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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2014

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number: 001-33004

Opexa Therapeutics, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Texas	76-0333165
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
2635 Technology Forest Blvd., The Woodlands, Texas	77381
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (281) 272-9331

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $.01 par value per share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

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. (check one):

☐ 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 ☑

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2014 based upon the closing price as of such date was $43,709,741.

As of February 20, 2015, 28,234,751 shares of the registrant's common stock, par value $0.01 per share, were outstanding.

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Forward Looking Statements

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 the Company'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 secondary progressive multiple sclerosis (MS) which, depending upon results, may determine whether Ares Trading SA (Merck Serono), a wholly owned subsidiary of Merck Serono S.A., elects to exercise its option (the Option) to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna program for the treatment of 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 the reports we file with the SEC.

PART I

Item 1. Business.

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

Opexa is a biopharmaceutical company developing a personalized immunotherapy with the potential to treat major illnesses, including multiple sclerosis (MS) 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 announced on September 8, 2014, that we are also developing 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 (ARTCs), 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.

Multiple Sclerosis—Background

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

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

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

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

Tcelna for MS

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

Tcelna Clinical Development Program

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

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

Summary of Phase I Dose Escalation Study in MS

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

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

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

Summary of Phase I/IIA Clinical Trial Data in MS

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

Subjects showed statistically significant 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.

The primary efficacy endpoint of the trial is the percentage of brain volume change (whole brain atrophy) at 24 months. Study investigators will also measure several important secondary outcomes commonly associated with MS including sustained disease progression as measured by EDSS, changes in EDSS, time to sustained progression, ARR, change in Multiple Sclerosis Functional Composite (MSFC) assessment of disability and change in Symbol Digit Modality Test. Data on certain exploratory endpoints such as quality of life metrics as measured by the Multiple Sclerosis Quality of Life Inventory (MSQLI), MRI measures and immune monitoring metrics are also being collected.

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

A scheduled Data Safety Monitoring Board meeting took place during the week of October 6, 2014, and a recommendation was made to continue the study. We reached our enrollment target for the Abili-T trial in June 2014, and a total of 190 patients have been enrolled in this two-year study. We expect top-line data for Tcelna to be available in the second half 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.

Tcelna Manufacturing

We manufacture Tcelna in our own current Good Manufacturing Practice (cGMP) facility. Tcelna is a personalized autologous immunotherapy that is not only manufactured for every individual subject but also is tailored to match each subject's evolving disease profile as defined by T-cell profiling against myelin antigens. In preparing Tcelna, the subject is pre-screened with our proprietary Epitope Profiling Assay (EPA) for immunodominant anti-myelin T-cell responses against specific peptides by assaying peripheral blood mononuclear cell (PBMC) reactivity against 109 peptides tested in pools of six derived from MBP, MOG and PLP. The EPA takes approximately 14 days to conduct and report data. The MRTC lines to each pool are expanded to therapeutic levels, mixed and cryopreserved until time for final formulation. The manufacturing and quality control process spans approximately 35 days. Prior to injection, the MRTCs are thawed, formulated and attenuated (by irradiation) to render them unable to replicate but viable for therapy. These attenuated T-cells are administered in a defined schedule of five subcutaneous injections. Patients will be treated with a new, personalized treatment series (five subcutaneous injections) each year based on their altered disease profile, or epitope shift, and the re-manufacture of a new Tcelna product representing the emerging immunodominant T-cell response to myelin.

If Merck Serono exercises its Option to acquire an exclusive, worldwide license for our Tcelna program for the treatment of MS, we retain certain rights with respect to the manufacture of Tcelna.

Personalized Therapy

The clinical symptoms of MS are the result of an immune attack against the myelin sheaths that insulate nerves in the brain and spinal cord that constitute the CNS. A subset of white cells, called T-cells, is the primary orchestrator of this immunity. Tcelna is an immunotherapy representing an enriched source of the patient's own MRTCs that are used to invoke a protective response to limit further damage to the myelin sheaths within the patient's CNS. Immunity to myelin in terms of the specificity of T-cells for myelin proteins varies between individuals. Therefore, Tcelna is further personalized by screening the immune response, and detecting those proteins that are preferentially targeted by T-cells on a per patient basis. This is achieved using protein fragments, called peptides, from the three major myelin proteins (MOG, MBP and PLP) as targets to finely map immunity to myelin. A limited number of peptides are chosen to which immunity appears greatest, and the Tcelna product is manufactured against these peptides. Thus, Tcelna is not only manufactured for each patient, but it is also tailored against each patient's personalized T-cell immune response to myelin. In preparing Tcelna for a patient, the patient-specific MRTCs are expanded from a unit of whole blood using the selected myelin peptides in the presence of growth factors.

Tcelna Safety and Tolerability

We believe that Tcelna treatment selectively targets, depletes and/or down-regulates the pathogenic T-cell population. It is not a general immune suppressant and, accordingly, it has not shown to be associated with the serious side effects seen by those MS treatments that function by systemically suppressing the immune system. We believe that this favorable safety profile may be an important advantage as patient compliance represents a significant challenge due to serious side effects associated with various MS treatments currently available.

NMO – OPX-212

In addition to our ongoing clinical development of Tcelna, we announced on September 8, 2014 that we are also developing 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 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 (ARTCs), 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 a 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 ARTCs from the blood product. Upon completion of the manufacturing process, ARTCs 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 ARTCs.

We initiated development activities for OPX-212, our drug development candidate for NMO, earlier this year and have achieved a number of regulatory and early development milestones to date. These include conducting a pre-Investigational New Drug application (pre-IND) meeting with the U.S. FDA and performing in-house manufacturing runs with NMO patient samples. We are continuing with preclinical development activities and expect to file an IND for OPX-212 with the FDA by mid-2015. We believe OPX-212 for NMO will qualify for Orphan drug designation, and we also expect to apply for Fast Track designation.

We believe part of the value of our T-cell platform comes from the ability to move relatively quickly and cost effectively into new autoimmune diseases. We do not expect our ongoing preclinical development activities related to the NMO program to materially affect the Company's cash burn through IND submission. Assuming successful completion of the preclinical development activities and submission and acceptance of the IND by the FDA and/or CTA by Health Canada, we may thereafter advance into clinical development with a Phase 1/2 proof-of-concept study. We intend to evaluate various options to fund such clinical study, including public or private capital raises as well as potential partnership and out-licensing activities.

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.

Licenses, Patents and Proprietary Rights

We believe that proprietary protection of our technologies is critical to the development of our business. We will continue to protect our intellectual property through patents and other appropriate means. We rely upon trade-secret protection for certain confidential and proprietary information and take active measures to control access to that information. We currently have non-disclosure agreements with all of our employees, consultants, vendors, advisory board members and contract research organizations.

The initial T-cell technology on which Tcelna is based was originally discovered by researchers at Baylor College of Medicine in Houston, Texas. Baylor granted Opexa an exclusive, worldwide right and license to commercially exploit such technology, which includes rights to issued patents and pending patent applications owned by Baylor. Opexa has since expanded the development of technology related to Tcelna and T-cell technology and has filed patent applications with respect thereto, from which several patents have issued (including with respect to the specificity and veracity of antigens that have been discovered). There is also substantial proprietary know-how surrounding the Tcelna development and manufacturing processes that remains a trade secret. Consequently, we consider barriers to entry, relative to Tcelna for the treatment of MS, to be high.

Our patent portfolio tracks our scientific development programs in autoimmune disease treatments, with an initial focus on MS. We believe that our scientific platform is adaptable in that any T-cell dependent autoimmune disease with known specific antigens, such as rheumatoid arthritis, may be a candidate for treatment, and we believe that our patent strategy is readily extendable to address these additional indications.

Competition

The development of therapeutic agents for human disease is intensely competitive. Major pharmaceutical companies currently offer a number of pharmaceutical products to treat MS and other diseases for which our technologies may be applicable. Many pharmaceutical and biotechnology companies are investigating new drugs and therapeutic approaches for the same purposes, which may achieve new efficacy profiles, extend the therapeutic window for such products, alter the prognosis of these diseases, or prevent their onset. We believe that our products, when and if successfully developed, will compete with these products principally on the basis of improved and extended efficacy and safety and their overall economic benefit to the health care system. We expect competition to increase. We believe that our most significant competitors will be fully integrated pharmaceutical companies and more established biotechnology companies. Smaller companies may also be significant competitors, particularly through collaborative arrangements with large pharmaceutical or biotechnology companies. Some of our primary competitors in the current treatment of, and in the development of treatments for, MS include Biogen-Idec, Elan, Merck-Serono (which is an affiliate of the entity that holds the Option), Teva, Bayer/Schering AG and Novartis. Some of our primary competitors in the development of treatments for NMO include Alexion, Biogen-Idec, Chugai Pharmaceuticals, Roche Holdings AG and Astra Zeneca.

Sales and Marketing

If Merck Serono exercises its Option to acquire an exclusive, worldwide license for our Tcelna program for the treatment of MS and pays us an upfront license fee, Merck Serono would be solely responsible for funding future 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. We would consider partnering with large biotech and pharmaceutical companies, if and when applicable, to assist with marketing and sales of an MS T-cell therapy in Japan as well as to assist with marketing and sales in indications beyond MS.

If Merck Serono does not exercise its Option, we may choose to partner with large biotech or other pharmaceutical companies for sales and marketing, if and when applicable, or alternatively develop our own sales force to market our MS cell therapy products in the U.S. Given the concentration of MS treatment among a relatively small number of specialized neurologists in the U.S., we believe that a modest size sales force would be sufficient to market an MS product in the U.S.

Government Regulation

Our research and development activities and the future manufacturing and marketing of our potential products are, and will be, subject to regulation for safety and efficacy by a number of governmental authorities in the U.S. and other countries.

In the U.S., pharmaceuticals, biologicals and medical devices are subject to FDA regulation. The Federal Food, Drug and Cosmetic Act, as amended, and the Public Health Service Act, as amended, the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing in human subjects, manufacture, safety, efficacy, labeling, storage, export, record keeping, approval, marketing, advertising and promotion of our potential products. Product development and approval within this regulatory framework take a number of years and involve significant uncertainty combined with the expenditure of substantial resources.

FDA Approval Process

We will need to obtain FDA approval of any therapeutic product we plan to market and sell. The FDA will only grant marketing approval if it determines that a product is both safe and effective. The testing and approval process will require substantial time, effort and expense. The steps required before our products may be marketed in the U.S. include:

Preclinical Laboratory and Animal Tests. Preclinical tests include laboratory evaluation of the product candidate and animal studies in specific disease models to assess the potential safety and efficacy of the product candidate as well as the quality and consistency of the manufacturing process.

Submission to the FDA of an Investigational New Drug Application, or IND, Which Must Become Effective Before U.S. Human Clinical Trials May Commence. The results of the preclinical tests are submitted to the FDA, and the IND becomes effective 30 days following its receipt by the FDA, as long as there are no questions, requests for delay or objections from the FDA. The sponsor of an IND must keep the FDA informed during the duration of clinical studies through required amendments and reports, including adverse event reports.

Adequate and Well-Controlled Human Clinical Trials to Establish the Safety and Efficacy of the Product Candidate. Clinical trials, which test the safety and efficacy of the product candidate in humans, are conducted in accordance with protocols that detail the objectives of the studies, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Any product candidate administered in a U.S. clinical trial must be manufactured in accordance with cGMP.

The protocol for each clinical study must be approved by an independent Institutional Review Board, or IRB, at the institution at which the study is conducted, and the informed consent of all participants must be obtained. The IRB will consider, among other things, the existing information on the product candidate, ethical factors, the safety of human subjects, the potential benefits of the therapy and the possible liability of the institution.

Clinical development is traditionally conducted in three sequential phases, which may overlap:

- In Phase I, product candidates are typically introduced into healthy human subjects or into selected patient populations (*i.e.,* patients with a serious disease or condition under study, under physician supervision) to test for adverse reactions, dosage tolerance, absorption and distribution, metabolism, excretion and clinical pharmacology.
- Phase II involves studies in a limited population of patients with the disease or condition under study to (i) determine the efficacy of the product candidates for specific targeted indications and populations, (ii) determine optimal dosage and dosage tolerance and (iii) identify possible and common adverse effects and safety risks. (Phase II may divided into Phase IIa and Phase IIb studies to address these issues.) When a dose is chosen and a candidate product is found to have preliminary evidence of effectiveness, and to have an acceptable safety profile in Phase II evaluations, Phase III trials begin.
- Phase III trials are undertaken to develop additional safety and efficacy information from an expanded patient population, generally at multiple study sites. This information obtained is used to develop a better understanding of the risks and benefits of the product candidate and to determine appropriate labeling for use.

Based on clinical trial progress and results, the FDA may request changes or may require discontinuance of the trials at any time if significant safety issues arise.

Submission to the FDA of Marketing Authorization Applications and FDA Review. The results of the preclinical studies and clinical studies are submitted to the FDA as part of marketing approval authorization applications such as New Drug Applications (NDAs) or Biologics License Applications (BLAs). The FDA will evaluate such applications for the demonstration of safety and effectiveness. A BLA is required for biological products subject to licensure under the Public Health Service Act and must show that the product is safe, pure and potent. In addition to preclinical and clinical data, the BLA must contain other elements such as manufacturing materials, stability data, samples and labeling. FDA approval of a BLA is required prior to commercial sale or shipment of a biologic. A BLA may only be approved once the FDA examines the product and inspects the manufacturing establishment to assure conformity to the BLA and all applicable regulations and standards for biologics.

The time for approval may vary widely depending on the specific product candidate and disease to be treated, and a number of factors, including the risk/benefit profile identified in clinical trials, the availability of alternative treatments, and the severity of the disease. Additional animal studies or clinical trials may be requested during the FDA review period, which might add substantially to the review time.

The FDA's marketing approval for a product is limited to the treatment of a specific disease or condition in specified populations in certain clinical circumstances, as described on the approved labeling. The approved use is known as the "indication." After the FDA approves a product for the initial indication, further clinical trials may be required to gain approval for the use of the product for additional indications. The FDA may also require post-marketing testing (Phase IV studies) and surveillance to monitor for adverse effects, which could involve significant expense. The FDA may also elect to grant only conditional approval.

Ongoing Compliance Requirements

Even after product approval, there are a number of ongoing FDA regulatory requirements, including:

- Registration and listing;
- Regulatory submissions relating to changes in an NDA or BLA (such as the manufacturing process or labeling) and annual reports;
- Adverse event reporting;
- Compliance with advertising and promotion restrictions that relate to drugs and biologics; and
- Compliance with GMP and biological product standards (subject to FDA inspection of facilities to determine compliance).

Other Regulations

In addition to safety regulations enforced by the FDA, we are also subject to regulations under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act and other present and potential future foreign, federal, state and local regulations. For instance, product manufacturing establishments located in certain states also may be subject to separate regulatory and licensing requirements.

Outside the U.S., we will be subject to regulations that govern the import of drug products from the U.S. or other manufacturing sites and foreign regulatory requirements governing human clinical trials and marketing approval for products. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursements vary widely from country to country.

Research and Development

Research and development expenses for the year ended December 31, 2014 were approximately $12.0 million, mainly reflecting the costs of the operation of the Abili-T clinical trial for Tcelna in patients with SPMS. Research and development expenses for the year ended December 31, 2013 were approximately $9.2 million, mainly reflecting the costs of the operation of the Abili-T clinical trial for Tcelna in patients with SPMS.

Organizational History

We have a limited operating history. Our predecessor company for financial reporting purposes was formed on January 22, 2003 to acquire rights to an adult stem cell technology. In November 2004, we acquired Opexa Pharmaceuticals, Inc. and its MS treatment technology. Currently, we remain focused on developing our T-cell technology for MS. To date, we have not generated any commercial revenues from operations. As we continue to execute our business plan, we expect our development and operating expenses to increase.

Employees

As of February 20, 2015, we had 39 full-time employees. We believe that our relations with our employees are good. None of our employees is represented by a union or covered by a collective bargaining agreement.

Available Information

We are subject to the information and reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, under which we file periodic reports, proxy and information statements and other information with the United States Securities and Exchange Commission, or SEC. Copies of the reports, proxy statements and other information may be examined without charge at the Public Reference Room of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, or on the Internet at http://www.sec.gov. Copies of all or a portion of such materials can be obtained from the Public Reference Room of the SEC upon payment of prescribed fees. Please call the SEC at 1-800-SEC-0330 for further information about the Public Reference Room.

Financial and other information about Opexa is available on our website (**www.opexatherapeutics.com**). Information on our website is not incorporated by reference into this report. We make available on our website, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. Copies are available in print to any Opexa shareholder upon request in writing to Attention: Investor Relations, Opexa Therapeutics, Inc., 2635 Technology Forest Blvd., The Woodlands, TX 77381.

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 secrities. The following factors affect our business, our intellectual property, the industry in which we operate and our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known or which we currently consider immaterial may also have an adverse effect on our business. If any of the matters discussed in the following risk factors were to occur, our business, financial condition, results of operations, cash flows or prospects could be materially adversely affected, the market price of our 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 significant additional capital, and our ability to obtain funding is uncertain. If sufficient capital is not available, we may not be able to continue our operations as proposed (including the Phase IIb clinical trial ongoing for Tcelna, or any study planned for OPX-212 in NMO), 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 December 31, 2014, we had cash and cash equivalents of approximately $9.9 million. During 2012, we closed a private offering in July 2012 consisting of convertible secured notes and warrants to purchase common stock which generated approximately $4.1 million in gross proceeds. These convertible secured notes were converted into equity during 2013 and an aggregate of 2,002,926 shares of common stock were issued. From November 2012 through January 2013, we sold an aggregate of 390,000 shares of our common stock to Lincoln Park for gross proceeds of $523,709 pursuant to our $1.5 million purchase agreement with Lincoln Park. We closed a private offering of unsecured convertible promissory notes and warrants to purchase common stock in January 2013 which generated $650,000 in gross proceeds. Upon receipt of the upfront payment from Merck Serono in February 2013, we repaid $550,000 principal amount plus accrued interest of the January 2013 notes and converted the remaining $100,000 principal amount into shares of common stock pursuant to the investor's election to convert into equity. In February 2013, we sold an aggregate of 167,618 shares of our common stock pursuant to a sales agreement executed on September 6, 2012 with Brinson Patrick Securities Corporation acting as sales agent under an "at-the-market" (ATM) program, for gross proceeds of $536,417. On February 4, 2013, we entered into an Option and License Agreement with Merck Serono pursuant to which we granted the Option to Merck Serono to acquire an exclusive, worldwide (excluding Japan) license to our Tcelna program for the treatment of MS in consideration for an upfront payment of $5 million. On February 11, 2013, we closed an offering of 1,083,334 shares of common stock and warrants to purchase 541,668 shares of common stock for gross proceeds of $3.25 million, or net proceeds of approximately $3.0 million after deducting commissions and offering expenses. On August 13, 2013, we closed an offering of 12 million shares of common stock for gross proceeds of $18 million, or net proceeds of approximately $16.2 million after deducting underwriting discounts and commissions and offering expenses, and we granted the underwriters a 30-day option to purchase up to an additional 1.8 million shares of common stock to cover over-allotments. During September 2013, the underwriters of the August 2013 underwritten public offering exercised the over-allotment option granted to them which resulted in the issuance of an additional 900,000 shares of common stock for gross proceeds of $1.35 million, or net proceeds of approximately $1.2 million after deducting underwriting discounts and commissions and offering expenses. On December 23, 2013, we closed an offering of 4,738,000 shares of common stock including the full exercise of the over-allotment option granted to the underwriters, raising gross proceeds of approximately $8.1 million or net proceeds of approximately $7.3 million after deducting the underwriting discounts and commission and offering expenses. Between March 5, 2014 and December 31, 2014, we generated gross and net proceeds including amortization of deferred financing costs of $674,126 and $648,175, respectively, on sales of an aggregate of 518,412 shares of our common stock under an amendment to our ATM sales agreement pursuant to which Meyers Associates, L.P. (doing business as Brinson Patrick, a division of Meyers Associates, L.P.) became the new sales agent.

Our operating cash burn rate during the 12 months ended December 31, 2014 was approximately $1.2 million per month. 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. Costs associated with the ongoing Abili-T trial and the potential commencement of a Phase 1/2 proof-of-concept study of OPX-212 in NMO may result in an increase in our monthly operating cash burn in 2015. However, costs associated with our ongoing preclinical and manufacturing activities for OPX-212 should not materially affect our cash burn through IND submission, which is expected by mid-2015. We will need to secure significant additional resources to complete the Abili-T trial of Tcelna in SPMS and, if initiated, to conduct a Phase 1/2 proof-of-concept study of OPX-212 in NMO, as well as to support our operations during the course of the trials. 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 activities for OPX-212 in NMO with a possible IND submission by mid-2015, and for general operations to sustain the Company and support such activities into the fourth quarter of 2015. Any other costs, however, such as costs associated with the initiation and completion of a Phase 1/2 proof-of-concept study of OPX-212 in NMO or with pursuing additional disease indications for our T-cell technology or other research or development programs, would of course shorten this period.

Given our need for substantial amounts of capital to complete the Abili-T clinical study of Tcelna in SPMS and to initiate and complete a Phase 1/2 proof-of-concept study of OPX-212 in NMO, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources, including one or more additional financing transactions, that will be necessary to complete the studies and to support our operations during the pendency of such studies. There can be no assurance that any such financings or potential opportunities and alternatives can be consummated on acceptable terms, if at all. If we are unable to obtain additional funding for operations beyond the projected runway, we will be forced to suspend or terminate any ongoing clinical trials, which may require us to modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws.

Other than the $1.5 million purchase agreement and the $15.0 million purchase agreement we entered into with Lincoln Park on November 5, 2012 and November 2, 2012, respectively, each of which is subject to certain limitations and conditions, we have no sources of debt or equity capital committed for funding and we must rely upon best efforts third-party debt or equity funding. We can provide no assurance that we will be successful in any funding effort. The timing and degree of any future capital requirements will depend on many factors, including:

- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- the accuracy of the assumptions underlying our estimates for capital needs in 2014 and beyond as well as for the clinical study of Tcelna;
- scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs;
- our progress with preclinical development and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- the number and type of product candidates that we pursue.

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

If we are unable to obtain additional funding to support our current clinical trial activities beyond the projected runway, we may not be able to continue or complete the Phase IIb clinical study of Tcelna in SPMS and, if initiated, to continue or complete a Phase 1/2 proof-of-concept study of OPX-212 in NMO, or otherwise continue our operations as proposed, which may require us to modify our business plan or curtail various aspects of our operations. If we are unable to maintain an adequate level of capital, it may be necessary to cease operations or seek relief under applicable bankruptcy laws. In such event, our shareholders may lose a portion or even all of their investment.

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

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

We may also incur discretionary expenses related to Phase 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 purchase agreements with Lincoln Park and our ATM facility may be limited or be insufficient to fund our operations or to implement our strategy.

Under our $1.5 million purchase agreement and our $15.0 million purchase agreement with Lincoln Park, we may direct Lincoln Park to purchase up to $16.5 million of shares of common stock, subject to certain limitations and conditions, over a 30-month period. From November 2012 through January 2013, we sold an aggregate of 390,000 shares to Lincoln Park pursuant to the $1.5 million purchase agreement, and we issued an aggregate of 56,507 initial commitment shares and 3,585 additional commitment shares in connection therewith. There can be no assurance that we will be able to receive any or all of the additional funds from Lincoln Park because the $1.5 million purchase agreement and the $15.0 million purchase agreement contain limitations, restrictions, requirements, events of default and other provisions that could limit our ability to cause Lincoln Park to buy common stock from us, including that the closing price of our stock is at least $1.00 and that Lincoln Park own no more than 4.99% of our common stock under the $1.5 million purchase agreement or no more than 9.99% of our common stock under the $15.0 million purchase agreement, and the requirement to keep current the prospectus included as part of the Form S-1 registration statement relating to the $15.0 million purchase agreement (which is not current as of this date). In addition, under the applicable rules of the NASDAQ Capital Market, if we seek to issue shares which may be aggregated with shares sold to Lincoln Park under the $1.5 million purchase agreement and the $15.0 million purchase agreement in excess of 1,151,829 shares or 19.99% of the total common stock outstanding as of the date of the $15.0 million purchase agreement, we may be required to seek shareholder approval in order to be in compliance with the NASDAQ Capital Market rules.

The extent to which we rely on Lincoln Park as a source of funding will depend on a number of factors, including the amount of working capital needed, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we would need to secure another source of funding.

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

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

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

Our business is at an early stage of development. We are largely dependent on the success of our 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. We announced the initiation of early development activities with our second pipeline candidate, OPX-212 in 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.

If Merck Serono exercises the Option, we would become reliant on Merck Serono's resources and efforts with respect to Tcelna in MS. 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 in the second half of 2016. In addition, we anticipate that at least a pivotal Phase III clinical trial would be necessary before an application could be submitted for approval of Tcelna for SPMS. Failure can occur at any stage of the trials, and problems could be encountered that would cause us or Merck 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 we the initiation of NMO as the second disease we are pursuing. As a platform technology, there exists the potential to address other autoimmune diseases with the technology. Early development activities including preclinical and manufacturing activities have been initiated in OPX-212. The work in NMO is modest compared to the effort that has been committed to the lead MS indication. Our business over the long term is substantially dependent on our ability to develop, license or acquire product candidates and further develop them for commercialization. The success of this strategy depends upon our ability to expand our existing platform or identify, select and acquire the right product candidates. We have limited experience identifying, negotiating and implementing economically viable product candidate acquisitions or licenses, which is a lengthy and complex process. Also, the market for licensing and acquiring product candidates is intensely competitive, and many of our competitors have greater resources than we do. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

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

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

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

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

If we fail to meet our obligations under our license agreements, we may lose our rights to key technologies on which our business depends.

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

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

We conduct our research and development in a 10,200 square foot facility in The Woodlands, Texas, which includes an approximately 1,200 square foot suite of three rooms for the manufacture of T-cell therapies. We believe our facility should have the capacity to support full clinical development of Tcelna in North American trials for SPMS and, if applicable, a 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.

Risks Related to Doing Business Internationally

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

Risks Related to Our Intellectual Property

Patents obtained by other persons may result in infringement claims against us that are costly to defend and which may limit our ability to use the disputed technologies and prevent us from pursuing research and development or commercialization of potential products, such as Tcelna.

If third party patents or patent applications contain claims infringed by either our licensed technology or other technology required to make or use our potential products, such as Tcelna, and such claims are ultimately determined to be valid, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost, if at all, or be able to develop or obtain alternative technology. If we are unable to obtain such licenses at a reasonable cost, we (or, in the event the Option is exercised, Merck 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 new laws may result in additional reductions in Medicare and other healthcare funding.

Another example of reform that could affect our business is drug reimportation into the United States (i.e., the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs were sold at lower prices). Initiatives in this regard could decrease the price we or any potential collaborators receive for our product candidates if they are ever approved for sale, adversely affecting our future revenue growth and potential profitability. Moreover, the pendency or approval of such proposals could result in a decrease in our stock price or adversely affect our ability to raise capital or to obtain strategic partnerships or licenses.

Risks Related to Our Securities

There is currently a limited market for our securities, and any trading market that exists in our securities may be highly illiquid and may not reflect the underlying value of our net assets or business prospects.

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

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

We are required to meet certain qualitative and financial tests (including a minimum 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. It is possible that we could fail to satisfy one or more of these requirements. Since November 2014, our stock has continued to trade below the minimum bid price continued listing requirement, and our common stock is in jeopardy of being delisted. On December 5, 2014, we received a staff deficiency letter from NASDAQ indicating that our common stock failed to comply with the minimum bid price requirement because it closed below the $1.00 minimum closing bid price for 30 consecutive trading days. The notice further stated that we will be provided a period of 180 calendar days to regain compliance. If our common stock maintains a closing bid price of $1.00 per share or more for a minimum of 10 consecutive business days (or such longer period of time as the NASDAQ staff may require in some circumstances, but generally not more than 20 consecutive business days) before June 3, 2015, we will achieve compliance with the listing standards. If our common stock does not achieve compliance with the minimum bid price by June 3, 2015, we may be eligible for an additional 180 day grace period so long as we continue to meet the other listing standards and provide timely notice of our intention to cure the deficiency. However, if it appears to the NASDAQ staff that we will not be able to cure the deficiency, or if we do not meet the other listing standards, NASDAQ could provide notice that our stock will become subject to delisting.

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.

In July 2012, we closed a private offering consisting of convertible secured notes and warrants to purchase common stock which generated approximately $4.1 million in gross proceeds, of which notes in the aggregate principal amount of $900,000 were converted into shares of Series A convertible preferred stock which, in turn, were converted into an aggregate of 288,229 shares of common stock during February 2013. The remaining notes were converted into an aggregate of 1,714,697 shares of common stock at $1.91 per share on September 24, 2013. From November 2012 through January 2013, we sold an aggregate of 390,000 shares to Lincoln Park pursuant to the $1.5 million purchase agreement and issued an additional 56,507 shares as initial commitment shares and 3,585 shares as additional commitment shares. In January 2013, we issued $650,000 principal amount of unsecured convertible promissory notes of which $100,000 was converted into 77,034 shares of common stock at $1.298125 per share during February 2013 and the remaining $550,000 of principal amount plus accrued interest was repaid during February 2013. Purchasers of such notes also received five-year warrants to acquire an aggregate of 243,750 shares of our common stock at an exercise price of $1.24 per share. In February 2013, we sold an aggregate of 167,618 shares of our common stock pursuant to the ATM Agreement for gross proceeds of $536,417. On February 11, 2013, we closed on an offering of 1,083,334 shares of common stock and warrants to purchase 541,668 shares of common stock for gross proceeds of $3.25 million, or net proceeds of approximately $3.0 million after deducting commissions and offering expenses. On August 13, 2013, we closed an offering of 12 million shares of common stock for gross proceeds of $18 million, or net proceeds of approximately $16.2 million after deducting underwriting discounts and commissions and offering expenses, and we granted the underwriters a 30-day option to purchase up to an additional 1.8 million shares of common stock to cover over-allotments. During September 2013, the underwriters of the August 2013 underwritten public offering exercised the over-allotment option granted to them which resulted in the issuance of an additional 900,000 shares of common stock for gross proceeds of $1.35 million, or net proceeds of approximately $1.2 million after deducting underwriting discounts and commissions and offering expenses. On December 23, 2013, we closed an offering of 4,738,000 shares of common stock, including the full exercise of the over-allotment option granted to the underwriters, raising gross proceeds of $8.1 million or net proceeds of approximately $7.3 million after deducting the underwriting discounts and commission and offering expenses. Between March 5, 2014 and December 31, 2014, we generated gross and net proceeds including amortization of deferred financing costs of $674,126 and $648,175, respectively, on sales of an aggregate of 518,412 shares of our common stock under the new ATM Agreement.

Sales of additional shares of our common stock, as well as securities convertible into or exercisable for common stock, could result in substantial dilution to our shareholders and cause the market price of our common stock to decline. An aggregate of 28,234,751 shares of common stock were outstanding as of December 31, 2014, 2014. As of such date, another (i) 2,423,253 shares of common stock were issuable upon exercise of outstanding options and (ii) 3,046,801 shares of common stock were issuable upon the exercise of outstanding warrants. A substantial majority of the outstanding shares of our common stock are freely tradable without restriction or further registration under the Securities Act of 1933.

We may sell additional shares of common stock, as well as securities convertible into or exercisable for common stock, in subsequent public or private offerings. We may also issue additional shares of common stock, as well as securities convertible into or exercisable for common stock, to finance future acquisitions. Among other requirements, we will need to raise significant additional capital in order to complete the Phase IIb clinical study of Tcelna in SPMS, and, if initiated, to complete a Phase 1/2 proof-of-concept study of OPX-212 in NMO, and this may require us to issue a substantial amount of securities (including common stock as well as securities convertible into or exercisable for common stock). There can be no assurance that our capital raising efforts will be able to attract the capital needed to execute on our business plan and sustain our operations. Moreover, we cannot predict the size of future issuances of our common stock, as well as securities convertible into or exercisable for common stock, or the effect, if any, that future issuances and sales of our securities will have on the market price of our common stock. Sales of substantial amounts of our common stock, as well as securities convertible into or exercisable for common stock, including shares issued in connection with an acquisition or securing funds to complete our clinical trial plans, or the perception that such sales could occur, may result in substantial dilution and may adversely affect prevailing market prices for our common stock.

Under the $1.5 million purchase agreement and $15.0 million purchase agreement with Lincoln Park, we may direct Lincoln Park to purchase up to $16.5 million of shares of common stock, subject to certain limitations and conditions, over a 30-month period. We have sold an aggregate of 390,000 shares to date under the $1.5 million purchase agreement. Additionally, we issued Lincoln Park 56,507 shares of common stock as initial commitment shares and have issued an aggregate of 3,585 additional commitment shares, and may in the future issue up to an additional 109,428 shares of common stock as additional commitment shares, as a fee for its commitment to purchase the shares under the $1.5 million purchase agreement and the $15.0 million purchase agreement. The purchase price for the shares that we may sell to Lincoln Park will fluctuate based on the price of our common stock and other factors determined by us. As such, Lincoln Park may ultimately purchase all, some or none of the shares of our common stock issuable pursuant to the purchase agreements after the date hereof and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Therefore, sales to Lincoln Park by us pursuant to either or both of the purchase agreements could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could cause the trading price of our common stock to decline and could make it more difficult for us to sell equity or equity-related securities in the future.

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

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

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

Our charter allows us to issue up to 100,000,000 shares of our common stock and to issue and designate the rights of, without shareholder approval, up to 10,000,000 shares of preferred stock. In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share paid by other investors, and dilution to our shareholders could result. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors, and investors purchasing shares or other securities in the future could have rights superior to existing shareholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by other investors.

We may issue debt and equity securities or securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquidation, which could negatively affect the value of our common stock.

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

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

In addition to general corporate purposes (including working capital, research and development, 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 in the second half of 2016. Our existing resources are not adequate to permit us to complete the ongoing Abili-T clinical study of Tcelna in patients with SPMS or, if initiated, to conduct a Phase 1/2 proof-of-concept study of OPX-212 in NMO. We will need to secure significant additional resources to complete the ongoing Abili-T clinical study of Tcelna in patients with SPMS and, if initiated, to conduct a Phase 1/2 proof-of-concept study of OPX-212 in NMO and to support our operations during the course of the trials.

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.

Risks Related to our Securities due to our Currently Proposed Rights Offering

On January 28, 2015, we filed a registration statement on Form S-1 (No. 333-201731) (the "registration statement") with the Securities and Exchange Commission for a proposed rights offering of subscription rights to purchase Units comprised of a share of our common stock and a warrant to purchase an additional share of our common stock (the "Rights Offering"). Holders of our common stock and holders of our Series L warrants on the record date for the Rights Offering, which is yet to be determined, would be eligible to participate. The registration statement has not yet become effective. We may not sell the securities that are the subject of the registration statement nor may offers to buy be accepted prior to the time the registration statement becomes effective. The Rights Offering, which is expected to commence immediately following the effectiveness of the registration statement, will only be made by means of a prospectus. The following risks related to our securities are due to the Rights Offering, however; we can give no assurance that the registration statement will become effective, that the Rights Offering will be commenced or that the Rights Offering will ultimately be consummated or be successful.

We will incur substantial expenses in connection with the Rights Offering, which may not return adequate value if the Rights Offering is ultimately not consummated or successful.

The estimated expenses for the Rights Offering are approximately $750,000, excluding fees and expenses of the dealer-managers that we have engaged to assist us with the Rights Offering. If the registration statement is not declared effective, the Rights Offering is not commenced or the Rights Offering is not ultimately consummated or successful, we will incur these expenses nonetheless. In addition, we have agreed to pay fees to the dealer-managers as follows: (i) to Maxim Group LLC, a cash fee equal to (a) 1% of the gross proceeds received by us directly from exercises of the subscription rights if the amount of such gross proceeds is less than $6 million; (b) 4% of the gross proceeds received by us directly from exercises of the subscription rights if the amount of such gross proceeds is at least $6 million but less than $10 million; and (c) 4.5% of the gross proceeds received by us directly from exercises of the subscription rights if the amount of such gross proceeds is at least $10 million; (ii) to National Securities Corporation, a cash fee equal to 2.75% of the gross proceeds received by us directly from exercises of the subscription rights if the amount of such gross proceeds is at least $6 million. We have also agreed to reimburse the dealer-managers for their expenses as follows: (i) up to $50,000 if the gross proceeds received by us directly from exercises of the subscription rights is less than $6 million; and (ii) up to $100,000 if the gross proceeds received by us directly from exercises of the subscription rights is at least $6 million.

Your interest in our company may be diluted as a result of the Rights Offering.

Shareholders who do not fully exercise their subscription rights should expect that they will, at the completion of the Rights Offering, own a smaller proportional interest in our company than would otherwise be the case had they fully exercised their basic subscription right and over-subscription privilege, as described in the registration statement. In addition, the shares issuable upon the exercise of the warrants to be issued pursuant to the Rights Offering will dilute the ownership interest of shareholders not participating in the offering or holders of warrants issued pursuant to the Rights Offering who do not exercise them.

Further, because the price per share of our common stock being offered may be substantially higher than the net tangible book value per share of our common stock, a purchase of shares of common stock in the Rights Offering offering at the subscription price described in the registration statement may cause the purchaser to suffer immediate and substantial dilution in the net tangible book value of the common stock.

Completion of the Rights Offering is not subject to us raising a minimum offering amount.

Completion of the Rights Offering is not subject to us raising a minimum offering amount and therefore proceeds may be insufficient to meet our objectives, thereby increasing the risk to investors who participate in the Rights Offering, including investing in a company that continues to require capital.

The dealer-managers are not underwriting, nor acting as placement agents of, the subscription rights or the securities underlying the subscription rights.

Maxim Group LLC and National Securities Corporation will act as dealer-managers for the Rights Offering. Under the terms and subject to the conditions contained in the dealer-manager agreement, the dealer-managers will provide marketing assistance in connection with the offering. The dealer-managers are not underwriting or placing any of the subscription rights or the shares of our common stock or warrants being issued in the Rights Offering and do not make any recommendation with respect to such subscription rights (including with respect to the exercise or expiration of such subscription rights), shares or warrants. The dealer-managers will not be subject to any liability to us in rendering the services contemplated by the dealer-manager agreement except for any act of bad faith or gross negligence by the dealer-managers. The services of the dealer-managers to us in this connection cannot be construed as any assurance that the offering will be successful.

The Rights Offering may cause the trading price of our common stock to decrease.

The subscription price, together with the number of shares of common stock we propose to issue and ultimately will issue if the Rights Offering is completed, may result in an immediate decrease in the market price of our common stock. This decrease may continue after the completion of the Rights Offering. We cannot predict the effect, if any, that the availability of shares for future sale represented by the warrants issued in connection with the Rights Offering will have on the market price of our common stock from time to time. Further, if a substantial number of subscription rights are exercised and the holders of the shares received upon exercise of those subscription rights or the related warrants choose to sell some or all of the shares underlying the subscription rights or the related warrants, the resulting sales could depress the market price of our common stock. Following the exercise of a holder's subscription rights, such holder may not be able to sell such holder's common stock at a price equal to or greater than the subscription price.

Purchasers may commit to buying shares of common stock above the prevailing market price.

Once an exercise is made of the subscription rights, the exercising holder may not revoke such exercise even if such holder later learns information that such holder considers to be unfavorable to the exercise of subscription rights. The market price of our shares of common stock may decline prior to the expiration of the offering or a subscribing rights holder may not be able to sell shares of common stock purchased in the offering at a price equal to or greater than the subscription price. Until shares of our common stock are delivered upon expiration of the Rights Offering, an exercising holder will not be able to sell or transfer the shares of our common stock that such holders purchases in the Rights Offering. Any such delivery will occur as soon as practicable after the Rights Offering has expired, payment for the shares of common stock and attached warrants subscribed for has cleared, and all prorating calculations and reductions contemplated by the terms of the Rights Offering have been effected.

If we terminate the Rights Offering for any reason, we will have no obligation other than to return subscription monies as soon as practicable.

We may decide, in our sole discretion and for any reason, to cancel or terminate the Rights Offering at any time prior to the expiration date. If the offering is cancelled or terminated, we will have no obligation with respect to subscription rights that have been exercised except to return as soon as practicable, without interest, the subscription payments deposited with the subscription agent. If we terminate the offering, the subscription rights will expire worthless.

Because we do not have any formal commitments from any of our shareholders to participate in the Rights Offering, the net proceeds we receive from the Rights Offering may not be significant.

We do not have any formal commitments from any of our shareholders to participate in the Rights Offering, and we cannot assure you that any of our shareholders or warrant holders will exercise all or any part of their basic subscription right or their over-subscription privilege. If our shareholders or warrantholders that may acquire subscription rights subscribe for a relatively small amount of shares of our common stock, the net proceeds we receive from the Rights Offering will not be significant.

The receipt of Subscription Rights may be treated as a taxable distribution.

We believe the distribution of the subscription rights in the Rights Offering should be a non-taxable distribution to holders of shares of common stock and our Series L warrants under Section 305(a) of the Internal Revenue Code of 1986, as amended (the "Code"). This position is not binding on the IRS, or the courts, however. If the Rights Offering is deemed to be part of a "disproportionate distribution" under Section 305 of the Code, a holder's receipt of subscription rights in the Rights Offering may be treated as the receipt of a taxable distribution to such holder equal to the fair market value of the subscription rights. Any such distribution would be treated as dividend income to the extent of our current and accumulated earnings and profits, if any, with any excess being treated as a return of capital to the extent thereof and then as capital gain. Each holder of shares of common stock and each holder of a Series L warrant is urged to consult his, her or its own tax advisor with respect to the particular tax consequences of the Rights Offering.

Our ability to use net operating loss carryovers to reduce future tax payments may be limited as a result of the Rights Offering.

As of December 31, 2014, we had net operating loss carryforwards (NOLs) for federal income tax purposes of approximately $70 million. We generally are able to carry NOLs forward to reduce taxable income in future years. These NOLs begin to expire at December 31, 2025. However, our ability to utilize the NOLs is subject to the rules of Section 382 of the Internal Revenue Code. Section 382 generally restricts the use of NOLs after an "ownership change." An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, five (5%) percent or more of our common stock or are otherwise treated as five (5%) percent stockholders under Section 382 and the regulations promulgated thereunder increase their aggregate percentage ownership of our stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over a three-year rolling period. 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. Because 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 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. Accordingly, no assurance can be given that our NOLs will be fully available. As a result, we could pay taxes earlier and in larger amounts than would be the case if the NOLs were available to reduce the federal income taxes without restriction.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our 10,200 square foot facility is located on three acres at 2635 Technology Forest Boulevard in The Woodlands, Texas. This location provides space for research and development and manufacturing capacity for clinical trials; a specialized Flow Cytometry and Microscopy lab; support of clinical trials with 800 square feet of cGMP manufacturing suites; Quality Systems management with a Quality Control Laboratory, Regulatory Affairs, and Quality Assurance; as well as administrative support space. Approximately 2,500 square feet of space remains available for future build-out. We lease the facility for a term ending in September 2015 with two options for an additional five years each at the then prevailing market rate.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information and Holders

Our common stock is traded on the NASDAQ Capital Market under the symbol "OPXA." Our common stock has, from time to time, traded on a limited, sporadic and volatile basis.

The table below shows the high and low sales prices for our common stock for the periods indicated, as reported by NASDAQ.

	Price Ranges	
	High	Low
Fiscal Year Ended December 31, 2013		
First Quarter	$ 5.19	$ 1.09
Second Quarter	2.44	1.44
Third Quarter	3.70	1.25
Fourth Quarter	2.56	1.65
Fiscal Year Ended December 31, 2014		
First Quarter	$ 2.20	$ 1.64
Second Quarter	1.93	1.26
Third Quarter	1.71	0.85
Fourth Quarter	1.07	0.70

The closing price of our common stock on February 19, 2015 was $0.73 per share, and there were approximately 175 holders of record of our common stock. This number does not include shareholders for whom shares were held in "nominee" or "street name."

Dividends

We have never declared or paid any cash dividends on our common stock and we do not intend to pay cash dividends in the foreseeable future. We currently expect to retain any future earnings to fund the operation and expansion of our business.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth information, as of December 31, 2014, with respect to our compensation plans under which common stock is authorized for issuance, which consist of our 2010 Stock Incentive Plan and its predecessor, our June 2004 Compensatory Stock Option Plan. We believe that the exercise price for all of the options granted under these plans reflect at least 100% of fair market value on the dates of grant for the options at issue.

Equity Compensation Plan Information

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (A)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column A) (C)
Equity Compensation Plans Approved by Stockholders	2,423,253	$2.92	1,509,479
Equity Compensation Plans Not Approved by Stockholders	—	—	—
Total	2,423,253	$2.92	1,509,479

Refer to Note 13 "Options and Warrants" in the Notes to our financial statements for the fiscal year ended December 31, 2014, included elsewhere in the annual report for a description of our 2010 Stock Incentive Plan and 2004 Compensatory Stock Option Plan.

Recent Sales of Unregistered Securities and Equity Purchases by Company

On October 21, 2014, we issued 54,664 restricted shares of common stock to a consultant for professional services in lieu of a cash payment of $50,000. The common stock was issued in reliance on the exemption from registration contained in Section 4(2) of the Securities Act of 1933 and Regulation D promulgated thereunder based on the offering of such securities to a single investor which represented that it was an accredited investor and that it was purchasing the shares for its own account and without a view to distribute them.

Item 6. Selected Financial Data.

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read in conjunction with the accompanying financial statements and the related footnotes thereto.

Organizational Overview

We have a limited operating history. Our predecessor company for financial reporting purposes was formed on January 22, 2003 to acquire rights to an adult stem cell technology. In November 2004 we acquired Opexa Pharmaceuticals, Inc. and its MS treatment technology. Currently we remain focused on developing our T-cell technology for MS. To date, we have not generated any commercial revenues from operations.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies affect our most significant judgments and estimates used in preparation of our financial statements.

Stock-Based Compensation. On January 1, 2006, we adopted the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("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 the expected term of stock options 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

Comparison of Year Ended December 31, 2014 with the Year Ended December 31, 2013

Net Sales. Revenues related to the $5 million upfront payment from Merck Serono in connection with the Option and License Agreement was $1,271,895 for the year ended December 31, 2014, compared to $1,266,611 for the year ended December 31, 2013. We recorded no commercial revenues for the years ended December 31, 2014 and December 31, 2013.

Research and Development Expenses. Research and development expenses were $12,118,629 for the year ended December 31, 2014, compared to $9,181,090 for the year ended December 31, 2013. The increase in expenses were primarily due to increases in staff and associated employee compensation expenses, increases in the cost of supplies used both in our laboratory and product manufacturing operations and increased clinical investigator costs associated with increased enrollment of patients in the Abili-T clinical study. We have made and expect to continue to make substantial investments in research and development in order to develop and market our technology. We expense research and development costs as incurred. Acquired research and development that has no alternative future use is expensed when acquired. Property and equipment for research and development that has an alternative future use is capitalized and the related depreciation is expensed.

General and Administrative Expenses. Our general and administrative expenses were $3,833,370 for the year ended December 31, 2014, compared to $3,670,769 for the year ended December 31, 2013. The increase in expense is due to a modest increase in stock compensation expense and an increase in the use of professional services, and was partially offset by lower NASDAQ listing fees.

Depreciation and Amortization Expenses. Depreciation and amortization expenses were $387,779 for the year ended December 31, 2014, compared to $335,597 for the year ended December 31, 2013. The increase in depreciation is due to the purchase of additional laboratory, manufaturing and computer equipment in 2014.

Interest Expense. Interest expense was $1,983 for the year ended December 31, 2014, compared to $2,267,302 for the year ended December 31, 2013. The decrease in interest expense was primarily due to the elimination of the July 2012 and January 2013 convertible notes in the calendar year 2013. Interest expense for the year ended December 31, 2014 related to the financing of insurance premiums and interest charged on a corporate credit card.

Interest Income. Interest income was $15,456 for the year ended December 31, 2014, compared to $14,985 for the year ended December 31, 2013, and related to the cash balances in our savings facility.

Net Loss. We had a net loss for the year ended December 31, 2014 of $15,052,263, or $0.54 per share (basic and diluted), compared with a net loss of $16,656,325, or $1.25 per share (basic and diluted), for the year ended December 31, 2013. The decrease in net loss is primarily due to substantially lower interest expense and elimination of the loss on extinguishment of debt offset by increases in research and development, general and administrative, depreciation and interest expenses.

Liquidity and Capital Resources

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of December 31, 2014, we had cash and cash equivalents of $9.9 million. Our financing activities generated approximately $28.4 million for the year ended December 31, 2013. The cash generated in 2013 was proceeds from underwritten public offerings of shares of our common stock, proceeds from a registered direct offering of shares of our common stock, proceeds from sales of shares of our common stock to Lincoln Park Capital Fund, LLC ("Lincoln Park"), proceeds from sales of shares of our common stock under an "at-the-market" (ATM) facility, proceeds from a January 2013 convertible secured note financing, the release of funds to us previously held in a controlled account and from an upfront payment received pursuant to an option granted to acquire an exclusive, worldwide (excluding Japan) license to our Tcelna program for the treatment of MS, as discussed below.

On November 2, 2012, we entered into a $15.0 million purchase agreement and registration rights agreement, and on November 5, 2012, we entered into a $1.5 million purchase agreement, each with Lincoln Park pursuant to which we have the right to sell to Lincoln Park an aggregate of up to $16.5 million in shares of our common stock, subject to certain conditions and limitations. Under the terms and subject to the conditions of the purchase agreements, Lincoln Park is obligated to purchase up to an aggregate of $16.5 million in shares of common stock (subject to certain limitations) from time to time over a 30-month period. We may direct Lincoln Park, at our sole discretion and subject to certain conditions, to purchase up to 100,000 shares of common stock in regular purchases, increasing to amounts of up to 300,000 shares depending upon the closing sale price of our common stock. In addition, we may direct Lincoln Park to purchase additional amounts as accelerated purchases. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to 12 business days leading up to such time), but in no event will shares be sold to Lincoln Park on a day the common stock closing price is less than the adjusted minimum floor price of $1.00. As of December 31, 2014, we have sold an aggregate of 390,000 shares of our common stock to Lincoln Park for gross proceeds of $523,709 and have a remaining commitment amount of $15,976,291 available to us through Lincoln Park purchase agreements. However, there can be no assurance that we will be able to receive any or all of the additional funds from Lincoln Park because the purchase agreements contain limitations, restrictions, requirements, events of default and other provisions that could limit our ability to cause Lincoln Park to buy common stock from us, including the requirement to keep current the prospectus included as part of the Form S-1 registration statement relating to the $15.0 million purchase agreement (which is not current as of this date) as well as a minimum floor price of $1.00 per share.

On September 6, 2012, we entered into a Sales Agreement (the "ATM Agreement") with Brinson Patrick Securities Corporation (the "Original Sales Manager") in which we could offer and sell shares of our common stock from time to time depending upon market demand, with the Original Sales Manager acting as an agent for the sale of shares in transactions deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933. During February 2013, we sold an aggregate of 167,618 shares of our common stock, for gross proceeds of $536,417 pursuant to the ATM Agreement. On March 5, 2014, we entered into a First Amendment to Sales Agreement with the Original Sales Manager and Meyers Associates, L.P. (doing business as Brinson Patrick, a division of Meyers Associates, L.P.) ("Brinson Patrick"), pursuant to which the ATM Agreement was assigned by the Original Sales Manager to Brinson Patrick. The ATM Agreement, as amended, is referred to herein as the "new ATM Agreement." Under the new ATM Agreement, we may offer and sell shares of our common stock from time to time depending upon market demand, with Brinson Patrick acting as an agent for the sale of shares in transactions deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933. We have registered up to an additional 2,500,000 shares of our common stock for potential sale under the new ATM Agreement. As of December 31, 2014, we have generated gross and net proceeds including amortization of deferred financing costs of $674,126 and $648,175, respectively, under the new ATM Agreement on sales of an aggregate of 518,412 shares of our common stock at average prices ranging from $1.68 to $1.12 per share.

Our operating cash burn rate during the twelve months ended December 31, 2014 was approximately $1.2 million per month. 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. Costs associated with the ongoing Abili-T trial and the potential commencement of a Phase 1/2 proof-of-concept study for OPX-212 in NMO may result in an increase in our monthly operating cash burn in 2015. However, costs associated with our ongoing preclinical and manufacturing activities for OPX-212 should not materially affect our cash burn through IND submission, which is expected by mid-2015.

We will need to secure significant additional resources to complete the Abili-T trial of Tcelna in SPMS and, if initiated, to conduct a Phase 1/2 proof-of-concept study of OPX-212 in NMO, as well as to support our operations during the course of the trials. 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 activities for OPX-212 in NMO with a possible IND submission by mid-2015, and for general operations to sustain the Company and support such activities into the fourth quarter of 2015. Any other costs, however, such as costs associated with the initiation and completion of a Phase 1/2 proof-of-concept study of OPX-212 in NMO or with pursuing additional disease indications for our T-cell technology or other research or development programs, would of course shorten this period.

We currently intend to use our available cash to fund general corporate purposes (including working capital, business development and operational purposes) and continue the ongoing Abili-T clinical study. We expect top-line data to be available in the second half of 2016. Our existing resources are not adequate to permit us to complete such study. We will need to secure significant additional capital to complete the trial and support our operations during the pendency of the trial. If we are unable to obtain additional funding for operations beyond the projected runway, we will be forced to suspend or terminate our current ongoing clinical trial for Tcelna, which may require us to modify our current business plan and curtail various aspects of our operations, as well as implement significant cost-reduction measures or potentially cease operations.

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

If Merck 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. Should we need any additional capital in the future beyond the purchase agreements with Lincoln Park and our at-the-market program with Brinson Patrick, management will be reliant upon "best efforts" debt or equity financings. As our prospects for funding, if any, develop during the fiscal year, we will assess our business plan and make adjustments accordingly. Although we have successfully funded our operations to date by attracting additional investors in our equity and debt securities, there is no assurance that our capital raising efforts will be able to attract additional necessary capital for our operations in the future.

Assuming we are able to achieve financing which is sufficient to continue the Abili-T study in North America and to support our operations during the pendency of such study, we are also able to concurrently manage a pivotal Phase III clinical study in RRMS in North America in our present facility. Any such RRMS studies, however, would also depend upon the availability of sufficient resources or a strategic partnering commitment.

Off-Balance Sheet Arrangements

None.

Inflation

We believe that inflation has not had a material impact on our results of operations for the two years ended December 31, 2014 and 2013, since inflation rates have generally remained at relatively low levels and our operations are not otherwise uniquely affected by inflation concerns.

Recently Issued Accounting Pronouncements

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

The financial statements and notes thereto and supplementary data required by this Item are presented beginning on page F-1 of this annual report on Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

In accordance with Exchange Act Rules 13a-15 and 15d-15, we carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2014 in enabling us to record, process, summarize and report information required to be included in our periodic SEC filings within the required time period.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on our evaluation under the framework in *Internal Control—Integrated Framework* issued by COSO, our management concluded that our internal control over financial reporting was effective as of December 31, 2014 in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting

There was no change in internal control over financial reporting (as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during our fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers

Our executive officers are elected by the Board of Directors and serve at the discretion of the Board. Our executive officers are as follows:

Name	Age	Position
Neil K. Warma	52	President, Chief Executive Officer and Director
Karthik Radhakrishnan	44	Chief Financial Officer
Donna R. Rill	61	Chief Development Officer

Biographical information for our executive officers is set forth below:

Neil K. Warma has served as President and Chief Executive Officer since June 2008 and as a Director since September 2008. He also previously served as our Acting Chief Financial Officer from March 2009 to August 2012. From July 2004 to September 2007, Mr. Warma served as president and chief executive officer of Viron Therapeutics Inc., a privately-held clinical stage biopharmaceutical company. From 2000 to 2003 Mr. Warma was co-founder and president of MedExact USA, Inc., an Internet company providing clinical information and services to physicians and pharmaceutical companies. From 1992 to 2000, Mr. Warma held senior positions of increasing responsibility at Novartis Pharmaceuticals (previously Ciba-Geigy Ltd.) at its corporate headquarters in Basel, Switzerland. While at Novartis, Mr. Warma served as the Head of International Pharma Policy & Advocacy and in senior management within global marketing where he worked on the international launch of a gastrointestinal product. Mr. Warma obtained an honors degree specializing in Neuroscience from the University of Toronto and an International M.B.A. from the Schulich School of Management at York University in Toronto. As our President and Chief Executive Officer, Mr. Warma is directly involved in all aspects of our operations. He has extensive experience in corporate business development within the biopharmaceutical industry, in addition to executive leadership and management experience.

Karthik Radhakrishnan has served as Chief Financial Officer since March 2013. Prior to joining Opexa, Mr. Radhakrishnan was most recently a Vice President at ING Investment Management in New York. While at ING from 2007 to 2012, he was responsible for healthcare investments in the small & small-mid cap core/growth products that are part of the Fundamental Equity product line. Previously, Mr. Radhakrishnan was the senior analyst at Eagle Asset Management from 2005 to 2007, responsible for large cap growth healthcare, and he served in various analyst positions including Senior Analyst at The Dow Chemical Company where he worked from 2002 to 2005. Mr. Radhakrishnan served as a member of the Board of Trustees at Cares Foundation, a non-profit organization serving the Congenital Adrenal Hyperplasia community, from 2008 to 2011. Mr. Radhakrishnan is a CFA charter holder and has an MBA degree from the University of Michigan, a Masters in Engineering from the State University of New York and a Bachelor's degree from the Indian Institute of Technology.

Donna R. Rill was appointed as our Chief Development Officer in April 2013 and previously served as Senior Vice President of Operations and Quality Systems since January 2009. From November 2004 until January 2009, she served as Vice President of Operations. From April 2003 to November 2004, she was the director of quality systems and process development at Opexa Pharmaceuticals, Inc. From November 1997 to April 2003, she was the director of translational research for the Center for Cell & Gene Therapy at Baylor College of Medicine. Ms. Rill has worked to design and qualify GMP Cell & Gene Therapy Laboratories, GMP Vector Production facilities, and Translational Research Labs at St. Jude Children's Research Hospital, Texas Children's Hospital, and Baylor College of Medicine. Ms. Rill received her B.S. in Medical Technology from the University of Tennessee, Memphis.

Directors

All of the current directors serve until the next annual shareholders' meeting or until their successors have been duly elected and qualified. Our current Board of Directors is as follows:

Name	Age	Position
Timothy C. Barabe	62	Director
Hans-Peter Hartung	60	Director
Gail J. Maderis	57	Director
Michael S. Richman	53	Director
Scott B. Seaman	59	Director
Neil K. Warma	52	Director, President and Chief Executive Officer

Timothy C. Barabe has served as a Director since March 2014. He retired in 2013 as Executive Vice President and Chief Financial Officer of Affymetrix, Inc. Previously, from July 2006 until March 2010, he was Senior Vice President and Chief Financial Officer of Human Genome Sciences, Inc. Mr. Barabe served as Chief Financial Officer of Regent Medical Limited, a U.K.-based, privately owned, surgical supply company, from 2004 to 2006. He was with Novartis AG from 1982 through August 2004, where he served in a succession of senior executive positions in finance and general management, most recently as the Chief Financial Officer of Sandoz GmbH, the generic pharmaceutical subsidiary of Novartis. Mr. Barabe serves on the board of ArQule, a Boston-based, NASDAQ-listed biotech company, Vigilant Biosciences, a private medical device company and Project Open Hand, a non-profit organization. He received his B.B.A. degree from the University of Massachusetts (Amherst) and his M.B.A. from the University of Chicago. Mr. Barabe has extensive experience as a senior financial executive of life sciences companies, giving him valuable operational and financial experience, including in the international setting, and knowledge of both the pharmaceutical and biotech industries.

Hans-Peter Hartung, M.D. has served as a Director since March 2014 and as a member of our Scientific Advisory Board since 2010. He has served as a professor and Chairman of the Department of Neurology at Heinrich Heine University of Düsseldorf, Germany since 2001. Dr. Hartung earned his M.D. degree from the University of Düsseldorf and received post-graduate training in immunology, neurology and neuroimmunology at the University of Mainz, Germany and the University of Düsseldorf. He is a member of several international and national medical societies, serves on various executive and academic boards, as well as on the editorial board of a number of international medical journals (including past-president of ECTRIMS, the European Neurological Society, the International Society for Neuroimmunology, the International Federation of Multiple Sclerosis Societies and the World Health Organization Advisory Board on Multiple Sclerosis). He has also been published extensively in the field of neuroimmunological disorders. Dr. Hartung has extensive experience in the field of drug discovery and development, is a leader in the field of clinical immunology and has broad leadership experience on various boards.

Gail J. Maderis has served as a Director since October 2011. Ms. Maderis has served as President and CEO of BayBio (Bay Area Bioscience Association), an independent, non-profit trade association serving the life sciences industry in Northern California, since October 2009 and joined BayBio's board in 2004. From July 2003 to June 2009, Ms. Maderis served as President and CEO of Five Prime Therapeutics, Inc., a biotechnology company focused on the discovery and development of innovative protein and antibody drugs, and served as a director until 2010. Prior to that, Ms. Maderis held general management positions at Genzyme Corporation from 1997 to 2003, including founder and president of Genzyme Molecular Oncology, a publicly traded division of Genzyme, and corporate vice president of Genzyme Corporation. Ms. Maderis has served as a director of NovaBay Pharmaceuticals, Inc. since October 2010. Ms. Maderis has also been a member of several private company boards. Ms. Maderis received a B.S. degree in business from the University of California at Berkeley and an M.B.A. from Harvard Business School. Ms. Maderis has extensive experience as a senior executive of life sciences companies, giving her valuable operational and industry experience and leadership skills, as well as an extensive network of contacts related to financing, partnering and support services in the biotech industry and visibility into business and policy trends that impact the biopharmaceutical industry.

Michael S. Richman has served as a Director since June 2006. Mr. Richman has served as president and chief executive officer of Amplimmune, Inc. since July 2008. Mr. Richman served as president and chief operating officer of Amplimmune, Inc. from May 2007 to July 2008. From April 2002 to May 2007, Mr. Richman served as executive vice president and chief operating officer of MacroGenics, Inc. Mr. Richman joined MacroGenics, Inc. in 2002 with approximately 20 years' experience in corporate business development within the biotechnology industry. Mr. Richman served as a director of Cougar Biotechnology from June 2006 to July 2009. Mr. Richman obtained his B.S. in Genetics/Molecular Biology at the University of California at Davis and his MSBA in International Business at San Francisco State University. He has extensive experience in business development and strategic planning for life science companies, as well as executive leadership and management experience.

Scott B. Seaman has served as a Director of since April 2006. Mr. Seaman has served for over five years as (i) the executive director and treasurer of the Albert and Margaret Alkek Foundation of Houston, Texas, a private foundation primarily supporting biomedical research and institutions in the Texas Medical Center in Houston, Texas, (ii) the chief financial officer of Chaswil Ltd., a private family management company, (iii) secretary and treasurer of M & A Properties Inc., a ranching and real estate concern, and (iv) director of Somebody Cares America. In March 2013, Mr. Seaman was elected a director of Gradalis, Inc., a privately held clinical stage biotechnology company developing cancer focused immunotherapies. In June 2013, Mr. Seaman became a director of Strike Bio, Inc., a privately held clinical stage biotechnology company developing gene interference therapeutics. In April 2009, Mr. Seaman became the Managing Member of ICT Development LLC which is the Managing Member of ICT Holdings LLC, an energy services supplier for which he serves as president. From October 2007 to December 2010, Mr. Seaman served on the board of GeneExcel, Inc., a privately held biotechnology company. From May 2004 to December 2010, Mr. Seaman served as a Member of the Investment Committee of Global Hedged Equity Fund LP, a hedge fund. Mr. Seaman received a bachelor's degree in business administration from Bowling Green State University and is a certified public accountant. Mr. Seaman has extensive experience in overall financial management and corporate development, combined with operational and corporate governance experience.

Neil K. Warma—refer to "Executive Officers" section above for Mr. Warma's biographical information.

Audit Committee

The Board of Directors has established a standing Audit Committee currently composed of three non-employee directors, Messrs. Seaman (Chair), Barabe and Ms. Maderis, each of whom the Board has determined is "independent" within the meaning of SEC rules and regulations and NASDAQ listing standards. The Audit Committee selects, on behalf of our Board, an independent public accounting firm to audit our financial statements, discusses with the independent auditors their independence, reviews and discusses the audited financial statements with the independent auditors and management, recommends to our Board whether the audited financials should be included in our Annual Report to be filed with the SEC, and oversees management's identification, evaluation, and mitigation of major risks to Opexa. The Board has determined that Mr. Seaman, Mr. Barabe and Ms. Maderis each qualify as an "audit committee financial expert" as defined in SEC rules and regulations and also possesses the financial sophistication and requisite experience as required under NASDAQ listing standards.

Code of Ethics

In 2005, in accordance with SEC rules, the then Audit Committee and the Board of Directors adopted the Policy on Whistleblower Protection and Code of Ethics which is applicable to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, which we sometimes refer to as our senior financial officers. The Board of Directors believes that these individuals must set an exemplary standard of conduct, particularly in the areas of accounting, internal accounting control, auditing and finance. This Code of Ethics sets forth ethical standards to which the designated officers must adhere and other aspects of accounting, auditing and financial compliance. The Code of Ethics is available on our website at **www.opexatherapeutics.com**. Please note that the information contained on our website is not incorporated by reference in, or considered to be a part of, this report.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who beneficially own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership. These reporting persons are required by SEC regulations to furnish us with copies of all such reports they file. To our knowledge, based solely on our review of the copies of such reports furnished to us and written representations from certain insiders that no other reports were required, we believe all of the reporting persons complied with all applicable Section 16(a) filing requirements applicable to them with respect to transactions during the fiscal year ended December 31, 2014.

Item 11. Executive Compensation.

Executive Officer Compensation

The following table sets forth certain information concerning compensation earned by or paid to certain persons who we refer to as our "Named Executive Officers" for services provided for the fiscal year ended December 31, 2014. Our Named Executive Officers include persons who (i) served as our principal executive officer or acted in a similar capacity during 2014, (ii) were serving at fiscal year-end as our two most highly compensated executive officers, other than the principal executive officer, whose total compensation exceeded $100,000, and (iii) if applicable, up to two additional individuals for whom disclosure would have been provided as a most highly compensated executive officer, but for the fact that the individual was not serving as an executive officer at fiscal year-end.

2014 Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards(1)	Options Awards(2)	All Other Compensation	Total
Neil K. Warma	2014	$ 406,464	$ 172,747(6)	$ 94,181	$ 1,137,357	$ 0	$ 1,810,749
President and Chief Executive Officer	2013	$ 396,550	$ 94,180	$ 53,713	$ 92,324	$ 0	$ 636,767
Karthik Radhakrishnan	2014	$ 246,000	$ 71,033(6)	$ 30,319	$ 232,417	$ 0	$ 579,769
Chief Financial Officer(3)	2013	$ 180,925	$ 30,319(4)	$ 0	$ 285,226	$ 20,099(5)	$ 516,569
Donna R. Rill	2014	$ 246,000	$ 72,109(6)	$ 22,500	$ 232,417	$ 0	$ 573,026
Chief Development Officer	2013	$ 240,006	$ 22,500	$ 37,750	$ 34,292	$ 0	$ 334,548

(1) Amounts in this column represent the aggregate grant date fair value of restricted stock awards computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 ("FASB ASC 718"). The fair value of restricted stock awards is based on the closing price of our common stock on the grant date, and we recognize the compensation expense over the vesting period.

(2) Amounts in this column represent the aggregate grant date fair value of option awards computed in accordance with FASB ASC 718. Each officer was granted two options on February 28, 2014, and the fair value of each was calculated using the Black-Scholes option-pricing model. The first option is based upon the achievement of a future performance-based strategic milestone objective, and the grant date fair value is based upon the probable outcome of the performance conditions. The second option is time-based. See Note 13 to our financial statements included in our annual report on Form 10-K for assumptions underlying the valuation of equity awards.

(3) Mr. Radhakrishnan was appointed as Chief Financial Officer on March 29, 2013 at an annual salary of $240,000.

(4) Mr. Radhakrishnan's bonus was pro-rated to reflect his March 2013 employment start state.

(5) Represents payments made to Mr. Radhakrishnan for relocation and temporary housing expenses.

(6) Of these amounts, 10% has been paid. Of the remaining 90%, half will be paid if the Company obtains an aggregate amount of financing in 2015 for its operations (regardless of source) of at least $6 million; the second half will be paid if the Company obtains an aggregate amount of financing in 2015 for its operations (regardless of source) of at least $12 million (cumulative); and the Board of Directors reserves discretion to determine a payout of between half and all of the remaining 90% if the Company obtains an aggregate amount of financing in 2015 for its operations (regardless of source) of between $6 million and $12 million (cumulative).

Executive Employment Agreements

Neil K. Warma. We entered into an employment agreement on June 16, 2008 with Neil K. Warma pursuant to which he serves as our President and Chief Executive Officer. Pursuant to the agreement, which automatically renews for 12-month periods, Mr. Warma is currently compensated at the rate of $406,464 per year. In addition, Mr. Warma is entitled to the following: (i) an annual cash bonus of up to 50% of his base salary based upon milestones to be agreed upon; and (ii) a one-time payment of $50,000 cash and 6,250 shares of our common stock to be issued if and when the closing bid price of our common stock equals or exceeds $16.00 for 20 consecutive trading days. In addition, we provide Mr. Warma with our standard benefits and insurance coverage as generally provided to our management, as well as contractual indemnification rights by reason of his service as an officer and employee. If his employment is terminated by the Board without cause, as defined in the agreement, Mr. Warma will be entitled to receive a severance payment equal to 12 months of his base salary plus a payment equal to 30% of base salary in lieu of any potential bonus, in addition any earned but unpaid bonus. In addition, vesting of stock options will accelerate in full. We will also reimburse Mr. Warma for COBRA expenses for a 12-month period, subject to a cap equal to Opexa's standard contribution to employee health benefits. Upon the effectiveness of a change in control, as defined in the agreement, Mr. Warma will receive 18 months of salary and COBRA reimbursement and a payment equal to 45% of base salary in lieu of any potential bonus, in addition to any earned but unpaid bonus. In addition, all vesting of options will accelerate in full. Any payment or benefit Mr. Warma might receive upon a change of control which would constitute a "parachute payment" under Section 280G of the Internal Revenue Code will be reduced so as not to trigger excise tax under Section 4999 of such Code. Mr. Warma's agreement also provides that for a 12-month period following his termination of employment, he will not engage or participate in any competitive business or solicit or recruit any of Opexa's employees. The severance and change of control benefits are subject to Mr. Warma executing and delivering a general release and waiver of claims in favor of Opexa.

Karthik Radhakrishnan. We entered into an employment offer letter with Karthik Radhakrishnan on March 12, 2013 pursuant to which we appointed Mr. Radhakrishnan as our Chief Financial Officer on March 29, 2013. Mr. Radhakrishnan is currently compensated at the rate of $246,000 per annum and is eligible to receive an annual discretionary bonus of up to 35% of his base salary per 12-month period, based on the achievement of objectives as determined by Opexa's Board and Chief Executive Officer. In addition, Mr. Radhakrishnan was granted a ten-year stock option to purchase 125,000 shares of Opexa's common stock that will vest in quarterly increments over a three-year period. As part of this agreement, Mr. Radhakrishnan was eligible for reimbursement of temporary housing of up to $2,500 per month for a maximum of three months, a several day house hunting-trip and a moving expense allowance of $15,000. Mr. Radhakrishnan receives our standard benefits and insurance coverage as generally provided to members of our management, as well as contractual indemnification rights by reason of his service as an officer and employee. Mr. Radhakrishnan's employment may be terminated at any time voluntarily by him or without cause (as defined in the offer letter) by the Board. If his employment is terminated by the Board without cause, Mr. Radhakrishnan will be entitled to receive a severance payment equal to six months of his base salary and vesting for any unvested stock options will accelerate by six additional months. The severance benefits are subject to Mr. Radhakrishnan having been continuously employed through the termination event, executing and delivering a general release and waiver of claims in favor of Opexa, not being in breach of the offer letter or Opexa's proprietary information and inventions agreement, and not engaging in any activity which is competitive with Opexa during the term of the offer letter or while receiving the severance benefits. The timing of any payments to Mr. Radhakrishnan under the offer letter is subject to applicable requirements of Section 409A of the Code and the related Treasury Regulations.

Donna R. Rill. We entered into an amended and restated employment agreement with Donna R. Rill on April 21, 2010 which is effective as of April 1, 2010, pursuant to which Ms. Rill serves as our Chief Development Officer. This agreement superseded Ms. Rill's prior agreement. Ms. Rill is currently compensated at the rate of $246,000 per annum and is eligible to receive an annual discretionary bonus of up to 20% of her base salary per 12-month period, based on the achievement of objectives as determined by Opexa's Board and Chief Executive Officer. In addition, Ms. Rill receives our standard benefits and insurance coverage as generally provided to our management, as well as contractual indemnification rights by reason of her service as an officer and employee. Ms. Rill's employment may be terminated at any time voluntarily by her or without cause (as defined in the agreement) by the Board. If her employment is terminated by the Board without cause, Ms. Rill will be entitled to receive a severance payment equal to six months of her base salary and vesting for any unvested stock options will accelerate by six additional months. The severance benefits are subject to Ms. Rill having been continuously employed through the termination event, executing and delivering a general release and waiver of claims in favor of Opexa, not being in breach of the employment agreement or Opexa's proprietary information and inventions agreement, and not engaging in any activity which is competitive with Opexa during the term of the employment agreement or while receiving the severance benefits. The timing of any payments to Ms. Rill under the employment agreement is subject to applicable requirements of Section 409A of the Code and the related Treasury Regulations.

2014 Grants of Plan Based Awards

The following table presents information regarding stock options granted during the fiscal year ended December 31, 2014 pursuant to our 2010 Stock Incentive Plan to our Named Executive Officers.

		Estimated Future Payouts Under Equity Incentive Plan Awards(1)						
Name	Grant Date	Threshold	Target	Maximum	All Other Stock Awards: Number of Shares of Stock or Units(2)	All Other Option Awards: Number of Securities Underlying Options(3)	Exercise Price of Option Awards	Grant Date Fair Value of Stock and Options Awards(4)
Neil K. Warma	2-28-14	--	316,250	316,250	--	--	$1.82	$572,331
	2-28-14	--	--	--	--	316,250	$1.82	$565,026
	2-28-14	--	--	--	51,748	--	--	$ 94,181
Karthik Radhakrishnan	2-28-14	--	64,625	64,625	--	--	$1.82	$116,955
	2-28-14	--	--	--	--	64,625	$1.82	$115,462
	2-28-14	--	--	--	16,659	--	--	$ 30,319
Donna R. Rill	2-28-14	--	64,625	64,625	--	--	$1.82	$116,955
	2-28-14	--	--	--	--	64,625	$1.82	$115,462
	2-28-14	--	--	--	12,363	--	--	$ 22,500

(1) The Target and Maximum amounts represent the number of shares of common stock underlying performance-based options that will vest, if at all, 100% in the event our ongoing Phase IIb Abili-T clinical trial for patients with SPMS meets its designated study endpoints. The performance options have a term of ten years.

(2) The restricted stock awards are time-based and are scheduled to vest in full on February 28, 2015.

(3) These options are time-based, have a term of ten years and vest quarterly over a four-year period, with 25% vesting on the one-year anniversary of the grant date and the remaining 75% vesting quarterly over the remaining three years.

(4) Amount represents the aggregate grant date fair value of equity awards computed in accordance with FASB ASC 718. For performance-based and time-based options, the fair value was calculated using the Black-Scholes option-pricing model, and is based upon the achievement of the probable outcome of the performance conditions for performance-based options. The fair value of restricted stock awards is based on the closing price of our common stock on the grant date, and we recognize the compensation expense over the vesting period. See Note 13 to our financial statements included in our annual report on Form 10-K for assumptions underlying the valuation of equity awards.

2014 Outstanding Equity Awards at Fiscal Year-End

The following table presents information regarding outstanding equity awards at December 31, 2014 for each of the Named Executive Officers.

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)[7]
Neil K. Warma	62,500	—	$ 4.04	06/16/18		
	37,500	—	$ 0.88	01/16/19		
	25,000	—	$ 8.20	11/30/19		
	18,750	—	$ 6.24	01/04/21		
	39,988	3,635[1]	$ 3.80	01/06/22		
	32,718	10,905[2]	$ 3.80	01/06/22		
	55,984	39,987[2]	$ 3.80	01/06/22		
	33,334	16,666[3]	$ 1.88	11/08/23		
	—	316,250[4]	$ 1.82	02/28/24	51,748[6]	$ 37,259
	—	316,250[5]	$ 1.82	02/28/24		
Karthik Radhakrishnan	72,917	52,083[1]	$ 2.34	03/29/23		
	—	64,625[4]	$ 1.82	02/28/24	16,659[6]	$ 11,994
	—	64,625[5]	$ 1.82	02/28/24		
Donna R. Rill	1,500	—	$ 28.00	12/05/15		
	5,845	—	$ 20.00	04/20/16		
	8,000	—	$ 21.88	06/18/17		
	750	—	$ 4.36	05/06/18		
	8,250	—	$ 4.68	06/26/18		
	10,000	—	$ 0.88	01/16/19		
	2,099	—	$ 1.88	02/06/19		
	12,500	—	$ 8.20	11/30/19		
	6,250	—	$ 6.24	01/04/21		
	8,797	800[1]	$ 3.80	01/06/22		
	7,852	2,617[2]	$ 3.80	01/06/22		
	12,215	8,724[2]	$ 3.80	01/06/22		
	10,000	10,000[1]	$ 1.75	04/29/23		
	—	64,625[4]	$ 1.82	02/28/24	12,363[6]	$ 8,901
	—	64,625[5]	$ 1.82	02/28/24		

(1) The shares vest quarterly over a three-year period from the grant date.

(2) The performance-based options began vesting quarterly over a three year-period upon achievement of certain key milestone events. On September 12, 2012, the first tranche of one-third of the performance option shares commenced three-year quarterly vesting upon achievement of the first key milestone, which was Opexa initiating a clinical trial for Tcelna in SPMS. On February 5, 2013, the second tranche of two-thirds of the performance option shares commenced three-year quarterly vesting upon achievement of the second key milestone, which was Opexa entering into a collaboration, partnership or other strategic arrangement involving rights in the United States for Tcelna.

(3) 25% of the shares vested on the date of the grant, with the balance vesting quarterly in equal amounts at the end of each of the next nine quarters.

(4) 25% of the shares vest on the one-year anniversary of the grant date, and the remaining 75% vesting quarterly over the remaining three years.

(5) The performance-based options will vest, if at all, 100% in the event our ongoing Phase IIb Abili-T clinical trial for patients with SPMS meets its designated study endpoints.

(6) The restricted stock awards are time-based and are scheduled to vest in full on February 28, 2015.

(7) Based on the closing market price of Opexa common stock on December 31, 2014.

2014 Director Compensation

The following table presents summary information regarding compensation of the non-employee members of our Board of Directors who served during any part of the fiscal year ended December 31, 2014.

Name	Fees Earned or Paid in Cash	Options Awards(5)(6)	All Other Compensation	Total
Timothy C. Barabe	$ 12,000(1)	$ 32,000(7)	$ 0	$ 44,000
Hans-Peter Hartung, M.D.	$ 12,000(2)	$ 32,000(7)	$ 1,000(9)	$ 45,000
Gail J. Maderis	$ 15,000(3)	$ 40,000(8)	$ 0	$ 55,000
Michael S. Richman	$ 15,000(3)	$ 40,000(8)	$ 0	$ 55,000
Scott B. Seaman	$ 15,000(4)	$ 40,000(8)	$ 0	$ 55,000

(1) In lieu of $12,000 cash, Mr. Barabe elected to receive 6,000 shares of restricted common stock on March 19, 2014, with 33-1/3% vesting on each of June 30, 2014, September 30, 2014 and December 31, 2014.

(2) In lieu of $12,000 cash, Dr. Hartung elected to receive an option to purchase 6,450 shares of common stock on March 19, 2014 at an exercise price of $2.00 per share, with 33-1/3% vesting on each of June 30, 2014, September 30, 2014 and December 31, 2014.

(3) In lieu of $15,000 cash, Ms. Maderis and Mr. Richman elected to receive 8,242 shares of restricted common stock on February 28, 2014, with 25% vesting on each of March 31, 2014, June 30, 2014, September 30, 2014 and December 31, 2014.

(4) In lieu of $15,000 cash, Mr. Seaman elected to receive an option to purchase 8,844 shares of common stock on February 28, 2014 at an exercise price of $1.82 per share, with 25% vesting on each of March 31, 2014, June 30, 2014, September 30, 2014 and December 31, 2014.

(5) Amount represents the aggregate grant date fair value of equity awards computed in accordance with FASB ASC 718. The fair value of time-based option awards is calculated using the Black-Scholes option-pricing model. See Note 13 to our financial statements included in our annual report on Form 10-K for assumptions underlying the valuation of equity awards.

(6) The aggregate number of shares underlying outstanding option awards as of December 31, 2014 was: Mr. Barabe, 17,200 shares; Dr. Hartung, 23,650 shares; Ms. Maderis, 59,230 shares; Mr. Richman, 88,884 shares; and Mr. Seaman, 99,603 shares.

(7) As compensation for Board services, Mr. Barabe and Dr. Hartung were issued the following two options on March 19, 2014 to purchase shares of common stock at an exercise price of $2.00 per share, the market value on the date of grant: (i) an option, with a term of the earlier of ten years or upon a change of control of Opexa, to purchase 12,900 shares, with 50% vesting immediately upon grant and the remaining 50% vesting on December 31, 2014; and (ii) an option, with a term of ten years, to purchase 4,300 shares, with 50% vesting immediately upon grant and the remaining 50% vesting on February 28, 2015.

(8) As compensation for Board services, Ms. Maderis and Messrs. Richman and Seaman were issued the following two options on February 28, 2014 to purchase shares of common stock at an exercise price of $1.82 per share, the market value on the date of grant: (i) an option, with a term of the earlier of ten years or upon a change of control of Opexa, to purchase 17,686 shares, with 50% vesting immediately upon grant and the remaining 50% vesting on December 31, 2014; and (ii) an option, with a term of ten years, to purchase 5,896 shares, with 50% vesting immediately upon grant and the remaining 50% vesting on February 28, 2015.

(9) Represents an honorarium paid for consulting services and participation in the American Academy of Neurology (AAN) analyst reception in April 2014.

Standard Compensation Arrangements

Employee directors do not receive any compensation for services as a member of our Board. We reimburse our directors for travel and lodging expenses in connection with their attendance at Board and committee meetings. Our standard annual compensation arrangements for our non-employee directors consists of the following, valued at $55,000:

(i) an option to purchase shares of our common stock having a Black-Scholes determined value of $30,000 on the date of grant and an exercise price equal to the fair market value of Opexa's common stock on such date, with 50% vesting upon grant and the balance vesting on December 31 of that year;

(ii) an option to purchase shares of our common stock having a Black-Scholes determined value of $10,000 on the date of grant and an exercise price equal to the fair market value of Opexa's common stock on such date, with 50% vesting upon grant and the balance vesting generally one year from the date of grant; and

(iii) $15,000 in cash, payable in equal quarterly installments in arrears, which, at the individual election of each director, may instead be paid in the form of a stock option or restricted shares of common stock, subject to quarterly vesting of such equity award.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth, as of February 16, 2015, the number and percentage of outstanding shares of our common stock beneficially owned by: (a) each person who is known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock; (b) each of our directors; (c) the Named Executive Officers; and (d) all current directors and executive officers, as a group. As of February 16, 2015, there were 28,234,751 shares of common stock issued and outstanding.

Beneficial ownership has been determined in accordance with Rule 13d-3 under the Exchange Act. Under this rule, certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire shares (for example, upon exercise of an option or warrant) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares is deemed to include the amount of shares beneficially owned by such person by reason of such acquisition rights. As a result, the percentage of outstanding shares of any person as shown in the following table does not necessarily reflect the person's actual voting power at any particular date.

To our knowledge, except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them.

Beneficial Ownership Table

Name and Address of Beneficial Owner(1)	Number of Shares Owned	Percentage of Class
Executive Officers and Directors:		
Scott B. Seaman (2)	857,955(3)	3.01%
Neil K. Warma	517,865(4)	1.81%
Karthik Radhakrishnan	174,149(5)	*
Donna R. Rill	148,065(6)	*
Michael S. Richman	97,126(7)	*
Gail J. Maderis	67,472(8)	*
Timothy Barabe	33,200(9)	*
Hans-Peter Hartung	23,650(10)	*
All directors and executive officers as a group (8 persons)**	1,919,482(11)	6.54%

* Less than 1%

** Includes only current directors and officers serving in such capacity as of the date of the table.

(1) Unless otherwise indicated in the footnotes, the mailing address of the beneficial owner is c/o Opexa Therapeutics, Inc., 2635 Technology Forest Boulevard, The Woodlands, Texas 77381.

(2) Scott B. Seaman is a principal of Chaswil, Ltd. ("Chaswil"), the investment manager of Alkek & Williams Ventures, Ltd. ("Ventures"). Chaswil holds voting power and investment power with respect to Company securities held by Ventures pursuant to a written agreement, and Mr. Seaman has shared voting power and shared investment power over all of the shares of common stock beneficially owned by Ventures. The information in this footnote is primarily based on the Schedule 13D/A filed with the SEC on August 23, 2012, by Ventures, Chaswil, Mr. Seaman, Albert and Margaret Alkek Foundation (the "Foundation"), DLD Family Investments, LLC ("DLD Family") and certain other reporting persons named therein (the "Foundation 13D") and other information available to us. The Foundation acts through an investment committee of its board of directors, which includes Mr. Seaman, Charles Williams, Daniel Arnold, Joe Bailey and Ms. Randa Duncan Williams. Mr. Seaman is the executive director of the Foundation and chairman of the investment committee. The investment committee has sole voting and investment power over all of the shares of common stock beneficially owned by the Foundation. However, pursuant to the Foundation 13D, neither the executive director nor any member of the investment committee may act individually to vote or sell shares of common stock held by the Foundation; therefore, the Foundation has concluded that no individual committee member is deemed to beneficially own, within the meaning of Rule 13d-3 of the Exchange Act, any shares of common stock held by the Foundation solely by virtue of the fact that he or she is a member of the investment committee. Additionally, pursuant to the Foundation 13D, the Foundation has concluded that because Mr. Seaman, in his capacity as executive director or chairman of the investment committee, cannot act in such capacity to vote or sell shares of common stock held by the Foundation without the approval of the investment committee, he is not deemed to beneficially own, within the meaning of Rule 13d-3 of the Exchange Act, any shares of common stock held by the Foundation by virtue of his position as executive director or chairman of the investment committee. Ms. Williams is the principal of DLD Family and she may be deemed to exercise voting and investment power with respect to such shares held by DLD Family. Pursuant to the Foundation 13D, the Foundation, Ventures, Chaswil, Mr. Seaman and certain other reporting persons named therein may be deemed to constitute a group for purposes of Section 13(d) or Section 13(g) of the Exchange Act. However, the Foundation, Ventures, Chaswil and Mr. Seaman expressly disclaim (i) that, for purposes of Section 13(d) or Section 13(g) of the Exchange Act, they are a member of a group with respect to securities of Opexa held by certain other reporting persons named therein and (ii) that they have agreed to act together with certain other reporting persons named therein other than as described in the Foundation 13D. Each reporting person disclaims beneficial ownership with respect to all other shares of common stock other than those securities whereby the reporting person possesses sole voting power and sole dispositive power. The mailing address of the beneficial owner is 1100 Louisiana, Suite 5250, Houston, Texas 77002.

(3) Consisting of: (i) 518,708 shares of common stock held by Ventures; (ii) 175,781 shares of common stock underlying Series I warrants held by Ventures; (iii) 22,950 shares of common stock underlying Series K warrants held by Ventures; (iv) 40,913 shares of common stock held by Mr. Seaman; and (v) 99,603 shares of common stock underlying currently exercisable stock options held by Mr. Seaman.

(4) Consisting of: (i) 107,634 shares of common stock; (ii) 5,273 shares of common stock underlying Series I Warrants; (iii) 688 shares of common stock underlying Series K Warrants; and (iv) 404,270 shares of common stock underlying currently exercisable stock options.

(5) Consisting of: (i) 74,659 shares of common stock; and (ii) 99,490 shares of common stock underlying currently exercisable stock options.

(6) Consisting of: (i) 32,765 shares of common stock; and (ii) 115,300 shares of common stock underlying currently exercisable stock options.

(7) Consisting of: (i) 8,242 shares of common stock; and (ii) 88,884 shares of common stock underlying currently exercisable stock options.

(8) Consisting of: (i) 8,242 shares of common stock; and (ii) 59,230 shares of common stock underlying currently exercisable stock options.

(9) Consisting of: (i) 16,000 shares of common stock; and (ii) 17,200 shares of common stock underlying currently exercisable stock options.

(10) Consisting of: 23,650 shares of common stock underlying currently exercisable stock options.

(11) Consisting of: (a) the following held by Mr. Seaman or for which Mr. Seaman may be deemed to have voting and investment power: (i) 518,708 shares of common stock held by Ventures; (ii) 175,781 shares of common stock underlying Series I warrants held by Ventures; (iii) 22,950 shares of common stock underlying Series K warrants held by Ventures; (iv) 40,913 shares of common stock held by Mr. Seaman; and (v) 99,603 shares of common stock underlying currently exercisable stock options held by Mr. Seaman; (b) the following held by Mr. Warma: (i) 107,634 shares of common stock; (ii) 5,273 shares of common stock underlying Series I Warrants; (iii) 688 shares of common stock underlying Series K Warrants; and (iv) 404,270 shares of common stock underlying currently exercisable stock options; (c) the following held by Mr. Radhakrishnan: (i) 74,659 shares of common stock; and (ii) and 99,490 shares of common stock underlying currently exercisable stock options ; (d) the following held by Ms. Rill: (i) 32,765 shares of common stock; and (ii) 115,300 shares of common stock underlying currently exercisable stock options; (e) the following held by Mr. Richman: (i) 8,242 shares of common stock; and (ii) 88,884 shares of common stock underlying currently exercisable stock options; (f) the following held by Ms. Maderis: (i) 8,242 shares of common stock; and (ii) 59,230 shares of common stock underlying currently exercisable stock options; (g) the following held by Mr. Barabe: (i) 16,000 shares of common stock; and (ii) 17,200 shares of common stock underlying currently exercisable stock options; and (h) 23,650 shares of common stock underlying currently exercisable stock options held by Dr. Hartung.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Transactions with Related Persons

Since January 1, 2014, we have engaged in no reportable transactions with our directors, executive officers, beneficial holders of more than 5% of our voting securities, and affiliates or their immediately family members.

Director Independence

The Board determined that Ms. Maderis, Dr. Hartung and Messrs. Barabe, Richman and Seaman are each an independent director within the meaning of NASDAQ listing standards, which directors constitute a majority of the Board. The Board has determined that each member of the Board's Audit, Compensation and Nominating and Corporate Governance Committees is independent (or similarly designated) based on the Board's application of the standards of NASDAQ, the rules and regulations promulgated by the SEC or the Internal Revenue Service, as appropriate for such committee membership. The current members of these committees are as follows:

Director	Independent	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee
Timothy C. Barabe	X	X	X	
Hans-Peter Hartung	X			
Gail J. Maderis	X	X	X	X
Michael S. Richman	X		X	X
Scott B. Seaman	X	X		X

Item 14. Principal Accountant Fees and Services.

The following table presents the estimated aggregate fees billed by MaloneBailey, LLP for services performed during our last two fiscal years.

	Years Ended December 31,	
	2014	2013
Audit fees[1][2][3][4]	$ 75,000	$ 45,000
Tax fees	—	
All other fees[5]	16,500	46,000
	$ 91,500	$ 91,000

(1) Audit fees include professional services rendered for (i) the audit of our annual financial statements for the fiscal years ended December 31, 2014 and 2013, and (ii) the reviews of the financial statements included in our quarterly reports on Form 10-Q for such years.
(2) Fees of $15,000 out of the $30,000 total fees for the audit of Financial Statements included in our 2012 annual report on Form 10-K were paid in January of 2013
(3) Fees of $30,000 for the audit of Financial Statements included in our 2013 annual report on Form 10-K were paid in January of 2014
(4) Fees of $15,000 out of the $30,000 of total fees for the audit of Financial Statements included in our 2014 annual report on Form 10-K were paid in December of 2014.
(5) Other fees include professional services for review of various filings and issuance of consents.

Policy on Audit Committee Pre-Approval and Permissible Non-Audit Services of Independent Auditors

The Board's policy is to pre-approve all audit and permissible non-audit services provided by the independent auditors. These services may include audit services, audit-related services, tax services and other services. Pre-approval is generally provided for up to one year and any pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. The independent auditors and management are required to periodically report to the Board regarding the extent of services provided by the independent auditors in accordance with this pre-approval, and the fees for the services performed to date. The Board of Directors may also pre-approve particular services on a case-by-case basis. The Audit Committee pre-approved 100% of the tax services and other services provided by our independent auditors during the last two fiscal years.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) 1. Financial Statements

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Audited Financial Statements for years ended December 31, 2014 and December 31, 2013

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2. Financial Statement Schedules

The required information is included in the financial statements or notes thereto.

3. List of Exhibits

Exhibit No.	Description
3.1	Restated Certificate of Formation of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 26, 2012).
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 26, 2012).
3.3	Certificate of Amendment of the Restated Certificate of Formation of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 14, 2012).
3.4	Amended and Restated By-laws, as amended (incorporated by reference to Exhibit 3.3 to the Company's Annual Report on form 10-K filed on March 8, 2011).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-3 filed on November 13, 2009, File No. 333-163108).
4.2	Form of Securities Purchase Agreement dated as of December 9, 2009 by and between Opexa Therapeutics, Inc. and each investor signatory thereto for Unit offering of Common Stock and Series A Warrants (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 10, 2009).
4.3	Form of Common Stock Purchase Warrant for Series A Warrants (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed December 10, 2009).
4.4	Form of Series H Warrant issued on February 11, 2011 (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed February 8, 2011).
4.5	Form of Series I Warrant issued on July 25, 2012 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on July 26, 2012).
4.6	Form of Series J Warrant issued on January 23, 2013 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 23, 2013).
4.7	Form of Series K Warrant issued on January 30, 2013 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 30, 2013).
4.8	Form of Series L Warrant issued on February 11, 2013 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 7, 2013).
4.9	Form of Securities Purchase Agreement, dated as of February 7, 2013, by and between Opexa Therapeutics, Inc. and each investor signatory thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 7, 2013).

Exhibit No.	Description
10.1+	Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan (incorporated by reference to Exhibit B to the Company's Definitive Information Statement on Schedule 14C filed on June 29, 2004, File No. 000-25513).
10.2+	Certificate of Amendments to the Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan (incorporated by reference to Exhibit 10.15 of the Company's Annual Report on Form 10-K filed March 5, 2010).
10.3+	Opexa Therapeutics, Inc. 2010 Stock Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 12, 2013).
10.4+	Form of award agreement for awards to be made under the Opexa Therapeutics, Inc. 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed August 14, 2014).
10.5+	Employment Agreement dated June 16, 2008 by and between Opexa Therapeutics, Inc. and Neil K. Warma (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 18, 2008).
10.6+	Amended and Restated Employment Agreement entered into on April 21, 2010 by and between Opexa Therapeutics, Inc. and Donna R. Rill (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed April 27, 2010).
10.7+	Offer Letter, effective March 29, 2013, by and between Opexa Therapeutics, Inc. and Karthik Radhakrishnan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 1, 2013).
10.8	License Agreement dated September 5, 2001 by and between Opexa Therapeutics, Inc. and Baylor College of Medicine (incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-KSB filed April 15, 2005, File No. 000-25513).
10.9	Lease dated August 19, 2005 by and between Opexa Therapeutics, Inc. and Dirk D. Laukien (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-KSB filed March 31, 2006, File No. 000-25513).
10.10	License Agreement dated January 13, 2006 by and between Opexa Therapeutics, Inc. and Shanghai Institute for Biological Services (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form SB-2 (Amendment No. 1) filed February 9, 2006, File No. 333-126687).
10.11	Sales Agreement, dated September 6, 2012, by and between Opexa Therapeutics, Inc. and Brinson Patrick Securities Corporation (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 7, 2012).
10.12	First Amendment to Sales Agreement, dated March 5, 2014, by and among Opexa Therapeutics, Inc., Meyers Associates, L.P. (doing business as Brinson Patrick, a division of Meyers Associates, L.P.) and Brinson Patrick Securities Corporation (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 5, 2014).
10.13	$15.0 million Purchase Agreement, dated as of November 2, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 5, 2012).
10.14	$1.5 million Purchase Agreement, dated as of November 5, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 5, 2012).
10.15	Registration Rights Agreement, dated as of November 2, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed November 5, 2012).
10.16#	Option and License Agreement, dated February 4, 2013, by and between Ares Trading SA, a wholly owned subsidiary of Merck Serono S.A., and Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 5, 2013).

Exhibit No.	Description
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed on March 29, 2013).
23.1*	Consent of Independent Registered Public Accounting Firm MaloneBailey, LLP, dated February 20, 2015 to the incorporation by reference of their report dated February 20, 2015 in the Company's Registration Statements on Form S-1, S-3 and S-8.
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Annual Report on Form 10-K of the Company as of and for the period ended December 31, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations; (iii) Consolidated Statements of Changes in Stockholders' Equity; (iv) Consolidated Statements of Cash Flows; and (v) Notes to Consolidated Financial Statements.

* Filed herewith
\+ Management contract or compensatory plan or arrangement.
\# Confidential treatment was granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

By: /s/ Neil K. Warma
Neil K. Warma
President and Chief Executive Officer
Date: February 20, 2015

Pursuant to the requirements of the Securities Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacity and on the dates indicated.

Signature	Title	Date
/s/ Neil K. Warma Neil K. Warma	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 20, 2015
/s/ Karthik Radhakrishnan Karthik Radhakrishnan	Chief Financial Officer and Director *(Principal Financial and Accounting Officer)*	February 20, 2015
/s/ Tim Barabe Timothy Barabe	Director	February 20, 2015
/s/ Hans-Peter Hartung Hans-Peter Hartung	Director	February 20, 2015
/s/ Gail J. Maderis Gail J. Maderis	Director	February 20, 2015
/s/ Michael S. Richman Michael S. Richman	Director	February 20, 2015
/s/ Scott B. Seaman Scott B. Seaman	Director	February 20, 2015

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors
Opexa Therapeutics, Inc.
The Woodlands, Texas

We have audited the accompanying consolidated balance sheets of Opexa Therapeutics, Inc. and its subsidiary (collectively, the "Company") as of December 31, 2014 and 2013 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the years then ended. These financial statements are the responsibility of Opexa's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatements. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Opexa Therapeutics, Inc. and its subsidiary as of December 31, 2014 and 2013 and the results of their operations and their cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ MALONEBAILEY, LLP
www.malonebailey.com
Houston, Texas
February 20, 2015

OPEXA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 9,906,373	$ 23,644,542
Other current assets	758,943	1,122,576
Total current assets	10,665,316	24,767,118
Property & equipment, net of accumulated depreciation of $2,099,389 and $1,718,477, respectively	1,098,104	1,295,024
Other long term assets	38,939	177,666
Total assets	$ 11,802,359	$ 26,239,808
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 702,494	$ 696,155
Accrued expenses	1,199,184	1,232,990
Deferred revenue	1,230,746	1,395,348
Total current liabilities	3,132,424	3,324,493
Long term liability:		
Deferred revenue	1,230,748	2,338,041
Total liabilities	4,363,172	5,662,534
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, no par value, 10,000,000 shares authorized, none issued and outstanding	—	—
Common stock, $0.01 par value, 100,000,000 shares authorized, 28,234,751 and 27,546,058 shares issued and outstanding	282,348	275,461
Additional paid in capital	148,477,047	146,569,758
Accumulated deficit	(141,320,208)	(126,267,945)
Total stockholders' equity	7,439,187	20,577,274
Total liabilities and stockholders' equity	$ 11,802,359	$ 26,239,808

See accompanying summary of accounting policies and notes to consolidated financial statements

OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
Years ended December 31, 2014 and 2013

	2014	2013
Revenue:		
Option revenue	$ 1,271,895	$ 1,266,611
Research and development	12,118,629	9,181,090
General and administrative	3,833,370	3,670,769
Depreciation	387,779	335,597
Loss on disposal of fixed assets	—	2,161
Operating loss	(15,067,883)	(11,923,006)
Interest income	15,456	14,985
Other income and expense, net	2,147	37,910
Loss on extinguishment of debt	—	(2,518,912)
Interest expense	(1,983)	(2,267,302)
Net loss	$ (15,052,263)	$ (16,656,325)
Basic and diluted loss per share	$ (0.54)	$ (1.25)
Weighted average shares outstanding	27,821,056	13,332,350

See accompanying summary of accounting policies and notes to consolidated financial statements

OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
Years ended December 31, 2014 and 2013

	Common Stock Shares	Par	Additional Paid in Capital	Accumulated Deficit	Total
Balances at December 31, 2012	6,249,369	$ 62,494	$ 112,432,458	$ (109,611,620)	$ 2,883,332
Shares issued due to conversion of convertible notes	2,079,960	20,799	4,254,254	—	4,275,053
Discount related to beneficial conversion feature	—	—	141,829	—	141,829
Discount on warrants attached to debt	—	—	195,969	—	195,969
Shares issued for:					
cash, net of offering costs	19,013,952	190,140	28,157,960	—	28,348,100
commitment on Lincoln Park $1.5 million share purchase agreement	975	10	1,224	—	1,234
accrued interest	123,231	1,232	187,311	—	188,543
restricted stock awards	78,571	786	69,113	—	69,899
Warrant expense	—	—	219,553	—	219,553
Option expense	—	—	910,087	—	910,087
Net loss	—	—	—	(16,656,325)	(16,656,325)
Balances at December 31, 2013	27,546,058	275,461	$ 146,569,758	(126,267,945)	20,577,274
Shares issued for services	170,281	1,703	304,400	—	306,103
Shares sold for cash	518,412	5,184	642,991	—	648,175
Option expense	—	—	959,898	—	959,898
Net loss	—	—	—	(15,052,263)	(15,052,263)
Balances at December 31, 2014	28,234,751	$ 282,348	$ 148,477,047	$ (141,320,208)	$ 7,439,187

See accompanying summary of accounting policies and notes to consolidated financial statements

OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2014 and 2013

	2014	2013
Cash flows from operating activities		
Net loss	$ (15,052,263)	$ (16,656,325)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock issued for services	306,103	69,899
Amortization of discount on notes payable due to warrants and beneficial conversion feature	—	1,613,354
Loss on extinguishment of debt	—	2,518,912
Depreciation	387,779	335,597
Amortization of debt financing costs	—	125,248
Option and warrant expense	959,898	1,129,640
Loss on disposal of fixed assets	—	2,161
Changes in:		
Other current assets	363,633	104,051
Accounts payable	6,339	147,923
Accrued expenses	(33,806)	928,549
Other assets	138,727	(177,667)
Deferred revenue	(1,271,895)	3,733,389
Net cash used in operating activities	(14,195,485)	(6,125,269)
Cash flows from investing activities		
Purchase of property & equipment	(190,859)	(259,224)
Restricted cash	—	1,000,000
Net cash provided by (used in) investing activities	(190,859)	740,776
Cash flows from financing activities		
Common stock and warrants sold for cash, net of offering costs	648,175	28,484,878
Proceeds from third party debt	—	550,000
Proceeds from related party debt	—	100,000
Deferred financing and offering costs	—	(147,847)
Repayment on related party notes payable	—	(100,000)
Repayments on notes payable	—	(450,000)
Net cash provided by financing activities	648,175	28,437,031
Net change in cash and cash equivalents	(13,738,169)	23,052,538
Cash and cash equivalents at beginning of period	23,644,542	592,004
Cash and cash equivalents at end of period	$ 9,906,373	$ 23,644,542
Cash paid for:		
Income tax	$ —	$ —
Interest	$ 1,983	$ 19,648
NON-CASH TRANSACTIONS		
Issuance of common stock for accrued interest	—	188,543
Conversion of notes payable to common stock	—	4,275,053
Discount on convertible notes relating to:		
Warrants	—	195,969
Beneficial conversion feature	—	141,829
Unpaid additions to property and equipment	—	108,516
Shares issued as deferred offering costs	—	1,234
Unpaid offering costs	—	136,776

See accompanying summary of accounting policies and notes to consolidated financial statements

NOTE 1—BUSINESS OVERVIEW AND SUMMARY OF ACCOUNTING POLICIES

Description of Business. Opexa Therapeutics, Inc. ("Opexa", "we", "our", or "the Company") was initially incorporated as Sportan United Industries, Inc. ("Sportan") in Texas in March 1991. In June 2004, PharmaFrontiers Corp. ("PharmaFrontiers") was acquired by Sportan in a transaction accounted for as a reverse acquisition. In October 2004, PharmaFrontiers acquired all of the outstanding stock of Opexa Pharmaceuticals, Inc. ("Opexa Pharmaceuticals"), a biopharmaceutical company that previously acquired the exclusive worldwide license from Baylor College of Medicine to an patient specific, autologous T-cell immunotherapy, Tcelna® (formerly known as Tovaxin), for the initial treatment of multiple sclerosis (MS). In June 2006, the Company changed its name to Opexa Therapeutics, Inc. from PharmaFrontiers Corp. and, in January 2007, Opexa Therapeutics, Inc., the parent, merged with its wholly owned subsidiary, Opexa Pharmaceuticals with Opexa Therapeutics, Inc. being the surviving company.

In September 2012, Opexa initiated a Phase IIb clinical trial of Tcelna in patients with secondary progressive MS ("SPMS"). Previously, in September 2008, the Company completed a Phase IIb clinical study of Tcelna in the relapsing-remitting MS ("RRMS") indication.

Opexa operates in a highly regulated and competitive environment. The manufacturing and marketing of pharmaceutical products require approval from, and are subject to, ongoing oversight by the Food and Drug Administration, or FDA, in the United States, by the European Medicines Agency, or EMA, in the E.U. and by comparable agencies in other countries. Obtaining approval for a new therapeutic product is never certain and may take many years and may involve expenditure of substantial resources. Tcelna is in development stage and Opexa has not applied for a Biologics License Application (BLA) for Tcelna with the FDA nor a similar regulatory licensure in any other country, and thus Tcelna is not approved to be marketed in any country.

Principals of Consolidation. The financial statements include the accounts of Opexa and its former wholly-owned subsidiary, Opexa Pharmaceuticals through December 31, 2006. All intercompany accounts and transactions have been eliminated.

The consolidated financial statements include the accounts of Opexa and its wholly owned subsidiary, Opexa Hong Kong Limited ("Opexa Hong Kong"). Opexa Hong Kong was formed in the Hong Kong Special Administrative Region during 2012 in order to facilitate potential development collaborations in the pan-Asian region. Presently, Opexa Hong Kong has not entered into any agreements and has not recognized any revenues as of December 31, 2014. All intercompany transactions and balances between Opexa and Opexa Hong Kong are eliminated in consolidation.

Use of Estimates in Financial Statement Preparation. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Certain Risks and Concentrations. Opexa is exposed to risks associated with foreign currency transactions insofar as it has used U.S. dollars to fund Opexa Hong Kong's bank account denominated in Hong Kong dollars. As the net position of the unhedged Opexa Hong Kong bank account fluctuates, Opexa's earnings may be negatively affected. In addition, the reported carrying value of the Company's Hong Kong dollar-denominated assets and liabilities that remain in Opexa Hong Kong will be affected by fluctuations in the value of the U.S. dollar as compared to the Hong Kong dollar. Opexa currently does not utilize forward exchange contracts or any type of hedging instruments to hedge foreign exchange risk as Opexa believes that its overall exposure is relatively limited. As of December 31, 2014, Opexa Hong Kong reported cash and cash equivalents of $10,090 in converted U.S. dollars and does not have any reported liabilities in the consolidated balance sheets.

Revenue Recognition. 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 the Company's Tcelna program for the treatment of multiple sclerosis ("MS"). Tcelna is currently in a Phase IIb clinical trial in patients with Secondary Progressive MS ("SPMS"). The option may be exercised by Merck Serono prior to or upon the Company's completion of the Phase IIb Trial.

Opexa received an upfront payment of $5 million for granting the option. If the option is exercised, Merck 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.

Opexa recognized revenues from nonrefundable, up-front $5 million option fees related to the Merck Serono Agreement on a straightline basis over the estimated option exercise period. Opexa is required to make estimates regarding the clinical trial timelines which impact the period over which the option exercise may occur. Opexa's estimates regarding the option exercise period were adjusted in 2014 once the enrollments for the Abili-T clinical trial were completed. This adjustment was made on a prospective basis beginning in the periods in which the change was identified and resulted in a decrease in the amount of revenue we recognized on a quarterly basis from the Merck Serono Agreement.

Cash and Cash Equivalents. For purposes of the consolidated statements of cash flows, cash equivalents include all highly liquid investments with original maturities of three months or less. The primary objectives for the fixed income investment portfolio are liquidity and safety of principal. Investments are made with the objective of achieving the highest rate of return consistent with these two objectives. Opexa's investment policy limits investments to certain types of instruments issued by institutions primarily with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

Supplies Inventory. Supplies inventory at December 31, 2013 includes reagents and supplies that will be used to manufacture Tcelna and placebo product in Opexa's Phase IIb clinical study. Opexa amortized these prepaid reagents and supplies to research and development costs in the consolidated statements of operations over the period that these supplies were used. The supplies inventory was fully amortized as of December 31, 2014. Future purchases of reagents and supplies are expensed directly to research and development costs.

Long-lived Assets. Property and equipment are stated on the basis of historical cost less accumulated depreciation. Depreciation is provided using the straight-line method over the estimated useful lives of the assets. Major renewals and improvements are capitalized, while minor replacements, maintenance and repairs are charged to current operations. Impairment losses are recorded on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amount.

Deferred costs. Opexa incurs costs in connection with a debt or equity offering or in connection with the proceeds pursuant to an execution of a strategic agreement. These costs are recorded as deferred offering or deferred financing costs in the consolidated balance sheets. Such costs may consist of legal, accounting, underwriting fees and other related items incurred through the date of the debt or equity offering or the date of the execution of the strategic agreement. Costs in connection with a debt offering are amortized to interest expense over the term of the note instrument. Costs in connection with the execution of a strategic agreement in which an initial upfront payment is received are offset to the gain recognized in the consolidated statements of operations. Additional paid in capital includes costs recorded as an offset to proceeds in connection with the completion of an equity offering.

Income Taxes. Income tax expense is based on reported earnings before income taxes. Deferred income taxes reflect the impact of temporary differences between assets and liabilities recognized for financial reporting purposes and such amounts recognized for tax purposes, and are measured by applying enacted tax rates in effect in years in which the differences are expected to reverse. A valuation allowance is recorded to reduce the net deferred tax asset to zero because it is more likely than not that the deferred tax asset will not be realized. The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained upon an examination.

Stock-Based Compensation. Opexa accounts for share-based awards issued to employees in accordance with FASB ASC 718. Accordingly, employee share-based payment compensation is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the requisite service period (generally the vesting is over a 3-year period). Additionally, share-based awards to non-employees are expensed over the period in which the related services are rendered at their fair value.

Research and Development. Research and development expenses are expensed in the consolidated statements of operations as incurred in accordance with FASB ASC 730, *Research and Development*. Research and development expenses include salaries, related employee expenses, clinical trial expenses, research expenses, consulting fees, and laboratory costs. In instances in which the Company enters into agreements with third parties for research and development activities, Opexa may prepay fees for services at the initiation of the contract. Opexa records the prepayment as a prepaid asset in the consolidated balance sheets and amortizes the asset into research and development expense in the consolidated statements of operations over the period of time the contracted research and development services are performed. Other types of arrangements with third parties may be fixed fee or fee for service, and may include monthly payments or payments upon completion of milestones or deliverables. Opexa expenses the costs of licenses of patents and the prosecution of patents until the issuance of such patents and the commercialization of related products is reasonably assured. Research and development expense for the years ended December 31, 2014 and 2013 was $12,026,970 and $9,181,090, respectively.

Foreign Currency Translation and Transaction Gains and Losses. Opexa records foreign currency translation adjustments and transaction gains and losses in accordance with FASB ASC 830, *Foreign Currency Matters*. For the Company's operations that have a functional currency other than the U.S. dollar, gains and losses resulting from the translation of the functional currency into U.S. dollars for financial statement presentation are not included in determining net loss, but are accumulated in the cumulative foreign currency translation adjustment account as a separate component of stockholders' equity. Opexa Hong Kong's functional currency is deemed to be the US Dollar; consequently, Opexa records transaction gains and losses in its consolidated statements of operations related to the recurring measurement and settlement of foreign currency denominated transactions and balances.

Net Loss per Share. Basic and diluted net loss per share is calculated based on the net loss attributable to common shareholders divided by the weighted average number of shares outstanding for the period excluding any dilutive effects of options, warrants and unvested share awards.

NOTE 2—CASH AND CASH EQUIVALENTS

As of December 31, 2014, Opexa invested approximately $8.7 million in a savings account. For the year ended December 31, 2014, the savings account recognized an average market yield of 0.10%. Interest income of $15,431 from the savings account was recognized for the year ended December 31, 2014 in the consolidated statements of operations.

As of December 31, 2014 and 2013, Opexa invested approximately $24,500 in a money market fund investing exclusively in high-quality, short-term money market instruments consisting of U.S. government obligations and repurchase agreements collateralized by the U.S. Government. While this fund seeks current income while preserving capital and liquidity, the fund is subject to risk, including U.S. government obligations risk, and is not federally insured or guaranteed by or obligations of the Federal Deposit Insurance Corporation or any other agency. For the years ended December 31, 2014 and 2013, the money market fund recognized an average market yield of 0.01%. Interest income of $3 was recognized for the year ended December 31, 2014 in the consolidated statements of operations.

NOTE 3—OTHER CURRENT ASSETS

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

Description	2014	2013
Supplies inventory	$ 0	$ 673,044
Deferred offering costs	259,989	134,518
Prepaid expenses	498,954	315,014
	$ 758,943	$ 1,122,576

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

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

As of December 31, 2013, deferred offering costs of $103,636 in connection with the implementation of the $15.0 million Purchase Agreement are capitalized and included in other long term assets in the consolidated balance sheets (see Note 5). As of December 31, 2014, this amount was reclassified to other current assets since the Purchase Agreement will expire in 2015.

During December 2013, the remaining costs in connection with the implementation of the ATM Agreement were charged to general and administrative expense in the consolidated statements of operations as the Company determined that the ATM Agreement would need to be refreshed with a successor sales agent to the original sales agent. During 2014, deferred offering costs of $27,547, incurred in connection with the successor sales agent, were capitalized with $21,835 remaining unamortized in connection with the ATM Program at December 31, 2014.

Prepaid expenses at December 31, 2014 and 2013 also include costs incurred from third parties in connection with the Merck Serono Agreement (see Note 1). As of December 31, 2014, the remaining costs of $38,939 in connection with the Merck Serono Agreement that are expected to be amortized over the upcoming twelve month period are capitalized and included in other current assets in the consolidated balance sheets. The remaining costs of $38,939 in connection with the Merck Serono Agreement that are expected to be amortized beyond the upcoming twelve month period are capitalized and included in other long term assets in the consolidated balance sheets (see Note 5).

NOTE 4—PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31, 2014 and 2013:

Description	Life	2014	2013
Computer equipment	3 years	$ 168,209	$ 121,921
Office furniture and equipment	5-7 years	247,679	245,297
Software	3 years	116,022	121,378
Laboratory equipment	7 years	1,100,559	1,270,858
Leasehold improvements	10 years	675,672	665,158
Manufacturing equipment	7 years	889,352	588,889
Subtotal		3,197,493	3,013,501
Less: accumulated depreciation		(2,099,389)	(1,718,477)
Property and equipment, net		$ 1,098,104	$ 1,295,024

Property and equipment is carried at cost less accumulated depreciation. Depreciation is calculated by the straight-line method over the estimated useful life of three to ten years, depending upon the type of equipment, except for leasehold improvements which are amortized using the straight-line method over the remaining lease term or the life of the asset, whichever is shorter. The cost of repairs and maintenance is charged as an expense to the consolidated statements of operations as incurred. Depreciation expense totaled $387,779 and $335,597 for the years ended December 31, 2014 and 2013, respectively.

NOTE 5—OTHER LONG TERM ASSETS

Other long term assets at December 31, 2013 include deferred offering costs of $103,636 which were incurred from third parties in connection with the implementation of a $15.0 million Purchase Agreement in November 2012 pursuant to which Opexa has the right to sell to Lincoln Park up to $15.0 million in shares of its common stock, subject to certain conditions and limitations. As of December 31, 2014, this amount was reclassified to other current assets since the Purchase Agreement will expire in 2015.

Other long term assets also include costs incurred from third parties in connection with the Merck Serono Agreement (see Note 1). At December 31, 2014 and December 31, 2013 the unamortized costs that are expected to be amortized beyond the upcoming twelve month period amounted to $38,939 and $74,030, respectively.

NOTE 6—DEFERRED REVENUE

On February 4, 2013, Opexa entered into the Merck Serono Agreement (see Note 1). Opexa received an upfront payment of $5 million for granting the option. 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 option exercise period based on the expected completion term of the Phase IIb clinical trial in SPMS. Opexa includes the unrecognized portion of the $5 million as deferred revenue on the consolidated balance sheets.

NOTE 7—INCOME TAXES

Opexa uses the liability method, where deferred tax assets and liabilities are determined based on the expected future tax consequences of temporary differences between the carrying amounts of assets and liabilities for financial and income tax reporting purposes.

At December 31, 2014 and 2013, Opexa had approximately $70 million and approximately $68 million of unused net operating losses (NOLs), respectively, available for carry forward to future years. For tax purposes, Opexa elects to capitalize research & development expenses and amortize them over a 10-year period. The unused NOLs begin to expire at December 31, 2025. At December 31, 2014 and 2013, capitalized R&D amounted to $25.1 million and $13.9 million, respectively.

At December 31, 2014 and 2013, Opexa had a deferred tax asset which is covered by a full valuation allowance due to uncertainty of Opexa's ability to generate future taxable income necessary to realize the related deferred tax asset consisting of:

Deferred tax asset resulting from:	December 31, 2014	December 31, 2013
Net Operating Loss	$ 24,531,026	$ 23,631,749
Research and development tax credits	1,778,030	1,228,997
Capitalized research and development costs	8,803,914	4,886,605
Subtotal	35,112,970	29,747,351
Less valuation allowance	(35,112,970)	(29,747,351)
Net deferred tax asset	$ -	$ -

Opexa's ability to utilize the NOLs is subject to the rules of Section 382 of the Internal Revenue Code. Section 382 generally restricts the use of NOLs after an "ownership change" (generally defined as a greater than 50% change (by value) in the Company's equity ownership over a three-year period). The Section 382 limitation is applied annually and is equal to the value of Opexa's stock on the date of the ownership change, multiplied by a designated federal long-term tax-exempt rate.

NOTE 8—CONVERTIBLE PROMISSORY NOTES

On July 25, 2012, Opexa issued a total of $4,085,000 in principal amount of secured convertible promissory notes (the "Notes" or the "July 2012 Notes") to third parties and related parties (collectively, the "Noteholders"), of which an aggregate of $630,000 was issued to related parties (See Note 9). The Notes were originally scheduled to mature on July 25, 2014 and accrued interest at the rate of 12% per annum, compounded annually. Interest was payable semi-annually on June 30 and December 31 in either cash or registered shares of common stock, at Opexa's election. The Notes were secured by substantially all of Opexa's assets and were convertible into a new class of non-voting Series A convertible preferred stock. The Notes could be converted into Series A convertible preferred stock at the option of the investors at a price of $100.00 per share, subject to certain limitations and adjustments. Additionally, Opexa could elect to convert the Notes into Series A convertible preferred stock if (i) Opexa's common stock closed at or above $10.00 per share for 20 consecutive trading days or (ii) Opexa achieved certain additional funding milestones to continue its clinical trial program. These milestones included (x) executing a strategic agreement with a partner or potential partner by which Opexa will receive a minimum of $5 million to partially fund, or an option to partner with Opexa for, its Phase II clinical trial for Tcelna in patients with SPMS and (y) receiving a minimum of $25 million in additional capital (including the Note offering proceeds) from any partner, potential partner or any other source.

The Series A convertible preferred stock accrued dividends at the rate of 8% per annum, which are cumulative and payable semi-annually on June 30 and December 31 in either cash or registered shares of common stock at Opexa's election. The Series A convertible preferred stock had a liquidation preference of $100.00 per share, entitling holders to payment from the assets of the Company available for distribution to its shareholders before any payment is made to the holders of the common stock. The Series A convertible preferred stock participated in any dividends or other distributions on shares of common stock (other than dividends payable in shares of common stock) along with the common stock. As a result of anti-dilution adjustments following the November 2012 sale of shares of Opexa's common stock, the Series A convertible preferred stock was convertible into shares of the Company's common stock at a price of $3.12 per share (the floor price), subject to certain limitations and conditions, and up to 1,308,236 shares of common stock were issuable if all 12% convertible secured promissory notes issued in the July 2012 financing and outstanding at December 31, 2012 were converted to Series A convertible preferred stock and such stock is then converted into common stock. Additionally, Opexa could elect to convert the Series A convertible preferred stock into common stock if the Company's common stock closes at or above $16.00 per share for 20 consecutive trading days. As of December 31, 2013 and 2012, no shares of Series A convertible preferred stock were outstanding.

As part of the security interest in all of the Company's assets granted to the Noteholders, $1.0 million of the proceeds was originally maintained in a controlled account . During the year ended December 31, 2013, the restricted cash was reduced to $0 and the controlled account was terminated.

The Notes were analyzed at issuance for a beneficial conversion feature and Opexa concluded that a beneficial conversion feature exists. The beneficial conversion feature was measured using the commitment-date stock price and was determined to be $1,497,634, of which $230,969 was attributable to related parties. During the year ended December 31, 2012, the Company recorded $1,497,634 as a debt discount and this amount was amortized to interest expense in the consolidated statements of operations over the term of the Notes. Opexa also analyzed the Notes for derivative accounting consideration and determined that derivative accounting does not apply.

In connection with the issuance of the Notes, Opexa also issued Series I warrants to the Noteholders to initially purchase an aggregate of 957,422 shares of Opexa's common stock at $5.00 per share, subject to certain limitations and adjustments. The warrants have a five-year term and are exercisable six months from the date of issuance, or January 25, 2013. As a result of anti-dilution adjustments, the number of warrant shares for which the Series I warrants are exercisable increased to an aggregate increase of 1,436,121 shares of Opexa's common stock at an adjusted exercise price of $2.56 per share, subject to further certain limitations and adjustments. As a result, Opexa accounted for these reset provisions in accordance with FASB ASC 815-40, which requires Opexa to record the warrants as a derivative liability at the grant date and to record changes in fair value relating to the warrants at each subsequent balance sheet date (see Note 13). Opexa can redeem the warrants at $0.01 per share if its common stock closes at or above $10.00 per share for 20 consecutive trading days.

The initial fair value of the warrant liabilities of $2,314,635, together with the beneficial conversion feature of $1,497,634 were recognized as a debt discount and were amortized to interest expense in the consolidated statements of operations over the term of the Notes using the effective interest method. During the year ended December 31, 2012, the amortized debt discount was $104,032 and Opexa recognized $552,978 as a derivative gain in the consolidated statements of operations due to the change in fair value of the liability. The unamortized discount as of December 31, 2012 amounted to $3,708,237.

In February 2013, three of the third party holders of the Notes elected to convert their principal amounts of $900,000 into shares of the Company's Series A convertible preferred stock with further immediate conversion into 288,229 shares of the Company's common stock.

On September 23, 2013, the Company entered into an amendment to the Notes with certain Noteholders with respect to certain terms relating to conversion of the Notes. Pursuant to the Note amendment, all outstanding Notes were amended such that, in addition to the existing conversion arrangements, the Notes became convertible at the Company's election directly into shares of common stock (rather than any intermediate conversion to shares of Series A convertible preferred stock), at a conversion price of not less than $1.50 nor more than $2.25, based on the most recent closing market price of the Company's common stock on the NASDAQ Stock Market at the time of the Company's election to convert the Notes (including any accrued but unpaid interest through the conversion date) into shares of common stock. Notes in the aggregate principal amount of $3,185,000 were outstanding at the time of the Note amendment.

On September 24, 2013, the Company converted the principal amount of the Notes and unpaid interest totaling $3,275,053 into an aggregate of 1,714,697 shares of common stock at a conversion price of $1.91, which was the most recent closing market price of the Company's common stock on the NASDAQ Stock Market when the Company effected such conversion. The Company determined that the conversion of the Notes qualifies as a debt extinguishment since the Notes were converted based on the amended conversion price. Consequently, the Company recorded a loss on extinguishment of debt of $2,518,912 in the consolidated statements of operations, which represents the difference in the fair value of the shares issued of $3,275,053 and the carrying amount of the Notes (including accrued interest of $98,053) of $756,141 at the date of conversion. The carrying amount of the Notes is net of the unamortized discount and deferred financing costs at the date of conversion amounting to $2,432,681 and $86,231, respectively.

On January 23, 2013, Opexa closed a private offering consisting of convertible notes (the "January 2013 Notes") and warrants to purchase shares of common stock for gross proceeds of $650,000 of which $100,000 was from a related party (see Note 9). The January 2013 Notes were originally scheduled to mature on January 23, 2014 and accrued interest at the rate of 12% per annum, compounded annually. The January 2013 Notes were convertible into common stock at the option of the investors at a price of $1.30 per share, subject to certain limitations. The principal balance plus accrued interest was payable within five business days of the receipt by Opexa of an aggregate of at least $7.5 million in proceeds from the sale of its equity securities and/or as payments from one or more partners or potential partners in return for granting a license, other rights, or an option to license or otherwise acquire rights with respect to Tcelna.

The January 2013 Notes were analyzed at issuance for a beneficial conversion feature and Opexa concluded that a beneficial conversion feature existed. The beneficial conversion feature was measured using the commitment-date stock price and was determined to be $141,829 of which $21,820 was attributable to the related party. Opexa also analyzed the Notes for derivative accounting consideration and determined that derivative accounting does not apply.

In connection with the issuance of the January 2013 Notes, Opexa also issued Series J warrants to purchase an aggregate of 243,750 shares of Opexa's common stock (see Note 13), subject to certain limitations and adjustments. The relative fair value of the warrant liability of $195,969, together with the beneficial conversion feature of $141,829, were recognized as a debt discount and were amortized to interest expense during the year ended December 31, 2013 in the consolidated statements of operations over the term of the January 2013 Notes using the effective interest method.

On February 26, 2013, following the receipt of $3.25 million in gross proceeds during February 2013 from the sale of common stock and Series L warrants to purchase shares of common stock, and following the receipt of the upfront payment of $5 million from Merck Serono on February 20, 2013, Opexa paid principal and interest totaling $567,368 to holders of the January 2013 Notes, of which $100,000 was to a related party, and issued 77,034 shares of common stock to one holder of the January 2013 Notes who elected to convert the principal of $100,000.

During the year ended December 31, 2013, the debt discount of $337,798 in connection with the January 2013 Notes was fully amortized to interest expense in the consolidated statements of operations.

The following table provides a summary of the changes in convertible debt – third parties, net of unamortized discount, during the year ended December 31, 2013:

Balance at December 31, 2012	$	318,658
January 2013 Notes, face value		550,000
Discount on beneficial conversion feature of January 2013 Notes at issuance		(120,009)
Discount on fair value of Series J warrant liability at issuance		(165,820)
Repayment of January 23, 2013 Notes		(450,000)
Conversion of January 23, 2013 Notes into common stock		(100,000)
Conversion of July 25, 2012 Notes into common stock		(900,000)
Conversion of July 25, 2012 Notes into common stock		(2,555,000)
Unamortized discount closed to loss on debt extinguishment		1,949,003
Amortization of debt discount to interest expense through December 31, 2013		1,473,168
Balance at December 31, 2013	$	—

NOTE 9—RELATED PARTY TRANSACTIONS

Investors in the July 25, 2012 Note offering included two members of Opexa's Board of Directors and entities affiliated with a third director. Opexa issued an aggregate of $630,000 in principal amount of Notes to the two directors and an entity for which a third director reports beneficial ownership of Opexa securities. In connection with the issuance of such Notes, Opexa also issued warrants to purchase an aggregate of 221,483 shares of common stock. The fair value of the warrants was $356,969. Opexa also determined the Notes contained a beneficial conversation feature with fair value of $230,969. Opexa recorded a total of $587,939 as debt discount associated with the Notes issued to the related parties and amortized $16,044 as interest expense in the consolidated statements of operations for the year ended December 31, 2012.

Entities affiliated with related parties were issued Series K warrants to purchase an aggregate of 65,636 shares of common stock in connection with the January 29, 2013 waiver with respect to the July 2012 Notes.

The Company issued shares of common stock to holders of the July 2012 Notes in payment of accrued interest on July 1, 2013, of which related parties were issued an aggregate of 55,328 shares of common stock.

On September 24, 2013, the July 2012 Notes held by two members of Opexa's Board of Directors and an entity affiliated with a third director in an aggregate of $647,813 in principal amount and unpaid interest were converted into an aggregate of 339,170 shares of common stock at a conversion price of $1.91, which was the most recent closing market price of the Company's common stock on the NASDAQ Stock Market when the Company effected such conversion.

Investors in the January 2013 Note offering included one member of Opexa's Board of Directors who was issued a Note with a principal amount of $100,000 (see Note 8).

The following table provides a summary of the changes in convertible debt – related parties, net of unamortized discount, during 2013:

Balance at December 31, 2012	$	58,105
January 2013 Notes, face value		100,000
Discount on beneficial conversion feature of January 2013 Notes at issuance		(21,820)
Discount on fair value of Series J warrant liability at issuance		(30,149)
Repayment of January 23, 2013 Notes		(100,000)
Conversion of July 25, 2012 Notes into common stock		(630,000)
Unamortized debt discount closed to loss on debt extinguishment		483,678
Amortization of debt discount to interest expense through December 31, 2013		140,186
Balance at December 31, 2013	$	—

NOTE 10—COMMITMENTS AND CONTINGENCIES

In October 2005, Opexa entered into a ten-year lease for its office and research facilities. The facility including the property is leased for a term of ten years with two options for an additional five years each at the then prevailing market rate. Future minimum lease payments under the non-cancellable operating lease are $118,422 for 2015. Rent expense in the consolidated statements of operations was approximately $136,000 for each of the years ended December 31, 2014 and 2013.

NOTE 11—SIGNIFICANT CONTRACTUAL SERVICE AND MILESTONE AGREEMENTS

In February 2012, Opexa entered into an agreement with Pharmaceutical Research Associates, Inc. ("PRA"), a contract research organization, in which PRA will provide Opexa with services related to the design, implementation and management of Opexa's ongoing Phase IIb clinical trial program in SPMS (the "PRA Agreement"). Payments by Opexa to PRA under the PRA Agreement are based on the achievement of certain time and performance milestones as presented in the PRA Agreement. Total payments to PRA during the years ended December 31, 2014 and 2013, which were charged to research and development expense on the consolidated statements of operations, amounted to $1,557,824 and $1,582,380, respectively. Unless terminated by either party without cause on 60 days prior notice or on shorter notice with cause, the initial term of the PRA Agreement is for four years and automatically renews for successive one year terms.

Through December 31, 2014, Opexa entered into individual Clinical Trial Agreements with 36 Institutions and 36 principal investigators acting within their employment or agent positions within their clinical institution. Under the terms of each Clinical Trial Agreement, each of the Investigators will identify and recruit subjects with SPMS meeting certain enrollment requirements and conduct clinical research in conjunction with Opexa's Phase IIb clinical study, and each of the Institutions will provide appropriate resources and facilities so the Institution's Investigator can conduct Opexa's Phase IIb clinical study in a timely and professional manner and according to the terms of the Clinical Trial Agreement. Under the terms of each Clinical Trial Agreement, Opexa paid an upfront cash payment to each Institution for start-up and other costs which were charged directly to expense. Future payments by Opexa to the Institutions during the term of each Clinical Trial Agreement are based on the achievement of certain performance milestones as presented in each Clinical Trial Agreement. Unless terminated by Opexa without cause with 30 days' notice, or unless terminated by the Institution, Investigator or Opexa for health or safety reasons, the initial term of the Clinical Trial Agreements with each Institution and Investigator is for the duration of their enrolled subjects in the Phase IIb clinical study.

In November of 2014, Opexa entered into an agreement with Parexel International, LLC ("PAREXEL"), a contract research organization, in which PAREXEL will provide Opexa Regulatory Services for the conduct of the Neuromyelitis Optica ("NMO") program. In addition, three Institutional agreements were executed in 2014, to provide preclinical research activities. Services include identification, collection and shipping of blood samples to Opexa for research purposes.

NOTE 12—EQUITY

Summary information regarding equity related transactions for the years ended December 31, 2013 and December 31, 2014 is as follows:

During 2013, equity related transactions were as follows:

- In January 2013, 125,000 shares of common stock were sold and 975 additional commitment shares were issued to Lincoln Park under the $1.5 million purchase agreement for net proceeds of $142,400.
- An aggregate of 365,263 shares of common stock were issued in connection with the conversion of the January 2013 and July 2012 Notes (see Note 8).
- In February 2013, Opexa sold an aggregate of 167,618 shares of common stock under the ATM Agreement for gross proceeds of $536,417.
- On February 11, 2013, Opexa sold an aggregate of 1,083,334 units in a registered offering, with each unit consisting of one share of common stock and a warrant to purchase half (0.5) a share of common stock, at a price of $3.00 per unit, for gross proceeds of $3,250,002. The shares of common stock and warrants were immediately separable and were issued separately such that no units were issued. The warrants are exercisable immediately upon issuance, have a four-year term and an exercise price of $3.00 per share. A fee of 6.0% of the gross proceeds was paid to the placement agent.
- On July 1, 2013, Opexa issued 123,231 shares of common stock to the Noteholders of the July 2012 Notes as payment of accrued interest totaling $188,543 through June 30, 2013.
- On August 13, 2013, Opexa sold 12,000,000 shares of common stock in an underwritten public offering at a price of $1.50 per share for gross proceeds of $18,000,000.
- In September 2013, exercise of the over-allotment option granted to the underwriters of the August 2013 underwritten public offering resulted in the issuance of an additional 900,000 shares of common stock at a price of $1.50 per share for gross proceeds of $1,350,000.
- On September 24, 2013, 1,714,697 shares of common stock were issued in connection with the conversion of the remaining outstanding July 2012 Notes (see Note 8).
- On November 8, 2013, 78,571 shares of restricted common stock with an aggregate fair value of $147,713 were issued to certain members of Opexa's management. Opexa recognized stock based compensation expense of $69,899 and $77,814, related to these shares for the years ended December 31, 2013 and 2014, respectively.
- On December 23, 2013, Opexa sold 4,738,000 shares of its common stock, including the full exercise of the over-allotment option granted to the underwriters, at a price of $1.70 per share for gross proceeds of $8,054,600.
- For the year ended December 31, 2013, $2,985,319 was netted against additional paid in capital as stock offering costs.

During 2014, equity related transactions were as follows:

- On February 28, 2014, 109,617 shares of restricted common stock with an aggregate fair value of $199,503 were issued to certain members of Opexa's management and certain members of the board of directors. Opexa recognized stock based compensation expense of $168,412 related to these shares for the year ended December 31, 2014. The restricted shares issued to management vest in full on the earlier of the first anniversary of the grant date or termination of employment without cause following a change of control. The restricted shares issued to members of the board of directors vest in four quarterly increments beginning on March 31, 2014.
- On March 19, 2014, 6,000 shares of restricted common stock with an aggregate fair value of $12,000 were issued to a certain member of Opexa's board of directors. Opexa recognized stock based compensation expense of $9,877 related to these shares for the year ended December 31, 2014. The restricted shares vest in three quarterly increments beginning on June 30, 2014.
- In the third quarter of 2014, Opexa settled sales of 518,412 shares of common stock generating gross and net proceeds including amortization of deferred financing costs of $674,126 and $648,175, respectively, which were issued pursuant to the ATM.
- In the fourth quarter of 2014, Opexa issued 54,664 shares of restricted stock with an aggregate fair market value of $50,000 in partial consideration for the performance of services rendered by a consultant pursuant to a consulting agreement dated October 21, 2014.

NOTE 13—OPTIONS AND WARRANTS

The Board initially adopted the Opexa Therapeutics, Inc. 2010 Stock Incentive Plan on September 2, 2010 for the granting of equity incentive awards to employees, directors and consultants of Opexa, and the Plan was initially approved by the Company's shareholders on October 19, 2010. On September 25, 2013, the Board approved the Amended and Restated 2010 Stock Incentive Plan ("the 2010 Plan"), and the Company's shareholders approved the amended 2010 Plan on November 8, 2013, in order to (i) increase the number of shares of common stock reserved for issuance by 3,000,000 shares and (ii) reset the number of stock-based awards issuable to a participant in any calendar year to align with the increase in the shares reserved. The 2010 Plan is the successor to and continuation of Opexa's June 2004 Compensatory Stock Option Plan (the "2004 Plan"). The 2004 Plan reserved a maximum of 575,000 shares of common stock for issuance pursuant to incentive stock options and nonqualified stock options granted to employees, directors and consultants. Awards were made as either incentive stock options or nonqualified stock options, with the Board having discretion to determine the number, term, exercise price and vesting of grants made under the 2004 Plan. All outstanding equity awards granted under the 2004 Plan continue to be subject to the terms and conditions as set forth in the agreements evidencing such stock awards and the terms of the 2004 Plan, but no additional awards will be granted under the 2004 Plan subsequent to approval of the 2010 Plan. The 2010 Plan reserves a maximum of 3,625,000 shares of common stock for issuance plus the number of shares subject to stock options outstanding under the 2004 Plan that are forfeited or terminate prior to exercise and would otherwise be returned to the share reserves under the 2004 Plan and any reserved shares not issued or subject to outstanding grants, up to a maximum of 513,220 shares. The 2010 Plan provides for the grant of incentive stock options or nonqualified stock options, as well as restricted stock, stock appreciation rights, restricted stock units and performance awards that may be settled in cash, stock or other property. The Board of Directors or Compensation Committee, as applicable, administers the 2010 Plan and has discretion to determine the recipients, the number and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and vesting. Subject to a limitation on repricing without shareholder approval, the Board or Compensation Committee, as applicable, may also determine the exercise price of options granted under the 2010 Plan.

Employee Options:

During 2013, options to purchase an aggregate of 338,500 shares were granted to employees, at exercise prices ranging from $1.45 to $2.34. These options have terms of ten years and have a vesting schedule of three years. Fair value of $659,601 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for these options include (1) discount rate range of 1.73% and 2.78%, (2) expected term of 5.25 to 6 years, (3) expected volatility range of 191.83% and 203.69% and (4) zero expected dividends.

During 2013, options to purchase 78,171 shares were forfeited and cancelled.

Opexa recorded $766,875 stock-based compensation expense to management and employees during 2013, which included the related expense for the options that are expected to vest based on achievement of their related performance conditions. Unamortized stock compensation expense as of December 31, 2013 amounted to $894,821.

During 2014, performance-based options to purchase an aggregate of 510,125 shares at an exercise price of $1.82 were granted to senior management. These options have a term of ten years and vest 100% upon the earlier of achievement of a performance-based, strategic milestone objective or termination of employment without cause following a change of control. Fair value of $918,554 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for these options include (1) discount rate of 2.65%, (2) expected term of 10 years, (3) expected volatility of 172.33% and (4) zero expected dividends.

During 2014, incentive based options to purchase an aggregate of 772,875 shares were granted to employees, at exercise prices ranging from $0.86 to $1.82. These options have terms of ten years and have a vesting schedule of four years. Fair value of $1,324,070 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for these options include (1) discount rate range of 2.26 to 2.79%, (2) expected term of 6.25 years, (3) expected volatility range of 176.37% to 315.10% and (4) zero expected dividends.

During 2014, options to purchase 104,886 shares were forfeited and cancelled.

Opexa recorded $748,697 stock-based compensation expense to management and employees during 2014, which included the related expense for the options that are expected to vest based on achievement of their related performance conditions. Unamortized stock compensation expense as of December 31, 2014 amounted to $2,239,522.

Non-Employee Options:

During 2013, options to purchase an aggregate of 88,572 shares were granted to directors for service on Opexa's Board at an exercise price of $1.75. Options to purchase an aggregate of 20,000 shares have terms of 10 years, with 50% of the shares vesting immediately and 50% vesting one year from the date of grant. Options to purchase the remaining 68,572 shares will expire on the earlier of 10 years or a change in control of the Company, with 50% of the shares vesting immediately and 50% vesting on December 31, 2013. Fair value of $151,867 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for these options include (1) discount rate of 1.73%, (2) expected term of 5.25 years, (3) expected volatility of 201.21% and (4) zero expected dividends.

During 2013, options to purchase 11,072 shares were forfeited and cancelled.

Opexa recorded $143,212 of stock-based compensation expense to consultants and directors during 2013. Unamortized stock compensation expense as of December 31, 2013 amounted to $4,190.

During 2014, options to purchase an aggregate of 120,440 shares were granted to directors for service on Opexa's Board at an exercise price ranging from $1.82 to $2.00. Options to purchase an aggregate of 26,288 shares have terms of 10 years, with 50% of the shares vesting on the grant date and 50% vesting one year from the date of grant. Options to purchase 78,858 shares have terms of 10 years, with 50% of the shares vesting on the grant date and 50% vesting on December 31, 2014. An option to purchase 8,844 shares has a term of 10 years, with quarterly vesting ending on December 31, 2014. An option to purchase the remaining 6,450 shares has a term of 10 years, with 33.3% vesting quarterly ending on December 31, 2014. Fair value of $211,097 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for these options include (1) discount rate range of 2.65% to 2.77%, (2) expected term of 5.25 years, (3) expected volatility range of 155% to 157% and (4) zero expected dividends.

During 2014, options to purchase 37,750 shares were forfeited and cancelled.

Opexa recorded $211,201 of stock-based compensation expense to consultants and directors during 2014. Unamortized stock compensation expense as of December 31, 2014 amounted to $4,086.

Broker and Investor Warrants:

In connection with Opexa's July 25, 2012 private offering of the July 2012 Notes (see Note 8), Opexa issued warrants to the holders of the July 2012 Notes to purchase an aggregate of 1,436,121 shares of common stock at a current adjusted exercise price of $2.56 per share, subject to certain limitations and adjustments. These warrants have a term of five years and are initially exercisable on January 25, 2013.

During 2013, warrants to purchase 1,482,892 shares were forfeited. During 2014, warrants to purchase 22,312 shares were forfeited.

In connection with Opexa's January 23, 2013 private offering of the January 2013 Notes (see Note 8), Opexa issued warrants to the holders of the January 2013 Notes to purchase an aggregate of 243,750 shares of common stock at an exercise price of $1.24 per share, subject to certain limitations and adjustments. These warrants have a term of five years and were immediately exercisable. The estimated relative fair value of the investor warrants was $195,969 and was calculated using the Black-Scholes valuation model. The following assumptions were used: (1) no expected dividends, (2) risk free interest rate of 0.76%, (3) expected volatility of 191% and (4) expected life of five years. Opexa can redeem the warrants at $0.01 per share if the Company's common stock closes at or above $10.00 per share for 20 consecutive trading days.

Pursuant to a waiver executed by the holders of in excess of two-thirds (66-2/3%) of the principal amount of the outstanding July 2012 Notes and accepted by Opexa, the amount of the cash subject to a deposit control agreement was reduced to $500,000 during January 2013. In exchange for such waiver, the Company issued warrants to the holders of the July 2012 Notes to purchase an aggregate of 187,500 shares of common stock at an exercise price of $1.21 per share, subject to certain limitations and adjustments. The warrants have a term of five years and were immediately exercisable. The estimated fair value of the warrants was $219,553 and was calculated using the Black-Scholes valuation model. The following assumptions were used: (1) no expected dividends, (2) risk free interest rate of 0.90%, (3) expected volatility of 191% and (4) expected life of five years. Opexa can redeem the warrants at $0.01 per underlying share of common stock if the common stock closes at or above $10.00 per share for 20 consecutive trading days. The fair value of the warrants was recognized as additional interest expense during the year ended December 31, 2013.

In connection with Opexa's February 2013 registered offering (See Note 12), Opexa issued warrants to the investors to purchase an aggregate of 541,668 shares of common stock at an exercise price of $3.00 per share, subject to certain limitations and adjustments. These warrants have a term of four years and were immediately exercisable.

At December 31, 2013, the aggregate intrinsic value of the outstanding options and warrants was $49,851 and $255,750, respectively. At December 31, 2014, the aggregate intrinsic value of the outstanding options and warrants was $0 and $0 respectively.

Summary information regarding options and warrants for the years ended December 31, 2013 and 2014 are as follows:

	Options	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2012	824,620	$ 5.54	3,579,087	$ 5.64
Year ended December 31, 2013:				
Granted	427,072	1.94	972,918	2.21
Exercised	—	—	—	—
Forfeited and canceled	(89,243)	4.55	(1,482,892)	6.54
Outstanding at December 31, 2013	1,162,449	$ 4.30	3,069,113	$ 4.12
Granted	1,403,440	1.78	—	—
Exercised	—	—	—	—
Forfeited and canceled	(142,636)	2.98	(22,312)	10.00
Outstanding at December 31, 2014	2,423,253	$ 2.92	3,046,801	$ 4.08

Summary of options outstanding and exercisable as of December 31, 2014 is as follows:

Range of Exercise Prices	Weighted Average Remaining Contractual Life (years)	Number of Options Outstanding	Number of Options Exercisable
$ 0.86 to $ 4.99	7.70	2,241,808	725,523
5.00 to 9.99	0.30	136,575	136,575
10.00 to 39.20	0.03	44,870	44,870
$ 0.86 to $ 39.20	8.04	2,423,253	906,968

Summary of warrants outstanding and exercisable as of December 31, 2014 is as follows:

Range of Exercise Prices	Weighted Average Remaining Contractual Life (years)	Number of Warrants Outstanding	Number of Warrants Exercisable
$ 1.21 to $ 4.99	2.02	2,409,033	2,409,033
5.00 to 10.44	0.19	637,768	637,768
$ 1.21 to $ 10.44	2.21	3,046,801	3,046,801

NOTE 14—LICENSES AND GAIN ON EXTINGUISHMENT OF LIABILITY

Stem Cell Technology Agreement

In August 2009, Opexa entered into an exclusive agreement with Novartis for the further development of its stem cell technology. This technology, which has generated preliminary data, was in early preclinical development. Under the terms of the agreement, Novartis acquired the stem cell technology from Opexa and Novartis had full responsibility for funding and carrying out all research, development and commercialization activities. Opexa received an upfront cash payment of $3 million at the time the agreement was entered into and subsequently received $0.5 million as a technology transfer milestone fee.

In November 2011, Opexa re-acquired the stem cell assets from Novartis in consideration for releasing Novartis with respect to any further payment obligations owed to Opexa by Novartis In connection with the re-acquisition of the stem cell assets, a related license agreement with the University of Chicago was re-assigned to Opexa. Opexa and the University of Chicago entered into a Fourth Amended and Restated License Agreement in connection with such assignment to Opexa.

On August 12, 2014, we provided notice to the University of Chicago of our election to discontinue further prosecution of certain patents relating to the proprietary adult stem cell technology that we licensed from the University of Chicago pursuant to the Fourth Amended and Restated License Agreement dated November 2, 2011. Pursuant to the termination notice, we exercised our contractual option to return the licensed patent rights back to the University of Chicago and terminate the Fourth Amended and Restated License Agreement effective November 10, 2014 in accordance with the terms thereof.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Restated Certificate of Formation of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 26, 2012).
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 26, 2012).
3.3	Certificate of Amendment of the Restated Certificate of Formation of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 14, 2012).
3.4	Amended and Restated By-laws, as amended (incorporated by reference to Exhibit 3.3 to the Company's Annual Report on form 10-K filed on March 8, 2011).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-3 filed on November 13, 2009, File No. 333-163108).
4.2	Form of Securities Purchase Agreement dated as of December 9, 2009 by and between Opexa Therapeutics, Inc. and each investor signatory thereto for Unit offering of Common Stock and Series A Warrants (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 10, 2009).
4.3	Form of Common Stock Purchase Warrant for Series A Warrants (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed December 10, 2009).
4.4	Form of Series H Warrant issued on February 11, 2011 (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed February 8, 2011).
4.5	Form of Series I Warrant issued on July 25, 2012 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on July 26, 2012).
4.6	Form of Series J Warrant issued on January 23, 2013 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 23, 2013).
4.7	Form of Series K Warrant issued on January 30, 2013 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 30, 2013).
4.8	Form of Series L Warrant issued on February 11, 2013 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 7, 2013).
4.9	Form of Securities Purchase Agreement, dated as of February 7, 2013, by and between Opexa Therapeutics, Inc. and each investor signatory thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 7, 2013).

Exhibit No.	Description
10.1+	Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan (incorporated by reference to Exhibit B to the Company's Definitive Information Statement on Schedule 14C filed on June 29, 2004, File No. 000-25513).
10.2+	Certificate of Amendments to the Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan (incorporated by reference to Exhibit 10.15 of the Company's Annual Report on Form 10-K filed March 5, 2010).
10.3+	Opexa Therapeutics, Inc. 2010 Stock Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 12, 2013).
10.4+	Form of award agreement for awards to be made under the Opexa Therapeutics, Inc. 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed August 14, 2014).
10.5+	Employment Agreement dated June 16, 2008 by and between Opexa Therapeutics, Inc. and Neil K. Warma (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 18, 2008).
10.6+	Amended and Restated Employment Agreement entered into on April 21, 2010 by and between Opexa Therapeutics, Inc. and Donna R. Rill (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed April 27, 2010).
10.7+	Offer Letter, effective March 29, 2013, by and between Opexa Therapeutics, Inc. and Karthik Radhakrishnan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 1, 2013).
10.8	License Agreement dated September 5, 2001 by and between Opexa Therapeutics, Inc. and Baylor College of Medicine (incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-KSB filed April 15, 2005, File No. 000-25513).
10.9	Lease dated August 19, 2005 by and between Opexa Therapeutics, Inc. and Dirk D. Laukien (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-KSB filed March 31, 2006, File No. 000-25513).
10.10	License Agreement dated January 13, 2006 by and between Opexa Therapeutics, Inc. and Shanghai Institute for Biological Services (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form SB-2 (Amendment No. 1) filed February 9, 2006, File No. 333-126687).
10.11	Sales Agreement, dated September 6, 2012, by and between Opexa Therapeutics, Inc. and Brinson Patrick Securities Corporation (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 7, 2012).
10.12	First Amendment to Sales Agreement, dated March 5, 2014, by and among Opexa Therapeutics, Inc., Meyers Associates, L.P. (doing business as Brinson Patrick, a division of Meyers Associates, L.P.) and Brinson Patrick Securities Corporation (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 5, 2014).
10.13	$15.0 million Purchase Agreement, dated as of November 2, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 5, 2012).
10.14	$1.5 million Purchase Agreement, dated as of November 5, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 5, 2012).
10.15	Registration Rights Agreement, dated as of November 2, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed November 5, 2012).
10.16#	Option and License Agreement, dated February 4, 2013, by and between Ares Trading SA, a wholly owned subsidiary of Merck Serono S.A., and Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 5, 2013).

Exhibit No.	Description
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed on March 29, 2013).
23.1*	Consent of Independent Registered Public Accounting Firm MaloneBailey, LLP, dated February 20, 2015 to the incorporation by reference of their report dated February 20, 2015 in the Company's Registration Statements on Form S-1, S-3 and S-8.
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Annual Report on Form 10-K of the Company as of and for the period ended December 31, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations; (iii) Consolidated Statements of Changes in Stockholders' Equity; (iv) Consolidated Statements of Cash Flows; and (v) Notes to Consolidated Financial Statements.

* Filed herewith
\+ Management contract or compensatory plan or arrangement.
\# Confidential treatment was granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements on Form S-1 (File No. 333-201731 and 333-185738), Form S-3 (File No. 333-191655, 333-185003 and 333-185001) and Form S-8 (File No. 333-192215, 333-176934 and 333-139196) of our report dated February 20, 2015 with respect to the audited consolidated financial statements of Opexa Therapeutics, Inc. as of December 31, 2014 and 3013 and for the years then ended.

We also consent to the references to us under the heading "Experts" in such Registration Statements.

/s/ *MaloneBailey, LLP*
www.malonebailey.com
Houston, Texas
February 20, 2015

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Neil K. Warma, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: February 20, 2015

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

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Karthik Radhakrishnan, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: February 20, 2015

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

Exhibit 32.1

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

In connection with the Annual Report of Opexa Therapeutics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2014 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Neil K. Warma, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

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

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

Date: February 20, 2015

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

Exhibit 32.2

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

In connection with the Annual Report of Opexa Therapeutics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2014 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Karthik Radhakrishnan, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

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

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

Date: February 20, 2015

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