OPEXA THERAPEUTICS, INC.

FORM 10-Q
(Quarterly Report)

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Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
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Symbol	OPXA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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 June 30, 2014

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. The Woodlands, Texas 77381**	**76-0333165**
(State or other jurisdiction of Incorporation or organization)	(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 August 1, 2014, there were 27,753,172 shares of the issuer's Common Stock outstanding.

OPEXA THERAPEUTICS, INC.
For the Six Months Ended June 30, 2014

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

OPEXA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 16,214,690	$ 23,644,542
Other current assets	1,481,526	1,122,576
Total current assets	17,696,216	24,767,118
Property & equipment, net of accumulated depreciation of $1,905,854 and $1,718,477, respectively	1,234,826	1,295,024
Other long-term assets	162,045	177,666
Total assets	$ 19,093,087	$ 26,239,808
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 835,570	$ 696,155
Accrued expenses	1,627,271	1,232,990
Deferred revenue	1,230,746	1,395,348
Total current liabilities	3,693,587	3,324,493
Long term liabilities:		
Deferred revenue, net of current portion	1,846,120	2,338,041
Total liabilities	5,539,707	5,662,534
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, 27,661,675 and 27,546,058 shares issued and outstanding	276,617	275,461
Additional paid in capital	147,363,541	146,569,758
Accumulated deficit	(134,086,778)	(126,267,945)
Total stockholders' equity	13,553,380	20,577,274
Total liabilities and stockholders' equity	$ 19,093,087	$ 26,239,808

See accompanying notes to unaudited consolidated financial statements

OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
Revenue:				
Option revenue	$ 307,686	$ 348,837	$ 656,523	$ 568,937
Research and development	3,409,210	2,223,030	6,220,349	3,844,396
General and administrative	967,367	750,605	2,070,247	1,853,040
Depreciation and amortization	98,658	88,898	194,244	167,209
Operating loss	(4,167,549)	(2,713,696)	(7,828,317)	(5,295,708)
Interest income	4,290	3,066	9,484	4,940
Other income, net	-	-	-	37,910
Interest expense	-	(285,800)	-	(1,921,054)
Net loss	$ (4,163,259)	$ (2,996,430)	$ (7,818,833)	$ (7,173,912)
Basic and diluted loss per share	$ (0.15)	$ (0.37)	$ (0.28)	$ (0.94)
Weighted average shares outstanding - Basic and diluted	27,661,675	7,991,559	27,623,358	7,617,409

See accompanying notes to unaudited consolidated financial statements

OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Par			
Balances at December 31, 2013	27,546,058	$ 275,461	$ 146,569,758	$(126,267,945)	$ 20,577,274
Shares issued for services	115,617	1,156	152,314	—	153,470
Shares subscribed under the at-the-market program	—	—	49,847	—	49,847
Option expense	—	—	591,622	—	591,622
Net loss	—	—	—	(7,818,833)	(7,818,833)
Balances at June 30, 2014	27,661,675	$ 276,617	$ 147,363,541	$(134,086,778)	$ 13,553,380

See accompanying notes to unaudited consolidated financial statements

OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,	
	2014	**2013**
Cash flows from operating activities		
Net loss	$ (7,818,833)	$ (7,173,912)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Restricted stock issued to employees	153,470	-
Amortization of discount on notes payable due to warrants and beneficial conversion feature	-	1,382,977
Depreciation	194,244	167,209
Amortization of debt financing costs	-	98,964
Option and warrant expense	591,622	714,871
Changes in:		
Other current assets	(309,103)	(369,383)
Accounts payable - third parties and related parties	132,591	635,368
Accrued expenses	394,281	637,636
Deferred revenue	(656,523)	4,431,063
Other assets	15,621	(96,064)
Net cash provided by (used in) operating activities	(7,302,630)	428,729
Cash flows from investing activities		
Purchase of property & equipment	(127,222)	(22,894)
Restricted cash		500,000
Net cash provided by (used in) investing activities	(127,222)	477,106
Cash flows from financing activities		
Common stock and warrants sold for cash, net of offering costs	-	3,578,288
Proceeds from third party debt	-	550,000
Proceeds from related party debt	-	100,000
Deferred financing and offering costs	-	(147,847)
Repayment on related party notes payable	-	(100,000)
Repayments on notes payable	-	(450,000)
Net cash provided by financing activities	-	3,530,441
Net change in cash and cash equivalents	(7,429,852)	4,436,276
Cash and cash equivalents at beginning of period	23,644,542	592,004
Cash and cash equivalents at end of period	$ 16,214,690	$ 5,028,280

Cash paid for:		
Interest	$ -	$ 19,128
NON-CASH TRANSACTIONS		
Conversion of notes payable to common stock	-	1,000,000
Discount on convertible notes relating to:		
Warrants	-	195,969
Beneficial conversion feature	-	141,829
Unpaid additions to property and equipment	6,825	108,607
Subscription receivable	49,847	-
Shares issued as deferred offering costs	-	1,234

See accompanying notes to unaudited consolidated financial statements

OPEXA THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1. Basis of Presentation

The accompanying interim unaudited consolidated financial statements of Opexa Therapeutics, Inc. ("Opexa" or the "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 consolidated financial statements include the accounts of Opexa and its wholly owned subsidiary, Opexa Hong Kong Limited ("Opexa Hong Kong"). All intercompany balances and transactions have been eliminated in the consolidation.

During the six months ended June 30, 2014, the Company has elected to early adopt Accounting Standards Update No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements. The adoption of this ASU allows the Company to remove the inception to date information and all references to development stage.

Note 2. Significant Accounting Polices

Revenue Recognition. Opexa recognizes revenue in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 605, "Revenue Recognition." ASC 605 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) consideration is fixed or determinable; and (4) collectability is reasonably assured.

On February 4, 2013, Opexa entered into an Option and License Agreement (the "Merck Agreement") with Ares Trading SA ("Merck"), a wholly owned subsidiary of Merck Serono S.A. Pursuant to the terms, Merck has an option to acquire an exclusive, worldwide (excluding Japan) license of the Company's Tcelna® program for the treatment of multiple sclerosis ("MS"). Tcelna is currently in a Phase IIb clinical trial in patients with Secondary Progressive MS ("SPMS"). The option may be exercised by Merck prior to or upon the Company's completion of the Phase IIb Trial.

Opexa received an upfront payment of $5 million for granting the option. If the option is exercised, Merck would pay the Company an upfront license fee of $25 million unless Merck is unable to advance directly into a Phase III clinical trial of Tcelna for SPMS without a further Phase II clinical trial (as determined by Merck), in which event the upfront license fee would be $15 million. After exercising the option, Merck would be solely responsible for funding development, regulatory and commercialization activities for Tcelna in MS, although the Company would retain an option to co-fund certain development in exchange for increased royalty rates. The Company would also retain rights to Tcelna in Japan, certain rights with respect to the manufacture of Tcelna, and rights outside of MS.

Opexa evaluated the Merck Agreement and determined that the $5 million upfront payment from Merck has "stand-alone value." Opexa's continuing performance obligations, in connection with the $5 million payment, include the execution and completion of the Phase IIb clinical trial in SPMS using commercially reasonable efforts at the Company's own costs. As a "stand-alone value" term in the Merck Agreement, the $5 million upfront payment is determined to be a single unit of accounting, and is recognized as revenue on a straight-line basis over the exclusive option period based on the expected completion term of the Phase IIb clinical trial in SPMS. Opexa includes the unrecognized portion of the $5 million as deferred revenue on the consolidated balance sheets. During the second quarter of 2014, Opexa adjusted the number of months over which it was recognizing the deferred revenue from 43 to 47 months. This extension will align the period for recognition of the revenue to the present projection for expiration of the Merck Agreement.

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.

Opexa primarily maintains cash balances on deposit in accounts at a U.S.-based financial institution. The aggregate cash balance on deposit in these accounts is insured by the Federal Deposit Insurance Corporation up to $250,000. Opexa's cash balances on deposit in these accounts may, at times, exceed the federally insured limits. Opexa has not experienced any losses in such accounts.

At June 30, 2014, Opexa has approximately $15.5 million in a savings account. For the six months ended June 30, 2014, the savings account recognized an average market yield of 0.10%. Interest income of $9,484 was recognized for the six months ended June 30, 2014 in the consolidated statements of operations.

Note 3. Other Current Assets

Other current assets consisted of the following at June 30, 2014 and December 31, 2013:

Description	June 30, 2014	Dec 31, 2013
Prepaid expenses	$ 670,041	$ 315,014
Subscriptions receivable	49,847	-
Supplies inventory	599,572	673,044
Deferred offering costs	162,066	134,518
	$ 1,481,526	$ 1,122,576

Prepaid expenses at June 30, 2014 and December 31, 2013 include advance payments totaling $415,685 and $21,982, respectively, made to vendors and consultants for the conduct of the Phase IIb clinical trial in SPMS.

Prepaid expenses at June 30, 2014 and December 31, 2013 also include costs incurred from third parties in connection with the Merck Agreement (see Note 2). As of June 30, 2014 and December 31, 2013, the remaining costs of $38,938 in connection with the Merck Agreement that are expected to be amortized over the upcoming 12-month period are capitalized and included in other current assets in the consolidated balance sheets. The remaining costs of $58,409 in connection with the Merck Agreement that are expected to be amortized beyond the upcoming 12-month period are capitalized and included in other long term assets in the consolidated balance sheets (see Note 4).

Supplies inventory at June 30, 2014 and December 31, 2013 includes reagents and supplies that will be used to manufacture Tcelna and placebo product in Opexa's Phase IIb clinical study. Opexa expects to amortize these prepaid reagents and supplies to research and development costs in the consolidated statements of operations over the course of the clinical study.

Deferred offering costs at June 30, 2014 and December 31, 2013 include costs incurred from third parties in connection with the implementation of a $1.5 million Purchase Agreement in November 2012 pursuant to which Opexa has the right to sell to Lincoln Park Capital Fund, LLC ("Lincoln Park") up to $1.5 million in shares of its common stock, subject to certain conditions and limitations. As of June 30, 2014 and December 31, 2013, the remaining costs of $134,518 in connection with the implementation of the $1.5 million Purchase Agreement remained capitalized and are included in other current assets in the consolidated balance sheets. Upon the sales of shares of common stock under the $1.5 million Purchase Agreement, the remaining capitalized costs are offset against the proceeds of such sales of shares of common stock.

Deferred offering costs at June 30, 2014 also include costs incurred from third parties in connection with the implementation of an at-the-market program ("ATM Agreement") in March 2014 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 June 30, 2014, the remaining costs of $27,548 in connection with the implementation of the ATM Agreement remained capitalized and are included in other current assets in the consolidated balance sheets. Upon the sales of shares of common stock under the ATM Agreement, the remaining capitalized costs are offset against the proceeds of such sales of shares of common stock.

Note 4. Other Long Term Assets

Other long term assets at June 30, 2014 and December 31, 2013 include deferred offering costs of $103,636 which were incurred from third parties in connection with the implementation of a $15.0 million Purchase Agreement in November 2012 pursuant to which Opexa has the right to sell to Lincoln Park up to $15.0 million in shares of its common stock, subject to certain conditions and limitations.

Other long term assets at June 30, 2014 and December 31, 2013 also include costs incurred from third parties in connection with the Merck Agreement (see Note 2) amount to $58,409 that are expected to be amortized beyond the upcoming 12-month period.

Note 5. Equity

For the six months ended June 30, 2014, equity related transactions were as follows:

- Opexa recognized stock based compensation expense of $77,814 during the six months ended June 30, 2014 related to shares o restricted common stock issued to certain members of Opexa's management on November 8, 2013. The shares vested in full o February 28, 2014.
- On February 28, 2014, 109,617 shares of restricted common stock with an aggregate fair value of $199,503 were issued to certai members of Opexa's management and certain non-employee directors for service on Opexa's Board. Opexa recognized stock base compensation expense of $71,656 related to these shares during the six months ended June 30, 2014. The restricted shares issued t management vest in full on the earlier of the first anniversary of the grant date or termination of employment without cause following change of control. The restricted shares issued to non-employee directors vest in four quarterly increments beginning on March 31 2014.
- On March 19, 2014, 6,000 shares of restricted common stock with an aggregate fair value of $12,000 were issued to a non-employe director for service on Opexa's Board. Opexa recognized stock based compensation of $4,000 related to these shares during the si months ended June 30, 2014. The shares vest in three quarterly increments beginning on June 30, 2014.
- In late June 2014, Opexa sold an aggregate of 30,700 shares of common stock under the ATM Agreement for gross and net proceed of $51,390 and $49,847, respectively. These sales settled and the shares were issued in early July 2014.

Note 6. 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 625,000 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 June 30, 2014, options to purchase an aggregate of 2,465,691 shares were issued and outstanding.

Opexa accounts for share-based compensation, including options and nonvested shares, according to the provisions of FASB ASC 718, "Share Based Payment." During the six months ended June 30, 2014, Opexa recognized option expense of $591,622. Unamortized stock compensation expense as of June 30, 2014 amounted to $1,783,965.

Stock Option Activity

A summary of stock option activity for the six months ended June 30, 204 is presented below:

	Number of Shares	Wtd. Avg. Exercise Price	Wtd. Avg. Remaining Contract Term (# years)	Intrinsic Value
Outstanding at January 1, 2014	1,162,449	$ 4.30		
Granted	1,350,440	1.82		
Exercised	-	-		
Forfeited and canceled	(47,198)	3.40		
Outstanding at June 30, 2014	2,465,691	$ 2.96	8.5	$ 43,363
Exercisable at June 30, 2014	828,235	$ 4.83	6.7	$ 41,848

Employee Options:

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 six months ended June 30, 2014, performance-based options to purchase an aggregate of 510,125 shares at an exercise price of $1.82 were granted to senior management. These options have a term of ten years and vest 100% upon the earlier of achievement of a performance-based, strategic milestone objective or termination of employment without cause following a change of control. Fair value of $918,554 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 2.65%, (2) expected term of 10 years, (3) expected volatility of 172% and (4) zero expected dividends.

During the six months ended June 30, 2014, time-based options to purchase an aggregate of 719,875 shares at exercise prices ranging from $1.65 to $1.82 were granted to employees. These options have a term of ten years and have a vesting schedule of the earlier of four years or termination of employment without cause following a change of control. Fair value of $1,274,918 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 range of 2.63% and 2.79%, (2) expected term of 6.25 years, (3) expected volatility range of 182%-186% and (4) zero expected dividends.

During the six months ended June 30, 2014, options to purchase 47,198 shares were forfeited and cancelled.

Non-Employee Options:

During the six months ended June 30, 2014, options to purchase an aggregate of 120,440 shares at exercise prices ranging from $1.82 to $2.00 were granted to non-employee directors for service on Opexa's Board. Options to purchase an aggregate of 78,858 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, 2014. Options to purchase an aggregate of 26,288 shares have terms of 10 years, with 50% of the shares vesting immediately and 50% vesting on February 28, 2015. An option to purchase 8,844 shares will expire on the earlier of 10 years or a change in control of the Company, with vesting in quarterly increments beginning on March 31, 2014. An option to purchase 6,450 shares will expire on the earlier of 10 years or a change in control of the Company, with vesting in three quarterly increments beginning June 30, 2014. Fair value of $211,097 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 range of 2.65% and 2.77%, (2) expected term of 5.25 years, (3) expected volatility range of 155% and 157% and (4) zero expected dividends.

Restricted Stock

See Note 5 for a description of restricted stock awards made to employees and non-employee directors under the 2010 Plan during the six months ended June 30, 2014.

Warrant Activity

A summary of warrant activity for the six months ended June 30, 2014 is presented below:

	Number of Shares	Wtd. Avg. Exercise Price	Wtd. Avg. Remaining Contract Term (# years)	Intrinsic Value
Outstanding at January 1, 2014	3,069,113	$ 4.12		
Granted	-	-		
Exercised	-	-		
Forfeited and canceled	-	-		
Outstanding at June 30, 2014	3,069,113	$ 4.12	2.7	$ 186,750
Exercisable at June 30, 2014	3,069,113	$ 4.12	2.7	$ 186,750

Note 7. Subsequent events

Subsequent to June 30, 2014 and through August 1, 2014, Opexa issued an aggregate of 91,497 shares of common stock under the ATM Agreement for gross and net proceeds of $152,687 and $148,103, respectively.

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 June 30, 2014. 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, 2013.

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," "hopes," "anticipates," "estimates," "may," "could," "intends," "exploring," "evaluating," "progressing," "proceeding," and similar expressions are intended to identify forward-looking statements. 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 (including for Tcelna (imilecleucel T)), 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:

- market conditions;
- our capital position;
- our ability to compete with larger, better financed pharmaceutical and biotechnology companies;
- new approaches to the treatment of our targeted diseases such as Multiple Sclerosis (MS);
- 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 or clinical studies related to our T-cell platform);
- our ability to maintain compliance with NASDAQ listing standards;
- the success of our clinical trials (including the Phase IIb trial for Tcelna in secondary progressive MS which, depending upon results, may determine whether Ares Trading SA (Merck), a wholly owned subsidiary of Merck Serono S.A., elects to exercise its option (Option) to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna program for the treatment of MS);
- whether Merck exercises its Option and, if so, whether we receive any development or commercialization milestone payments or royalties from Merck pursuant to the Option;
- our dependence (if Merck exercises its Option) on the resources and abilities of Merck for the further development of Tcelna;
- 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 and future pipeline candidates);
- 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 suppliers and 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 or revise any forward-looking statements contained herein to reflect any changes in its 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 our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the SEC.

Business Overview

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

Opexa is a biopharmaceutical company developing a personalized immunotherapy with the potential to treat major illnesses, including multiple sclerosis (MS). This therapy is based on our proprietary T-cell technology. Our mission is to lead the field of Precision Immunotherapy ™ by aligning the interests of patients, employees and shareholders. Information related to our product candidate, Tcelna®, is preliminary and investigative. Tcelna has not been approved by the U.S. Food and Drug Administration (FDA) or other global regulatory agencies for marketing.

MS is an inflammatory autoimmune disease of the central nervous system (CNS), which is made up of the brain, spinal cord and optic nerves, with a clinically heterogeneous and unpredictable course that persists for decades. MS attacks the covering surrounding nerve cells, or myelin sheaths, leading to loss of myelin (demyelination) and nerve damage. In addition to demyelination, the neuropathology of MS is characterized by variable loss of oligodendroglial cells and axonal degeneration and manifests in neurological deficits. Symptoms may be mild, such as numbness in the limbs, or severe, such as paralysis or loss of vision. This inflammatory, demyelinating, autoimmune disease has varied clinical presentations, ranging from relapses and remissions (relapsing remitting MS, or RRMS) to slow accumulation of disability with or without relapses (secondary progressive MS, or SPMS). There are approximately 450,000 MS patients in North America and over 2,000,000 patients worldwide according to estimates from The National MS Society. The portion of the MS patient population that can be classified as SPMS is estimated by various industry sources to be between 30-45% of the total MS patient population.

We believe that our product candidate, Tcelna, has the potential to fundamentally address the root cause of MS by stopping the demyelination process and supporting the generation of new myelin sheaths where demyelination has occurred (remyelination). Tcelna is an autologous T-cell immunotherapy that is currently being developed for the treatment of SPMS and is specifically tailored to each patient's immune response profile to myelin. Tcelna is designed to reduce the number and/or functional activity of specific subsets of myelin-reactive T-cells (MRTCs) known to attack myelin. This technology was originally licensed from Baylor College of Medicine in 2001.

Tcelna is manufactured using our proprietary method for the production of an autologous T-cell product, which comprises the collection of blood from the MS patient and the expansion of MRTCs from the blood. Upon completion of the manufacturing process, an annual course of therapy consisting of five doses is cryopreserved. At each dosing time point, a single dose of Tcelna is formulated and attenuated by irradiation before returning the final product to the clinical site for subcutaneous administration to the patient.

Tcelna has received Fast Track designation from the FDA in SPMS, and we believe it is positioned as a potential first-to-market personalized T-cell therapy for MS patients. The FDA's Fast Track program is designed to facilitate the development and expedite the review of drug candidates intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

Opexa was incorporated in Texas in March 1991. Our principal executive offices are located at 2635 Technology Forest Blvd., The Woodlands, Texas 77381, and our telephone number is (281) 775-0600.

Multiple Sclerosis—Background

MS is a disease that is more common in females than males (2:1) between the ages of 20 and 40, with a peak onset of approximately 25 years of age. MS frequently causes impairment of motor, sensory, coordination and balance, visual, and/or cognitive functions, as well as urinary (bladder) or bowel dysfunction and symptoms of fatigue. The identified autoimmune mechanisms directed at myelin tissue of the CNS may play an important role in the pathogenesis of MS. Epidemiologic studies suggest that a variety of genetic, immunologic, and environmental factors including viral infections may play a role in defining the etiology and in triggering the onset and progression of MS.

At the onset of MS, approximately 85% of MS patients have RRMS. Without disease-modifying medication, one-half of these RRMS patients will develop steadily progressive disease, SPMS, within 10 years, increasing to 90% within 25 years of MS diagnosis. The MS drug market was approximately $13 billion in 2012 and is forecasted to reach as much as $16 billion by 2015.

MS remains a challenging autoimmune disease to treat because the pathophysiologic mechanisms are diverse, and the chronic, unpredictable course of the disease makes it difficult to determine whether the favorable effects of short-term treatment will be sustained. Therapies that are easy to use and can safely prevent or stop the progression of disease represent the greatest unmet need in MS.

In recent years, the understanding of MS pathogenesis has evolved to comprise an initial, T-cell-mediated inflammatory activity followed by selective demyelination (erosion of the myelin coating of the nerve fibers) and then neurodegeneration. The discovery of disease-relevant immune responses has accelerated the development of targeted therapeutic products for the treatment of the early stages of MS. Some subjects, who have the appropriate genetic background, have increased susceptibility for the in vivo activation and expansion of MRTCs. These MRTCs may remain dormant, but at some point they are activated in the periphery, thus enabling them to cross the blood-brain barrier and infiltrate the healthy tissue of the brain and spinal cord. The cascade of pathogenic events leads to demyelination of protrusions from nerve cells called axons, which causes nerve impulse transmissions to diffuse into the tissue resulting in disability to the individual.

Tcelna for MS

We believe that Tcelna works selectively on the MRTCs by harnessing the body's natural immune defense system and feedback mechanisms to deplete these T-cells and induce favorable immune regulatory responses by rebalancing the immune system. Tcelna is a personalized immunotherapy that is specifically tailored to each patient's disease profile. Tcelna is manufactured by 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 MRTCs raised against selected peptides from myelin basic protein (MBP), myelin oligodendrocyte glycoprotein (MOG) and proteolipid protein (PLP), expanding these MRTCs to a therapeutic dose ex-vivo, and attenuating them with gamma irradiation to prevent DNA replication and thereby cellular proliferation. These attenuated MRTCs are then injected subcutaneously into the body in therapeutic dosages. The body recognizes specific T-cell receptor molecules of these MRTCs as immunogenic and initiates an immune response reaction against them, resulting in the depletion and/or immunosuppression of circulating MRTCs carrying the peptide-specific T-cell receptor molecules. In addition, we believe that T-cell activation molecules on the surface of the activated MRTCs promote anti-inflammatory responses. We believe that because the therapy uses an individual's own cells, the only direct identifiable side effect observed thus far is injection site reactions which typically are minor and generally clear within 24 hours.

Tcelna Clinical Development Program

Tcelna is a novel T-cell immunotherapy in Phase IIb clinical development for the treatment of patients with SPMS. It is also positioned to enter Phase III clinical development for the treatment of patients with RRMS, subject to the availability of sufficient resources or a strategic partnering commitment.

The Tcelna clinical development program spans studies conducted by Baylor College of Medicine and by Opexa.

Summary of Phase I Dose Escalation Study in MS

A Phase 1 dose escalation study completed in 2006 was conducted in patients with both RRMS and SPMS who were intolerant or unresponsive to current approved therapies for MS. The open-label, dose escalation study evaluated safety and clinical benefit by administering a primary series of four treatments at one of three dose levels administered at baseline and weeks 4, 8 and 12. Results of the efficacy analyses provide some evidence of the effectiveness of Tcelna in the treatment of MS. Data from the Phase I study evaluating the Expanded Disability Status Scale (EDSS) showed improvements in some subjects in comparison to baseline for weeks 20 and 28.

Subjects showed statistically significant improvement in overall reduction of MRTC counts over baseline at all visits through week 52 for subjects receiving 30-45 million cells per dose, as assessed by total MRTC count percentage changes. These data indicate that Tcelna treatment causes a depletion or immunomodulation of these cells, most obvious at time points closer to the injections. These findings were published in Clinical Immunology (2009) 131, 202-215.

Overall, results of the safety analyses indicate that treatment with Tcelna is well-tolerated. Reported adverse events were mostly mild or moderate in intensity. Mild injection site reactions were observed but all resolved rapidly without treatment. In conclusion, data from this study suggest that Tcelna is safe for the treatment of MS.

Summary of Phase I/IIA Clinical Trial Data in MS

The second clinical study performed by Opexa was an open-label extension study completed in 2007 to treat patients who were previously treated with T-cell immunotherapy but who saw a rebound in MRTC activity. The purpose of this extension study was to continue evaluating the efficacy, safety and tolerability of Tcelna in patients with RRMS and SPMS with repeated administration of Tcelna. Results of the study provide evidence of the effectiveness of Tcelna in the treatment of MS with repeated dosing. Improvements from baseline at both week 28 and week 52 of the extension study were observed for the frequency of MS exacerbations, or annualized relapse rate (ARR). Evaluation of the Multiple Sclerosis Impact Scale (MSIS-29) component scores suggests a trend for Tcelna therapy in the improvement of physical and psychological parameters assessed by the MSIS-29. The EDSS score analysis revealed an upward trend for the percentage of subjects that reported improvement and sustained improvement over baseline as a result of Tcelna treatment.

Subjects showed statistically significant improvement over baseline in the MRTC counts for each time point through month nine of the extension study. These results indicate that Tcelna treatment results in a statistically significant impact on these cells.

Overall, results of the safety analyses indicate that repeated treatment with Tcelna is well-tolerated. Reported adverse events (AEs) were mostly mild or moderate in intensity. Mild injection site reactions were observed but all resolved rapidly without treatment. Furthermore, results from this study suggest that repeated dosing of Tcelna has a substantive effect in reduction of ARR in subjects with MS and was well-tolerated.

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 magnetic resonance imaging (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. The inclusion criteria for TERMS was an EDSS score of 0 to 5.5. 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 consisting of all patients who received at least one dose of study product and had at least one MRI scan at week 28 or later (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, an 88% reduction in whole brain atrophy and a statistically significant improvement in disability (EDSS) compared to placebo ($p<0.045$) at week 52 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, the results showed that patients, when treated with Tcelna, had a 56% to 73% reduction in ARR versus placebo for the various subsets and p values ranged from 0.009 to 0.06.

We remain committed to further advancing Tcelna in RRMS at a later date assuming the availability of sufficient resources or a strategic partnering commitment. For Opexa, however, SPMS is an area which we believe represents a higher unmet medical need. Depending upon the outcome of further feasibility analyses, the T-cell platform may have applications in development treatments for other autoimmune disorders such as rheumatoid arthritis, Type 1 diabetes, and orphan indications such as myasthenia gravis. The primary focus of Opexa remains the development of Tcelna in SPMS.

SPMS Overview and Tcelna Mechanism of Action

SPMS is characterized by a steady accrual of irreversible disability, despite, in some cases, relapses followed by 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 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. Meningeal follicles close to cortical gray matter lesions suggests that adaptive immune responses involving antibody and complement contribute to progression in SPMS. Furthermore, chronic MRTCs may be contributing to the development of both innate and adaptive immune responses persisting in the CNS.

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.

Tcelna immunotherapy in SPMS may reduce the drivers of this chronic disease by down-regulating anti-myelin immunity through priming regulatory responses that may act in the periphery as well as within the CNS. We believe that our clinical results show therapeutic subcutaneous dosing of 30-45 million cells of Tcelna stimulates host reactivity to the over-represented MRTCs and, as a consequence, a dominant negative regulatory T-cell response is induced leading to down-regulation of similar endogenous disease-causing MRTCs.

We believe that Tcelna has the potential to induce an up-regulation of regulatory cells, such as Foxp3+ Treg cells and IL-10 secreting Tr1 cells, which may effect a reduction in inflammation and provide neuroprotection should they gain entry to the CNS. Data from our TERMS study showed statistically significant changes from baseline ($p=0.02$) in Foxp3+ Treg cells for the subset of Tcelna patients who had ARR >1. The placebo arm for this subset was not statistically different from its baseline levels. Three SPMS patients from prior clinical studies, whose blood samples were analyzed to measure Tr1 cells prior to treatment and post treatment, showed an increase in the levels of Tr1 cells from non-detectable levels to the range of healthy donor samples. These three patients who had relapses in the preceding 12-24 month period remained relapse free during the 52-week assessment period and also showed a 57% to 67% reduction in MRTCs.

Current Treatment Options for SPMS

Only one product, mitoxantrone, is currently approved for the indication of SPMS in the US. However, since 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 144 MS patients have received Tcelna in previously conducted Opexa 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.

In a pooled assessment of data from 36 SPMS patients treated in Phase I open label studies at the Baylor College of Medicine completed in 1998 and in Opexa-sponsored studies completed in 2006 and 2007, approximately 80% of the 35 SPMS patients who completed two years of treatment showed disease stabilization as measured by EDSS following two years of treatment with Tcelna, with the other 20% showing signs of progression. This compares to historical control data which showed a progression rate of 40% in SPMS patients (as reported in ESIMS Study published in Hommes Lancet 2004). The 10 SPMS patients in Opexa sponsored studies showed a substantial reduction in ARR at two years from 0.5 to an ARR less than 0.1. Only 1 out of the 10 patients experienced one episode of relapse during the two years of assessment. This same cohort showed no worsening of physical or psychological condition (key quality of life indicators as measured by the MS Impact Scale) after two years of treatment with Tcelna. Additionally, there were no reported serious adverse events (SAEs) in any of the patients. Based on preliminary data suggesting stabilized or improved disability among SPMS subjects receiving Tcelna, we believe that further development of this product candidate in SPMS is warranted.

Abili-T Trial: Phase IIb Clinical Study in Patients with SPMS

In September 2012, we announced the initiation of 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 Abili-T trial is a double-blind, 1:1 randomized, placebo-controlled study in SPMS patients who demonstrate evidence of disease progression with or without associated relapses. The trial is being conducted at approximately 35 leading clinical sites in the U.S. and Canada and has enrolled patients who have Expanded Disability Status Scale (EDSS) scores between 3.0 and 6.0. According to the study protocol, patients are receiving 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 (whole brain atrophy) at 24 months. Study investigators will also measure several important secondary outcomes commonly associated with MS including sustained disease progression as measured by EDSS, changes in EDSS, time to sustained progression, ARR, change in Multiple Sclerosis Functional Composite (MSFC) assessment of disability and change in Symbol Digit Modality Test. Data on certain exploratory endpoints such as quality of life metrics as measured by the Multiple Sclerosis Quality of Life Inventory (MSQLI), MRI measures and immune monitoring metrics are also being collected.

As part of the Abili-T trial, we are undertaking a comprehensive immune monitoring program for all patients enrolled in the study. The goals of this program are to further understand the biology behind the mechanism of action for Tcelna and to possibly identify novel biomarkers that are dominant in the pathophysiology of SPMS patients. The program encompasses an analysis of various pro-inflammatory and anti-inflammatory biomarkers and biomarker data is being gathered during the course of the trial on a blinded basis. We believe that directional movement of certain biomarkers, when corroborated with final clinical trial data, may be indicative of responders and disease stabilization or progression.

A scheduled Data Safety Monitoring Board meeting took place during the week of April 7, 2014, and a recommendation was made to continue the study. We reached our enrollment target for the Abili-T trial in June 2014, and a total of 190 patients have been enrolled in this two-year study. We expect top-line data to be available in the second half of 2016.

Our existing resources are not adequate to permit us to complete such study. We will need to secure significant additional resources to complete the Abili-T trial and support our operations during the pendency of the trial. We believe we have sufficient liquidity to support our current clinical activities for the Abili-T trial and general operations to sustain the Company and support such trial into the fourth quarter of 2015. Any other costs, however, such as costs associated with pursuing additional disease indications for our T-cell technology or other research or development programs, would of course shorten this period. Given our need for substantial amounts of capital to continue the Abili-T clinical study and potentially other clinical programs, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources, including one or more additional financings, that will be necessary to complete the Abili-T study and to support our operations and potentially other research and development programs during the pendency of such study. There can be no assurance that any such financings or potential opportunities and alternatives can be consummated on acceptable terms, if at all.

Option and License Agreement with Merck Serono

On February 4, 2013, we entered into an Option and License Agreement with Merck. Pursuant to the agreement, Merck has an option (the "Option") to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna program for the treatment of MS. The Option may be exercised by Merck prior to or upon completion of our ongoing Abili-T trial of Tcelna in patients with SPMS. Under the terms of the agreement, we received an upfront payment of $5 million for granting the Option. If the Option is exercised, Merck would pay us an upfront license fee of $25 million unless Merck is unable to advance directly into a Phase III clinical trial of Tcelna for SPMS without a further Phase II clinical trial (as determined by Merck), in which event the upfront license fee would be $15 million. After exercising the Option, Merck would be solely responsible for funding development, regulatory and commercialization activities for Tcelna in MS, although we would retain an option to co-fund certain development in exchange for increased royalty rates. We would also retain rights to Tcelna in Japan, certain rights with respect to the manufacture of Tcelna, and rights to use for other indications outside of MS.

Based upon the achievement of development milestones by Merck for Tcelna in SPMS, we would be eligible to receive one-time milestone payments totaling up to $70 million as follows: (i) milestone payments aggregating $35 million if Tcelna is submitted for regulatory approval and commercialized in the United States; (ii) milestone payments aggregating $30 million if Tcelna is submitted for regulatory approval in Europe and commercialized in at least three major countries in Europe; and (iii) a milestone payment of $5 million if Tcelna is commercialized in certain markets outside of the United States and Europe. If Merck elects to develop and commercialize Tcelna in RRMS, we would be eligible to receive milestone payments aggregating up to $40 million based upon the achievement by Merck of various development, regulatory and first commercial sale milestones.

If Tcelna receives regulatory approval and is commercialized by Merck, we would be eligible to receive royalties pursuant to a tiered structure at rates ranging from 8% to 15% of annual net sales, with step-ups over such range occurring when annual net sales exceed $500 million, $1 billion and $2 billion. Any royalties would be subject to offset or reduction in various situations, including if third party rights are required or if patent protection is not available in an applicable jurisdiction. We would also be responsible for royalty obligations to certain third parties, such as Baylor College of Medicine from which we originally licensed related technology. If we were to exercise an option to co-fund certain of Merck's development, the royalty rates payable by Merck would be increased to rates ranging from 10% to 18%. In addition to royalty payments, we would be eligible to receive one-time commercial milestones totaling up to $85 million, with $55 million of such milestones achievable at annual net sales targets in excess of $1 billion.

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 associated with MS. Depending upon the outcome of further feasibility analysis, the T-cell platform may have applications in developing treatments for other autoimmune disorders such as rheumatoid arthritis, Type 1 diabetes, and orphan indications such as myasthenia gravis. While the primary focus of Opexa remains the development of Tcelna in SPMS, we are also investigating the expansion of the T-cell platform into other autoimmune diseases as well as potential in-licensing.

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.

Revenue Recognition. We adopted the provisions of FASB ASC 605, "Revenue Recognition." ASC 605 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) consideration is fixed or determinable; and (4) collectability is reasonably assured.

We evaluated the Merck Agreement and determined that the $5 million upfront payment from Merck has stand-alone value. Opexa's continuing performance obligations, in connection with the $5 million payment, include the execution and completion of the Abili-T clinical trial in SPMS using commercially reasonable efforts at our own costs. As a stand-alone value term in the Merck Agreement, the $5 million upfront payment is determined to be a single unit of accounting, and is recognized as revenue on a straight-line basis over the exclusive option period based on the expected completion term of the Abili-T clinical trial in SPMS.

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

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

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

Results of Operations and Financial Condition

Comparison of the Three Months Ended June 30, 2014 with the Three Months Ended June 30, 2013

Revenue. Revenues of $307,686 and $348,837 related to the $5 million upfront payment from Merck in connection with the Option and License Agreement dated February 5, 2013 were recognized for the three months ended June 30, 2014 and 2013, respectively. The decrease in revenue is primarily a reflection of an increase in the number of months over which the deferred revenue is being recognized from 43 months to 47 months.

Research and Development Expenses. Research and development expenses were $3,409,210 for the three months ended June 30, 2014, compared with $2,223,030 for the three months ended June 30, 2013. The increase in expenses is primarily due to an increase in the costs in connection with the increasing enrollment of patients for the ongoing clinical trial of Tcelna in SPMS, an increase in the procurement and use of supplies for product manufacturing and development, and increases in the number of employees to support the ongoing clinical trial, employee compensation expense and stock compensation expense.

General and Administrative Expenses. General and administrative expenses for the three months ended June 30, 2014 were $967,367 compared with $750,605 for the three months ended June 30, 2013. The increase in expense is due to increases in employee compensation and stock compensation expenses, and was partially offset by decreases in legal and professional fees related to financing activities.

Depreciation and Amortization Expenses. Depreciation and amortization expenses for the three months ended June 30, 2014 were $98,658 compared with $88,898 for the three months ended June 30, 2013. The increase in expense is due to increases in depreciation for laboratory, manufacturing and computer equipment acquired during 2013 and 2014 and leasehold improvements during 2013 and 2014 to support increased development activities.

Interest Expense. Interest expense of $285,800 for the three months ended June 30, 2013 was primarily related to the amortized debt discount and interest on both the July 25, 2012 convertible secured promissory notes and the January 23, 2013 convertible promissory notes and the amortization of the financing fees over the life of the notes. No interest expense was recorded for the three months ended June 30, 2014.

Interest Income. Interest income was $4,290 for the three months ended June 30, 2014, compared to $3,066 for the three months ended June 30, 2013.

Other Income . We recorded no other income for the three months ended June 30, 2014 and June 30, 2013, respectively.

Net loss. We had a net loss for the three months ended June 30, 2014 of approximately $4.2 million, or $0.15 loss per share (basic and diluted), compared with a net loss of approximately $3 million or $0.37 loss per share (basic and diluted) for the three months ended June 30, 2013. The increased net loss is primarily related to a decrease in revenue and an increase in research and development expenses, higher general and administrative expenses and higher depreciation expenses partially offset by decreased interest expense for the quarter ending June 30, 2014.

Comparison of the Six Months Ended June 30, 2014 with the Six Months Ended June 30, 2013

Revenue. Revenues of $656,523 and $568,937 related to the $5 million upfront payment from Merck in connection with the Option and License Agreement dated February 5, 2013 were recognized for the six months ended June 30, 2014 and 2013, respectively.

Research and Development Expenses. Research and development expenses were $6,220,349 for the six months ended June 30, 2014, compared with $3,844,396 for the six months ended June 30, 2013. The increase in expenses is primarily due to an increase in the costs in connection with the increasing enrollment of patients for the ongoing clinical trial of Tcelna in SPMS, an increase in the procurement and use of supplies for product manufacturing and development, and increases in the number of employees to support the ongoing clinical trial, employee compensation expense and stock compensation expense.

General and Administrative Expenses. General and administrative expenses for the six months ended June 30, 2014 were $2,070,247, compared with $1,853,040 for the six months ended June 30, 2013. The increase in expense is due to increases in employee compensation and stock compensation expenses, and was partially offset by decreases in legal and professional fees related to financing activities.

Depreciation and Amortization Expenses. Depreciation and amortization expenses for the six months ended June 30, 2014 were $194,244, compared with $167,209 for the six months ended June 30, 2013. The increase in expense is due to increases in depreciation for laboratory, manufacturing and computer equipment acquired during 2013 and 2014 and leasehold improvements during 2013 and 2014 to support increased development activities.

Interest Expense. Interest expense of $1,921,054 for the six months ended June 30, 2013 was primarily related to the amortized debt discount and interest on both the July 25, 2012 convertible secured promissory notes and the January 23, 2013 convertible promissory notes and the amortization of the financing fees over the life of the notes. No interest expense was recorded for the six months ended June 30, 2014.

Interest Income. Interest income was $9,484 for the six months ended June 30, 2014, compared to $4,940 for the six months ended June 30, 2013.

Other Income. Other income of $37,910 for the six months ended June 30, 2013 was related to the extinguishment of membership interests in the mutual insurance company that we participated in for our product liability insurance through January 1, 2013. We recorded no other income for the six months ended June 30, 2014.

Net loss. We had a net loss for the six months ended June 30, 2014 of approximately $7.8 million, or $0.28 loss per share (basic and diluted), compared with a net loss of approximately $7.2 million or $0.94 loss per share (basic and diluted) for the six months ended June 30, 2013. The increased net loss is primarily related to increases in the costs associated with enrollment of patients for the clinical study of Tcelna in SPMS, the procurement and use of supplies for product manufacturing and development, additions to staff and increased compensation costs, and higher depreciation expenses partially offset by decreased interest expense and increases in revenue.

Liquidity and Capital Resources

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of June 30, 2014, we had cash and cash equivalents of $16,214,690. Our financing activities generated approximately $28.4 million for the year ended December 31, 2013. The cash generated in 2013 was proceeds from underwritten public offerings of shares of our common stock, proceeds from a registered direct offering of shares of our common stock, proceeds from sales of shares of our common stock to Lincoln Park Capital Fund, LLC ("Lincoln Park"), proceeds from sales of shares of our common stock under an "at-the-market" (ATM) facility, proceeds from a January 2013 convertible secured note financing, the release of funds to us previously held in a controlled account and from an upfront payment received pursuant to an option granted to acquire an exclusive, worldwide (excluding Japan) license to our Tcelna program for the treatment of MS, as discussed below.

On November 2, 2012, we entered into a $15.0 million purchase agreement and registration rights agreement, and on November 5, 2012, we entered into a $1.5 million purchase agreement, each with Lincoln Park pursuant to which we have the right to sell to Lincoln Park an aggregate of up to $16.5 million 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 $16.5 million in shares of common stock (subject to certain limitations) from time to time over a 30-month period. 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. 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 adjusted minimum floor price of $1.00. As of June 30, 2014, we have sold an aggregate of 390,000 shares of our common stock to Lincoln Park for gross proceeds of $523,709 and have a remaining commitment amount of $15,976,291 available to us through Lincoln Park purchase agreements. 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, including the requirement to keep current the prospectus included as part of the Form S-1 registration statement relating to the $15.0 million purchase agreement (which is not current as of this date).

On September 6, 2012, we entered into a Sales Agreement (the "ATM Agreement") with Brinson Patrick Securities Corporation (the "Original Sales Manager") in which we could offer and sell shares of our common stock from time to time depending upon market demand, with the Original Sales Manager acting as an agent for the sale of shares in transactions deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933. During February 2013, we sold an aggregate of 167,618 shares of our common stock, for gross proceeds of $536,417 pursuant to the ATM Agreement. On March 5, 2014, we entered into a First Amendment to Sales Agreement with the Original Sales Manager and Meyers Associates, L.P. (doing business as Brinson Patrick, a division of Meyers Associates, L.P.) ("Brinson Patrick"), pursuant to which the ATM Agreement was assigned by the Original Sales Manager to Brinson Patrick. The ATM Agreement, as amended, is referred to herein as the "new ATM Agreement." Under the new ATM Agreement, we may offer and sell shares of our common stock from time to time depending upon market demand, with Brinson Patrick acting as an agent for the sale of shares in transactions deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933. We have registered up to an additional 2,500,000 shares of our common stock for potential sale under the new ATM Agreement. As of June 30, 2014, we have generated gross and net proceeds of $51,390 and $49,847, respectively, under the new ATM Agreement on sales of an aggregate of 30,700 shares of our common stock at average prices ranging from $1.64 to $1.68 per share. Between March 5, 2014 and August 1, 2014, we generated gross and net proceeds of $152,687and $148,103, respectively, on sales of an aggregate of 91,497 shares of our common stock under the new ATM Agreement, including gross and net proceeds of $101,297and $98,256, respectively, on sales of an aggregate of 60,797 shares of our common stock subsequent to June 30, 3014.

Our operating cash burn rate during the six months ended June 30, 2014 was approximately $1.2 million per month. Significant activities in the conduct of the Abili-T clinical trial are expected to result in a similar monthly operating cash burn in the second half of 2014. We believe that we have sufficient liquidity to support our current clinical activities for the Abili-T trial and general operations to sustain the Company and support such trial into the fourth quarter of 2015. Any other costs, however, such as costs associated with pursuing additional disease indications for our T-cell technology or other research or development programs, would of course shorten this period.

We currently intend to use our available cash to fund general corporate purposes (including working capital, business development and operational purposes) and continue the ongoing Abili-T clinical study. We reached our enrollment target for the Abili-T trial in June 2014, and a total of 190 patients have been enrolled in this two-year study. We expect top-line data to be available in the second half of 2016.

Our existing resources are not adequate to permit us to complete such study. We will need to secure significant additional capital to complete the trial and support our operations during the pendency of the trial. If we are unable to obtain additional funding for operations beyond the projected runway, 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.

Given our need for substantial amounts of capital to complete the Abili-T clinical study and potentially other clinical programs, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources, including one or more additional financing transactions, that will be necessary to complete the Abili-T study and to support our operations and potentially other research and development programs during the pendency of such study. There can be no assurance that any such financings or potential opportunities and alternatives can be consummated on acceptable terms, if at all.

If Merck does not exercise the Option and acquire the exclusive, worldwide (excluding Japan) license of our Tcelna program for MS, or if we are not successful in attracting another partner and entering into a 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 undertake, or complete, any Phase III clinical study of Tcelna in SPMS, assuming the results of the Abili-T Phase IIb study warrant such a further study. 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.

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 with Brinson Patrick, 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.

Assuming we are able to achieve financing which is sufficient to continue the Abili-T 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, however, would also depend upon the availability of sufficient resources or a strategic partnering commitment.

Off-Balance Sheet Arrangements

None.

Recent Accounting Pronouncements

In June 2014, the FASB issued Accounting Standards Update ("ASU") 2014-10, "Development Stage Entities," which eliminated the concept of a development stage entity from U.S. GAAP and among other things removed the presentation and disclosure requirements specific to development stage entities, such as the inception-to-date financial information. We have adopted ASU 2014-10 as of January 1, 2014, and as an early adopter, we will no longer be providing inception-to-date information in our financial statements.

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 June 30, 2014, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of June 30, 2014, 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.

Item 5. Other Information

On August 12, 2014, we provided notice to the University of Chicago that we have elected to discontinue further prosecution of certain patents relating to the proprietary adult stem cell technology that we license from the University of Chicago pursuant to a Fourth Amended and Restated License Agreement dated November 2, 2011. Pursuant to the termination notice, we exercised our contractual option to return the licensed patent rights back to the University of Chicago and terminate the license agreement effective November 10, 2014 in accordance with the terms thereof. The stem cell program has been in the early (pre-clinical) development stage at Opexa and returning such technology will allow us to focus our resources and development on our T-cell platform and Tcelna, our lead product candidate. This decision does not affect the patent portfolio behind the T-cell platform or surrounding Tcelna.

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, 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 June 30, 2014, we had cash and cash equivalents of $16,214,690. During 2012, we closed a private offering in July 2012 consisting of convertible secured notes and warrants to purchase common stock which generated approximately $4.1 million in gross proceeds. These convertible secured notes were converted into equity during 2013 and an aggregate of 2,002,926 shares of common stock were issued. From November 2012 through January 2013, we sold an aggregate of 390,000 shares of our common stock to Lincoln Park for gross proceeds of $523,709 pursuant to our $1.5 million purchase agreement with Lincoln Park. We closed a private offering of unsecured convertible promissory notes and warrants to purchase common stock in January 2013 which generated $650,000 in gross proceeds. Upon receipt of the upfront payment from Merck in February 2013, we repaid $550,000 principal amount plus accrued interest of the January 2013 notes and converted the remaining $100,000 principal amount into shares of common stock pursuant to the investor's election to convert into equity. In February 2013, we sold an aggregate of 167,618 shares of our common stock pursuant to the ATM Agreement for gross proceeds of $536,417. On February 4, 2013, we entered into an Option and License Agreement with Merck pursuant to which we granted the Option to Merck to acquire an exclusive, worldwide (excluding Japan) license to our Tcelna program for the treatment of MS in consideration for an upfront payment of $5 million. On February 11, 2013, we closed an offering of 1,083,334 shares of common stock and warrants to purchase 541,668 shares of common stock for gross proceeds of $3.25 million, or net proceeds of approximately $3.0 million after deducting commissions and offering expenses. On August 13, 2013, we closed an offering of 12 million shares of common stock for gross proceeds of $18 million, or net proceeds of approximately $16.2 million after deducting underwriting discounts and commissions and offering expenses, and we granted the underwriters a 30-day option to purchase up to an additional 1.8 million shares of common stock to cover over-allotments. During September 2013, the underwriters of the August 2013 underwritten public offering exercised the over-allotment option granted to them which resulted in the issuance of an additional 900,000 shares of common stock for gross proceeds of $1.35 million, or net proceeds of approximately $1.2 million after deducting underwriting discounts and commissions and offering expenses. On December 23, 2013, we closed an offering of 4,738,000 shares of common stock including the full exercise of the over-allotment option granted to the underwriters, raising gross proceeds of approximately $8.1 million or net proceeds of approximately $7.3 million after deducting the underwriting discounts and commission and offering expenses. Between March 5, 2014 and August 1, 2014, we generated gross and net proceeds of $152,687 and $148,103, respectively, on sales of an aggregate of 91,497 shares of our common stock under the new ATM Agreement.

Our operating cash burn rate during the six months ended June 30, 2014 was approximately $1.2 million per month. Significant activities in the conduct of the Abili-T clinical trial are expected to result in a similar monthly operating cash burn in the second half of 2014. We reached our enrollment target for the Abili-T trial in June 2014, and a total of 190 patients have been enrolled in this two-year study. We expect top-line data to be available in the second half of 2016.

We will need to secure significant additional resources to complete the trial and support our operations during the pendency of the trial. We believe that we have sufficient liquidity to support our current clinical activities for the Abili-T trial and general operations to sustain the Company and support such trial into the fourth quarter of 2015. Any other costs, however, such as costs associated with pursuing additional disease indications for our T-cell technology or other research or development programs, would of course shorten this period.

Given our need for substantial amounts of capital to complete the Abili-T clinical study and potentially other clinical programs, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources, including one or more additional financing transactions, that will be necessary to complete the Abili-T study and to support our operations and potentially other research and development programs during the pendency of such study. There can be no assurance that any such financings or potential opportunities and alternatives can be consummated on acceptable terms, if at all. If we are unable to obtain additional funding for operations beyond the projected runway, we will be forced to suspend or terminate our 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.

Other than the $1.5 million purchase agreement and the $15.0 million purchase agreement we entered into with Lincoln Park on November 5, 2012 and November 2, 2012, respectively, each of which is subject to certain limitations and conditions, we have no sources of debt or equity capital committed for funding and we must rely upon best efforts third-party debt or equity funding. 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 2014 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 by issuing equity securities, shareholders 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 shareholders. 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 to support our current clinical trial activities beyond the projected runway, 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 we are unable 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 shareholders may lose a portion or even all of their investment.

We may make changes to discretionary R&D investments that may have an impact on costs.

We are presently complementing the Abili-T clinical trial with an immune monitoring program. Expenses associated with the immune monitoring program are incurred at our discretion and are not required to satisfy any FDA-mandated criteria. Consequently, we may make changes to the parameters that are being analyzed, and these changes may result in either increased or decreased expenses for the study.

We may also incur discretionary expenses related to Phase III development, manufacturing scale-up/automation and technology transfer, research on additional indications and business development activities. There is no assurance that any such future expenses would be recovered by us.

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

Under our $1.5 million purchase agreement and our $15.0 million purchase agreement with Lincoln Park, we may direct Lincoln Park to purchase up to $16.5 million of shares of common stock, subject to certain limitations and conditions, over a 30-month period. From November 2012 through January 2013, we sold an aggregate of 390,000 shares to Lincoln Park pursuant to the $1.5 million purchase agreement, and we issued an aggregate of 56,507 initial commitment shares and 3,585 additional commitment shares in connection therewith. There can be no assurance that we will be able to receive any or all of the additional funds from Lincoln Park because the $1.5 million purchase agreement and the $15.0 million purchase agreement 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 $1.00 and that Lincoln Park own no more than 4.99% of our common stock under the $1.5 million purchase agreement or no more than 9.99% of our common stock under the $15.0 million purchase agreement, and the requirement to keep current the prospectus included as part of the Form S-1 registration statement relating to the $15.0 million purchase agreement (which is not current as of this date). In addition, 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 $1.5 million purchase agreement and the $15.0 million purchase agreement in excess of 1,151,829 shares or 19.99% of the total common stock outstanding as of the date of the

$15.0 million 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.

We will need to keep current the offering prospectus relating to the new ATM Agreement with Brinson Patrick, a division of Meyers Associates, L.P., in order to use the program to sell shares of our common stock. The number of shares and price at which we may be able to sell shares under the new ATM Agreement may be limited due to market conditions and other factors beyond our control.

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. In September 2012, we announced the initiation of 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 have provided Merck with the Option, which provides Merck with the opportunity, if exercised, to control the development and commercialization of Tcelna in MS.

In February 2013, we granted the Option to Merck. The Option permits Merck to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna program for the treatment of MS. The Option may be exercised by Merck prior to or upon completion of our ongoing Phase IIb trial of Tcelna in patients with SPMS. If Merck exercises the Option, Merck would be solely responsible for funding development, regulatory and commercialization activities for Tcelna in MS, although we would retain an option to co-fund certain development in exchange for increased royalty rates. We would also retain rights to Tcelna in Japan, certain rights with respect to the manufacture of Tcelna, and rights outside of MS. In consideration for the Option, we received an upfront payment of $5 million and may be eligible to receive an option exercise fee as well as milestone and royalty payments based on achievement of development and commercialization milestones. The rights we have relinquished to our product candidate Tcelna, including development and commercialization rights, may harm our ability to generate revenues and achieve or sustain profitability.

If Merck exercises the Option, we would become reliant on Merck's resources and efforts with respect to Tcelna in MS. In such an event, Merck may fail to develop or effectively commercialize Tcelna for a variety of reasons, including that Merck:

- does not have sufficient resources or decides not to devote the necessary resources due to internal constraints such as limited cash or human resources;

- decides to pursue a competitive potential product;

- cannot obtain the necessary regulatory approvals;
- determines 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.

If Merck does not exercise the Option, we may be unable to enter into a collaboration with any other potential partner 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 Merck does not exercise the Option, and we are not successful in attracting another 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 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.

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 reached our enrollment target for the Abili-T trial in June 2014, and a total of 190 patients have been enrolled in this two-year study. We expect top-line data to be available in the second half of 2016. In addition, we anticipate that at least a pivotal Phase III clinical trial would be necessary before an application could be submitted for approval of Tcelna for SPMS. Failure can occur at any stage of the trials, and problems could be encountered that would cause us or Merck (in the event the Option is exercised) 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 subsequen design modifications;
- unforeseen safety issues;
- determination of dosing issues, epitope profiles, 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 (e.g., patients' failure to return for follow-up visits detection of epitope profiles in subsequent visits, etc.); and
- failure of medical investigators to follow our clinical protocols.

In addition, we, Merck (if the Option is exercised) 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 any product candidate, 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 regulatory approval is obtained for any product candidate, such as Tcelna, any such 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, whether directly or through any development arrangement (such as where Merck exercises the Option) will be limited by any failure to obtain or limitation on necessary regulatory approvals.

If Merck exercises the Option, Merck would be solely responsible for funding development, regulatory and commercialization activities for Tcelna in MS, although we would retain an option to co-fund certain development in exchange for increased royalty rates.

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, including the Phase IIb trial of Tcelna in patients with SPMS.

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;
- licenses needed from third parties for manufacturing in order to conduct Phase III trials or to conduct commercial manufacturing, if applicable, are not obtained;
- 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. We may also need to seek additional licenses as we move into Phase III trials and, if applicable, the commercial stage of operations. These licenses may require increased payments to the licensors. 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 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 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, contract with corporate collaborators or other third parties to assist with future drug production and commercialization, or defer to Merck (in the event the Option is exercised) to address manufacturing requirements.

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.

Problems with our manufacturing process or with a manufacturing facility (whether ours or a third party's) could result in the failure to produce, or a delay in producing, adequate supplies of Tcelna. A number of factors could cause interruptions or delays, including equipment malfunctions or failures, destruction or damage to a manufacturing facility due to natural disasters or otherwise, contamination of materials, changes in regulatory requirements or standards that require modifications to our manufacturing process, action by a regulatory agency or by a manufacturer (whether us or a third party) that results in the halting or slowdown of production due to regulatory issues, any third-party manufacturer going out of business or failing to produce as contractually required, or other similar factors.

Difficulties, delays or interruptions in the manufacture and supply of Tcelna could require us to stop treating patients in our clinical development of Tcelna and/or require a halt to or suspension of, or otherwise adversely affect, a clinical trial, thus increasing our costs and damaging our reputation. If Tcelna is approved, difficulties, delays or interruptions in the manufacture and supply of Tcelna could cause a delay in or even halt or suspend the commercialization of Tcelna, potentially causing a partial or complete loss of revenue or market share.

Tcelna is manufactured using our proprietary Immpath® technology for the production of an autologous T-cell immunotherapy utilizing a patient's own blood. Our manufacturing process may raise development issues that may not be resolvable, regulatory issues that could delay or prevent approval, or personnel issues that may prevent the further development or commercialization, if approved, of any product candidate such as Tcelna.

Tcelna is based on our novel T-cell immunotherapy platform, Immpath, which produces an autologous T-cell immunotherapy utilizing a patient's own blood. The manufacture of living T-cell products requires specialized facilities, equipment and personnel which are different than the resources required for manufacturing chemical or biologic compounds. Scaling-out the manufacture of living cell products to meet demands for commercialization will require substantial amounts of such specialized facilities, equipment and personnel, especially where, as is the case for Teclna, the product is personalized and must be made for each patient individually. Because our manufacturing process for Teclna is complex, requires facilities and personnel that are not widely available in the industry, involves equipment and training with long lead times, and the establishment of new manufacturing facilities is subject to a potentially lengthy regulatory approval process, alternative qualified production capacity may not be available on a timely basis or on reasonably terms, if at all. In addition, not many consultants or advisors in the industry have relevant experience and can provide guidance or assistance because active immune therapies such as Tcelna are fundamentally a new category of product in two major ways: (i) the product consists of living T-cells, not chemical or biologic compounds; and (ii) the product is personalized. There can be no assurance that manufacturing problems will not arise in the future which we may not be able to resolve or which

may cause significant delays in development or, if Tcelna is approved, commercialization.

Regulatory approval of product candidates such as Tcelna that are manufactured using novel manufacturing processes such as ours can be more expensive and take longer than other, more well-known or extensively studied pharmaceutical or biopharmaceutical products, due to a lack of experience with them. FDA approval of personalized immunotherapy products has been limited to date. This lack of experience and precedent may lengthen the regulatory review process, require that additional studies or clinical trials be conducted, increase development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization, or lead to significant post-approval limitations or restrictions.

In addition, the novel nature of Tcelna also means that fewer people are trained in or experienced with product candidates of this type, which may make it difficult to find, hire and retain capable personnel for research, development and manufacturing positions.

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.

In the instance of Tcelna, if Merck exercises the Option then our ability to achieve revenue will be dependent upon the efforts and success of Merck in developing and commercializing Tcelna. Our ability to successfully commercialize any product we may eventually have, to the extent applicable, and/or our ability to receive any revenue associated with Tcelna in the event Merck exercises the Option, 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 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 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 adequate coverage of and reimbursement for any product from third-party payors cannot be obtained, 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 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, 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 sales and marketing strategies for the product and competition for such product;
- 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 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 and Compensation Committees must be an independent director. If any vacancies on our Board or our Audit or Compensation Committees 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.

Any acquisitions that we make could disrupt our business and harm our financial condition

We expect to evaluate potential strategic acquisitions of complementary businesses, products or technologies on a global geographic footprint. We may also consider joint ventures, licensing and other collaborative projects. We may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance or integrate acquisitions of any businesses, products or technologies. Furthermore, the integration of any acquisition and management of any collaborative project may divert our management's time and resources from our core business and disrupt our operations. We do not have any experience with acquiring companies, or with acquiring products outside of the United States. Any cash acquisition we pursue would potentially divert the cash we have on our balance sheet from our present clinical development programs. Any stock acquisitions would dilute our shareholders' ownership. While we from time to time evaluate potential collaborative projects and acquisitions of businesses, products and technologies, and anticipate continuing to make these evaluations, we have no present commitments or agreements with respect to any acquisitions or collaborative projects.

Risks Related to Doing Business Internationally

We plan to do business internationally, which may prove to be difficult and fraught with economic, regulatory and political issues. We may acquire or in-license foreign companies or technologies or commercialize our T-cell or stem cell platform in countries where the business, economic and political climates are very different from those of the United States. We may not be aware of some of these issues and it may be difficult for a U.S. company to overcome these issues and ultimately become profitable. Certain foreign countries may favor businesses that are owned by nationals of those countries as opposed to foreign-owned business operating locally. As a small company, we may not have the resources to engage in the negotiation and time-consuming work needed to overcome some of these potential issues.

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 (or, in the event the Option is exercised, Merck with respect to Tcelna) may not be able to develop any affected product candidate commercially. There can be no assurance that we will not be obliged to defend ourselves (or, in the event the Option is exercised, Merck with respect to Tcelna) 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 certain 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 may not maintain control over the payment of all such 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 (such as Merck, in the event the Option is exercised, with respect to Tcelna), 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 Merck exercises the Option, Merck would be solely responsible for funding development, regulatory and commercialization activities for Tcelna in MS, although we would retain an option to co-fund certain development in exchange for increased royalty rates. Otherwise, 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.

Beginning August 1, 2013, the Physician Payments Sunshine Act (the "Sunshine Act"), which is part of the Patient Protection and Affordable Care Act, requires manufacturers of drugs, medical devices, biologicals or medical supplies that participate in U.S. federal health care programs to track and then report certain payments and items of value given to U.S. physicians and U.S. teaching hospitals (defined as "Covered Recipients"). The Sunshine Act requires that manufacturers collect this information on a yearly basis and then report it to Centers for Medicare & Medicaid Services by the 90th day of each subsequent year.

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 partners (such as Merck, in the event the Option is exercised, with respect to Tcelna), and our partners 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 insurance coverage as of the date hereof 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.

Government controls and 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 foreign countries, particularly in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of any product candidate, such as Tcelna, to other available therapies. If reimbursement of any product candidate such as Tcelna, if approved, is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability in such country. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. Any negotiated prices for any product candidate such as Tcelna, if approved, covered by a Part D prescription drug plan will likely be lower than the prices that might otherwise be obtained outside of the Medicare Part D prescription drug plan. Moreover, while Medicare Part D applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment under Medicare Part D may result in a similar reduction in payments from non-governmental payors.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any product candidate such as Tcelna, if approved. Among policy-makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect: the demand for any product candidate such as Tcelna, if approved; the ability to set a price that we believe is fair for any product candidate such as Tcelna, if approved; our ability to generate revenues and achieve or maintain profitability; the level of taxes that we are required to pay; and the availability of capital.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the ACA), became law in the United States. The goal of the ACA is to reduce the cost of healthcare and substantially change the way healthcare is financed by both governmental and private insurers. The ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of any product candidate such as Tcelna, if approved. Provisions of the ACA relevant to the pharmaceutical industry include the following: an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs; an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively; a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability; expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; new requirements under the federal Open Payments program and its implementing regulations; and expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding.

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 is 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 of $2.5 million and a minimum bid price for our common stock of $1.00 per share), as well as certain corporate governance standards, to maintain the listing of our common stock on the NASDAQ Capital Market. It is possible that we could fail to satisfy one or more of these requirements. For example, our stockholders' equity of $1,341,611 as of June 30, 2013 was below the minimum stockholders' equity of $2.5 million required by NASDAQ to maintain compliance. However, on August 13, 2013, we raised gross proceeds of $18 million through the sale of shares of our common stock in an underwritten public offering, or net proceeds of approximately $16.2 million after deducting underwriting discounts and commissions and offering expenses, and the proceeds of such sale of shares of our common stock enabled us to attain the required level of stockholders' equity to maintain compliance. The trading price of our common stock has at certain times in the past failed to comply with the minimum bid price requirement.

While we are exercising diligent efforts to maintain the listing of our common stock on NASDAQ, there can be no assurance that we will be able to maintain compliance with the stockholder's equity, minimum bid price or other listing standards in the future. 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. In such event, NASDAQ rules permit us to appeal any delisting determination to a NASDAQ Hearings Panel. If we are unable to maintain or regain compliance in a timely manner 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.

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 (such as developments involving Merck and the Option Agreement, including a decision by Merck to exercise or not exercise the Option) 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, and sales of common stock acquired upon exercise o 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 majority shareholders.

Our charter authorizes the issuance of "blank check" preferred stock with such designations, rights and preferences as may be determined by our Board of Directors without shareholder 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 shareholders from receiving a premium for their shares in connection with a change of

control.

Future sales of our securities could cause dilution, and the sale of such securities, or the perception that such sales may occur, could cause the price of our stock to fall.

In 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 notes in the aggregate principal amount of $900,000 were converted into shares of Series A convertible preferred stock which, in turn, were converted into an aggregate of 288,229 shares of common stock. The remaining notes were converted into an aggregate of 1,714,697 shares of common stock at $1.91 per share on September 24, 2013. From November 2012 through January 2013, we sold an aggregate of 390,000 shares to Lincoln Park pursuant to the $1.5 million purchase agreement and issued an additional 56,507 shares as initial commitment shares and 3,585 shares as additional commitment shares. In January 2013, we issued $650,000 principal amount of unsecured convertible promissory notes of which $100,000 was converted into 77,034 shares of common stock at $1.298125 per share during February 2013 and the remaining $550,000 of principal amount plus accrued interest was repaid during February 2013. Purchasers of such notes also received five-year warrants to acquire an aggregate of 243,750 shares of our common stock at an exercise price of $1.24 per share. In February 2013, we sold an aggregate of 167,618 shares of our common stock pursuant to the ATM Agreement for gross proceeds of $536,417. On February 11, 2013, we closed on an offering of 1,083,334 shares of common stock and warrants to purchase 541,668 shares of common stock for gross proceeds of $3.25 million, or net proceeds of approximately $3.0 million after deducting commissions and offering expenses. On August 13, 2013, we closed an offering of 12 million shares of common stock for gross proceeds of $18 million, or net proceeds of approximately $16.2 million after deducting underwriting discounts and commissions and offering expenses, and we granted the underwriters a 30-day option to purchase up to an additional 1.8 million shares of common stock to cover over-allotments. During September 2013, the underwriters of the August 2013 underwritten public offering exercised the over-allotment option granted to them which resulted in the issuance of an additional 900,000 shares of common stock for gross proceeds of $1.35 million, or net proceeds of approximately $1.2 million after deducting underwriting discounts and commissions and offering expenses. On December 23, 2013, we closed an offering of 4,738,000 shares of common stock, including the full exercise of the over-allotment option granted to the underwriters, raising gross proceeds of $8.1 million or net proceeds of approximately $7.3 million after deducting the underwriting discounts and commission and offering expenses. Between March 5, 2014 and August 1, 2014, we generated gross and net proceeds of $152,687 and $148,103, respectively, on sales of an aggregate of 91,497 shares of our common stock under the new ATM Agreement.

Sales of additional shares of our common stock, as well as securities convertible into or exercisable for common stock, could result in substantial dilution to our shareholders and cause the market price of our common stock to decline. An aggregate of 27,753,172 shares of common stock were outstanding as of August 1, 2014. As of such date, another (i) 2,465,691 shares of common stock were issuable upon exercise of outstanding options and (ii) 3,069,113 shares of common stock were issuable upon the exercise of outstanding warrants. 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 in order to 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). There can be 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. Moreover, 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 result in substantial dilution and may adversely affect prevailing market prices for our common stock.

Under the $1.5 million purchase agreement and $15.0 million purchase agreement with Lincoln Park, we may direct Lincoln Park to purchase up to $16.5 million of shares of common stock, subject to certain limitations and conditions, over a 30-month period. We have sold an aggregate of 390,000 shares to date under the $1.5 million purchase agreement. Additionally, we issued Lincoln Park 56,507 shares of common stock as initial commitment shares and have issued an aggregate of 3,585 additional commitment shares, and may in the future issue up to an additional 109,428 shares of common stock as additional commitment shares, as a fee for its commitment to purchase the shares under the $1.5 million purchase agreement and the $15.0 million purchase agreement. 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 issuable pursuant to the purchase agreements after the date hereof 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 shareholders 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 shareholder approval, up to 10,000,000 shares of 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 paid by other investors, and dilution to our shareholders could result. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors, and investors purchasing shares or other securities in the future could have rights superior to existing shareholders. 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 other investors.

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.

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

In addition to general corporate purposes (including working capital, research and development and operational purposes), we currently intend to use our available cash to continue our ongoing Phase IIb clinical study of Tcelna in SPMS. We reached our enrollment target for the Abili-T trial in June 2014, and a total of 190 patients have been enrolled in this two-year study. We expect top-line data to be available in the second half of 2016. Our existing resources are not adequate to permit us to complete such study. 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 which may have the potential to decrease the forecasted cash runway. 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
10.1*	Form of Notice of Stock Option Grant and Stock Option Agreement for awards granted under the 2010 Stock Incentive Plan, as amended and restated.
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of 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 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 June 30, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations; (iii) Consolidated Statements of Changes in Stockholders' Equity; (iv) Consolidated Statements of Cash Flows; and (v) Notes to Consolidated Financial Statements.

* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OPEXA THERAPEUTICS, INC.

Date: August 14, 2014

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

Date: August 14, 2014

By: /s/ Karthik Radhakrishnan
Karthik Radhakrishnan
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

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* Filed herewith.

Exhibit 10.1

OPEXA THERAPEUTICS, INC.
AMENDED AND RESTATED 2010 STOCK INCENTIVE PLAN
NOTICE OF STOCK OPTION GRANT

You have been granted the following Option to purchase Common Stock of Opexa Therapeutics, Inc. (the "Company") under the Company's Amended and Restated 2010 Stock Incentive Plan (the "Plan"):

Name of Optionee:	[[FIRSTNAME]] [[LASTNAME]]
Total Number of Option Shares Granted:	[[SHARESGRANTED]]
Type of Option:	☒ Incentive Stock Option ☐ Nonstatutory Stock Option
Exercise Price Per Share:	$[___]
Grant Date:	[_____ __, 201__]
Vesting Commencement Date:	[_____ __, 201__]
Vesting Schedule:	The Shares subject to this Option become exercisable over a four-year period, with 25% vesting on the one-year anniversary of the Vesting Commencement Date and the remaining 75% vesting in equal increments quarterly thereafter (in arrears) over the remaining three years, subject to continuous Service from the Vesting Commencement Date.
Vesting Acceleration:	The Shares will become fully vested if your Service is terminated by the Company without "Cause" following a "Change in Control," as described in the Stock Option Agreement.
Expiration Date:	[_____ __, 201__]. This Option expires earlier if your Service terminates earlier, as described in the Stock Option Agreement.

By your signature and the signature of the Company's representative below, you and the Company agree that this Option is granted under and governed by the term and conditions of the Plan and the Stock Option Agreement (the "Agreement"), both of which are attached to and made a part of this document.

By signing this document you further agree that the Company may deliver by e-mail all documents relating to the Plan or this Award (including without limitation, prospectuses required by the Securities and Exchange Commission) and all other documents that the Company is required to deliver to its security holders (including without limitation, annual reports and proxy statements). You also agree that the Company may deliver these documents by posting them on a website maintained by the Company or by a third party under contract with the Company. If the Company posts these documents on a website, it will notify you by e-mail.

OPTIONEE:	**OPEXA THERAPEUTICS, INC.**
	By:
Optionee's Signature	
[[FIRSTNAME]] [[LASTNAME]]	Title: President & CEO
Optionee's Printed Name	

OPEXA THERAPEUTICS, INC.
AMENDED AND RESTATED 2010 STOCK INCENTIVE PLAN
STOCK OPTION AGREEMENT

Tax Treatment

This Option is intended to be an incentive stock option under Section 422 of the Internal Revenue Code or a nonstatutory option, as provided in the Notice of Stock Option Grant. Even if this Option is designated as an incentive stock option, it shall be deemed to be a nonstatutory option to the extent required by the $100,000 annual limitation under Section 422(d) of the Internal Revenue Code.

Vesting

This Option becomes exercisable in installments, as shown in the Notice of Stock Option Grant. The Shares will become fully vested if your Service is terminated by the Company without "Cause" following a Change in Control (as defined in the Plan), so long as you execute and deliver a general release (in a customary form provided by the Company) of all claims against the Company or persons affiliated with the Company within forty-five (45) days following the date of termination, or such shorter period as the Company may require (with any potential revocation periods having expired). "Cause" means (A) you commit a felony or another crime involving moral turpitude; (B) you fail to maintain an immigration status which allows you to work in the United States; (C) you materially violate any of the Company's rules and regulations (including, without limitation, the rules of conduct) or any other policies and practices established by the Board of Directors; (D) you materially violate any agreement with the Company (including, without limitation, any Proprietary Information and Inventions Agreement); (E) you fail to exercise reasonable efforts to perform duties consistent with your position with the Company (including, without limitation, as reasonably instructed by the CEO) and such failure has not been cured within ten (10) days of notice to such effect from the Company; or (F) you commit any breach of fiduciary duty or misconduct that is likely to cause a material adverse effect upon the financial condition or business operations of the Company.
This Option will in no event become exercisable for additional Shares after your Service has terminated for any reason.

Term

This Option expires in any event at the close of business at Company headquarters on the 10th anniversary of the Grant Date, as shown on the Notice of Stock Option Grant (fifth anniversary for a more than 10% stockholder as provided under the Plan if this is an incentive stock option). This Option may expire earlier if your Service terminates, as described below.

Regular Termination

If your Service terminates for any reason except death or "Total and Permanent Disability" (as defined in the Plan), then this Option will expire at the close of business at Company headquarters on the date three (3) months after the date your Service terminates (or, if earlier, the Expiration Date). The Company determines when your Service terminates for this purpose and all purposes under the Plan and its determinations are conclusive and binding on all persons.

Death	If your Service terminates because of death, then this Option will expire at the close of business at Company headquarters on the date 12 months after the date your Service terminates (or, if earlier, the Expiration Date). During that period of up to 12 months, your estate or heirs may exercise the Option.
Disability	If your Service terminates because of your Total and Permanent Disability, then this Option will expire at the close of business at Company headquarters on the date 12 months after the date your Service terminates (or, if earlier, the Expiration Date).
Leaves of Absence	For purposes of this Option, your Service does not terminate when you go on a military leave, a sick leave or another *bona fide* leave of absence, if the leave was approved by the Company in writing and if continued crediting of Service is required by the terms of the leave or by applicable law. But your Service terminates when the approved leave ends, unless you immediately return to active work. If you go on a leave of absence, then the vesting schedule specified in the Notice of Stock Option Grant may be adjusted in accordance with the Company's leave of absence policy or the terms of your leave. If you commence working on a part-time basis, then the vesting schedule specified in the Notice of Stock Option Grant may be adjusted in accordance with the Company's part-time work policy or the terms of an agreement between you and the Company pertaining to your part-time schedule.
Restrictions on Exercise	The Company will not permit you to exercise this Option if the issuance of Shares at that time would violate any law or regulation. The inability of the Company to obtain approval from any regulatory body having authority deemed by the Company to be necessary to the lawful issuance and sale of the Company stock pursuant to this Option shall relieve the Company of any liability with respect to the non-issuance or sale of the Company stock as to which such approval shall not have been obtained.
Notice of Exercise	When you wish to exercise this Option you must provide a notice of exercise form in accordance with such procedures as are established by the Company and communicated to you from time to time. Any notice of exercise must specify how many Shares you wish to purchase and how your Shares should be registered. The notice of exercise will be effective when it is received by the Company. If someone else wants to exercise this Option after your death, that person must prove to the Company's satisfaction that he or she is entitled to do so.

Form of Payment

When you submit your notice of exercise, you must include payment of the Option exercise price for the Shares you are purchasing. Payment may be made in the following form(s):

- Your personal check, a cashier's check or a money order.

- Certificates for Shares that you own, along with any forms needed to effect a transfer of those Shares to the Company. The value of the Shares, determined as of the effective date of the Option exercise, will be applied to the Option exercise price. Instead of surrendering Shares, you may attest to the ownership of those Shares on a form provided by the Company and have the same number of Shares subtracted from the Shares issued to you upon exercise of the Option. However, you may not surrender or attest to the ownership of Shares in payment of the exercise price if your action would cause the Company to recognize a compensation expense (or additional compensation expense) with respect to this Option for financial reporting purposes.

- By delivery on a form approved by the Company of an irrevocable direction to a securities broker approved by the Company to sell all or part of the Shares that are issued to you when you exercise this Option and to deliver to the Company from the sale proceeds an amount sufficient to pay the Option exercise price and any withholding taxes. The balance of the sale proceeds, if any, will be delivered to you. The directions must be given by providing a notice of exercise form approved by the Company.

- By delivery on a form approved by the Company of an irrevocable direction to a securities broker or lender approved by the Company to pledge Shares that are issued to you when you exercise this Option as security for a loan and to deliver to the Company from the loan proceeds an amount sufficient to pay the Option exercise price and any withholding taxes. The directions must be given by providing a notice of exercise form approved by the Company.

- Any other form permitted by the Committee in its sole discretion.

Notwithstanding the foregoing, payment may not be made in any form that is unlawful, as determined by the Committee in its sole discretion.

Withholding Taxes and Stock Withholding

You will not be allowed to exercise this Option unless you make arrangements acceptable to the Company to pay any withholding taxes that may be due as a result of this Award or the Option exercise. These arrangements, at the sole discretion of the Company, may include (a) having the Company withhold taxes from the proceeds of the sale of the Shares, either through a voluntary sale or through a mandatory sale arranged by the Company (on your behalf pursuant to this authorization), (b) having the Company withhold Shares that otherwise would be issued to you when you exercise this Option having a Fair Market Value equal to the amount necessary to satisfy the minimum statutory withholding amount, or (c) any other arrangement approved by the Company. The Fair Market Value of any Shares withheld, determined as of the effective date of the Option exercise, will be applied as a credit against the withholding taxes. You also authorize the Company, or your actual employer, to satisfy all withholding obligations of the Company or your actual employer with respect to this Award from your wages or other cash compensation payable to you by the Company or your actual employer.

Restrictions on Resale

You agree not to sell any Shares at a time when applicable laws, Company policies or an agreement between the Company and its underwriters prohibit a sale. This restriction will apply as long as your Service continues and for such period of time after the termination of your Service as the Company may specify.

Transfer of Option

In general, only you can exercise this Option prior to your death. You may not sell, transfer, assign, pledge or otherwise dispose of this Option, other than as designated by you by will or by the laws of descent and distribution, except as provided below. For instance, you may not use this Option as security for a loan. If you attempt to do any of these things, this Option will immediately become invalid. You may in any event dispose of this Option in your will. Regardless of any marital property settlement agreement, the Company is not obligated to honor a notice of exercise from your former spouse, nor is the Company obligated to recognize your former spouse's interest in your Option in any other way.

However, if this Option is designated as a nonstatutory stock option in the Notice of Stock Option Grant, then the Committee may, in its sole discretion, allow you to transfer this Option as a gift to one or more family members. For purposes of this Agreement, "family member" means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law (including adoptive relationships), any individual sharing your household (other than a tenant or employee), a trust in which one or more of these individuals have more than 50% of the beneficial interest, a foundation in which you or one or more of these persons control the management of assets, and any entity in which you or one or more of these persons own more than 50% of the voting interest.

In addition, if this Option is designated as a nonstatutory stock option in the Notice of Stock Option Grant, then the Committee may, in its sole discretion, allow you to transfer this option to your spouse or former spouse pursuant to a domestic relations order in settlement of marital property rights.

The Committee will allow you to transfer this Option only if both you and the transferee(s) execute the forms prescribed by the Committee, which include the consent of the transferee(s) to be bound by this Agreement.

Retention Rights	Neither your Option nor this Agreement gives you the right to be employed or retained by the Company or a subsidiary of the Company in any capacity. The Company and its subsidiaries reserve the right to terminate your Service at any time, with or without cause.
Stockholder Rights	Your Options carry neither voting rights nor rights to dividends. You, or your estate or heirs, have no rights as a stockholder of the Company unless and until you have exercised this Option by giving the required notice to the Company and paying the exercise price. No adjustments will be made for dividends or other rights if the applicable record date occurs before you exercise this Option, except as described in the Plan.
Adjustments	In the event of a stock split, a stock dividend or a similar change in Company Shares, the number of Shares covered by this Option and the exercise price per Share shall be adjusted pursuant to the Plan.
Successors and Assigns	Except as otherwise provided in the Plan or this Agreement, every term of this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, legatees, legal representatives, successors, transferees and assigns.
Notice	Any notice required or permitted under this Agreement shall be given in writing and shall be deemed effectively given upon the earliest of personal delivery, receipt or the third full day following mailing with postage and fees prepaid, addressed to the other party hereto at the address last known in the Company's records or at such other address as such party may designate by ten (10) days' advance written notice to the other party hereto.
Applicable Law	This Agreement will be interpreted and enforced under the laws of the State of Delaware (without regard to their choice-of-law provisions).
The Plan and Other Agreements	The text of the Plan is incorporated in this Agreement by reference. All capitalized terms in the Agreement shall have the meanings assigned to them in the Plan. This Agreement and the Plan constitute the entire understanding between you and the Company regarding this Option. Any prior agreements, commitments or negotiations concerning this Option are superseded. This Agreement may be amended by the Committee without your consent; however, if any such amendment would materially impair your rights or obligations under the Agreement, this Agreement may be amended only by another written agreement, signed by you and the Company.

BY SIGNING THE COVER SHEET OF THIS AGREEMENT,

YOU AGREE TO ALL OF THE TERMS AND CONDITIONS

DESCRIBED ABOVE AND IN THE PLAN.

OPEXA THERAPEUTICS, INC.
AMENDED AND RESTATED 2010 STOCK INCENTIVE PLAN
NOTICE OF CASH EXERCISE OF STOCK OPTION

OPTIONEE INFORMATION:

Name: _____ Social Security Number: _____

Address: _____ Employee Number: _____

OPTION INFORMATION:

Date of Grant: _____, 201___
Exercise Price per Share: $_____
Total number of Shares of OPEXA THERAPEUTICS, INC. (the "Company") covered by option: _____

Type of Stock Option:
☐ ___Nonstatutory (NSO)
☐ ___Incentive (ISO)

Number of Shares of the Company for which option is being exercised now: _____ ("Purchased Shares").
Total exercise price for the Purchased Shares: $ _____
Form of payment enclosed **:**

Check for $ _____, payable to "Opexa Therapeutics, Inc."

Name(s) in which the Purchased Shares should be registered:
_____

The certificate for the Purchased Shares should be sent to the following address: _____
_____
_____
_____

ACKNOWLEDGMENTS:

1. I understand that all sales of Purchased Shares are subject to compliance with the Company's policy on securities trades.
2. I hereby acknowledge that I received and read a copy of the prospectus describing the Company's Amended and Restated 2010 Stock Incentive Plan and the tax consequences of an exercise.
3. In the case of a nonstatutory option, I understand that I must recognize ordinary income equal to the spread between the fair market value of the Purchased Shares on the date of exercise and the exercise price. I further understand that I am required to pay withholding taxes at the time of exercising a nonstatutory option.
4. In the case of an incentive stock option, I agree to notify the Company if I dispose of the Purchased Shares before I have met both of the tax holding periods applicable to incentive stock options (that is, if I make a disqualifying disposition).

SIGNATURE AND DATE:

_____ _____ __, 201__

EXHIBIT 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Neil K. Warma, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Opexa Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2014

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

EXHIBIT 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Karthik Radhakrishnan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Opexa Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14,2014

By: /s/ Karthik Radhakrishnan
Karthik Radhakrishnan
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Opexa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2014 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Neil K. Warma, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2014

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

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Opexa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2014 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Karthik Radhakrishnan, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2014

By: /s/ Karthik Radhakrishnan
Karthik Radhakrishnan
Chief Financial Officer
(Principal Financial and Accounting Officer)