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

FORM 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Quarterly Period Ended March 31, 2016

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period from _____ to _____

Commission File Number: 001-33004

Opexa Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Texas	**2635 Technology Forest Blvd.**	**76-0333165**
(State or other jurisdiction of Incorporation or organization)	**The Woodlands, Texas 77381** (Address of principal executive offices and zip code)	(I.R.S. Employer Identification No.)

(281) 272-9331
Registrant's telephone number, including area code

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☑ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☑
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

As of May 1, 2016, there were 6,982,909 shares of the issuer's Common Stock outstanding.

OPEXA THERAPEUTICS, INC.
For the Three Months Ended March 31, 2016

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

OPEXA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 9,955,449	$ 12,583,764
Other current assets	932,409	995,067
Total current assets	10,887,858	13,578,831
Property & equipment, net of accumulated depreciation of $2,516,189 and $2,443,600, respectively	765,763	837,867
Total assets	$ 11,653,621	$ 14,416,698
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 562,218	$ 739,850
Accrued expenses	1,210,608	1,008,077
Deferred revenue	2,178,874	2,905,165
Notes payable - insurance	93,200	148,344
Total current liabilities	$ 4,044,900	$ 4,801,436
Total liabilities	$ 4,044,900	$ 4,801,436
Stockholders' equity:		
Preferred stock, no par value, 10,000,000 shares authorized, none issued and outstanding	—	—
Common stock, $0.01 par value, 150,000,000 shares authorized, 6,982,909 and 6,982,909 shares issued and outstanding	69,829	69,829
Additional paid in capital	163,038,772	162,884,919
Accumulated deficit	(155,499,880)	(153,339,486)
Total stockholders' equity	7,608,721	9,615,262
Total liabilities and stockholders' equity	$ 11,653,621	$ 14,416,698

See accompanying notes to unaudited consolidated financial statements

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

	Three Months Ended March 31,	
	2016	**2015**
Revenue:		
Option revenue	$ 726,291	$ 377,453
Research and development	1,829,062	2,636,999
General and administrative	987,248	1,006,130
Depreciation and amortization	72,589	96,982
Operating loss	(2,162,608)	(3,362,658)
Interest income, net	108	731
Other income and expense, net	2,106	11,047
Net loss	$ (2,160,394)	$ (3,350,880)
Basic and diluted loss per share	$ (0.31)	$ (0.95)
Weighted average shares outstanding - Basic and diluted	6,982,909	3,529,344

See accompanying notes to unaudited consolidated financial statements

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

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Par			
Balances at December 31, 2015	6,982,909	$ 69,829	$ 162,884,919	$ (153,339,486)	$ 9,615,262
Option expense	—	—	153,853	—	153,853
Net loss	—	—	—	(2,160,394)	(2,160,394)
Balances at March 31, 2016	6,982,909	$ 69,829	$ 163,038,772	$ (155,499,880)	$ 7,608,721

See accompanying notes to unaudited consolidated financial statements

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

	Three Months Ended March 31,	
	2016	**2015**
Cash flows from operating activities		
Net loss	$ (2,160,394)	$ (3,350,880)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Shares issued for services	—	44,463
Depreciation	72,589	96,982
Option expense	153,853	266,954
Changes in:		
Other current assets	98,565	75,491
Accounts payable	(186,027)	(61,033)
Accrued expenses	202,531	73,515
Deferred revenue	(726,291)	2,622,548
Other long-term assets	—	9,735
Net cash used in operating activities	(2,545,174)	(222,225)
Cash flows from investing activities		
Purchase of property & equipment	(485)	(6,411)
Net cash used in investing activities	(485)	(6,411)
Cash flows from financing activities		
Note payable - insurance	(55,144)	—
Payment of deferred offering costs	(27,512)	(104,857)
Net cash used in financing activities	(82,656)	(104,857)
Net change in cash and cash equivalents	(2,628,315)	(333,493)
Cash and cash equivalents at beginning of period	12,583,764	9,906,373
Cash and cash equivalents at end of period	$ 9,955,449	$ 9,572,880
Cash paid for:		
Interest	$ 1,371	$ 747
Income taxes	—	—
NON-CASH TRANSACTIONS		
Unpaid offering costs	$ 8,395	$ 511,031

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 consolidated financial statements that would substantially duplicate the disclosure contained in the audited consolidated 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.

Note 2. Significant Accounting Polices

Revenue Recognition. Opexa recognizes revenue in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("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.

On February 4, 2013, Opexa entered into an Option and License Agreement (the "Merck Serono Agreement") with Ares Trading SA ("Merck Serono"), a wholly owned subsidiary of Merck Serono S.A. Pursuant to the terms, Merck Serono has an option to acquire an exclusive, worldwide (excluding Japan) license of Opexa's Tcelna® program for the treatment of multiple sclerosis ("MS"). Tcelna is currently in a Phase IIb clinical trial ("Abili-T") in patients with Secondary Progressive MS ("SPMS"). The option may be exercised by Merck Serono prior to or upon Opexa's completion of the Phase IIb Trial.

Opexa received an upfront payment of $5 million for granting the option. Opexa recognized revenues from nonrefundable, up-front $5 million option fees related to the Merck Serono Agreement on a straight-line basis over the estimated option exercise period which coincides with the expected completion term of the Abili-T clinical trial in SPMS. If the option is exercised, Merck Serono would pay the Company an upfront license fee of $25 million unless Merck Serono 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 Serono), in which event the upfront license fee would be $15 million. After exercising the option, Merck Serono 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.

On March 9, 2015 Opexa entered into a First Amendment of Option and License Agreement with Merck Serono, to amend the Merck Serono Agreement (the "Merck Serono Amendment"). Opexa received $3 million in consideration for the following:

(i) Creating a detailed plan for potential Phase III development of Tcelna (the "Pre-Phase III Plan"), including documenting all of the activities necessary for laboratory facilities both in the U.S. and Europe to reach operational readiness by the end of December 2016. The Joint Steering Committee ("JSC") established pursuant to the Merck Serono Agreement will be responsible for reviewing, approving and ultimately overseeing Opexa's completion of the Pre-Phase III Plan. In the event the JSC has not approved the Pre-Phase III Plan prior to the end of the period in the Merck Serono Agreement within which Merck Serono may exercise its option, such period will be extended for 60 days following approval of the Pre Phase III Plan by the JSC.

(ii) Providing Merck Serono with updates and analysis on a blinded basis, grouped in patient batches according to Opexa's analysis timetable, on the progress of Opexa's immune monitoring program being conducted in conjunction with the ongoing Abili-T clinical trial.

Opexa evaluated the Merck Serono Amendment and determined that the $3 million payment from Merck Serono has stand-alone value. Opexa's continuing performance obligations in connection with the $3 million payment include the creation of the Pre-Phase III Plan and delivery of updates and analysis relating to Opexa's immune monitoring program. As a stand-alone value term in the Merck Serono Amendment, the $3 million payment is determined to be a single unit of accounting, and is recognized as revenue on a straight-line basis over the period equivalent to the expected completion of the Pre-Phase III Plan in December 2016. Opexa includes the unrecognized portion of the $5 million option payment and the $3 million amendment payment as deferred revenue on its consolidated balance sheets.

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.

As of March 31, 2016, Opexa had approximately $9.3 million in a savings account. For the three months ended March 31, 2016, the savings account recognized an average market yield of 0.06%. Interest income of $1,479 was recognized for the three months ended March 31, 2016 in the consolidated statements of operations.

Reclassifications. Certain reclassifications of prior year reported amounts have been made for comparative purposes. Opexa does not consider such reclassifications to be material and they had no effect on net income.

Note 3. Other Current Assets

Other current assets consisted of the following at March 31, 2016 and December 31, 2015:

Description	March 31, 2016	December 31, 2015
Custom reagents	$ 496,269	$ 496,269
Deferred offering costs	64,783	28,876
Prepaid expense	371,357	469,922
Total Other Current Assets	$ 932,409	$ 995,067

Custom reagents include a single custom reagent that will be used primarily for the NMO program and other Pre-Phase III research activities. Upon consumption, the cost of this reagent will be amortized to research and development expenses in the consolidated statements of operations. No custom reagents were consumed during the three months ended March 31, 2016.

Deferred offering costs at March 31, 2016 and December 31, 2015 were $64,783 and $28,876 respectively. The March 31, 2016 balance includes costs incurred from third parties in connection with the March 25, 2016 implementation of a new Sales Agreement ("ATM Agreement") with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.) as sales agent, pursuant to which Opexa can offer and sell shares of common stock from time to time depending upon market demand, in transactions deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933. These are included in other current assets in the consolidated balance sheets. Upon the sales of shares of common stock under the ATM Agreement, these capitalized costs will be offset against the proceeds of such sales of shares of common stock and recorded in additional paid in capital.

Prepaid expenses at March 31, 2016 and December 31, 2015 include costs incurred from third parties in connection with the Merck Serono Agreement (see Note 2). As of March 31, 2016 and December 31, 2015, the remaining costs of $29,203 and $38,938, respectively, in connection with the Merck Serono Agreement are expected to be amortized over the upcoming 9-month period. Also included in prepaid expenses at March 31, 2016 and December 31, 2105 is an advance to Pharmaceutical Research Associates, Inc. ("PRA"), a contract research organization providing services to Opexa, in the amount of $45,365 and $45,365 respectively, as well as $18,750 and $31,250 remaining from a prior payment to PRA of $75,000 upon execution of an amendment to Opexa's agreement with PRA. The remaining balance of Opexa's NASDAQ Capital Market All-Inclusive Annual Fee is also in the March 31, 2016 balance. Prepaid insurance is included in prepaid expenses at March 31, 2016 and December 31, 2015 as well as the remaining balances attributable to various service and maintenance contracts.

Note 4. Equity

For the three months ended March 31, 2016, equity related transactions were as follows:

On March 14, 2016, Opexa entered into an amendment to the September 1, 2015 Stock Purchase Agreement with the purchasers party thereto, to extend by six months the original dates for the milestones relating to the subsequent tranches. As part of the amendment, the expiration date of the Series N warrants issued pursuant to the Stock Purchase Agreement was also extended from April 9, 2018 to October 9, 2018. The Company determined that there is no accounting impact to the modification of the Series N warrants since these are investor warrants.

Note 5. Stock-Based Compensation

Stock Options

Opexa accounts for stock-based compensation, including options and nonvested shares, according to the provisions of FASB ASC 718, "Share Based Payment." During the three months ended March 31, 2016, Opexa recognized stock-based compensation expense of $153,853. Unamortized stock-based compensation expense as of March 31, 2015 amounted to $1,471,941.

Stock Option Activity

A summary of stock option activity for the three months ended March 31, 2016 is presented below:

	Number of Shares	Weighted Avg. Exercise Price	Weighted Average Remaining Contract Term (# years)	Intrinsic Value
Outstanding at December 31, 2015	417,404	$ 18.04		
Granted	—	—		
Exercised	—	—		
Forfeited and canceled	(22,063)	7.79		
Outstanding at March 31, 2016	395,341	$ 18.61	7.4	$ —
Exercisable at March 31, 2016	261,469	$ 21.81	6.9	$ —

Employee Options, Non-Employee Options and Restricted Stock Awards:

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.

No option or restricted stock awards were granted during the three months ended March 31, 2016. During the three months ended March 31, 2016, options to purchase 22,063 shares of common stock were forfeited and cancelled.

Opexa recognized stock based compensation expense of $153,853 and $266,954 during the three months ended March 31, 2016 and March 31, 2015, respectively, for grants made to employees in prior periods.

Warrant Activity

A summary of warrant activity for the three months ended March 31, 2016 is presented below:

	Number of Shares	Weighted Avg. Exercise Price	Weighted Average Remaining Contract Term (# years)	Intrinsic Value
Outstanding at December 31, 2015	3,662,954	$ 6.30		
Granted	—	—		
Exercised	—	—		
Forfeited and canceled	(51,823)	83.52		
Outstanding at March 31, 2016	3,611,131	$ 5.19	1.96	$ —
Exercisable at March 31, 2016	3,611,131	$ 5.19	1.96	$ —

In connection with the amended stock purchase agreement entered in on March 14, 2016 (See Note 4), the Company also amended and restated the Series N Warrants to purchase shares of the Company's common stock previously issued to the Purchasers, and extend the expiration date of the Series N Warrants by six months (i.e., from April 9, 2018 to October 9, 2018). The Company determined that there is no accounting impact to the modification of the Series N warrants since these are investor warrants.

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

The following discussion and analysis of our financial condition is as of March 31, 2016. 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, 2015.

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, costs, returns, royalties, performance and position, plans and objectives for future operations, plans and objectives for product development, plans and objectives for present and future clinical trials and results of such trials, plans and objectives for regulatory approval, litigation, intellectual property, product development, manufacturing plans and performance, management's initiatives and strategies, and the development of Opexa's product candidates, Tcelna (imilecleucel-T) and OPX-212, 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;
- 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 OPX-212);
- our ability to maintain compliance with NASDAQ listing standards;
- the success of our clinical trials (including the Phase IIb trial for Tcelna in SPMS which, depending upon results, may determine whether Merck Serono elects to exercise its Option to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna program for the treatment of multiple sclerosis (MS);
- whether Merck Serono exercises its Option and, if so, whether we receive any development or commercialization milestone payments or royalties from Merck Serono pursuant to the Option;
- our dependence (if Merck Serono exercises its Option) on the resources and abilities of Merck Serono for the further development of Tcelna;
- the efficacy of Tcelna for any particular indication, such as for relapsing remitting MS or secondary progressive MS, and the efficacy of OPX-212 for neuromyelitis optica (NMO);
- 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 OPX-212);
- the risk of litigation regarding our intellectual property rights or the rights of third parties;
- the success of third party development and commercialization efforts with respect to products covered by intellectual property rights that we may license or transfer;
- our limited manufacturing capabilities;
- our dependence on third-party manufacturers;
- our ability to hire and retain skilled personnel;
- our volatile stock price; and
- other risks detailed in our filings with the SEC.

These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update any forward-looking statements to reflect any changes in expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in our Annual Report 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 personalized immunotherapies with the potential to treat major illnesses, including multiple sclerosis (MS) as well as other autoimmune diseases such as neuromyelitis optica (NMO). These therapies are 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 candidates, Tcelna® and OPX-212, is preliminary and investigative. Tcelna and OPX-212 have 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 lead 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.

In addition to our ongoing clinical development of Tcelna, we are also in preclinical development of OPX-212 as an autologous T-cell immunotherapy for the treatment of NMO. NMO is an autoimmune disorder in which immune system cells and antibodies attack and destroy astrocytic/myelin cells in the optic nerves and the spinal cord leading to demyelination and loss of axons. There are currently no FDA-approved therapies for NMO, other than to treat an attack while it is happening, to reduce symptoms and to prevent relapses. OPX-212 is specifically tailored to each patient's immune response to a protein, aquaporin-4, which is the targeted antigen in NMO. In NMO, the immune system recognizes aquaporin-4 as foreign, thus triggering the attack. We believe a mechanism of action of OPX-212 may be to reduce the number and/or regulate aquaporin-4 reactive T-cells (ARTC), thereby reducing the frequency of clinical relapses and subsequent progression in disability. See "—NMO – OPX-212" below for more information on our development plans for OPX-212 in NMO.

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 forecasted to reach as much as $16 billion in 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 reduction over baseline in the MRTC counts for each time point through month nine of the extension study. 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.

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 U.S. 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. 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.

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 (DSMB) meeting took place during the week of February 22, 2016, and a recommendation was made to continue the study. The DSMB also stated that because dosing has been completed and no concerns over safety had been noted to date, no further DSMB meetings would be required for the Abili-T study.

The final dose for the last patient enrolled in the Abili-T study was completed during the week of February 22, 2016. We expect top-line data for the Abili-T trial to be available early in the fourth quarter of 2016.

Option and License Agreement with Merck Serono

On February 4, 2013, we entered into an Option and License Agreement with Ares Trading SA ("Merck Serono"), a wholly owned subsidiary of Merck Serono S.A. Pursuant to the agreement, Merck Serono 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 Serono 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 Serono would pay us an upfront license fee of $25 million unless Merck Serono 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 Serono), in which event the upfront license fee would be $15 million. After exercising the Option, Merck Serono 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 Serono 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 Serono 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 Serono of various development, regulatory and first commercial sale milestones.

If Tcelna receives regulatory approval and is commercialized by Merck Serono, 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 Serono's development, the royalty rates payable by Merck Serono 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.

On March 9, 2015, we entered into a First Amendment of Option and License Agreement with Merck Serono to amend the Merck Serono Agreement (the "Merck Serono Amendment"). We received a payment of $3 million in consideration for the following:

- Creating a detailed plan for potential Phase III development of Tcelna (the "Pre-Phase III Plan"), including documenting all of the activities necessary for laboratory facilities both in the U.S. and Europe to reach operational readiness by the end of December 2016. The Joint Steering Committee ("JSC") established pursuant to the Merck Serono Agreement will be responsible for reviewing, approving and ultimately overseeing our completion of the Pre-Phase III Plan. In the event the JSC has not approved the Pre-Phase III Plan prior to the end of the period in the Merck Serono Agreement within which Merck Serono may exercise its option, such period will be extended for 60 days following approval of the Pre-Phase III Plan by the JSC.

- Providing Merck Serono with updates and analysis on a blinded basis, grouped in patient batches according to our analysis timetable, on the progress of our immune monitoring program being conducted in conjunction with our ongoing Abili-T clinical trial.

NMO – OPX-212

In addition to our ongoing clinical development of Tcelna, we are also developing OPX-212 as an autologous T-cell immunotherapy for the treatment of NMO. This program is currently in the preclinical development stage. NMO is an autoimmune disorder in which immune system cells and antibodies attack astrocytes leading to the secondary destruction of nerve cells (axons) in the optic nerves and the spinal cord. OPX-212 is specifically tailored to each patient's immune response to a protein, aquaporin-4 expressed by astrocytes, which is the targeted antigen in NMO. In NMO, the immune system recognizes aquaporin-4 as foreign, thus triggering the attack. We believe a mechanism of action of OPX-212 may be to reduce the number and/or regulate aquaporin-4 reactive T-cells (ARTC), thereby reducing the frequency of clinical relapses and subsequent progression in disability.

Patients with NMO present with acute, often severe, attacks of blindness in one or both eyes followed within days or weeks by varying degrees of paralysis in the arms and legs. Most patients have relapsing attacks (separated by months or years with partial recovery), with usually sequential index episodes of optic neuritis (ON) and myelitis. A relapsing course is more frequent in women, and nearly 90% of patients are female (typically late middle-aged). It is estimated that there are approximately 4,800 cases of NMO in the U.S. NMO has a worldwide estimated prevalence of 1-2 people per 100,000 population.

There are currently no FDA-approved therapies for NMO. An initial attack is usually treated with a combination of corticosteroids and/or by plasma exchange to limit the severity of the attack. Although not approved for NMO, some physicians may utilize an immunosuppressant such as Rituximab as long-term therapy to provide protection from increasing neurological impairments through relapse.

We expect to manufacture OPX-212 using ImmPath, our proprietary method for the production of an autologous T-cell product, which comprises the collection of a blood product from the NMO patient and the expansion of ARTC from the blood product. Upon completion of the manufacturing process, ARTC are cryopreserved in dose-equivalents until required for use. On demand, a dose-equivalent is thawed, formulated and attenuated by irradiation before being returned to the patient for subcutaneous injection, with the express purpose of inducing a regulatory immune response to reduce the frequency and/or function of pathogenic ARTC.

We initiated development activities for OPX-212, our drug development candidate for NMO, in 2014 and have achieved a number of regulatory and early development milestones to date, which include conducting a pre-Investigational New Drug application (pre-IND) meeting with the U.S. FDA. We are continuing with preclinical development and IND enabling activities. Assuming it advances to clinical development, we believe OPX-212 for NMO will qualify for Orphan drug designation, and we also expect to apply for Fast Track designation.

In November 2015, we announced that we had completed an animal study as part of our preclinical development activities to support OPX-212 in NMO. The results of this study show that T-cell immunotherapy with attenuated antigen-specific T-cells suppress the T-cell response to Aquaporin-4 (AQP4) in a dose-dependent manner, compared to vehicle control, as measured by reduction in both aquaporin-4 reactive T-cell (ARTC) proliferation and associated cytokine activity. The results were statistically significant.

As part of our preclinical development activities for OPX-212, we conducted a bioactivity study to demonstrate the ability of T-cell immunotherapy using attenuated T-cells to suppress a T-cell response to the NMO-associated autoantigen, AQP4. No animal model of NMO has been described that exhibits both endogenous T-cell dependent immunity and autoantibody production to AQP4 and that subsequently leads to the immunopathology and clinical symptoms observed in human NMO. To study the bio-activity of attenuated T-cells on AQP4 T-cell immunity, mice were pre-treated with attenuated antigen-specific T-cells and subsequently primed with AQP4 antigen.

In NMO, activated T-cells (ARTC) mount an attack against Aquaporin-4, the autoantigen in NMO, leading to secondary demyelination of nerve fibers within the optic nerves and the spinal cord, resulting in the clinical symptoms of the disease. Our therapeutic approach is to suppress or reduce the number of these activated ARTC in patients with NMO. The results of the preclinical animal study provide evidence that T-cell immunotherapy reduces the level of activated ARTC in a murine (mouse) model.

Although we have previously indicated that an IND submission to the FDA and/or a CTA submission to Health Canada followed by commencement of a phase 1/2 proof of concept study of OPX-212 in NMO (assuming acceptance of such IND and/or CTA) may occur in the first half of 2016 assuming the availability of sufficient resources, we are currently uncertain with respect to both the pace of our ongoing preclinical development and manufacturing activities for OPX-212 in NMO as well as the potential outcome of such activities. OPX-212 in NMO remains an active preclinical program for Opexa, and we continue to believe that progress in this program is reasonably possible. However, we have been confronted with challenges in the development of OPX-212 in NMO, including with respect to the manufacture of OPX-212. For example, it has taken us longer than we expected to manufacture certain of the peptides associated with NMO due to their hydrophobic nature. We currently do not expect to provide further guidance in the foreseeable future on any timetable with respect to our development of OPX-212 in NMO, but instead to report substantive milestones only when and if they occur.

On September 1, 2015, we entered into a Stock Purchase Agreement with certain purchasers party thereto to fund our NMO program, pursuant to which we sold in tranche one of a private placement 113,636 shares of common stock for a per share purchase price of $4.40 and issued Series N warrants to purchase a like number of shares, for a total purchase price of $499,999. We also agreed to sell and the purchasers agreed to purchase an additional aggregate of $4.5 million of common stock in four additional tranches upon our achievement of certain milestones to further the clinical development of OPX-212. On March 14, 2016, we entered into an amendment to the Stock Purchase Agreement to extend the timeframes for achieving the milestones relating to the subsequent tranches. As part of the amendment, the expiration date of the Series N warrants issued to the purchasers as part of the Stock Purchase Agreement was extended from April 9, 2018 to October 9, 2018. As amended, subsequent tranches are based on the completion of the ongoing preclinical development and manufacturing activities and subsequent submission of an IND for OPX-212 in NMO no later than August 15, 2016; the review and acceptance of the IND by the FDA no later than November 15, 2016; enrollment of the first patient in a potential Phase 1/2 proof-of-concept study no later than February 28, 2017; and enrollment of 30% of the patients in such Phase 1/2 study no later than June 30, 2017. Each subsequent tranche will include the sale of common stock only (i.e., no additional warrants will be issued), with such shares priced at 90% of the 10-day volume weighted average price of Opexa's common stock immediately preceding the occurrence of the related milestone. In addition to certain other termination rights as provided in the Stock Purchase Agreement, either we or the purchasers may unilaterally terminate the then remaining obligations to sell and purchase shares under one or more additional tranches upon notice if a substantially equivalent Phase 1/2 clinical trial is initiated by a third party and such clinical trial is supported by the National Institutes of Health or its affiliated agencies or designees. Additionally, any then remaining obligations we may have to sell, and of the purchasers to purchase, shares under one or more additional tranches are automatically terminated if the next potential issuance would entail an amount which, when aggregated with all prior issuances to the purchasers under the agreement plus the shares of common stock issued or issuable under the warrant, would exceed 1,328,020 shares of our common stock, subject to adjustment.

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. While the primary focus of Opexa remains the development of Tcelna in SPMS, as well as our development plans for OPX-212 in NMO, we continue to investigate the expansion of the T-cell platform into other autoimmune diseases as well as potential in-licensing of other novel technologies.

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 Serono Agreement and determined that the $5 million upfront payment from Merck Serono 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 Serono 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.

We evaluated the Merck Serono Amendment and determined that the $3 million payment from Merck Serono has stand-alone value. Opexa's continuing performance obligations, in connection with the $3 million payment, include the creation of the Pre-Phase III Plan and delivery of updates and analysis relating to the Program. As a stand-alone value term in the Merck Serono Amendment, the $3 million payment is determined to be a single unit of accounting, and is recognized as revenue on a straight-line basis over the period equivalent to the expected completion of the Pre-Phase III Plan in December 2016. Opexa includes the unrecognized portion of the $3 million as deferred revenue on the consolidated balance sheets.

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

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

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

Results of Operations and Financial Condition

Comparison of the Three Months Ended March 31, 2016 with the Three Months Ended March 31, 2015

Revenue. Revenues of $726,291 and $377,453 for the three months ended March 31, 2016 and 2015, respectively, included $307,686 and $377,453, respectively, related to the $5 million payment from Merck Serono in connection with the Merck Serono Agreement. Revenues for the three months ended March 31, 2016 also include $418,605 related to the $3 million payment from Merck Serono in connection with the Merck Serono Amendment (see Revenue Recognition).

Research and Development Expenses. Research and development expenses were $1,829,062 for the three months ended March 31, 2016, compared with $2,636,999 for the three months ended March 31, 2015. The decrease in expenses is primarily due to a decrease in the costs in connection with the ongoing clinical trial of Tcelna in SPMS, a decrease in the procurement and use of supplies for product manufacturing and development, a decrease in employee and stock-based compensation expense as well as a reduction in the facility cost.

General and Administrative Expenses. General and administrative expenses were $987,248 for the three months ended March 31, 2016, compared with $1,006,130 for the three months ended March 31, 2015. The decrease in expenses is primarily due to the reduction in employee stock-based compensation expense and a decline in consulting services. This is offset by an increase in employee compensation including severance payments and severance accruals due to the March 2016 restructuring initiative.

Depreciation and Amortization Expenses. Depreciation and amortization expenses for the three months ended March 31, 2016 were $72,589, compared with $96,982 for the three months ended March 31, 2015. The decrease in depreciation is mainly due to laboratory equipment, software and leasehold improvements becoming fully depreciated. There were also no fixed assets acquired in March 2016 compared to March 2015.

Interest Income, Net. Interest income was $108 for the three months ended March 31, 2016, compared to $731 for the three months ended March 31, 2015.

Other Income and Expense, Net . Other Income and Expense, net was $2,106 for the three months ended March 31, 2016, compared to $11,047 in the three months ended March 31, 2015. This was primarily driven by a gain on the currency fluctuation between the U.S. dollar and the Canadian dollar relating to payments to the clinical sites located in Canada. The March 31, 2016 realized gain was partially offset by a reduction in the previous quarter's spot conversion.

Net Loss. We had a net loss for the three months ended March 31, 2016 of approximately $2.2 million, or $0.31 loss per share (basic and diluted), compared with a net loss of approximately $3.4 million or $0.95 loss per share (basic and diluted) for the three months ended March 31, 2015. The decreased net loss is primarily related to the decrease in research and development expenses, specifically site payments relating to the ongoing Abili-T clinical trial and related lab supplies. The decreased net loss is also due to the increase in revenue of $348,838 recognized in connection with the additional $3.0 million in funding from Merck Serono for Phase III planning. General and administrative expenses, specifically a reduction in the Black Sholes and consulting expenses, also reduced our net loss for the three months ended March 31, 2016.

Liquidity and Capital Resources

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of March 31, 2016, we had cash and cash equivalents of approximately $10.0 million. Our operating cash burn rate during the three months ended March 31, 2016 was approximately $849,000 per month.

On March 2, 2016, we announced implementation of a restructuring initiative which included a reduction of approximately 30% of our then full-time workforce of 36 employees in order to reduce operating expenses and conserve cash resources. The restructuring initiative was driven by reduced operational demands associated with the Abili-T clinical trial for Tcelna in patients with SPMS following administration of the final dose to the last patient in such trial, which occurred in the last week of February 2016. It is intended to allow us to focus our resources on completion of the Abili-T clinical trial, for which top-line data is expected early in the fourth quarter of 2016.

On March 25, 2016, we entered into a new Sales Agreement with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.) as sales agent, pursuant to which we can offer and sell shares of our common stock from time to time depending upon market demand, in transactions deemed to be an "at the market" offering. We registered up to 1,000,000 shares of common stock for potential sale under the new ATM facility, and no shares have yet been sold. We will need to keep current our shelf registration statement and the offering prospectus relating to the ATM facility in order to use the program to sell shares of common stock in the future.

We believe that we have sufficient liquidity to support our current clinical activities for the Abili-T trial of Tcelna in SPMS, to continue planned preclinical development and manufacturing activities for OPX-212 in NMO, and for general operations to sustain the Company and support such activities through the first quarter of 2017. Alternatives available to us if needed to extend our cash runway include but are not limited to using our ATM facility and/or cutting expenses. We expect top-line data for the Abili-T trial to be available early in the fourth quarter of 2016, and thus believe we have sufficient resources to complete the trial. However, if our projections prove to be inaccurate, or if we encounter additional costs to complete the trial or to sustain our operations, or if we incur other costs such as those associated with pursuing additional disease indications for our T-cell technology or pursuing clinical development of OPX-212 in NMO following an IND filing in the absence of funding under the Stock Purchase Agreement entered into on September 1, 2015 described below, we would need to raise additional capital to complete the Abili-T trial.

In April 2015, we raised $13,804,140 in gross proceeds, before expenses, through subscriptions for 3,137,305 units in a Rights Offering to holders of our common stock and holders of our outstanding Series L warrants who were entitled to participate. Each unit was composed of common stock and a warrant to purchase additional common stock. The Rights Offering was completed on April 9, 2015. We issued an aggregate of 3,137,305 shares of common stock and Series M warrants to purchase a like number of shares. Net proceeds, after deduction of fees and expenses, including dealer-manager fees, were $12.1 million.

From March 5, 2014 through December 31, 2015, we generated gross and net proceeds including amortization of deferred financing costs of $1,397,902 and $1,335,001, respectively, on sales of an aggregate 254,308 shares of our common stock under our at-the-market sales agreement.

On September 1, 2015, we entered into a Stock Purchase Agreement with certain purchasers party thereto pursuant to which we sold in tranche one of a private placement 113,636 shares of common stock for a per share purchase price of $4.40 and issued Series N warrants to purchase a like number of shares, for a total purchase price of $499,999. We also agreed to sell and the purchasers agreed to purchase an additional aggregate of $4.5 million of common stock in four additional tranches upon our achievement of certain milestones to further the clinical development of OPX-212. The Stock Purchase Agreement was subsequently amended on March 14, 2016 to extend by six months the original dates for the achievement of milestones relating to the subsequent tranches and to extend by six months the expiration date of the Series N warrants issued to the purchasers.

While the additional proceeds anticipated to be received from the sale of the additional securities under the September 1, 2015 Stock Purchase Agreement, as amended, are anticipated to provide sufficient funding for a potential Phase 1/2 proof of concept study, assuming an IND is filed with and accepted by the FDA and that the applicable milestones under the Stock Purchase Agreement are achieved and/or such funding is otherwise available, such amounts would not be sufficient to pay our general operations during the pendency of such proof of concept study. Depending upon the specific timing for any such study, we may need to secure additional resources to support our operations during the course of such study. We may also need to secure additional resources to pay for the costs of any such study if we are unable to obtain funding under the Stock Purchase Agreement, as amended, including as a result of failing to meet the associated milestones. In addition to certain other termination rights as provided in the Stock Purchase Agreement, either we or the purchasers may unilaterally terminate the then remaining obligations to sell and purchase shares under one or more additional tranches upon notice if a substantially equivalent Phase 1/2 clinical trial is initiated by a third party and such clinical trial is supported by the National Institutes of Health or its affiliated agencies or designees. Additionally, any then remaining obligations we may have to sell, and of the purchasers to purchase, shares under one or more additional tranches are automatically terminated if the next potential issuance would entail an amount which, when aggregated with all prior issuances to the purchasers under the agreement plus the shares of common stock issued or issuable under the warrant, would exceed 1,328,020 shares of our common stock, subject to adjustment.

Given our need for additional amounts of capital to support our current business plan, we intend to continue to explore potential opportunities and alternatives to obtain additional resources, including one or more additional financing transactions. 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 to support our current clinical trial activities and operations beyond the projected runway, we may not be able to continue our operations as proposed, which may require us to suspend or terminate any ongoing clinical trials (including the Abili-T clinical study) or any other development activities (such as our preclinical development and manufacturing activities for OPX-212 in NMO), modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws. In such event, our shareholders may lose a portion or even all of their investment.

If Merck Serono 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 or have any sources of debt or equity capital committed for funding, other than our at-the-market program and the September 1, 2015 Stock Purchase Agreement, as amended, which may result in our sale of an additional $4.5 million in shares of common stock, subject to achievement of certain milestones to further the clinical development of OPX-212 as well as other limitations potentially applicable to the availability of financing under the Stock Purchase Agreement. Should we need any additional capital in the future beyond these sources, 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.

Off-Balance Sheet Arrangements

None.

Recent Accounting Pronouncements

For the three months ended March 31, 2016, there were no accounting standards or interpretations issued that are expected to have a material impact on our financial position, operations or cash flows.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not Applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit to the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified by the Securities and Exchange Commission's rules and forms, and that information is accumulated and communicated to our management, including our principal executive (whom we refer to in this periodic report as our Certifying Officer), as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Certifying Officer, the effectiveness of our disclosure controls and procedures as of March 31, 2016, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officer concluded that, as of March 31, 2016, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. You should consider the following risk factors, as well as other information contained or incorporated by reference in this report, before deciding to invest in our securities. 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 consider immaterial as of the date hereof 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 securities could decline and you could lose all or part of your investment in our securities.

Risks Related to Our Business

We will be required to raise 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 potential study for OPX-212 in NMO and any Phase III studies of Tcelna without Merck Serono's financial support), 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 March 31, 2016, we had cash and cash equivalents of $10.0 million. Our operating cash burn rate during the three months ended March 31, 2016 was approximately $849,000 per month.

On March 2, 2016, we announced implementation of a restructuring initiative which included a reduction of approximately 30% of our then full-time workforce of 36 employees in order to reduce operating expenses and conserve cash resources. The restructuring initiative was driven by reduced operational demands associated with the Abili-T clinical trial for Tcelna in patients with SPMS following administration of the final dose to the last patient in such trial, which occurred in the last week of February 2016. It is intended to allow us to focus our resources on completion of the Abili-T clinical trial, for which top-line data is expected early in the fourth quarter of 2016.

We believe that we have sufficient liquidity to support our current clinical activities for the Abili-T trial of Tcelna in SPMS, to continue planned preclinical development and manufacturing activities for OPX-212 in NMO, and for general operations to sustain the Company and support such activities through the first quarter of 2017. Alternatives available to us if needed to extend our cash runway include but are not limited to using our ATM facility and/or cutting expenses. We expect top-line data for the Abili-T trial to be available early in the fourth quarter of 2016, and thus believe we have sufficient resources to complete the trial. However, if our projections prove to be inaccurate, or if we encounter additional costs to complete the trial or to sustain our operations, or if we incur other costs such as those associated with pursuing additional disease indications for our T-cell technology or pursuing clinical development of OPX-212 in NMO following an IND filing in the absence of funding under the Stock Purchase Agreement entered into on September 1, 2015 as described below, we would need to raise additional capital to complete the Abili-T trial.

On September 1, 2015, we entered into a Stock Purchase Agreement with certain purchasers party thereto pursuant to which we sold in tranche one of a private placement 113,636 shares of common stock for a per share purchase price of $4.40 and issued warrants to purchase a like number of shares, for a total purchase price of $499,999. We also agreed to sell and the purchasers agreed to purchase an additional aggregate of $4.5 million of common stock in four additional tranches upon our achievement of certain milestones to further the clinical development of OPX-212. On March 14, 2016, we entered into an amendment to the Stock Purchase Agreement to extend the timeframes for achieving the milestones relating to the subsequent tranches. As part of the amendment, the expiration date of the Series N warrants issued to the purchasers as part of the Stock Purchase Agreement was extended from April 9, 2018 to October 9, 2018. As amended, the milestones for the subsequent tranches are as follows:

- Tranche 2 : $1,000,000 in shares of common stock, at a per share purchase price of 90% of the 10-day volume weighted average price of the common stock for the 10 trading days (the "10-day VWAP") immediately preceding the Tranche 2 milestone, which is the submission to the FDA of a preclinical study package to support the filing of an IND application for OPX-212, so long as such submission occurs on or before August 15, 2016 or any later date agreed to by the purchasers.

- Tranche 3 : $1,500,000 in shares of common stock, at a per share purchase price of 90% of the 10-day VWAP immediately preceding the Tranche 3 milestone, which is the acceptance of such IND by the FDA, so long as such acceptance occurs on or before the later of November 15, 2016 or three months following the Tranche 2 closing, or any later date agreed to by the purchasers.

- Tranche 4 : $1,000,000 in shares of common stock, at a per share purchase price of 90% of the 10-day VWAP immediately preceding the Tranche 4 milestone, which is the enrollment of the first patient in a Phase 1/2 clinical study of OPX-212 in patients with NMO, so long as such enrollment occurs on or before the later of February 28, 2017 or five months following the Tranche 3 closing, or any later date agreed to by the purchasers.

- Tranche 5 : $1,000,000 in shares of common stock, at per share purchase price of 90% of the 10-day VWAP immediately preceding the Tranche 5 milestone, which is the enrollment of patients representing at least 30% of the minimum targeted enrollment in such Phase 1/2 study, so long as such enrollment occurs on or before the later of June 30, 2017 or four months following the Tranche 4 closing, or any later date agreed to by the purchasers.

There can be no assurance that will we achieve each of these milestones. Although we have previously indicated that an IND submission to the FDA and/or a CTA submission to Health Canada followed by commencement of a phase 1/2 proof of concept study of OPX-212 in NMO (assuming acceptance of such IND and/or CTA) may occur in the first half of 2016 assuming the availability of sufficient resources, we are currently uncertain with respect to both the pace of our ongoing preclinical development and manufacturing activities for OPX-212 in NMO as well as the potential outcome of such activities. OPX-212 in NMO remains an active preclinical program for Opexa, and we continue to believe that progress in this program is reasonably possible. However, we have been confronted with challenges in the development of OPX-212 in NMO, including with respect to the manufacture of OPX-212. For example, it has taken us longer than we expected to manufacture certain of the peptides associated with NMO due to their hydrophobic nature. We currently do not expect to provide further guidance in the foreseeable future on any timetable with respect to our development of OPX-212 in NMO, but instead to report substantive milestones only when and if they occur. While the additional proceeds anticipated to be received from the sale of the additional securities under the Stock Purchase Agreement, as amended, are anticipated to provide sufficient funding for a potential Phase 1/2 proof of concept study, assuming an IND is filed with and accepted by the FDA and that the applicable milestones under the Stock Purchase Agreement are achieved and/or such funding is otherwise available, such amounts would not be sufficient to pay our general operations during the pendency of such proof of concept study. Depending upon the specific timing for any such study, we may need to secure additional resources to support our operations during the course of such study. We may also need to secure additional resources to pay for the costs of any such study if we are unable to obtain funding under the Stock Purchase Agreement, as amended, including as a result of failing to meet the associated milestones.

In addition to certain other termination rights as provided in the Stock Purchase Agreement, either we or the purchasers may unilaterally terminate the then remaining obligations to sell and purchase shares under one or more additional tranches upon notice if (i) we receive an aggregate of at least $20 million in gross proceeds from financing activities during the succeeding one-year period, (ii) a substantially equivalent Phase 1/2 clinical trial is initiated by a third party and such clinical trial is supported by the National Institutes of Health or its affiliated agencies or designees, or (iii) any person or group becomes the beneficial owner of more than 50% of our capital stock or upon sale of all or substantially all of our assets. Additionally, any then remaining obligations we may have to sell, and of the purchasers to purchase, shares under one or more additional tranches are automatically terminated if the next potential issuance would entail an amount which, when aggregated with all prior issuances to the purchasers under the agreement plus the shares of common stock issued or issuable under the warrant, would exceed 1,328,020 shares of our common stock, subject to adjustment. The obligation of the purchasers to purchase any additional shares is suspended if we do not have sufficient shares of common stock available in respect of the remaining purchase obligations, and the purchasers may terminate any then remaining obligations if there is an uncured material breach of the agreement by Opexa.

Given our need for additional amounts of capital to support our current business plan, we intend to continue to explore potential opportunities and alternatives to obtain additional resources, including one or more additional financing transactions. 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 to support our current clinical trial activities and operations beyond the projected runway, we may not be able to continue our operations as proposed, which may require us to suspend or terminate any ongoing clinical trials (including the Abili-T clinical study) or any other development activities (such as our preclinical development and manufacturing activities for OPX-212 in NMO), modify our business plan, curtail various aspects of our operations, 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 do not maintain any external lines of credit or have any sources of debt or equity capital committed for funding, other than our at-the-market program and the September 1, 2015 Stock Purchase Agreement, as amended, which may result in our sale of an additional $4.5 million in shares of common stock, subject to achievement of certain milestones to further the clinical development of OPX-212 as well as other limitations potentially applicable to the availability of financing under the Stock Purchase Agreement. Should we need any additional capital in the future beyond these sources, management will be reliant upon “best efforts” debt or equity financings. 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 2015 and beyond as well as for the clinical study of Tcelna and OPX-212;
- 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.

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 preclinical, Phase I, Phase II and/or Phase III development programs, 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 ATM facility may be limited or be insufficient to fund our operations or to implement our strategy.

We will need to keep current our shelf registration statement and the offering prospectus relating to our at-the-market (ATM) sales agreement with Brinson Patrick (now a division of IFS Securities, Inc.) 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 our ATM facility 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 lead 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. Additionally, our second pipeline candidate, OPX-212 is currently in preclinical development for the treatment of NMO. Tcelna, and any other potential products, including OPX-212, 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 (such as OPX-212) or to commercialize any products. Tcelna, and any other potential products (such as OPX-212), 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 Serono with the Option, which provides Merck Serono with the opportunity, if exercised, to control the development and commercialization of Tcelna in MS.

In February 2013, we granted the Option to Merck Serono. The Option permits Merck Serono to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna program for the treatment of MS. The Option may be exercised by Merck Serono prior to or upon completion of our ongoing Phase IIb trial of Tcelna in patients with SPMS. If Merck Serono exercises the Option, Merck Serono 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. On March 9, 2015, we entered into the Merck Serono Amendment pursuant to which we agreed to perform additional development activities in preparation for a potential Phase III trial and to share with Merck Serono certain information from our immune monitoring program in consideration for payment by Merck Serono of $3 million.

If Merck Serono exercises the Option, we would become reliant on Merck Serono's resources and efforts with respect to Tcelna in MS, including the pace at which it moves forward with commencement of any Phase III study. In such an event, Merck Serono may fail to develop or effectively commercialize Tcelna for a variety of reasons, including that Merck Serono:

- 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 Serono 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 Serono 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 for Tcelna to be available early in the fourth quarter 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 Serono (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 subsequent 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, retention and data collection during or after treatment (e.g., patients' failure to return for follow-up visits or to complete the trial, detection of epitope profiles in subsequent visits, etc.); and
- failure of medical investigators to follow our clinical protocols.

In addition, we, Merck Serono with respect to Tcelna (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 Serono exercises the Option), will be limited by any failure to obtain or limitation on necessary regulatory approvals.

If Merck Serono exercises the Option, Merck Serono 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 focused on MS as the first disease to be pursued off our T-cell platform technology, and in 2014, we initiated development activities for OPX-212, our drug candidate for NMO, as the second disease we are pursuing. As a platform technology, there exists the potential to address other autoimmune diseases with the technology. While preclinical development and manufacturing activities have been conducted for OPX-212 in NMO, such work is modest compared to the effort that has been committed to Tcelna for 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, and our recent restructuring initiative may cause disruption or not achieve the savings anticipated.

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. On March 2, 2016, we announced implementation of a restructuring initiative which included a reduction of approximately 30% of our then full-time workforce of 36 employees, including our chief financial officer, in order to reduce operating expenses and conserve cash resources. The restructuring initiative was driven by reduced operational demands associated with the Abili-T clinical trial for Tcelna in patients with SPMS following administration of the final dose to the last patient in such trial, which occurred in the last week of February 2016. It is intended to allow us to focus our resources on completion of the Abili-T clinical trial, for which top-line data is expected early in the fourth quarter of 2016. However, the restructuring initiative may cause disruption to our business operations, and we may not be able to effectively realize the savings anticipated by the restructuring initiative and reduction-in-force. Additionally, there may be future possible changes in our workforce, including as a result of changes that may occur in our operations or operating plan, or other reasons or events. There may also be possible changes in the amount of charges and cash payments associated with the workforce reduction which occurred on March 2, 2016 or the retention plan we initiated for our continuing non-management employees as of that date, including the possibility that we may incur unanticipated charges or make cash payments that are not currently contemplated.

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 and, if applicable, a potential Phase 1/2 proof-of-concept study of OPX-212 in NMO. It is not sufficient, however, to support clinical trials outside North America including Europe and Asia, if required, or the commercial launch of Tcelna or any other product candidate. 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 Serono (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 a product candidate such as 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 a product candidate such as Tcelna could require us to stop treating patients in our clinical development of such product candidate 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 a product candidate such as Tcelna is approved, difficulties, delays or interruptions in the manufacture and supply of such product candidate could cause a delay in or even halt or suspend the commercialization of such product candidate, 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. OPX-212 is expected to be similarly produced. 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 Tcelna and expected to be the case for OPX-212, the products are personalized and must be made for each patient individually. Because our manufacturing processes are complex, require facilities and personnel that are not widely available in the industry, involve 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 any product candidate such as 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 product candidates such as 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 Serono exercises the Option then our ability to achieve revenue will be dependent upon the efforts and success of Merck Serono 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 Serono 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.

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 Serono 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 Serono 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.

Issued U.S. patents require the payment of maintenance fees to continue to be in force. We rely on a third party payor 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 direct control over the payment of all such annuities, we cannot assure you that our third party payor will timely pay such annuities and that the granted patents and pending patent applications will not become abandoned. In addition, we or 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 candidates such as 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 or OPX-212. Consequently, no assurance can be given that third-party patents containing claims covering Tcelna or OPX-212, their methods 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 Serono, 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 Serono exercises the Option, Merck Serono 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 Serono, 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 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 bid price for our common stock of $1.00 per share and a minimum stockholders' equity of $2.5 million), as well as certain corporate governance standards, to maintain the listing of our common stock on the NASDAQ Capital Market. We received a staff deficiency letter in December 2014 indicating that our common stock failed to comply with the minimum bid price requirement because it traded below the $1.00 minimum closing bid price for 30 consecutive trading days, and after an initial and an extended grace period, and implementation of a one-for-eight reverse stock split of our common stock on September 28, 2015, we regained compliance with the $1.00 minimum closing bid price listing standard and NASDAQ notified us that the matter was closed on October 14, 2015. However, there is no assurance that the closing bid price of our common stock will continue to stay above the minimum continued listing standard.

We previously received a similar staff deficiency letter in February 2012 indicating that our common stock failed to comply with the minimum bid price requirement because it traded below the $1.00 minimum closing bid price for 30 consecutive trading days, and after an initial and an extended grace period, and implementation of a one-for-four reverse stock split of our common stock on December 14, 2012, we regained compliance with the $1.00 minimum closing bid price listing standard and NASDAQ notified us that the matter was closed in January 2013. We also received a staff deficiency letter in November 2012 notifying us that the stockholders' equity of $2,339,285 as reported in our Quarterly Report on Form 10-Q for the period ended September 30, 2012 was below the minimum stockholders' equity of $2.5 million required for continued listing on NASDAQ. We were provided 45 calendar days, or until January 10, 2013, to submit a plan to regain compliance with the minimum stockholders' equity standard. We submitted such a plan and it was accepted, with NASDAQ thus granting us an extension until May 15, 2013 to evidence compliance with the minimum stockholders' equity standard. Upon executing the plan, we attained the necessary stockholders' equity level and subsequently received notice from NASDAQ that we had regained compliance with the listing standard and the matter was closed in May 2013.

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 minimum bid price, stockholder's equity 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 Serono and the Option, including a decision by Merck Serono 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 or conversion by the holders of warrants, options or convertible notes.

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

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

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

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

From March 5, 2014 through December 31, 2015, we generated gross and net proceeds including amortization of deferred financing costs of $1,397,902 and $1,335,001, respectively, on sales of an aggregate 254,308 shares of our common stock under our prior at-the-market facility. In April 2015, we raised $13,804,140 in gross proceeds, before expenses, through subscriptions for 3,137,305 units in a Rights Offering to holders of our common stock and holders of our outstanding Series L warrants who were entitled to participate. Each unit was composed of common stock and a Series M warrant to purchase additional common stock. The Rights Offering was completed on April 9, 2015. We issued an aggregate of 3,137,305 shares of common stock and Series M warrants to purchase a like number of shares. Net proceeds, after deduction of fees and expenses, including dealer-manager fees, were $12.1 million. On September 1, 2015, we entered into a Stock Purchase Agreement with certain purchasers party thereto pursuant to which we sold in tranche one of a private placement 113,636 shares of common stock for a per share purchase price of $4.40 and issued Series N warrants to purchase a like number of shares, for a total purchase price of $499,999. We also agreed to sell and the purchasers agreed to purchase an additional aggregate of $4.5 million of common stock in four additional tranches upon our achievement of certain milestones to further the clinical development of OPX-212. We also granted the purchasers certain registration rights with respect to the securities sold in the September 1, 2015 private placement transaction. This Stock Purchase Agreement was amended on March 14, 2016 to extend by six months the timeframes for achieving the milestones relating to funding under subsequent tranches and to extend by six months the expiration date for the Series N warrants issued to the purchasers. In addition to certain other termination rights as provided in the Stock Purchase Agreement, either we or the purchasers may unilaterally terminate the then remaining obligations to sell and purchase shares under one or more additional tranches upon notice if a substantially equivalent Phase 1/2 clinical trial is initiated by a third party and such clinical trial is supported by the National Institutes of Health or its affiliated agencies or designees. Additionally, any then remaining obligations we may have to sell, and of the purchasers to purchase, shares under one or more additional tranches are automatically terminated if the next potential issuance would entail an amount which, when aggregated with all prior issuances to the purchasers under the agreement plus the shares of common stock issued or issuable under the warrant, would exceed 1,328,020 shares of our common stock, subject to adjustment.

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 6,982,909 shares of common stock were outstanding as of March 31, 2016. As of such date, another (i) 395,341 shares of common stock were issuable upon exercise of outstanding options and (ii) 3,611,131 shares of common stock were issuable upon the exercise of outstanding warrants. A substantial majority of the outstanding shares of our common stock and warrants (as well as a substantial majority of the shares of common stock issuable upon exercise of outstanding options and warrants) 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. We may need to raise additional capital in order to initiate or complete additional development activities for Tcelna in MS and for OPX-212 in NMO, or to pursue additional disease indications for our T-cell technology, 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.

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 150,000,000 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, business development and operational purposes), we currently intend to use our available cash (i) to continue funding the ongoing Abili-T clinical study of Tcelna in patients with SPMS, and (ii) to continue preclinical and manufacturing activities for OPX-212 in patients with NMO, and if such activities are successful, to file an IND application with the FDA to initiate a Phase 1/2 proof-of-concept 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 for Tcelna to be available early in the fourth quarter of 2016. While we believe we have sufficient resources to complete the trial and support our operations during the pendency of the trial, if our projections prove to be inaccurate or we encounter additional costs to complete the trial or to sustain our operations, we may need to raise additional capital or modify either the Abili-T clinical study, our development of OPX-212 in NMO, or other aspects of our current business plan.

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 intentions regarding use of our available cash, our management will have significant flexibility with respect to such use. 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.

An active trading market may never develop for the Series M warrants issued in the Rights Offering, which may limit the ability to resell the warrants.

There is no established trading market for the Series M warrants we issued in April 2015 pursuant to the Rights Offering. While the warrants have been listed for trading on NASDAQ under the symbol "OPXAW," there can be no assurance that that a market will develop for the warrants. Even if a market for the warrants does develop, the price of the warrants may fluctuate and liquidity may be limited. If a market for the warrants does not develop, then holders of the warrants may be unable to resell the warrants or be able to sell them only at an unfavorable price for an extended period of time, if at all. Future trading prices of the warrants will depend on many factors, including our operating performance and financial condition, our ability to continue the effectiveness of the registration statement covering the warrants and the common stock issuable upon exercise of the warrants, the interest of securities dealers in making a market and the market for similar securities.

The market price of our common stock may not exceed the exercise price of the Series M warrants issued in connection with the Rights Offering.

The Series M warrants issued in April 2015 in connection with the Rights Offering will expire on April 9, 2018. The warrants entitle the holders to purchase shares of common stock at an exercise price of (i) $4.00 per share from the date of issuance through June 30, 2016 and (ii) $12.00 per share from July 1, 2016 through their expiration three years from the date of issuance. There can be no assurance that the market price of our common stock will exceed the exercise price of the warrants at any or all times prior to their expiration. Any warrants not exercised by their expiration date will expire worthless and we will be under no further obligation to the warrant holder.

The Series M warrants issued in connection with the Rights Offering may be redeemed on short notice. This may have an adverse impact on their price.

We may redeem the Series M warrants issued in the Rights Offering for $0.01 per warrant once the closing price of our common stock has equaled or exceeded $20.00 per share, subject to adjustment, for 10 consecutive trading days. If we give notice of redemption, holders will be forced to sell or exercise their warrants or accept the redemption price. The notice of redemption could come at a time when it is not advisable or possible to exercise the warrants. As a result, holders would be unable to benefit from owning the warrants being redeemed.

Our ability to use net operating loss carryovers to reduce future tax payments may be limited.

As of December 31, 2015, we had net operating loss carryforwards (NOLs) for federal income tax purposes of approximately $70 million. These NOLs are generally carried forward to reduce taxable income in future years. If unused, the NOLs will begin to expire December 31, 2025. However, our ability to utilize the NOLs is subject to the rules under Section 382 of the Internal Revenue code.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses ("NOLs"), to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders (generally 5% shareholders, applying certain look-through and aggregation rules) increases by more than 50 percentage points over such stockholders' lowest percentage ownership during the testing period (generally three years). In the event of an ownership change, Section 382 imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carryforwards. This annual limitation is generally equal to the product of the value of our stock on the date of the ownership change, multiplied by the long-term tax-exempt rate published monthly by the Internal Revenue Service. Any unused annual limitation may be carried over to later years until the applicable expiration date for the respective NOL carryforwards.

The rules of Section 382 are complex and subject to varying interpretations. As a result of our numerous capital raises, which have included the issuance of various classes of convertible securities and warrants, uncertainty exists as to whether we may have undergone an ownership change in the past or will undergo one as a result of the recently completed Rights Offering. Even if the Rights Offering does not cause an ownership change, it may increase the likelihood that we may undergo an ownership change in the future. Based on our recent stock prices, we believe any ownership change would severely limit our ability to utilize the NOLs. Limitations imposed on our ability to utilize NOL carryforward amounts could cause U.S. federal income taxes to be paid earlier than if such limitations were not in effect and could cause such NOL carryforward amounts to expire unused, in each case reducing or eliminating the expected benefit to us. Furthermore, we may not be able to generate sufficient taxable income to utilize our NOL carryforward amounts before they expire. If any of these events occur, we may not derive some or all of the benefits from our NOL carryforward amounts. Presently, impairment tests have not been conducted to verify NOL preservation. Accordingly, no assurance can be given that our NOLs will be fully available.

Item 6. Exhibits

Exhibit No.	Description
4.1	Amended and Restated Series N Warrants issued on March 14, 2016 (incorporated by reference to Exhibit 4.13 to the Company's Annual Report on Form 10-K filed on March 15, 2016).
10.1	Amendment to Stock Purchase Agreement by and between Opexa Therapeutics, Inc. and the purchasers party thereto, dated March 14, 2016 (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on March 15, 2016).
10.2	Sales Agreement, dated March 25, 2016, by and between Opexa Therapeutics, Inc. and IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 25, 2016).
31.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2016, 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: May 12, 2016

By: /s/ Neil K. Warma

Neil K. Warma
President, Chief Executive Officer and Acting Chief Financial Officer
(Principal Executive Officer, Principal Financial and Accounting Officer)

EXHIBIT INDEX

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* Filed herewith.

EXHIBIT 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Neil K. Warma, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 12, 2016

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

EXHIBIT 32.1

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

In connection with the Quarterly Report of Opexa Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2016 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Neil K. Warma, President, Chief Executive Officer and Acting Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

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

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

Date: May 12, 2016

By: /s/ Neil K. Warma

Neil K. Warma
President, Chief Executive Officer and Acting Chief Financial Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)