties and related parties, of which an aggregate of $630,000 was issued to related parties (See Note 7). The Notes mature on July 25, 2014 and accrue interest at the rate of 12% per annum, compounded annually. Interest is payable semi-annually on June 30 and December 31 in either cash or registered shares of common stock, at Opexa's election. The Notes are secured by substantially all of Opexa's assets and are convertible into a new class of non-voting Series A convertible preferred stock. The Notes can be converted into Series A convertible preferred stock at the option of the investors at a price of $100.00 per share, subject to certain limitations and adjustments. Additionally, Opexa can elect to convert the Notes into Series A convertible preferred stock if (i) Opexa's common stock closes at or above $2.50 per share for 20 consecutive trading days or (ii) Opexa achieves certain additional funding milestones to continue its clinical trial program. These milestones include (x) executing a strategic agreement with a partner or potential partner by which Opexa will receive a minimum of $5 million to partially fund, or an option to partner with Opexa for, its Phase II clinical trial for Tcelna in patients with SPMS and (y) receiving a minimum of $25 million in additional capital (including the Note offering proceeds) from any partner, potential partner or any other source.

The Series A convertible preferred stock accrues dividends at the rate of 8% per annum, which are cumulative and payable semi-annually on June 30 and December 31 in either cash or registered shares of common stock at Opexa's election. The Series A convertible preferred stock has a liquidation preference of $100.00 per share, entitling holders to payment from the assets of the Company available for distribution to its shareholders before any payment is made to the holders of the common stock. The Series A convertible preferred stock participates in any dividends or other distributions on shares of common stock (other than dividends payable in shares of common stock) along with the common stock. The Series A convertible preferred stock is convertible into shares of Opexa's common stock at the option of the holders at a price of $0.80 per share, subject to certain limitations and adjustments. Additionally, Opexa can elect to convert the Series A convertible preferred stock into common stock if Opexa's common stock closes at or above $4.00 per share for 20 consecutive trading days. If, as of December 31, 2012, Opexa has not entered into a strategic agreement with a partner or potential partner pursuant to which Opexa has or will receive at least $5 million in funding for use toward the clinical development of Tcelna or in return for granting a license, other rights, or an option to license or otherwise acquire rights with respect to Tcelna, the then applicable Series A convertible preferred stock conversion price will be adjusted in the event of the closing of the first down-round financing following July 25, 2012 for the issuance of common stock or common stock equivalents, to the price per share at which Opexa sells securities in such financing, subject to a floor of $0.780625.

As part of the security interest in all of Opexa's assets granted to the noteholders, $1,000,000 of the proceeds are maintained in a controlled account. The noteholders were granted certain registration rights for the shares of underlying common stock.

The Notes were analyzed for a beneficial conversion feature and Opexa concluded that a beneficial conversion feature exists. The beneficial conversion feature was measured using the commitment-date stock price and was determined to be $1,497,634, of which $230,969 was attributable to related parties. This amount was recorded as a debt discount and is amortized to interest expense over the term of the Notes. Opexa also analyzed the Notes for derivative accounting consideration and determined that derivative accounting does not apply.

In connection with the issuance of the Notes, Opexa also issued Series I warrants to the noteholders to purchase an aggregate of 3,829,689 shares of Opexa's common stock at $1.25 per share, subject to certain limitations and adjustments. The warrants have a five-year term and are exercisable after six months from the date of issuance. Opexa can redeem the warrants at $0.01 per share if its common stock closes at or above $2.50 per share for 20 consecutive trading days. In the event Opexa issues shares of common stock or common stock equivalents at a price less than the then current warrant exercise price, then the warrant exercise price will be reduced to the price at which Opexa issues such shares, subject to a warrant exercise floor price of $0.64 per share. If an adjustment to the warrant exercise price would otherwise go below the warrant exercise price floor, but for the floor limit, the number of warrant shares for which the warrant is exercisable may be increased by a factor equal to the warrant exercise price floor dividend by the lower price, subject to an aggregate increase cap of 50% of the original number of warrant shares. As a result, Opexa accounted for these reset provisions in accordance with Accounting Standards Codification ("ASC") ASC 815-40, which requires Opexa to record the warrants as a derivative liability at the grant date and to record changes in fair value relating to the warrants at each subsequent balance sheet date.

The initial fair value of the warrant liabilities of $2,314,635, together with the beneficial conversion feature of $1,497,634 were recognized as a debt discount and are amortized to interest expense over the term of the Notes using the effective interest method. The amortized debt discount for the quarter-ended September 30, 2012 was $34,600 and Opexa recognized $136,889 as a derivative loss due to the change in fair value of the liability. The unamortized discount as of September 30, 2012 amounted to $3,777,668.

Note 7. Related Party Transactions

Investors in the July 25, 2012 Note offering included two members of Opexa's Board of Directors and entities affiliated with a third director (See Note 6). Opexa issued an aggregate of $630,000 in principal amount of Notes to the two directors and an entity for which a third director reports beneficial ownership of Opexa securities. In connection with the issuance of such Notes, Opexa also issued warrants to purchase an aggregate of 590,625 shares of common stock. The fair value of the warrants was $356,969. Opexa also determined the Notes contained a beneficial conversation feature with fair value of $230,969. Opexa recorded a total of $587,939 as debt discount associated with the Notes issued to the related parties and amortized $5,336 as interest expense for the quarter ended September 30, 2012.

On August 15, 2012, Opexa appointed director David E. Jorden as its Acting Chief Financial Officer. As a non-employee officer of Opexa, Mr. Jorden will receive cash compensation of $100,000 per annum for his service. As of September 30, 2012, cash compensation totaling $8,333 was due to Mr. Jorden and is reported as accounts payable-related parties in the consolidated balance sheets.

Note 8. Fair Value of Financial Instruments

The carrying value of cash and cash equivalents, receivables, accounts payable and accrued expenses approximates their fair values because of the short-term nature of these instruments. The carrying value of the Notes approximates fair value since the related rate of interest approximates current market rates. Management believes Opexa is not exposed to significant interest or credit risks arising from these financial instruments.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. Opexa utilizes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable.

- Level 1 — Quoted prices in active markets for identical assets or liabilities. These are typically obtained from real-time quotes for transactions in active exchange markets involving identical assets.

- Level 2 — Quoted prices for similar assets and liabilities in active markets; quoted prices included for identical or similar assets and liabilities that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets. These are typically obtained from readily-available pricing sources for comparable instruments.

- Level 3 — Unobservable inputs, where there is little or no market activity for the asset or liability. These inputs reflect the reporting entity's own beliefs about the assumptions that market participants would use in pricing the asset or liability, based on the best information available in the circumstances.

The following table presents the derivative financial instruments, Opexa's only financial liabilities measured and recorded at fair value on the Company's consolidated balance sheets on a recurring basis, and their level within the fair value hierarchy as of September 30, 2012:

	September 30, 2012	Level 1	Level 2	Level 3
Warrant derivative liabilities	$ 2,451,524	$ -	$ -	$ 2,451,524
Total	$ 2,451,524	$ -	$ -	$ 2,451,524

The following table provides a summary of the changes in fair value, including net transfers in and/or out, of the derivative financial instruments, measured at fair value on a recurring basis using significant unobservable inputs:

Balance at December 31, 2011	$ -
Fair value of warrant derivative liabilities at issuance	$ 2,314,635
Unrealized derivative losses included in other income (expense)	$ 136,889
Balance at September 30, 2012	$ 2,451,524

The fair value of the derivative liabilities are calculated at the time of issuance using the Lattice option pricing model with Monte Carlo simulation. Opexa records a derivative liability for the calculated value. Changes in the fair value of the derivative liabilities are reported in other income (expense) in the consolidated statements of expenses. The variables used in the Lattice option pricing model for the derivative liabilities during the nine months ended September 30, 2012 include:

	July 25, 2012	September 30, 2012
Market value of common stock on measurement date	$0.64	$0.68
Projected exercise price	$1.25	$1.13
Risk free interest rate	0.56%	0.56%
Warrant lives in years	5	4.88
Expected volatility	193%	193%
Expected dividend yields	0%	0%
Offering price range	$0.64-$1.64	$0.68-$1.68

Note 9. 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 September 30, 2012, options to purchase an aggregate of 3,278,222 shares were issued and outstanding.

Opexa accounts for share-based compensation, including options and nonvested shares, according to the provisions of ASC 718, "Share Based Payment." During the nine months ended September 30, 2012, Opexa recognized option expense of $542,766 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 September 30, 2012 amounted to $651,689.

Stock Option Activity

A summary of stock option activity for the nine months ended September 30, 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	1,616,767	0.93		
Exercised	-	-		
Forfeited and canceled	(110,250)	3.13		
Outstanding at September 30, 2012	3,278,222	$ 1.39	7.9	$ 145,443
Exercisable at September 30, 2012	1,681,544	$ 1.78	6.6	$ 136,943

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 nine months ended September 30, 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 these options 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 nine months ended September 30, 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 individually 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 these options 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 nine months ended September 30, 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 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 these options 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 nine months ended September 30, 2012, an option to purchase an aggregate of 75,000 shares was granted to Opexa's Acting Chief Financial Officer at an exercise price of $0.51 in connection with his appointment. This option has a term of ten years, with one-third of the shares vesting immediately, one-third of the shares vesting on December 31, 2012 and the remaining one-third of the shares vesting at the earlier of June 30, 2013 or the appointment of a permanent chief financial officer. Fair value of $37,096 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for this option include (1) discount rate of 1.80%, (2) expected term of 5.25 years, (3) expected volatility of 185.45% and (4) zero expected dividends.

During the nine months ended September 30, 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 these options 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 nine months ended September 30, 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	3,829,689	1.25		
Exercised	-	-		
Forfeited and canceled	(1,858,336)	1.53		
Outstanding at September 30, 2012	12,401,639	$ 1.72	2.4	$ 120,912
Exercisable at September 30, 2012	8,571,950	$ 1.93	1.3	$ 120,912

In connection with Opexa's July 25, 2012 private offering of the Notes (see Note 6), Opexa issued Series I warrants to purchase an aggregate of 3,829,689 shares of common stock at an exercise price of $1.25 per share, subject to certain limitations and adjustments. These warrants have a term of five years and are initially exercisable on January 25, 2013.

Note 10. Subsequent Events

On November 2, 2012, Opexa entered into a $15,000,000 purchase agreement and a registration rights agreement, and on November 5, 2012, Opexa entered into a $1,500,000 purchase agreement, each with Lincoln Park Capital Fund, LLC ("Lincoln Park") pursuant to which Opexa has the right to sell to Lincoln Park an aggregate of up to $16,500,000 in shares of its common stock, subject to certain conditions and limitations.

Under the terms and subject to the conditions of the purchase agreements, Lincoln Park is obligated to purchase up to an aggregate of $16,500,000 in shares of common stock (subject to certain limitations) from time to time over a 30-month period (which, as it relates to the $15,000,000 purchase agreement, commences on the date that a registration statement is declared effective by the SEC and a final prospectus in connection therewith is filed). Opexa may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 100,000 shares of common stock in regular purchases, increasing to amounts of up to 300,000 shares depending upon the closing sale price of the Company's common stock. In addition, Opexa may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the Company's common stock equals or exceeds $0.75 per share. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to 12 business days leading up to such time), but in no event will shares be sold to Lincoln Park on a day the common stock closing price is less than the floor price of $0.45, subject to adjustment. As of November 8, 2012, Opexa had sold 100,000 shares to Lincoln Park under the $1,500,000 purchase agreement for gross proceeds of $50,000.

The purchase agreements also limit Opexa's sales of shares of common stock to Lincoln Park to the lesser of (i) the maximum number of shares of common stock issuable under applicable rules of the NASDAQ Capital Market, unless shareholder approval to exceed that maximum is obtained or the average price of all applicable sales of common stock exceed a "base price" (or $0.7739, representing Opexa's closing consolidated bid price on November 2, 2012 plus an incremental amount to account for the issuance of commitment shares) such that the sales to Lincoln Park are considered to be at least "at market" under applicable NASDAQ rules, (ii) no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than a stated percentage of the then outstanding shares of common stock (i.e., 4.99% under the $1,500,000 purchase agreement, and 9.99% under the $15,000,000 purchase agreement) and (iii) with respect to the $1,500,000 purchase agreement only, the maximum number of shares of common stock that Opexa may issue without exceeding the ceiling set forth in General Instruction I.B.6. of Form S-3 and the applicable interpretive guidance of the SEC (i.e., an amount based on one-third of the market value of our outstanding common stock held by non-affiliates), noting that shares Opexa may sell under its at-the-market offering program effectively reduce such ceiling.

As consideration for its commitment to purchase shares of common stock pursuant to the purchase agreements, Opexa issued to Lincoln Park 226,027 shares of common stock and agreed to issue up to an aggregate of an additional 452,055 shares of common stock on a pro rata basis as, when and if Lincoln Park purchases shares of common stock under the purchase agreements.

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

The following discussion and analysis of our financial condition is as of September 30, 2012. Our results of operations and cash flows should be read in conjunction with our unaudited consolidated 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; the rights and preferences provided to the Series A Convertible Preferred Stock and investors in the convertible secured notes we issued in July 2012 (including a secured interest in all of our assets); our ability to enter into and benefit from a partnering arrangement for our product candidate, Tcelna, 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 Tcelna; 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 development programs (including to undertake and complete any ongoing or further clinical studies for Tcelna), including in this regard our ability to satisfy various conditions required to access the financing potentially available under the purchase agreements with Lincoln Park (such as the minimum closing price for our common stock, the registration of the underlying shares of common stock under the Securities Act of 1933, as amended, and the requirement for an ongoing trading market for our stock); the success of our clinical trials; the efficacy of Tcelna for any particular indication, such as for relapsing remitting MS or secondary progressive 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 Tcelna); the risk of litigation regarding our intellectual property rights or the rights of third parties; 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.

Opexa is 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 candidate is preliminary and investigative. Our product candidate has not been approved by the U.S. Food and Drug Administration (FDA) for marketing.

Our product candidate, Tcelna™ (formerly known as Tovaxin®), is a personalized T-cell therapy licensed from Baylor College of Medicine, which is in clinical development for the treatment of MS.

T-Cell Therapy and Tcelna™

Tcelna™ is a novel T-cell immunotherapy in Phase IIb clinical development for the treatment of patients with secondary progressive MS (SPMS). It is also positioned to enter Phase III clinical development for the treatment of patients with relapsing remitting MS (RRMS), subject to the availability of sufficient resources. Tcelna is a personalized therapy that is specifically tailored to each patient's disease profile. Tcelna is manufactured using ImmPath™, 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.

Initiation of Phase IIb Clinical Study in Patients with SPMS

We recently initiated a Phase IIb clinical trial of Tcelna in patients with SPMS. The trial is entitled: A Phase II Double-Blind, Placebo Controlled Multi-Center Study to Evaluate the Efficacy and Safety of Tcelna in Subjects with Secondary Progressive Multiple Sclerosis and has been named the "Abili-T" trial. The newly-initiated Abili-T trial is a double-blind, 1:1 randomized, placebo-controlled study in SPMS patients who demonstrate evidence of disease progression without associated relapses. The trial is expected to enroll 180 patients at approximately 30 leading clinical sites in the U.S. and Canada and is expected to take approximately three years to complete. According to the study protocol, patients will receive two annual courses of Tcelna treatment consisting of five subcutaneous injections per year at weeks 0, 4, 8, 12 and 24. The primary efficacy endpoint of the trial is the percentage of brain volume change (atrophy) at 24 months. Study investigators will also measure several important secondary outcomes commonly associated with MS including disease progression as measured by Expanded Disability Status Scale (EDSS), annualized relapse rate (ARR) and changes in disability as measured by EDSS and the Multiple Sclerosis Functional Composite (MSFC). The Abili-T clinical trial is expected to enroll over a 12-month period and the resulting top-line data is expected by the end of 2015.

Tcelna is the first ever personalized T-cell therapy for MS patients and has received Fast Track designation from the FDA in SPMS. 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.

The costs of the Phase IIb clinical study of Tcelna in SPMS, as well as the ongoing expenses of our operations through the expected completion date of such study are estimated at approximately $35 million. Our existing resources are not adequate to permit us to proceed materially beyond the initiation of the study (*i.e.*, the dosing of the first patients) or to continue and complete such study or any significant portion of it. We will need to secure significant additional resources to complete the trial and support our operations during the pendency of the trial. We believe we have sufficient liquidity to support our clinical trial activities into December 2012. If we are unable to obtain additional funding for operations in the immediate future, we will be forced to suspend or terminate our current ongoing clinical trial for Tcelna and curtail various aspects of our operations, as well as implement significant cost-reduction measures or potentially cease operations.

Given our need for substantial amounts of capital to continue and complete the Phase IIb clinical study in North America of Tcelna in SPMS, we intend to continue to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to continue and complete the 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.

SPMS Overview

SPMS is characterized by a steady accrual of irreversible disability, despite, in some cases, reversible relapses, remissions or clinical plateaus. Older age at onset of MS diagnosis is the strongest predictor of conversion to SPMS. Males have a shorter time to conversion to SPMS compared with females. Available immunomodulating and immunosuppressive therapies used for RRMS have not been effective in SPMS. In clinical trials, these therapies have demonstrated anti-inflammatory properties as measured by the reduction in number and volume of contrast-enhancing or acutely inflammatory central nervous system (CNS) lesions most commonly seen in patients with RRMS. The typical SPMS patient, however, has little or no radiographic evidence of acute inflammation. It is commonly observed that contrast-enhancing CNS lesions are uncommon among these patients, despite a clearly deteriorating neurologic course. The lack of effect of conventional MS therapeutics in SPMS suggests that the cerebral deterioration characterizing progressive disease may be driven by factors other than acute inflammation. For instance, the immunopathology of SPMS is more consistent with a transition to a chronic T-cell dependent inflammatory type, which may encompass the innate immune response and persistent activation of microglia cells. Radiographic features that stand out among patients with SPMS include significantly more atrophy of gray matter compared with RRMS patients. Of note, long-term disability

in MS in general appears more closely correlated to gray matter atrophy than to white matter inflammation. Such atrophy may be suggestive of progressive clinical disability. Both clinically and radiographically, SPMS represents a disease process with certain features distinct from those of RRMS, and one with extremely limited treatment options.

Current Treatment Options for SPMS

Only one product, mitoxantrone, is currently approved for the indication of SPMS. However, as of 2005, this drug carries a black box warning, due to significant risks of decreased systolic function, heart failure, and leukemia. The American Academy of Neurology has issued a report indicating that these risks are even higher than suggested in the original report leading to the black box warning. Hence, a safe and effective treatment for SPMS remains a significant unmet medical need.

Tcelna Clinical Overview in SPMS

In multiple previously conducted clinical trials for the treatment of patients with MS (which have been weighted significantly toward patients with RRMS), Tcelna has demonstrated one of the safest side effect profiles for any marketed or development-stage MS therapy, as well as encouraging efficacy signals. A total of 142 MS patients have received Tcelna in previously conducted trials for RRMS and SPMS. The therapy has been well tolerated in all subjects and has demonstrated an excellent overall safety profile. The most common side effect is mild to moderate irritation at the site of injection, which is typically resolved in 24 hours. Tcelna has been administered to a total of 36 subjects with SPMS across three previous clinical studies. Based on preliminary data suggesting stabilized or improved disability among SPMS subjects receiving Tcelna, Opexa believes that further development of this product in SPMS is warranted.

Summary of TERMS Phase IIb Clinical Trial Data in RRMS

Tovaxin for Early Relapsing Multiple Sclerosis (TERMS) was a Phase IIb clinical study of Tcelna in RRMS patients completed in 2008. 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 RRMS 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 included:

- In the modified intent to treat patient population (n=142), the ARR for Tcelna-treated patients was 0.214 as compared to 0.339 for placebo-treated patients, which represented a 37% decrease in ARR for Tcelna as compared to placebo in the general population;

- In a prospective group of patients with more active disease (ARR>1, n=50), Tcelna demonstrated a 55% reduction in ARR as compared to placebo, and a 73% reduction in relapse rate was observed in Tcelna 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 Tcelna, had a 64% reduction in ARR versus placebo (p=0.046, n=70).

We remain committed to further advancing Tcelna in RRMS at a later date assuming the availability of sufficient resources. For Opexa, however, progressive MS is an area which we believe represents a higher unmet medical need.

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 (and, in part, in licensed from the University of Chicago) 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 for this technology 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.

Accounting for Derivative Instruments. FASB ASC 815, "Accounting for Derivatives and Hedging Activities" ("FASB ASC 815"), specifies that a contract that would otherwise meet the definition of a derivative, but is both (a) indexed to its own stock and (b) classified in stockholders' equity in the statement of financial position would not be considered a derivative financial instrument. FASB ASC 815 provides a two-step model to be applied in determining whether a financial instrument or an embedded feature is indexed to an issuer's own stock, including evaluating the instrument's contingent exercise and settlement provisions, and thus able to qualify for the FASB ASC 815-10 scope exception.

We determined that the Series I warrants associated with the July 25, 2012 convertible secured promissory note financing qualified for treatment under FASB ASC 815. The initial fair value of $2,314,635 of these warrants as of July 25, 2012 was classified as a current derivative liability. The impact of FASB ASC 815 for the year to date period ending September 30, 2012 resulted in an increase in the derivative liability of $136,889 with a corresponding loss on derivative instruments.

Measuring Fair Value. As defined in FASB ASC 820, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). We utilize market data or assumptions that market participants would use in pricing the asset or liability, including assumptions about risk and the risks inherent in the inputs to the valuation technique. These inputs can be readily observable, market corroborated, or generally unobservable. We classify fair value balances based on the observability of those inputs. FASB ASC 820 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurement) and the lowest priority to unobservable inputs (1evel 3 measurement).

The three levels of the fair value hierarchy defined by FASB ASC 820 are as follows:

Level 1 – Quoted prices are available in active markets for identical assets or liabilities as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis. Level 1 primarily consists of financial instruments such as exchange-traded derivatives, marketable securities and listed equities.

Level 2 – Pricing inputs are other than quoted prices in active markets included in level 1, which are either directly or indirectly observable as of the reported date. Level 2 includes those financial instruments that are valued using models or other valuation methodologies. These models are primarily industry-standard models that consider various assumptions, including quoted forward prices for commodities, time value, volatility factors, and current market and contractual prices for the underlying instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace throughout the full term of the instrument, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace. Instruments in this category generally include non-exchange-traded derivatives such as commodity swaps, interest rate swaps, options and collars.

Level 3 – Pricing inputs include significant inputs that are generally less observable from objective sources. These inputs may be used with internally developed methodologies that result in management's best estimate of fair value.

As required by FASB ASC 820, financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the fair value measurement requires judgment, and may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels.

We determined that the fair value of the Series I warrants associated with the July 25, 2012 convertible secured promissory note financing is classified as Level 3 on the fair value hierarchy and should be recognized as a warrant derivative liability at issuance.

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

Results of Operations and Financial Condition

Comparison of the Three Months Ended September 30, 2012 with the Three Months Ended September 30, 2011

Net Sales. We recorded no commercial revenues for the three months ended September 30, 2012 and 2011.

Research and Development Expenses. Research and development expenses were $1,455,938 for the three months ended September 30, 2012, compared with $654,772 for the three months ended September 30, 2011. The increase in expenses is primarily related to an increase of staff to conduct increased development activities, increases in the procurement and use of supplies for both our laboratory and our product manufacturing operations, the engagement of consultants for the clinical study of Tcelna in SPMS, increases in legal costs related to our intellectual property, stock compensation expense and facilities costs.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2012 were $532,474, compared with $584,794 for the three months ended September 30, 2011. The decrease in expense is due to decreases in business development expenses and was partially offset by increases in stock compensation expense and investor outreach activities.

Depreciation and Amortization Expenses. Depreciation and amortization expenses for the three months ended September 30, 2012 were $81,514, compared with $56,888 for the three months ended September 30, 2011. The increase in expense is due to 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 $151,029 for the three months ended September 30, 2012, compared to $638 for the three months ended September 30, 2011. The increase in interest expense was primarily related to the amortized debt discount and interest on the July 25, 2012 convertible secured promissory notes and the amortization of the financing fees over the life of the notes. Interest expense for the three months ended September 30, 2011 related solely to the financing of insurance premiums.

Interest Income. Interest income was $61 for the three months ended September 30, 2012, compared to $227 for the three months ended September 30, 2011.

Net loss. We had a net loss for the three months ended September 30, 2012 of approximately $2.36 million, or $0.10 per share (basic and diluted), compared with a net loss of approximately $1.30 million or $0.06 per share (basic and diluted) for the three months ended September 30, 2011. The increased net loss is primarily related to increases in compensation costs, the procurement and use of supplies for both our laboratory and our product manufacturing operations, consulting expenses, facilities costs, depreciation expense and interest expense, and was partially offset by a decrease in business development expenses.

Comparison of the Nine Months Ended September 30, 2012 with the Nine Months Ended September 30, 2011

Net Sales. We recorded no commercial revenues for the nine months ended September 30, 2012 and 2011.

Research and Development Expenses. Research and development expenses were $4,504,243 for the nine months ended September 30, 2012, compared with $2,194,141 for the nine months ended September 30, 2011. The increase in expenses is primarily related to increases of staff to conduct increased development activities, the procurement and use of supplies used in both our laboratory and product manufacturing operations, the engagement of consultants in preparation for our planned clinical study, facilities costs and stock compensation expense.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2012 were $1,878,236, compared with $1,737,686 for the nine months ended September 30, 2011. The increase in expense is due to increases in compensation expense to employees, legal expenses, investor outreach and capital financing activities, and was partially offset by a decrease in business development expenses.

Depreciation and Amortization Expenses. Depreciation and amortization expenses for the nine months ended September 30, 2012 were $225,365, compared with $157,254 for the nine months ended September 30, 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 $152,002 for the nine months ended September 30, 2012, compared to $2,643 for the nine months ended September 30, 2011. The increase in interest expense was primarily related to the amortized debt discount and interest on the July 25, 2012 convertible notes and the amortization of the financing fees over the life of the notes. Interest expense for the nine months ended September 30, 2011 related solely to the financing costs on insurance policies and the loan payable on an equipment line.

Interest Income. Interest income was $256 for the nine months ended September 30, 2012, compared to $698 for the nine months ended September 30, 2011.

Net loss. We had a net loss for the nine months ended September 30, 2012 of approximately $6.90 million, or $0.30 per share (basic and diluted), compared with a net loss of approximately $4.09 million, or $0.18 per share (basic and diluted), for the nine months ended September 30, 2011. The increased net loss is primarily related to increases in compensation expense, procurement and use of supplies used in both our laboratory and our product manufacturing operations, legal and consulting expenses, facilities costs, depreciation and interest expense.

Liquidity and Capital Resources

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of September 30, 2012, we had cash and cash equivalents of $2,237,618. During July 2012, we closed a private offering consisting of convertible secured notes and Series I warrants to purchase common stock which generated $4,085,000 in gross proceeds (of which $1,000,000 is held in a controlled account).

Our burn rate during the nine months ended September 30, 2012, inclusive of the cost of preparations to commence the Phase IIb clinical study, was approximately $885,000 per month. We will need to raise additional capital to fund our current business plan and support our clinical trial operations. Based on our current burn rate in conjunction with our expanded clinical trial activities, we believe we have sufficient liquidity to support operations into December 2012. If we are unable to obtain additional funding for operations in the immediate future, we will be forced to suspend or terminate our current ongoing clinical trial for Tcelna, which may require us to modify our current business plan and curtail various aspects of our operations, as well as implement significant cost-reduction measures or potentially cease operations.

We currently intend to continue to use our available cash to fund general corporate purposes (including working capital and operational purposes) and conduct the ongoing Phase IIb clinical study of Tcelna in SPMS. The Phase IIb clinical study in North America of Tcelna is expected to involve 180 patients and take approximately three years to complete. The costs of such study as well as the ongoing expenses of our operations through the expected completion date of such a study are estimated at approximately $35 million. While we initiated the trial with our existing resources, including the proceeds from the July 25, 2012 private offering of convertible secured notes and warrants, they are not adequate to permit us to proceed materially beyond the initiation of the study (*i.e.*, the dosing of the first patients) or to complete such study or any significant portion of it. We will need to secure significant additional resources to complete the trial and support our operations during the pendency of the trial.

On November 2, 2012 and November 5, 2012, we entered into a $15,000,000 purchase agreement and registration rights agreement, and on November 5, 2012, we entered into a $1,500,000 purchase agreement, each with Lincoln Park Capital Fund, LLC ("Lincoln Park") pursuant to which we have the right to sell to Lincoln Park an aggregate of up to $16,500,000 in shares of our

common stock, subject to certain conditions and limitations. Under the terms and subject to the conditions of the purchase agreements, Lincoln Park is obligated to purchase up to an aggregate of $16,500,000 in shares of common stock (subject to certain limitations) from time to time over a 30-month period (which, as it relates to the $15,000,000 purchase agreement, commences on the date that a registration statement is declared effective by the SEC and a final prospectus in connection therewith is filed). We may direct Lincoln Park, at our sole discretion and subject to certain conditions, to purchase up to 100,000 shares of common stock in regular purchases, increasing to amounts of up to 300,000 shares depending upon the closing sale price of our common stock. In addition, we may direct Lincoln Park to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of our common stock equals or exceeds $0.75 per share. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to 12 business days leading up to such time), but in no event will shares be sold to Lincoln Park on a day the common stock closing price is less than the floor price of $0.45, subject to adjustment. As of November 8, 2012, we had sold 100,000 shares at $0.50 per share to Lincoln Park under the $1,500,000 purchase agreement for gross proceeds of $50,000. We intend to continue to sell shares of our common stock to Lincoln Park under the $1,500,000 purchase agreement in the near-term; however, there can be no assurance that we will be able to receive any or all of the additional funds from Lincoln Park because the purchase agreements contain limitations, restrictions, requirements, events of default and other provisions that could limit our ability to cause Lincoln Park to buy common stock from us.

On September 6, 2012, we entered into a sales agreement with Brinson Patrick Securities Corporation in connection with the implementation of an at-the-market program pursuant to which we may sell shares of our common stock directly into the open market from time to time depending upon market demand, through our sales agent, in transactions deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933. While we have registered up to 4,000,000 shares of our common stock for potential sale under this program, as of November 8, 2012, no shares had been sold.

We do not maintain any external lines of credit. Should we need any additional capital in the future beyond the purchase agreements with Lincoln Park and our at-the-market program, 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.

Given our need for substantial amounts of capital to undertake and complete a Phase IIb clinical study in North America of Tcelna in SPMS, we intend to continue to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to complete the ongoing 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 continue the Phase IIb study in North America and to support our operations during the pendency of such study, we are also able to concurrently manage a pivotal Phase III clinical study in RRMS in North America in our present facility. Any such RRMS studies would also depend upon the availability of sufficient resources.

Off-Balance Sheet Arrangements

None.

Recent Accounting Pronouncements

For the nine months ended September 30, 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 Officers), as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Certifying Officers, the effectiveness of our disclosure controls and procedures as of September 30, 2012, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of September 30, 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. 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. The following factors affect our business, our intellectual property, the industry in which we operate and our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known or which we currently consider immaterial may also have an adverse effect on our business. If any of the matters discussed in the following risk factors were to occur, our business, financial condition, results of operations, cash flows or prospects could be materially adversely affected, the market price of our common stock could decline and you could lose all or part of your investment.

Risks Related to Our Business

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 Phase IIb clinical trial initiated or ongoing for Tcelna), which may require us to modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws.

As of September 30, 2012, we had cash and cash equivalents of $2,237,618. During July 2012, we closed a private offering consisting of convertible secured notes and warrants to purchase common stock which generated approximately $4.1 million in gross proceeds (of which $1.0 million is held in a controlled account). Our current burn rate, inclusive of the cost of preparations to commence the Phase IIb clinical study, during the first nine months of 2012 was approximately $885,000 per month. We believe we have sufficient liquidity to support our current clinical trial activities into December 2012. The Phase IIb clinical study of Tcelna in patients with SPMS is expected to involve 180 patients and take approximately three years to complete. The costs of the study, as well as the ongoing expenses of our operations through the expected completion date of such study, are estimated at approximately $35 million. Our existing resources are not adequate to permit us to proceed materially beyond the initiation of the study (i.e., the dosing of the first patients) or to complete such study or any significant portion of it. We will need to secure significant additional resources to continue and complete the trial and support our operations during the pendency of the trial.

Given our need for substantial amounts of capital to continue and complete the Phase IIb clinical study for Tcelna in SPMS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to continue and complete the Phase IIb 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. If we are unable to obtain additional funding for operations in the immediate future, we will be forced to suspend or terminate our current ongoing clinical trial for Tcelna, which may require us to modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws.

Assuming we are able to achieve financing which is sufficient to support the Phase IIb study of Tcelna in SPMS and to support our operations during the pendency of such study, we are also exploring a pivotal Phase III clinical study of Tcelna in RRMS. Any such study of Tcelna in RRMS would also depend upon the availability of sufficient resources.

As we have no sources of debt or equity capital committed for funding, we must rely upon best efforts third-party debt or equity funding and we can provide no assurance that we will be successful in any funding effort. The timing and degree of any future capital requirements will depend on many factors, including:

- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- the accuracy of the assumptions underlying our estimates for capital needs in 2012 and beyond as well as for the clinical study of Tcelna;
- scientific progress in our research and development programs;

- the magnitude and scope of our research and development programs;
- our progress with preclinical development and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- the number and type of product candidates that we pursue.

If we raise additional funds through any collaboration, partnering or licensing arrangements with third parties, we may need to relinquish some rights to our product candidate Tcelna, including commercialization rights, which may harm our ability to generate revenues and achieve or sustain profitability.

If we raise additional funds by issuing equity securities, stockholders may experience substantial dilution. Debt financing, if available, may involve restrictive covenants that may impede our ability to operate our business. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. There is no assurance that our capital raising efforts will be able to attract the capital needed to execute on our business plan and sustain our operations.

If we are unable to obtain additional funding or secure a development partner, we may not be able to continue or complete the Phase IIb clinical study of Tcelna in SPMS or otherwise continue our operations as proposed, which may require us to modify our business plan or curtail various aspects of our operations. If these measures are not sufficient to maintain an adequate level of capital, it may be necessary to cease operations or seek relief under applicable bankruptcy laws. In such event, our stockholders may lose a portion or even all of their investment.

Funding from our purchase agreements with Lincoln Park may be limited or be insufficient to fund our operations or to implement our strategy.

Under our purchase agreements with Lincoln Park, we may direct Lincoln Park to purchase up to $1,500,000 of shares of common stock subject to certain limitations over a 30-month period, and, upon effectiveness of a registration statement for resale of the applicable shares and subject to other conditions, we also may direct Lincoln Park to purchase up to $15,000,000 of our shares of common stock over a 30-month period. There can be no assurance that we will be able to receive any or all of the additional funds from Lincoln Park because the purchase agreements contain limitations, restrictions, requirements, events of default and other provisions that could limit our ability to cause Lincoln Park to buy common stock from us including that the closing price of our stock is at least $0.45. For example, under the applicable rules of the NASDAQ Capital Market, if we seek to issue shares which may be aggregated with shares sold to Lincoln Park under the purchase agreement in excess of 4,607,392 shares or 19.99% of the total common stock outstanding as of the date of the $1,500,000 purchase agreement, we may be required to seek shareholder approval in order to be in compliance with the NASDAQ Capital Market rules.

The extent to which we rely on Lincoln Park as a source of funding will depend on a number of factors, including the amount of working capital needed, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we would need to secure another source of funding. Even if we sell all $16,500,000 of common stock under the $1,500,000 purchase agreement and the $15,000,000 purchase agreement with Lincoln Park, we will still need additional capital to fully implement our current business, operating and development plans, including to complete the Phase IIb clinical study of Tcelna in patients with SPMS and to conduct our operations through the expected completion date of such study.

We have a history of operating losses and do not expect to be profitable in the foreseeable future.

We have not generated any profits since our entry into the biotechnology business and we have incurred significant operating losses. We expect to incur additional operating losses for the foreseeable future. We have not received, and we do not expect to receive for at least the next several years, any revenues from the commercialization of any potential products. We do not currently have any sources of revenues and may not have any in the foreseeable future.

Our business is at an early stage of development. We are largely dependent on the success of our product candidate, Tcelna and we cannot be certain that Tcelna will receive regulatory approval or be successfully commercialized.

Our business is at an early stage of development. We do not have any product candidates that have completed late-stage clinical trials nor do we have any products on the market. We have only one product candidate, Tcelna, which has progressed to the stage of being studied in human clinical trials in the United States. We recently initiated a Phase IIb study of Tcelna in patients with SPMS. We are still in the very early stages of identifying and conducting research on any other potential products. Tcelna, and any

other potential products, will require regulatory approval prior to marketing in the United States and other countries. Obtaining such approval requires significant research and development and preclinical and clinical testing. We may not be able to develop any products, to obtain regulatory approvals, to continue clinical development of Tcelna, to enter clinical trials (or any development activities) for any other product candidates or to commercialize any products. Tcelna, and any other potential products, may prove to have undesirable or unintended side effects or other characteristics adversely affecting their safety, efficacy or cost-effectiveness that could prevent or limit their use. Any product using any of our technology may fail to provide the intended therapeutic benefits or to achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production.

We might be unable to service our current debt due to a lack of cash flow or otherwise fail to comply with terms of the convertible secured promissory notes or related agreements and might be subject to default. The convertible secured promissory notes are secured by a pledge of all of our assets. The antidilution adjustments applicable to the securities ultimately issuable upon conversion of these secured notes, as well as the antidilution adjustments of the warrants issued in tandem with the notes, could result in significant dilution to existing shareholders based upon any sale of shares under our purchase agreements with Lincoln Park.

On July 25, 2012, we closed a private offering consisting of convertible secured notes and warrants to purchase shares of common stock which generated approximately $4.1 million in gross proceeds ($1.0 million of which is held in a controlled account). The notes mature on July 25, 2014 and accrue interest at the rate of 12% per annum, compounded annually. Interest is payable semi-annually in either cash or registered shares of common stock at our election. The notes are secured by substantially all of our assets and are convertible into a new class of non-voting Series A convertible preferred stock. The notes can be converted into Series A convertible preferred stock at the option of the investors at a price of $100.00 per share, subject to certain limitations and adjustments. Additionally, we can elect to convert the notes into Series A convertible preferred stock if (i) our common stock closes at or above $2.50 per share for 20 consecutive trading days or (ii) we achieve certain additional funding milestones to continue our clinical trial program. These milestones include (x) executing a strategic agreement with a partner or potential partner by which we will receive a minimum of $5 million to partially fund, or an option to partner with us for, our Phase II clinical trial for Tcelna in patients with SPMS and (y) receiving a minimum of $25 million in additional capital (including the note offering proceeds) from any partner, potential partner or any other source. The Series A convertible preferred stock accrues dividends at the rate of 8% per annum, which are cumulative and payable semi-annually in either cash or registered shares of the common stock at our election. The Series A convertible preferred stock is convertible into shares of our common stock at the option of the holders at a price of $0.80 per share, subject to certain limitations and adjustments. Additionally, we can elect to convert the Series A convertible preferred stock into common stock if our common stock closes at or above $4.00 per share for 20 consecutive trading days. The warrants have an exercise price of $1.25 per share, a five-year term and are exercisable for 75% of the number of shares of common stock into which the initial principal amount of the notes is ultimately convertible, subject to certain limitations and adjustments. The warrants are exercisable after six months from the date of issuance. We can redeem the warrants at $0.01 per share if our common stock closes at or above $2.50 per share for 20 consecutive trading days. As part of the security interest in all of our assets granted to the noteholders, $1.0 million of the proceeds is maintained in a controlled account. The noteholders were granted certain registration rights for the shares of underlying common stock.

If we do not make the required payments when due, either at maturity, or at applicable installment payment dates, or if we breach other terms of the convertible secured notes or related agreements, the noteholders could elect to declare all amounts outstanding, together with accrued and unpaid interest, to be immediately due and payable. Even if we were able to prepay the full amount in cash, any such repayment could leave us with little or no working capital for our business. If we are unable to repay those amounts, the noteholders will have a first claim on our assets pledged under the convertible secured notes. If the noteholders should attempt to foreclose on the collateral, it is unlikely that there would be any assets remaining after repayment in full of such secured indebtedness. Any default under the convertible secured notes and resulting foreclosure would have a material adverse effect on our financial condition and our ability to continue our operations.

Although up to 5,106,250 shares of common stock were initially issuable if all 12% convertible secured promissory notes outstanding were converted to Series A convertible preferred stock and such stock was then converted into common stock, this amount of shares will increase by up to 126,725 shares, to a total of up to 5,232,975 shares of common stock, if shares are sold after December 31, 2012 to Lincoln Park pursuant to the $1,500,000 purchase agreement or the $15,000,000 purchase agreement at a per share price of less than $0.80. In addition, the warrants issued to the purchasers of the 12% convertible secured promissory notes to acquire up to 3,829,689 shares of common stock in the aggregate at an exercise price of $1.25 per share include antidilution provisions whereby if shares are sold to Lincoln Park pursuant to the $1,500,000 purchase agreement or the $15,000,000 purchase agreement at a per share price of (i) less than $1.25, then the exercise price will be reset to such lower per share price, subject to a floor of $0.64, and (ii) less than $0.64, then the number of shares issuable pursuant to such warrants will increase by a factor equal to $0.64 divided by such lower price, subject to a cap on the amount of any such increase of 50% (or an additional 1,914,841 shares of common stock in the aggregate). Opexa commenced sales to Lincoln Park under the $1,500,000 purchase agreement on November 8, 2012 at a per share price of $0.50 that triggers the foregoing antidilution adjustment.

We will depend on strategic collaborations with third parties to develop and commercialize product candidates, such as Tcelna, and we may not have control over a number of key elements relating to the development and commercialization of any such product candidate.

A key aspect of our strategy, including with respect to Tcelna, is to seek collaboration with a partner, such as a large pharmaceutical organization, that is willing to further develop and commercialize a selected product candidate. To date, we have not entered into any such collaborative arrangement with respect to Tcelna. However, we will need to raise significant additional capital in order to continue and complete the Phase IIb clinical study of Tcelna in SPMS as the total costs of conducting this study, as well as the ongoing expenses of our operations through the expected completion date of such study, are estimated at approximately $35 million.

By entering into any such strategic collaboration, we may rely on our partner for financial resources and for development, regulatory and commercialization expertise. Our partner may fail to develop or effectively commercialize our product candidate because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decide to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determine that the market opportunity is not attractive; or
- cannot manufacture or obtain the necessary materials in sufficient quantities from multiple sources or at a reasonable cost.

We may not be able to enter into collaboration, including with respect to Tcelna, on acceptable terms, if at all. We face competition in our search for partners from other organizations worldwide, many of whom are larger and are able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support.

If we are not successful in attracting a partner and entering into collaboration on acceptable terms, we may not be able to complete development of or commercialize any product candidate, including Tcelna. In particular, we may be unable to continue or complete the Phase IIb clinical study of Tcelna in SPMS. In such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered and 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.

Third parties to whom we may license or transfer development and commercialization rights for products covered by intellectual property rights may not be successful in their efforts, and as a result, we may not receive future royalty or other milestone payments relating to those products or rights.

We will need regulatory approvals for any product candidate, including Tcelna, 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 Tcelna, 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.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous FDA requirements, and must otherwise comply with federal, state and local requirements and policies of the medical institutions where they are conducted. The clinical trial process is also time-consuming. We estimate that the Phase IIb clinical trial in North America of our lead product candidate, Tcelna, in SPMS will take approximately three years to complete. In addition, we anticipate that a pivotal Phase III clinical trial would be necessary before we could submit an application for approval of Tcelna for SPMS. Failure can occur at any stage of the trials, and we could encounter problems that cause us to be unable to initiate a trial, or to abandon or repeat a clinical trial.

The commencement and completion of clinical trials, including the continuation and completion of the Phase IIb clinical trial of Tcelna in SPMS, may be delayed or prevented by several factors, including:

- FDA or IRB objection to proposed protocols;

- discussions or disagreement with the FDA over the adequacy of trial design to potentially demonstrate effectiveness, and subsequent design modifications;
- unforeseen safety issues;
- determination of dosing issues and related adjustments;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- product quality problems (e.g., sterility or purity);
- challenges to patient monitoring and data collection during or after treatment (for example, patients' failure to return for follow-up visits); and
- failure of medical investigators to follow our clinical protocols.

In addition, we or the FDA (based on its authority over clinical studies) may delay a proposed investigation or suspend clinical trials in progress at any time if it appears that the study may pose significant risks to the study participants or other serious deficiencies are identified. Prior to approval of our product the FDA must determine that the data demonstrate safety and effectiveness. The large majority of drug candidates that begin human clinical trials fail to demonstrate the desired safety and efficacy characteristics.

Furthermore, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols, or otherwise modify our intended course of clinical development, to reflect these changes. This, too, may impact the costs, timing or successful completion of a clinical trial. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the U.S. Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products, and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Even if we obtain regulatory approvals for any product candidate, such as Tcelna, that approval may be subject to limitations on the indicated uses for which it may be marketed. Our ability to generate revenues from the commercialization and sale of any potential products will be limited by any failure to obtain or limitation on necessary regulatory approvals.

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 Tcelna.

Although we have participated in the design and management of our past clinical trials, we do not have the ability to conduct clinical trials directly for any product candidate, including Tcelna. We will need to rely on contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials and to perform data collection and analysis.

Our clinical trials may be delayed, suspended or terminated if:

- any third party upon whom we rely does not successfully carry out its contractual duties or regulatory obligations or meet expected deadlines;
- any such third party needs to be replaced; or
- the quality or accuracy of the data obtained by the third party is compromised due to its failure to adhere to clinical protocols or regulatory requirements or for other reasons.

Failure to perform by any third party upon whom we rely may increase our development costs, delay our ability to obtain regulatory approval and prevent the commercialization of any product candidate, including Tcelna. While we believe that there are numerous alternative sources to provide these services, we might not be able to enter into replacement arrangements without delays or additional expenditures if we were to seek such alternative sources.

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 have targeted MS as the first disease to be pursued off our T-cell platform technology. As a platform technology, there exists the potential to address other autoimmune diseases with the technology. Minimal work has been done outside the lead MS indication. Our business over the long term is substantially dependent on our ability to develop, license or acquire product candidates and further develop them for commercialization. The success of this strategy depends upon our ability to expand our existing platform or identify, select and acquire the right product candidates. We have limited experience identifying, negotiating and implementing economically viable product candidate acquisitions or licenses, which is a lengthy and complex process. Also, the market for licensing and acquiring product candidates is intensely competitive, and many of our competitors have greater resources than we do. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

Moreover, any product candidate acquisition that we do complete will involve numerous risks, including:

- difficulties in integrating the development program for the acquired product candidate into our existing operations;
- diversion of financial and management resources from existing operations;
- risks of entering new potential markets or technologies;
- inability to generate sufficient funding to offset acquisition costs; and
- delays that may result from our having to perform unanticipated preclinical trials or other tests on the product candidate.

We are dependent upon our management team and a small number of employees.

Our business strategy is dependent upon the skills and knowledge of our management team. If any critical employee leaves, we may be unable on a timely basis to hire suitable replacements to operate our business effectively. We also operate with a very small number of employees and thus have little or no backup capability for their activities. The loss of the services of any member of our management team or the loss of just a few other employees could have a material adverse effect on our business and results of operations.

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 business depends on licenses from third parties. These third party license agreements impose obligations on us, such as payment obligations and obligations diligently to pursue development of commercial products under the licensed patents. If a licensor believes that we have failed to meet our obligations under a license agreement, the licensor could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights. During the period of any such litigation, our ability to carry out the development and commercialization of potential products could be significantly and negatively affected. If our license rights were restricted or ultimately lost, our ability to continue our business based on the affected technology platform could be adversely affected.

Our current research and manufacturing facility is not large enough to manufacture product candidates, such as Tcelna, for certain clinical trials or, if such clinical trials are successful, commercial applications.

We conduct our research and development in a 10,200 square foot facility in The Woodlands, Texas, which includes an approximately 1,200 square foot suite of three rooms for the manufacture of T-cell therapies. We believe our current facility should have the capacity to support full clinical development of Tcelna in North American trials for SPMS. It is not sufficient, however, to support clinical trials outside North America including Europe and Asia, if required, or the commercial launch of Tcelna. In this case, we would need to expand our manufacturing staff and facility, obtain a new facility or contract with corporate collaborators or other third parties to assist with future drug production and commercialization.

In the event that we decide to establish a commercial-scale manufacturing facility, we will require substantial additional funds and will be required to hire and train significant numbers of employees and comply with applicable regulations, which are extensive. We do not have funds available for building a manufacturing facility, and we may not be able to build a manufacturing facility that both meets regulatory requirements and is sufficient for our commercial-scale manufacturing.

We may arrange with third parties for the manufacture of our future products, if any. However, our third-party sourcing strategy may not result in a cost-effective means for manufacturing our future products. If we employ third-party manufacturers, we will not control many aspects of the manufacturing process, including compliance by these third parties with cGMP and other regulatory requirements. We further may not be able to obtain adequate supplies from third-party manufacturers in a timely fashion for development or commercialization purposes, and commercial quantities of products may not be available from contract manufacturers at acceptable costs.

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.

Our ability to successfully commercialize any product we may eventually have will depend in significant part on the extent to which appropriate coverage of and reimbursement for such product and any related treatments are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. Third-party payors are increasingly challenging the prices charged for medical products and services. We cannot provide any assurances that third-party payors will consider any product we may eventually have cost-effective or provide coverage of and reimbursement for such product, in whole or in part.

Uncertainty exists as to the coverage and reimbursement status of newly approved medical products and services and newly approved indications for existing products. Third-party payors may conclude that any product we may eventually have is less safe, less clinically effective, or less cost-effective than existing products, and third-party payors may not approve such product for coverage and reimbursement. If we are unable to obtain adequate coverage of and reimbursement for any product we may eventually have from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them. Such reduction or limitation in the use of any such product would cause sales to suffer. Even if third-party payors make reimbursement available, payment levels may not be sufficient to make the sale of any such product profitable.

In addition, the trend towards managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of medical services and products, may result in inadequate coverage of and reimbursement for any product we may eventually have. Many third-party payors, including in particular HMOs, are pursuing various ways to reduce pharmaceutical costs, including, for instance, the use of formularies. The market for any product we may eventually have depends on access to such formularies, which are lists of medications for which third-party payors provide reimbursement. These formularies are increasingly restricted, and pharmaceutical companies face significant competition in their efforts to place their products on formularies of HMOs and other third-party payors. This increased competition has led to a downward pricing pressure in the industry. The cost containment measures that third-party payors are instituting could have a material adverse effect on our ability to operate profitably.

Any product candidate that we develop, such as Tcelna, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

Even if a product candidate, such as Tcelna, is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product candidate by physicians, healthcare professionals and third-party payors, and our profitability and growth, will depend on a number of factors, including:

- demonstration of efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability and cost of alternative treatments, including cheaper generic drugs;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategies;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other

regulatory authorities, likely will not achieve market acceptance and our ability to generate revenues from that product candidate would be substantially reduced.

We have incurred, and expect to continue to incur, increased costs and risks as a result of being a public company.

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, or SOX, as well as rules and regulations implemented by the SEC and The NASDAQ Stock Market (NASDAQ). Changes in the laws and regulations affecting public companies, including the provisions of SOX and rules adopted by the SEC and by NASDAQ, have resulted in, and will continue to result in, increased costs to us as we respond to their requirements. Given the risks inherent in the design and operation of internal controls over financial reporting, the effectiveness of our internal controls over financial reporting is uncertain. If our internal controls are not designed or operating effectively, we may not be able to conclude an evaluation of our internal control over financial reporting as required or we or our independent registered public accounting firm may determine that our internal control over financial reporting was not effective. In addition, our registered public accounting firm may either disclaim an opinion as it relates to management's assessment of the effectiveness of our internal controls or may issue an adverse opinion on the effectiveness of our internal controls over financial reporting. Investors may lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and which could affect our ability to run our business as we otherwise would like to. New rules could also make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our Board committees and as executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

Under the corporate governance standards of NASDAQ, a majority of our Board of Directors and each member of our Audit Committee must be an independent director. If any vacancies on our Board or our Audit Committee occur that need to be filled by independent directors, we may encounter difficulty in attracting qualified persons to serve on our Board and, in particular, our Audit Committee. If we fail to attract and retain the required number of independent directors, we may be subject to SEC enforcement proceedings and delisting of our common stock from the NASDAQ Capital Market.

Risks Related to our Intellectual Property

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 Tcelna.

If third party patents or patent applications contain claims infringed by either our licensed technology or other technology required to make or use our potential products, such as Tcelna, and such claims are ultimately determined to be valid, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost, if at all, or be able to develop or obtain alternative technology. If we are unable to obtain such licenses at a reasonable cost, we may not be able to develop any affected product candidate, such as Tcelna, commercially. There can be no assurance that we will not be obliged to defend ourselves in court against allegations of infringement of third party patents. Patent litigation is very expensive and could consume substantial resources and create significant uncertainties. An adverse outcome in such a suit could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties, or require us to cease using such technology.

If we are unable to obtain patent protection and other proprietary rights, our operations will be significantly harmed.

Our ability to compete effectively is dependent upon obtaining patent protection relating to our technologies. The patent positions of pharmaceutical and biotechnology companies, including ours, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent application can be denied or significantly reduced before or after the patent is issued. Consequently, we do not know whether pending patent applications for our technology will result in the issuance of patents, or if any issued patents will provide significant protection or commercial advantage or will be circumvented by others. Since patent applications are secret until the applications are published (usually 18 months after the earliest effective filing date), and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that the inventors of our owned or licensed intellectual property rights were the first to make the inventions at issue or that any patent applications at issue were the first to be filed for such inventions. There can be no assurance that patents will issue from pending patent applications or, if issued, that such patents will be of commercial benefit to us, afford us adequate protection from competing products, or not be challenged or declared invalid.

For our licensed intellectual property, we have limited control over the amount or timing of resources that are devoted to the prosecution of such intellectual property. Due to this lack of control and general uncertainties in the patent prosecution process, we cannot be sure that any licensed patents will result from licensed applications or, if they do, that they will be maintained. Issued U.S. patents require the payment of maintenance fees to continue to be in force. We rely on licensors to do this and their failure to do so could result in the forfeiture of patents not timely maintained. Many foreign patent offices also require the payment of periodic annuities to keep patents and patent applications in good standing. As we do not maintain control over the payment of annuities, we cannot assure you that our licensors will timely pay such annuities and that the granted patents and pending patent applications will not become abandoned. In addition, our licensors may have selected a limited amount of foreign patent protection, and therefore applications have not been filed in, and foreign patents may not have been perfected in, all commercially significant countries.

The patent protection of product candidates, such as Tcelna, involves complex legal and factual questions. To the extent that it would be necessary or advantageous for any of our licensors to cooperate or lead in the enforcement of our licensed intellectual property rights, we cannot control the amount or timing of resources such licensors devote on our behalf or the priority they place on enforcing such rights. We may not be able to protect our intellectual property rights against third party infringement, which may be difficult to detect. Additionally, challenges may be made to the ownership of our intellectual property rights, our ability to enforce them, or our underlying licenses.

We cannot be certain that any of the patents issued to us or to our licensors will provide adequate protection from competing products. Our success will depend, in part, on whether we or our licensors can:

- obtain and maintain patents to protect our product candidates such as Tcelna;
- obtain and maintain any required or desirable licenses to use certain technologies of third parties, which may be protected by patents;
- protect our trade secrets and know-how;
- operate without infringing the intellectual property and proprietary rights of others;
- enforce the issued patents under which we hold rights; and
- develop additional proprietary technologies that are patentable.

The degree of future protection for our proprietary rights (owned or licensed) is uncertain. For example:

- we or our licensor might not have been the first to make the inventions covered by pending patent applications or issued patents owned by, or licensed to, us;
- we or our licensor might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of the technologies owned by, or licensed to, us;
- it is possible that none of the pending patent applications owned by, or licensed to, us will result in issued patents;
- any patents under which we hold rights may not provide us with a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties as invalid, or unenforceable under U.S. or foreign laws; or
- any of the issued patents under which we hold rights may not be valid or enforceable or may be circumvented successfully in light of the continuing evolution of domestic and foreign patent laws.

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.

We rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property.

However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Further, we have limited control, if any, over the protection of trade secrets developed by our licensors. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

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.

A number of pharmaceutical, biotechnology and other companies, universities and research institutions have filed patent applications or have been issued patents relating to cell therapy, T-cells, and other technologies potentially relevant to or required by our product candidate Tcelna. We cannot predict which, if any, of such applications will issue as patents or the claims that might be allowed. We are aware of a number of patent applications and patents claiming use of modified cells to treat disease, disorder or injury.

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, such as Tcelna, or their methods of use, manufacturing or other technologies or activities infringe the intellectual property rights of such third parties. If our product candidates, such as Tcelna, or their methods of manufacture are found to infringe any such patents, we may have to pay significant damages or seek licenses under such patents. We have not conducted comprehensive searches of patents issued to third parties relating to Tcelna. Consequently, no assurance can be given that third-party patents containing claims covering Tcelna, its method of use or manufacture do not exist or have not been filed and will not be issued in the future. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, and because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, we cannot be certain that others have not filed patent applications that will mature into issued patents that relate to our current or future product candidates that could have a material effect in developing and commercializing one or more of our product candidates. A patent holder could prevent us from importing, making, using or selling the patented compounds. We may need to resort to litigation to enforce our intellectual property rights or to determine the scope and validity of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of actual damages, royalties, lost profits, potentially treble damages and attorneys' fees, if we are found to have willfully infringed a third party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell our products;
- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms if at all; or
- significant cost and expense, as well as distraction of our management from our business.

As a result, we could be prevented from commercializing current or future product candidates.

Risks Related to our Industry

We are subject to stringent regulation of our product candidates, such as Tcelna, which could delay development and commercialization.

We, our third-party contractors, suppliers and partners, and our product candidates, such as Tcelna, are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. None of our product candidates can be marketed in the United States until it has been approved by the FDA. No product candidate of ours has been approved, and we may never receive FDA approval for any product candidate. Obtaining FDA approval typically takes many years and requires substantial resources. Even if regulatory approval is obtained, the FDA may impose significant restrictions on the indicated uses, conditions for use and labeling of such products. Additionally, the FDA may require post-approval studies,

including additional research and development and clinical trials. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could substantially reduce our ability to generate revenues.

In addition, both before and after regulatory approval, we, our partners and our product candidates, such as Tcelna, are subject to numerous FDA requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our partners and our product candidates, such as Tcelna. Given the number of recent high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA's drug approval process and the agency's efforts to assure the safety of marketed drugs resulted in the enactment of legislation addressing drug safety issues, the FDA Amendments Act of 2007. This legislation provides the FDA with expanded authority over drug products after approval and the FDA's exercise of this authority could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, and increased costs to assure compliance with new post-approval regulatory requirements. We cannot predict the likelihood, nature or extent of government regulation that may arise from this or future legislation or administrative action, either in the United States or abroad.

In order to market any of our products outside of the United States, we and our strategic partners and licensees must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods and the time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States. Approval by the FDA does not automatically lead to the approval of authorities outside of the United States and, similarly, approval by other regulatory authorities outside the United States will not automatically lead to FDA approval. In addition, regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Our product candidates, such as Tcelna, may not be approved for all indications that we request, which would limit uses and adversely impact our potential royalties and product sales. Such approval may be subject to limitations on the indicated uses for which any potential product may be marketed or require costly, post-marketing follow-up studies.

If we fail to comply with applicable regulatory requirements in the United States and other countries, among other things, we may be subject to fines and other civil penalties, delays in approving or failure to approve a product, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, interruption of manufacturing or clinical trials, injunctions and criminal prosecution, any of which would harm our business.

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 we are successful in achieving approval to market one or more of our product candidates, our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing, and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Department of Health and Human Services, Office of Inspector General, or OIG, to issue a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion

from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing of qui tam actions has increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a False Claims Act action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties. Various states have also enacted laws modeled after the federal False Claims Act.

In addition to the laws described above, the Health Insurance Portability and Accountability Act of 1996 created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

If our operations are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare programs, and the curtailment or restructuring of our operations.

If our competitors develop and market products that are more effective than our product candidates, they may reduce or eliminate our commercial opportunities.

Competition in the pharmaceutical industry, particularly the market for MS products, is intense, and we expect such competition to continue to increase. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, in the United States and abroad. Our competitors have products that have been approved or are in advanced development and may succeed in developing drugs that are more effective, safer and more affordable or more easily administered than ours, or that achieve patent protection or commercialization sooner than our products. Our most significant competitors are fully integrated pharmaceutical companies and more established biotechnology companies. These companies have significantly greater capital resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals, and marketing than we currently do. However, smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies. In addition to the competitors with existing products that have been approved, many of our competitors are further along in the process of product development and also operate large, company-funded research and development programs. As a result, our competitors may develop more competitive or affordable products, or achieve earlier patent protection or further product commercialization than we are able to achieve. Competitive products may render any products or product candidates that we develop obsolete. Our competitors may also develop alternative therapies that could further limit the market for any products that we may develop.

Rapid technological change could make our products obsolete.

Biopharmaceutical technologies have undergone rapid and significant change, and we expect that they will continue to do so. As a result, there is significant risk that our product candidates, such as Tcelna, may be rendered obsolete or uneconomical by new discoveries before we recover any expenses incurred in connection with their development. If our product candidates, such as Tcelna, are rendered obsolete by advancements in biopharmaceutical technologies, our future prospects will suffer.

Consumers may sue us for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.

Developing and commercializing drug products entails significant product liability risks. Liability claims may arise from our and our collaborators' use of products in clinical trials and the commercial sale of those products.

In the event that any of our product candidates becomes an approved product and is commercialized, consumers may make product liability claims directly against us and/or our collaborators, and our collaborators or others selling these products may seek

contribution from us if they incur any loss or expenses related to such claims. We have insurance that covers clinical trial activities. We believe our current insurance coverage is reasonably adequate at this time. However, we will need to increase and expand this coverage as we commence additional clinical trials, as well as larger scale trials, and if any product candidate is approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the regulatory approval or commercialization of products that we or one of our collaborators develop. Product liability claims could have a material adverse effect on our business and results of operations. Liability from such claims could exceed our total assets if we do not prevail in any lawsuit brought by a third party alleging that an injury was caused by one or more of our products.

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States and in foreign jurisdictions, there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control, and we expect proposals to implement similar controls in the United States to continue. Another example of reform that could affect our business is drug reimportation into the United States (*i.e.*, the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs were sold at lower prices). Initiatives in this regard could decrease the price we or any potential collaborators receive for our product candidates if they are ever approved for sale, adversely affecting our future revenue growth and potential profitability. Moreover, the pendency or approval of such proposals could result in a decrease in our stock price or adversely affect our ability to raise capital or to obtain strategic partnerships or licenses.

Risks Related to our Securities

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.

Although our common stock and Series E warrants are traded on the NASDAQ Capital Market, there is currently a limited market for our securities and there can be no assurance that an active market will ever develop. Investors are cautioned not to rely on the possibility that an active trading market may develop.

Our stock may be delisted from NASDAQ, which could affect its market price and liquidity.

We are required to meet certain qualitative and financial tests (including a minimum stockholders' equity requirement of $2.5 million and bid price for our common stock of $1.00 per share) to maintain the listing of our common stock on the NASDAQ Capital Market. During portions of 2008 and 2009, our stockholders' equity was below the continued listing standard requirement of $2.5 million and the bid price for our common stock was below $1.00 per share for periods of time, and our common stock was in jeopardy of being delisted. During 2010, the trading price of our common stock was minimally above $1.00 per share for brief periods of time, and during 2011, the trading price of our common stock was minimally above and below $1.00 per share for periods of time. Since the end of December 2011, our stock has continued to trade below the minimum bid price continued listing requirement, and our common stock is in jeopardy of being delisted. In February 2012, we received a staff deficiency letter from NASDAQ indicating that our common stock failed to comply with the minimum bid price requirement because it traded below the $1.00 minimum closing bid price for 30 consecutive trading days. The notice further stated that we would be provided a period of 180 calendar days to regain compliance. In August 2012, we requested an additional 180-day grace period to regain compliance with NASDAQ's minimum bid price requirement because our stock has continued to trade below the $1.00 minimum closing bid price subsequent to receiving the NASDAQ staff deficiency letter. NASDAQ granted our extension request and we now have until February 4, 2013 to achieve compliance with this listing standard (*i.e.*, by our common stock maintaining a closing bid price of $1.00 per share or more for a minimum of 10 consecutive business days during the additional grace period, or such longer period of time as the NASDAQ staff may require). Although we are exercising diligent efforts to maintain the listing of our common stock and warrants on NASDAQ, there is no assurance we will be able to do so, and if not, our stock could be delisted. Our stockholders' equity as of September 30, 2012 was $2,339,285, which is below the NASDAQ minimum continued listing requirement of $2.5 million. It is also possible that we could fail to satisfy another NASDAQ requirement for continued listing of our stock, such as the market value or number of publicly held shares or number of shareholders, or a corporate governance requirement. We may receive additional future notices from NASDAQ that we have failed to meet its requirements, and proceedings to delist our stock could be commenced. If we are unable to regain compliance in a timely manner or if we do not meet the other listing standards and our common stock is delisted, it could be more difficult to buy or sell our common stock and obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting may also impair our ability to raise capital.

As our share price is volatile, and you may not be able to resell our shares at a profit or at all.

The market prices for securities of biopharmaceutical and biotechnology companies, and early-stage drug discovery and development companies like us in particular, have historically been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- the development status of any drug candidates, such as Tcelna, including clinical study results and determinations by regulatory authorities with respect thereto;
- the initiation, termination, or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;
- announcements of technological innovations, new commercial products or other material events by our competitors or us;
- disputes or other developments concerning our proprietary rights;
- changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;
- additions or departures of key personnel;
- discussions of our business, products, financial performance, prospects or stock price by the financial and scientific press and online investor communities;
- public concern as to, and legislative action with respect to, the pricing and availability of prescription drugs or the safety of drugs and drug delivery techniques;
- regulatory developments in the United States and in foreign countries; or
- dilutive effects of sales of shares of common stock by us or our shareholders, including Lincoln Park, and sales of common stock acquired upon exercise or conversion by the holders of warrants, options or convertible notes.

Broad market and industry factors, as well as economic and political factors, also may materially adversely affect the market price of our common stock.

We may be or become the target of securities litigation, which is costly and time-consuming to defend.

In the past, following periods of market volatility in the price of a company's securities or the reporting of unfavorable news, security holders have often instituted class action litigation. If the market value of our securities experience adverse fluctuations and we become involved in this type of litigation, regardless of the outcome, we could incur substantial legal costs and our management's attention could be diverted from the operation of our business, causing our business to suffer.

Our "blank check" preferred stock could be issued to prevent a business combination not desired by management or our current majority stockholders.

Our articles of incorporation authorize the issuance of "blank check" preferred stock with such designations, rights and preferences as may be determined by our Board of Directors without stockholder approval. Our preferred stock could be utilized as a method of discouraging, delaying, or preventing a change in our control and as a method of preventing stockholders from receiving a premium for their shares in connection with a change of control.

Future sales of our common stock in the public market could lower our stock price.

During 2011, we sold (i) an aggregate of 384,759 shares of common stock in January pursuant to an "at the market" continuous offering program and (ii) an aggregate of 4,146,500 shares of our common stock, and warrants to acquire another 1,658,600 shares, in a public offering in February. Sales of a substantial number of additional shares of our common stock in the public market could cause the market price of our common stock to decline. An aggregate of 23,048,488 shares of common stock were outstanding as of November 2, 2012. As of such date, excluding the impact of the antidilution adjustments described below, another (i) 3,275,222 shares were issuable upon exercise of outstanding options, (ii) 12,401,639 shares of common stock were issuable upon the exercise of outstanding warrants (provided, however, that the warrants issued to the purchasers of the outstanding 12% convertible promissory notes to acquire up to 3,829,689 shares of common stock in the aggregate at an exercise price of $1.25 per share include antidilution provisions whereby if shares are sold to Lincoln Park pursuant to our $1,500,000 purchase agreement

at a per share price of (i) less than $1.25, then the exercise price will be reset to such lower per share price, subject to a floor of $0.64, and (ii) less than $0.64, then the number of shares issuable pursuant to such warrants will increase by a factor equal to $0.64 divided by such lower price, subject to a cap on the amount of any such increase of 50% (or an additional 1,914,841 shares of common stock in the aggregate)), and (iii) 5,106,250 shares were issuable if all outstanding 12% convertible secured promissory notes were converted to Series A convertible preferred stock which was then ultimately converted into common stock (provided, however, that as a result of the antidilution provisions of the Series A convertible preferred stock, this amount of shares will increase by up to 126,725 shares, to a total of up to 5,232,975 shares of common stock, if shares are sold after December 31, 2012 to Lincoln Park pursuant to our $1,500,000 purchase agreement at a per share price of less than $0.80). Opexa commenced sales to Lincoln Park under the $1,500,000 purchase agreement on November 8, 2012 at a per share price of $0.50 that triggers the foregoing antidilution adjustment.

A substantial majority of the outstanding shares of our common stock are freely tradable without restriction or further registration under the Securities Act of 1933. We may sell additional shares of common stock, as well as securities convertible into or exercisable for common stock, in subsequent public or private offerings. We may also issue additional shares of common stock, as well as securities convertible into or exercisable for common stock, to finance future acquisitions. Among other requirements, we will need to raise significant additional capital, or secure a partnering arrangement, in order to continue and complete the Phase IIb clinical study of Tcelna in SPMS, and this may require us to issue a substantial amount of securities (including common stock as well as securities convertible into or exercisable for common stock). We cannot predict the size of future issuances of our common stock, as well as securities convertible into or exercisable for common stock, or the effect, if any, that future issuances and sales of our securities will have on the market price of our common stock. Sales of substantial amounts of our common stock, as well as securities convertible into or exercisable for common stock, including shares issued in connection with an acquisition or securing funds to complete our clinical trial plans, or the perception that such sales could occur, may adversely affect prevailing market prices for our common stock.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

Under our purchase agreements with Lincoln Park, we may direct Lincoln Park to purchase up to $1,500,000 of shares of common stock subject to certain limitations over a 30-month period, and, upon effectiveness of a registration statement for resale of the underlying shares and subject to other conditions, we may also direct Lincoln Park to purchase up to $15,000,000 of our shares of common stock over a 30-month period. Additionally, we issued Lincoln Park 226,027 shares of common stock as initial commitment shares, and may in the future issue up to an additional 452,055 shares of common stock as additional commitment shares, as a fee for its commitment to purchase the shares under the purchase agreements. The number of shares ultimately offered for sale by Lincoln Park is dependent upon the number of shares purchased by Lincoln Park. Depending on market liquidity at the time, sales of shares we issue to Lincoln Park may cause the trading price of our common stock to decline.

Subject to certain conditions, we generally have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of our agreements with Lincoln Park, we would be unable to sell shares to Lincoln Park if and when the market price of our common stock is below $0.45 per share, subject to adjustment. The purchase price for the shares that we may sell to Lincoln Park will fluctuate based on the price of our common stock and other factors determined by us. As such, Lincoln Park may ultimately purchase all, some or none of the shares of our common stock and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Therefore, sales to Lincoln Park by us pursuant to either or both of the purchase agreements could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could cause the trading price of our common stock to decline and could make it more difficult for us to sell equity or equity-related securities in the future.

We presently do not intend to pay cash dividends on our common stock.

We currently anticipate that no cash dividends will be paid on the common stock in the foreseeable future. While our dividend policy will be based on the operating results and capital needs of the business, it is anticipated that all earnings, if any, will be retained to finance the future expansion of our business.

Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock.

Our charter allows us to issue up to 100,000,000 shares of our common stock and to issue and designate the rights of, without stockholder approval, up to 10,000,000 shares of preferred stock. In connection with the July 25, 2012 convertible note financing, 80,000 shares of preferred stock were designated as non-voting Series A convertible preferred stock. In order to raise

additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in prior offerings and dilution to our stockholders could result. We may sell shares or other securities in other offerings at a price per share that is less than the price per share paid by investors in prior offerings, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in prior offerings.

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.

In the future, we may attempt to increase our capital resources by entering into debt or debt-like financing that is unsecured or secured by up to all of our assets, or by issuing additional debt or equity securities, which could include issuances of secured or unsecured commercial paper, medium-term notes, senior notes, subordinated notes, guarantees, preferred stock, hybrid securities, or securities convertible into or exchangeable for equity securities. In the event of our liquidation, our lenders and holders of our debt and preferred securities would receive distributions of our available assets before distributions to the holders of our common stock. Because our decision to incur debt and issue securities in future offerings may be influenced by market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings or debt financings. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future.

For example, on July 25, 2012, we closed a private offering consisting of convertible secured notes and warrants to purchase common stock which generated approximately $4.1 million in gross proceeds. The notes mature on July 25, 2014 and accrue interest at the rate of 12% per annum, compounded annually, payable in either cash or registered shares of common stock. The notes are secured by substantially all of our tangible and intangible assets, and $1.0 million of the proceeds from the note offering is being held in a controlled account as part of the security interest granted to the noteholders. The notes are convertible into a new class of non-voting Series A convertible preferred stock at a conversion price of $100.00, subject to certain limitations and adjustments. The Series A convertible preferred stock accrues cumulative dividends at the rate of 8% per annum, payable in either cash or registered shares of common stock, and carries a $100.00 per share liquidation preference. The Series A convertible preferred stock is convertible into common stock at a conversion price of $0.80, subject to certain limitations and adjustments. Although up to 5,106,250 shares of common stock were initially issuable if all 12% convertible secured promissory notes outstanding were converted to Series A convertible preferred stock and such stock was then converted into common stock, this amount of shares will increase by up to 126,725 shares, to a total of up to 5,232,975 shares of common stock if shares are sold after December 31, 2012 to Lincoln Park pursuant to our purchase agreements at a per share price of less than $0.80. In addition, the five-year warrants issued to the purchasers of the 12% convertible secured promissory notes to acquire up to 3,829,689 shares of common stock in the aggregate at an exercise price of $1.25 per share include antidilution provisions whereby if shares are sold to Lincoln Park pursuant to our purchase agreements at a per share price of (i) less than $1.25, then the exercise price will be reset to such lower per share price, subject to a floor of $0.64, and (ii) less than $0.64, then the number of shares issuable pursuant to such warrants will increase by a factor equal to $0.64 divided by such lower price, subject to a cap on the amount of any such increase of 50% (or an additional 1,914,841 shares of common stock in the aggregate). Opexa commenced sales to Lincoln Park under the $1,500,000 purchase agreement on November 8, 2012 at a per share price of $0.50 that triggers the foregoing antidilution adjustment.

Our management has significant flexibility in using our current available cash.

In addition to general corporate purposes (including working capital and operational purposes) , we currently intend to use our available cash to continue the Phase IIb clinical study of Tcelna in SPMS. The Phase IIb clinical study in North America of Tcelna is expected to involve 180 patients and take approximately three years to complete. The costs of the study as well as the ongoing expenses of our operations through the expected completion date of the study are estimated at approximately $35 million. Our existing resources are not adequate to permit us to proceed materially beyond the initiation of the study (i.e., the dosing of the first patients) or to complete such study or any significant portion of it. We will need to secure significant additional resources to complete the trial and support our operations during the pendency of the trial.

Depending on future developments and circumstances, we may use some of our available cash for other purposes. Notwithstanding our current intention to use our available cash for further clinical studies of Tcelna, our management will have significant flexibility in using our current available cash. The actual amounts and timing of expenditures will vary significantly depending on a number of factors, including the amount and timing of cash used in our operations and our research and development efforts. Management's failure to use these funds effectively would have an adverse effect on the value of our common stock and could make it more difficult and costly to raise funds in the future.

Item 6. Exhibits.

Exhibit No.	Description
3.1	Restated Certificate of Formation of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 26, 2012).
4.1	Form of Series I Warrant issued to investors (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on July 26, 2012).
4.2	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.1	Form of Note Purchase Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.2	Form of 12% Convertible Secured Promissory Note issued to investors (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.3	Form of Security Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc., the investors signatory thereto, and Alkek & Williams Ventures, Ltd. as collateral agent for the investors (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.4	Deposit Account Control Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc., Alkek & Williams Ventures, Ltd. as collateral agent for the investors, and Wells Fargo Bank, National Association (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.5	Form of Registration Rights Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.6	Sales Agreement, dated September 6, 2012, by and between Opexa Therapeutics, Inc. and Brinson Patrick Securities Corporation (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 7, 2012).
10.7	$15,000,000 Purchase Agreement, dated as of November 2, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 5, 2012).
10.8	$1,500,000 Purchase Agreement, dated as of November 5, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 5, 2012).
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Acting Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Acting Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*+	Financial statements from the Quarterly Report on Form 10-Q of the Company for the period ended September 30, 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: November 14, 2012

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

Date: November 14, 2012

By: /s/ David E. Jorden
David E. Jorden
Acting Chief Financial Officer
(Principal Financial and Accounting Officer)