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, 2015

☐ **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, 2015 based upon the closing price as of such date was $22,589,234.

As of March 10, 2016, 6,986,971 shares of the registrant's common stock, par value $0.01 per share, were outstanding.

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PRESENTATION NOTE: We implemented a one-for-eight reverse stock split of our common stock on September 28, 2015. All share numbers and prices have been adjusted to reflect the reverse stock split.

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 SPMS which, depending upon results, may determine whether Merck Serono elects to exercise its Option to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna program for the treatment of multiple sclerosis (MS);
- whether Merck Serono exercises its Option and, if so, whether we receive any development or commercialization milestone payments or royalties from Merck Serono pursuant to the Option;
- our dependence (if Merck Serono exercises its Option) on the resources and abilities of Merck Serono for the further development of Tcelna;
- the efficacy of Tcelna for any particular indication, such as for relapsing remitting MS or secondary progressive MS, and the efficacy of OPX-212 for neuromyelitis optica (NMO);
- our ability to develop and commercialize products;
- our ability to obtain required regulatory approvals;
- our compliance with all Food and Drug Administration regulations;
- our ability to obtain, maintain and protect intellectual property rights (including for Tcelna and OPX-212);
- the risk of litigation regarding our intellectual property rights or the rights of third parties;
- the success of third party development and commercialization efforts with respect to products covered by intellectual property rights that we may license or transfer;
- our limited manufacturing capabilities;
- our dependence on third-party manufacturers;
- our ability to hire and retain skilled personnel;
- our volatile stock price; and
- other risks detailed in our filings with the SEC.

These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update any forward-looking statements to reflect any changes in expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in 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 are also in preclinical development of OPX-212 as an autologous T-cell immunotherapy for the treatment of NMO. NMO is an autoimmune disorder in which immune system cells and antibodies attack and destroy astrocytic/myelin cells in the optic nerves and the spinal cord leading to demyelination and loss of axons. There are currently no FDA-approved therapies for NMO, other than to treat an attack while it is happening, to reduce symptoms and to prevent relapses. OPX-212 is specifically tailored to each patient's immune response to a protein, aquaporin-4, which is the targeted antigen in NMO. In NMO, the immune system recognizes aquaporin-4 as foreign, thus triggering the attack. We believe a mechanism of action of OPX-212 may be to reduce the number and/or regulate aquaporin-4 reactive T-cells (ARTC), thereby reducing the frequency of clinical relapses and subsequent progression in disability. See "—NMO – OPX-212" below for more information on our development plans for OPX-212 in NMO.

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

Multiple Sclerosis—Background

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

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

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

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

Tcelna for MS

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

Tcelna Clinical Development Program

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

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

Summary of Phase I Dose Escalation Study in MS

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

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

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

Summary of Phase I/IIA Clinical Trial Data in MS

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

Subjects showed statistically significant reduction over baseline in the MRTC counts for each time point through month nine of the extension study. Overall, results of the safety analyses indicate that repeated treatment with Tcelna is well-tolerated. Reported adverse events (AEs) were mostly mild or moderate in intensity. Mild injection site reactions were observed but all resolved rapidly without treatment. Furthermore, results from this study suggest that repeated dosing of Tcelna has a substantive effect in reduction of ARR in subjects with MS and was well-tolerated.

Summary of TERMS Phase IIb Clinical Trial Data in RRMS

Tovaxin for Early Relapsing Multiple Sclerosis (TERMS) was a Phase IIb clinical study of Tcelna in RRMS patients completed in 2008. Although the study did not show statistical significance in its primary endpoint (the cumulative number of gadolinium-enhanced brain lesions using magnetic resonance imaging (MRI) scans summed at various points in the study), the study showed compelling evidence of efficacy in various clinical and other MRI endpoints.

The TERMS study was a multi-center, randomized, double blind, placebo-controlled trial in 150 patients with RRMS or high risk Clinically Isolated Syndrome. The inclusion criteria for TERMS was an EDSS score of 0 to 5.5. Patients received a total of five subcutaneous injections at weeks 0, 4, 8, 12 and 24. Key results from the TERMS trial included:

- In the modified intent to treat patient population consisting of all patients who received at least one dose of study product and had at least one MRI scan at week 28 or later (n=142), the ARR for Tcelna-treated patients was 0.214 as compared to 0.339 for placebo-treated patients, which represented a 37% decrease in ARR for Tcelna as compared to placebo in the general population;

- In a prospective group of patients with more active disease (ARR>1, n=50), Tcelna demonstrated a 55% reduction in ARR as compared to placebo, an 88% reduction in whole brain atrophy and a statistically significant improvement in disability (EDSS) compared to placebo ($p<0.045$) at week 52 during the 24-week period following the administration of the full course of treatment; and

- In a retrospective analysis in patients naïve to previous disease modifying treatment, the results showed that patients, when treated with Tcelna, had a 56% to 73% reduction in ARR versus placebo for the various subsets and p values ranged from 0.009 to 0.06.

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

SPMS Overview and Tcelna Mechanism of Action

SPMS is characterized by a steady accrual of irreversible disability, despite, in some cases, relapses followed by remissions or clinical plateaus. Older age at onset of MS diagnosis is the strongest predictor of conversion to SPMS. Males have a shorter time to conversion to SPMS compared with females. Available immunomodulating and immunosuppressive therapies used for RRMS have not been effective in SPMS. In clinical trials, these therapies have demonstrated anti-inflammatory properties as measured by the reduction in number and volume of contrast-enhancing or acutely inflammatory CNS lesions most commonly seen in patients with RRMS. The typical SPMS patient, however, has little or no radiographic evidence of acute inflammation. It is commonly observed that contrast-enhancing CNS lesions are uncommon among these patients, despite a clearly deteriorating neurologic course.

The lack of effect of conventional MS therapeutics in SPMS suggests that the cerebral deterioration characterizing progressive disease may be driven by factors other than acute inflammation. For instance, the immunopathology of SPMS is more consistent with a transition to a chronic T-cell dependent inflammatory type, which may encompass the innate immune response and persistent activation of microglia cells. Meningeal follicles close to cortical gray matter lesions suggests that adaptive immune responses involving antibody and complement contribute to progression in SPMS. Furthermore, chronic MRTCs may be contributing to the development of both innate and adaptive immune responses persisting in the CNS.

Radiographic features that stand out among patients with SPMS include significantly more atrophy of gray matter compared with RRMS patients. Of note, long-term disability in MS in general appears more closely correlated to gray matter atrophy than to white matter inflammation. Such atrophy may be suggestive of progressive clinical disability. Both clinically and radiographically, SPMS represents a disease process with certain features distinct from those of RRMS, and one with extremely limited treatment options.

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

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

Current Treatment Options for SPMS

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

Tcelna Clinical Overview in SPMS

In multiple previously conducted clinical trials for the treatment of patients with MS (which have been weighted significantly toward patients with RRMS), Tcelna has demonstrated one of the safest side effect profiles for any marketed or development-stage MS therapy, as well as encouraging efficacy signals. A total of 144 MS patients have received Tcelna in previously conducted Opexa trials for RRMS and SPMS. The therapy has been well-tolerated in all subjects and has demonstrated an excellent overall safety profile. The most common side effect is mild to moderate irritation at the site of injection, which is typically resolved in 24 hours. Tcelna has been administered to a total of 36 subjects with SPMS across three previous clinical studies.

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

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

In September 2012, we announced the initiation of a Phase IIb clinical trial of Tcelna in patients with SPMS. The trial is entitled: A Phase II Double-Blind, Placebo Controlled Multi-Center Study to Evaluate the Efficacy and Safety of Tcelna in Subjects with Secondary Progressive Multiple Sclerosis and has been named the "Abili-T" trial. The Abili-T trial is a double-blind, 1:1 randomized, placebo-controlled study in SPMS patients who demonstrate evidence of disease progression with or without associated relapses. The trial is being conducted at approximately 35 leading clinical sites in the U.S. and Canada and has enrolled patients who have Expanded Disability Status Scale (EDSS) scores between 3.0 and 6.0. According to the study protocol, patients are receiving two annual courses of Tcelna treatment consisting of five subcutaneous injections per year at weeks 0, 4, 8, 12 and 24. We reached our enrollment target for the Abili-T trial in June 2014, and a total of 190 patients have been enrolled in this two-year study.

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

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

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

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

Option and License Agreement with Merck Serono

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

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

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

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

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

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

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 are 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 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 and depletes and/or down-regulates the pathogenic T-cell population. It is not a general immune suppressant and, accordingly, it is not associated with the serious side effects seen by those MS treatments that function by systemically suppressing the immune system. In previously conducted clinical trials, there have been no SAEs associated with Tcelna treatment. 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 and in development.

NMO – OPX-212

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

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

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

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

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

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

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

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

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

On September 1, 2015, we entered into a Stock Purchase Agreement with certain purchasers party thereto to fund our NMO program, pursuant to which we sold in tranche one of a private placement 113,636 shares of common stock for a per share purchase price of $4.40 and issued Series N warrants to purchase a like number of shares, for a total purchase price of $499,999. We also agreed to sell and the purchasers agreed to purchase an additional aggregate of $4.5 million of common stock in four additional tranches upon our achievement of certain milestones to further the clinical development of OPX-212. On March 14, 2016, we entered into an amendment to the Stock Purchase Agreement to extend the timeframes for achieving the milestones relating to the subsequent tranches. As part of the amendment, the expiration date of the Series N warrants issued to the purchasers as part of the Stock Purchase Agreement was extended from April 9, 2018 to October 9, 2018. As amended, subsequent tranches are based on the completion of the ongoing preclinical development and manufacturing activities and subsequent submission of an IND for OPX-212 in NMO no later than August 15, 2016; the review and acceptance of the IND by the FDA no later than November 15, 2016; enrollment of the first patient in a potential Phase 1/2 proof-of-concept study no later than February 28, 2017; and enrollment of 30% of the patients in such Phase 1/2 study no later than June 30, 2017. Each subsequent tranche will include the sale of common stock only (i.e., no additional warrants will be issued), with such shares priced at 90% of the 10-day volume weighted average price of Opexa's common stock immediately preceding the occurrence of the related milestone.

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 patents held by Baylor. Opexa has since expanded the development of technology related to Tcelna and T-cell technology. Currently, Opexa holds or has been licensed approximately 160 issued patents (inclusive of United States and international jurisdictions), including patents held by Opexa with respect to the specificity and veracity of antigens that have been discovered. Opexa also possesses substantial proprietary know-how surrounding the Tcelna development and manufacturing processes that is maintained as 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, Roche Holdings AG, 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, 2015 were approximately $10.0 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, 2014 were approximately $12.1 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 and NMO. 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 March 10, 2016, we had 26 full-time employees. On March 2, 2016, we announced implementation of a restructuring initiative which included a reduction of approximately 30% of our then full-time workforce of 36 employees in order to reduce operating expenses and conserve cash resources. The restructuring initiative was driven by reduced operational demands associated with the Abili-T clinical trial for Tcelna in patients with SPMS following administration of the final dose to the last patient in such trial, which occurred in the last week of February 2016. It is intended to allow us to focus our resources on completion of the Abili-T clinical trial, for which top-line data is expected early in the fourth quarter of 2016. We believe that our relations with our employees are good. None of our employees are 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 securities. The following factors affect our business, our intellectual property, the industry in which we operate and our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known or which we consider immaterial as of the date hereof may also have an adverse effect on our business. If any of the matters discussed in the following risk factors were to occur, our business, financial condition, results of operations, cash flows or prospects could be materially adversely affected, the market price of our securities could decline and you could lose all or part of your investment in our securities.

Risks Related to Our Business

We will be required to raise additional capital, and our ability to obtain funding is uncertain. If sufficient capital is not available, we may not be able to continue our operations as proposed (including any potential study for OPX-212 in NMO and any Phase III studies of Tcelna without Merck Serono's financial support), which may require us to modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws.

As of December 31, 2015, we had cash and cash equivalents of $12.6 million. Our operating cash burn rate during the 12 months ended December 31, 2015 was approximately $1.1 million per month.

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

We believe that we have sufficient liquidity to support our current clinical activities for the Abili-T trial of Tcelna in SPMS, to continue planned preclinical development and manufacturing activities for OPX-212 in NMO, and for general operations to sustain the Company and support such activities into the first quarter of 2017. We expect top-line data for the Abili-T trial to be available early in the fourth quarter of 2016, and thus believe we have sufficient resources to complete the trial. However, if our projections prove to be inaccurate, or if we encounter additional costs to complete the trial or to sustain our operations, or if we incur other costs such as those associated with pursuing additional disease indications for our T-cell technology or pursuing clinical development of OPX-212 in NMO following an IND filing in the absence of funding under the Stock Purchase Agreement entered into on September 1, 2015 as described below, we would need to raise additional capital to complete the Abili-T trial.

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

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

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

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

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

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

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

Given our need for additional amounts of capital to support our current business plan, we intend to continue to explore potential opportunities and alternatives to obtain additional resources, including one or more additional financing transactions. There can be no assurance that any such financings or potential opportunities and alternatives can be consummated on acceptable terms, if at all.

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

We do not maintain any external lines of credit or have any sources of debt or equity capital committed for funding, other than our at-the-market program and the September 1, 2015 Stock Purchase Agreement, as amended, which may result in our sale of an additional $4.5 million in shares of common stock, subject to achievement of certain milestones to further the clinical development of OPX-212. Should we need any additional capital in the future beyond these sources, management will be reliant upon "best efforts" debt or equity financings. We can provide no assurance that we will be successful in any funding effort. The timing and degree of any future capital requirements will depend on many factors, including:

- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- the accuracy of the assumptions underlying our estimates for capital needs in 2015 and beyond as well as for the clinical study of Tcelna and OPX-212;
- scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs;
- our progress with preclinical development and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- the number and type of product candidates that we pursue.

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

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

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

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

Funding from our ATM facility may be limited or be insufficient to fund our operations or to implement our strategy.

We will need to keep current our shelf registration statement and the offering prospectus relating to our at-the-market (ATM) sales agreement with Brinson Patrick (now a division of IFS Securities, Inc.) in order to use the program to sell shares of our common stock. The number of shares and price at which we may be able to sell shares under our ATM facility may be limited due to market conditions and other factors beyond our control.

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

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

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

Our business is at an early stage of development. We do not have any product candidates that have completed late-stage clinical trials nor do we have any products on the market. We have only one product candidate, Tcelna, which has progressed to the stage of being studied in human clinical trials in the United States. Additionally, our second pipeline candidate, OPX-212 is currently in preclinical development for the treatment of NMO. Tcelna, and any other potential products, including OPX-212, will require regulatory approval prior to marketing in the United States and other countries. Obtaining such approval requires significant research and development and preclinical and clinical testing. We may not be able to develop any products, to obtain regulatory approvals, to continue clinical development of Tcelna, to enter clinical trials (or any development activities) for any other product candidates (such as OPX-212) or to commercialize any products. Tcelna, and any other potential products (such as OPX-212), may prove to have undesirable or unintended side effects or other characteristics adversely affecting their safety, efficacy or cost-effectiveness that could prevent or limit their use. Any product using any of our technology may fail to provide the intended therapeutic benefits or to achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production.

We have provided Merck Serono with the Option, which provides Merck Serono with the opportunity, if exercised, to control the development and commercialization of Tcelna in MS.

In February 2013, we granted the Option to Merck Serono. The Option permits Merck Serono to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna program for the treatment of MS. The Option may be exercised by Merck Serono prior to or upon completion of our ongoing Phase IIb trial of Tcelna in patients with SPMS. If Merck Serono exercises the Option, Merck Serono would be solely responsible for funding development, regulatory and commercialization activities for Tcelna in MS, although we would retain an option to co-fund certain development in exchange for increased royalty rates. We would also retain rights to Tcelna in Japan, certain rights with respect to the manufacture of Tcelna, and rights outside of MS. In consideration for the Option, we received an upfront payment of $5 million and may be eligible to receive an option exercise fee as well as milestone and royalty payments based on achievement of development and commercialization milestones. The rights we have relinquished to our product candidate Tcelna, including development and commercialization rights, may harm our ability to generate revenues and achieve or sustain profitability. On March 9, 2015, we entered into the Merck Serono Amendment pursuant to which we agreed to perform additional development activities in preparation for a potential Phase III trial and to share with Merck Serono certain information from our immune monitoring program in consideration for payment by Merck Serono of $3 million.

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

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

If Merck Serono does not exercise the Option, we may be unable to enter into a collaboration with any other potential partner on acceptable terms, if at all. We face competition in our search for partners from other organizations worldwide, many of whom are larger and are able to offer more attractive deals in terms of financial commitments, contribution of human resources, or development, manufacturing, regulatory or commercial expertise and support.

If Merck Serono does not exercise the Option, and we are not successful in attracting another partner and entering into collaboration on acceptable terms, we may not be able to complete development of or commercialize any product candidate, including Tcelna. In such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered and we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations.

We will need regulatory approvals for any product candidate, including Tcelna, prior to introduction to the market, which will require successful testing in clinical trials. Clinical trials are subject to extensive regulatory requirements, and are very expensive, time-consuming and difficult to design and implement. Any product candidate, such as Tcelna, may fail to achieve necessary safety and efficacy endpoints during clinical trials in which case we will be unable to generate revenue from the commercialization and sale of our products.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous FDA requirements, and must otherwise comply with federal, state and local requirements and policies of the medical institutions where they are conducted. The clinical trial process is also time-consuming. We reached our enrollment target for the Abili-T trial in June 2014, and a total of 190 patients have been enrolled in this two-year study. We expect top-line data for Tcelna to be available early in the fourth quarter of 2016. In addition, we anticipate that at least a pivotal Phase III clinical trial would be necessary before an application could be submitted for approval of Tcelna for SPMS. Failure can occur at any stage of the trials, and problems could be encountered that would cause us or Merck Serono (in the event the Option is exercised) to be unable to initiate a trial, or to abandon or repeat a clinical trial.

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

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

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

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

Even if regulatory approval is obtained for any product candidate, such as Tcelna, any such approval may be subject to limitations on the indicated uses for which it may be marketed. Our ability to generate revenues from the commercialization and sale of any potential products, whether directly or through any development arrangement (such as where Merck Serono exercises the Option), will be limited by any failure to obtain or limitation on necessary regulatory approvals.

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

We will rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that may hamper our ability to successfully develop and commercialize any product candidate, including Tcelna.

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

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

- any third party upon whom we rely does not successfully carry out its contractual duties or regulatory obligations or meet expected deadlines;
- licenses needed from third parties for manufacturing in order to conduct Phase III trials or to conduct commercial manufacturing, if applicable, are not obtained;
- any such third party needs to be replaced; or
- the quality or accuracy of the data obtained by the third party is compromised due to its failure to adhere to clinical protocols or regulatory requirements or for other reasons.

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

If we fail to identify and license or acquire other product candidates, we will not be able to expand our business over the long term.

We have focused on MS as the first disease to be pursued off our T-cell platform technology, and last year, we announced 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 development 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, and our recent restructuring initiative may cause disruption or not achieve the savings anticipated.

Our business strategy is dependent upon the skills and knowledge of our management team. If any critical employee leaves, we may be unable on a timely basis to hire suitable replacements to operate our business effectively. We also operate with a very small number of employees and thus have little or no backup capability for their activities. The loss of the services of any member of our management team or the loss of just a few other employees could have a material adverse effect on our business and results of operations. On March 2, 2016, we announced implementation of a restructuring initiative which included a reduction of approximately 30% of our then full-time workforce of 36 employees, including our chief financial officer, in order to reduce operating expenses and conserve cash resources. The restructuring initiative was driven by reduced operational demands associated with the Abili-T clinical trial for Tcelna in patients with SPMS following administration of the final dose to the last patient in such trial, which occurred in the last week of February 2016. It is intended to allow us to focus our resources on completion of the Abili-T clinical trial, for which top-line data is expected early in the fourth quarter of 2016. However, the restructuring initiative may cause disruption to our business operations, and we may not be able to effectively realize the savings anticipated by the restructuring initiative and reduction-in-force. Additionally, there may be future possible changes in our workforce, including as a result of changes that may occur in our operations or operating plan, or other reasons or events. There may also be possible changes in the amount of charges and cash payments associated with the workforce reduction which occurred on March 2, 2016 or the retention plan we initiated for our continuing non-management employees as of that date, including the possibility that we may incur unanticipated charges or make cash payments that are not currently contemplated.

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

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

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

We conduct our research and development in a 10,200 square foot facility in The Woodlands, Texas, which includes an approximately 1,200 square foot suite of three rooms for the manufacture of T-cell therapies. We believe our facility should have the capacity to support full clinical development of Tcelna in North American trials for SPMS and, if applicable, a potential Phase 1/2 proof-of-concept study of OPX-212 in NMO. It is not sufficient, however, to support clinical trials outside North America including Europe and Asia, if required, or the commercial launch of Tcelna or any other product candidate. In this case, we would need to expand our manufacturing staff and facility, obtain a new facility, contract with corporate collaborators or other third parties to assist with future drug production and commercialization, or defer to Merck Serono (in the event the Option is exercised) to address manufacturing requirements.

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

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

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

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

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

Tcelna is based on our novel T-cell immunotherapy platform, ImmPath, which produces an autologous T-cell immunotherapy utilizing a patient's own blood. OPX-212 is expected to be similarly produced. The manufacture of living T-cell products requires specialized facilities, equipment and personnel which are different than the resources required for manufacturing chemical or biologic compounds. Scaling-out the manufacture of living cell products to meet demands for commercialization will require substantial amounts of such specialized facilities, equipment and personnel, especially where, as is the case for Tcelna and expected to be the case for OPX-212, the products are personalized and must be made for each patient individually. Because our manufacturing processes are complex, require facilities and personnel that are not widely available in the industry, involve equipment and training with long lead times, and the establishment of new manufacturing facilities is subject to a potentially lengthy regulatory approval process, alternative qualified production capacity may not be available on a timely basis or on reasonably terms, if at all. In addition, not many consultants or advisors in the industry have relevant experience and can provide guidance or assistance because active immune therapies such as Tcelna are fundamentally a new category of product in two major ways: (i) the product consists of living T-cells, not chemical or biologic compounds; and (ii) the product is personalized. There can be no assurance that manufacturing problems will not arise in the future which we may not be able to resolve or which may cause significant delays in development or, if any product candidate such as Tcelna is approved, commercialization.

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

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

If any product we may eventually have is not accepted by the market or if users of any such product are unable to obtain adequate coverage of and reimbursement for such product from government and other third-party payors, our revenues and profitability will suffer.

In the instance of Tcelna, if Merck Serono exercises the Option then our ability to achieve revenue will be dependent upon the efforts and success of Merck Serono in developing and commercializing Tcelna. Our ability to successfully commercialize any product we may eventually have, to the extent applicable, and/or our ability to receive any revenue associated with Tcelna in the event Merck Serono exercises the Option, will depend in significant part on the extent to which appropriate coverage of and reimbursement for such product and any related treatments are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. Third-party payors are increasingly challenging the prices charged for medical products and services. We cannot provide any assurances that third-party payors will consider any product cost-effective or provide coverage of and reimbursement for such product, in whole or in part.

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

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

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

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

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

If any product candidate does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance and our ability to generate revenues from that product candidate would be substantially reduced.

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

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

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

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

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

We plan to do business internationally, which may prove to be difficult and fraught with economic, regulatory and political issues.

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

Risks Related to Our Intellectual Property

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

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

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

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

Issued U.S. patents require the payment of maintenance fees to continue to be in force. We rely on a third party payor to do this and their failure to do so could result in the forfeiture of patents not timely maintained. Many foreign patent offices also require the payment of periodic annuities to keep patents and patent applications in good standing. As we may not maintain direct control over the payment of all such annuities, we cannot assure you that our third party payor will timely pay such annuities and that the granted patents and pending patent applications will not become abandoned. In addition, we or our licensors may have selected a limited amount of foreign patent protection, and therefore applications have not been filed in, and foreign patents may not have been perfected in, all commercially significant countries.

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

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

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

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

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

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

We rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Further, we have limited control, if any, over the protection of trade secrets developed by our licensors. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

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

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, such as Tcelna, or their methods of use, manufacturing or other technologies or activities infringe the intellectual property rights of such third parties. If our product candidates, such as Tcelna, or their methods of manufacture are found to infringe any such patents, we may have to pay significant damages or seek licenses under such patents. We have not conducted comprehensive searches of patents issued to third parties relating to Tcelna or OPX-212. Consequently, no assurance can be given that third-party patents containing claims covering Tcelna or OPX-212, their methods of use or manufacture do not exist or have not been filed and will not be issued in the future. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, and because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, we cannot be certain that others have not filed patent applications that will mature into issued patents that relate to our current or future product candidates that could have a material effect in developing and commercializing one or more of our product candidates. A patent holder could prevent us from importing, making, using or selling the patented compounds. We may need to resort to litigation to enforce our intellectual property rights or to determine the scope and validity of third-party proprietary rights. Similarly, we may be subject to claims that we have inappropriately used or disclosed trade secrets or other proprietary information of third parties. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

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

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

Risks Related to Our Industry

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

We, our third-party contractors, suppliers and partners (such as Merck Serono, in the event the Option is exercised, with respect to Tcelna), and our product candidates, such as Tcelna, are subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. None of our product candidates can be marketed in the United States until it has been approved by the FDA. No product candidate of ours has been approved, and we may never receive FDA approval for any product candidate. Obtaining FDA approval typically takes many years and requires substantial resources. Even if regulatory approval is obtained, the FDA may impose significant restrictions on the indicated uses, conditions for use and labeling of such products. Additionally, the FDA may require post-approval studies, including additional research and development and clinical trials. These regulatory requirements may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could substantially reduce our ability to generate revenues.

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

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

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

We may need to change our business practices to comply with health care fraud and abuse regulations, and our failure to comply with such laws could adversely affect our business, financial condition and results of operations.

If Merck Serono exercises the Option, Merck Serono would be solely responsible for funding development, regulatory and commercialization activities for Tcelna in MS, although we would retain an option to co-fund certain development in exchange for increased royalty rates. Otherwise, if we are successful in achieving approval to market one or more of our product candidates, our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing, and education programs.

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

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

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

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

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

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

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

Our competitors may also develop alternative therapies that could further limit the market for any products that we may develop.

Rapid technological change could make our products obsolete.

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

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

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

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

Government controls and health care reform measures could adversely affect our business.

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

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

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

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

Risks Related to Our Securities

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

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

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

We are required to meet certain qualitative and financial tests (including a minimum bid price for our common stock of $1.00 per share and a minimum stockholders' equity of $2.5 million), as well as certain corporate governance standards, to maintain the listing of our common stock on the NASDAQ Capital Market. We received a staff deficiency letter in December 2014 indicating that our common stock failed to comply with the minimum bid price requirement because it traded below the $1.00 minimum closing bid price for 30 consecutive trading days, and after an initial and an extended grace period, and implementation of a one-for-eight reverse stock split of our common stock on September 28, 2015, we regained compliance with the $1.00 minimum closing bid price listing standard and NASDAQ notified us that the matter was closed on October 14, 2015. However, there is no assurance that the closing bid price of our common stock will continue to stay above the minimum continued listing standard.

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

While we are exercising diligent efforts to maintain the listing of our common stock on NASDAQ, there can be no assurance that we will be able to maintain compliance with the minimum bid price, stockholder's equity or other listing standards in the future. We may receive additional future notices from NASDAQ that we have failed to meet its requirements, and proceedings to delist our stock could be commenced. In such event, NASDAQ rules permit us to appeal any delisting determination to a NASDAQ Hearings Panel. If we are unable to maintain or regain compliance in a timely manner and our common stock is delisted, it could be more difficult to buy or sell our common stock and obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting may also impair our ability to raise capital.

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

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

- the development status of any drug candidates, such as Tcelna, including clinical study results and determinations by regulatory authorities with respect thereto;
- the initiation, termination, or reduction in the scope of any collaboration arrangements (such as developments involving Merck Serono and the Option, including a decision by Merck Serono to exercise or not exercise the Option) or any disputes or developments regarding such collaborations;
- announcements of technological innovations, new commercial products or other material events by our competitors or us;
- disputes or other developments concerning our proprietary rights;
- changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;
- additions or departures of key personnel;
- discussions of our business, products, financial performance, prospects or stock price by the financial and scientific press and online investor communities;
- public concern as to, and legislative action with respect to, the pricing and availability of prescription drugs or the safety of drugs and drug delivery techniques;
- regulatory developments in the United States and in foreign countries; or
- dilutive effects of sales of shares of common stock by us or our shareholders, and sales of common stock acquired upon exercise or conversion by the holders of warrants, options or convertible notes.

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

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

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

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

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

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

From March 5, 2014 through December 31, 2015, we generated gross and net proceeds including amortization of deferred financing costs of $1,397,902 and $1,335,001, respectively, on sales of an aggregate 254,308 shares of our common stock under our at-the-market facility. In April 2015, we raised $13,804,140 in gross proceeds, before expenses, through subscriptions for 3,137,305 units in a Rights Offering to holders of our common stock and holders of our outstanding Series L warrants who were entitled to participate. Each unit was composed of common stock and a Series M warrant to purchase additional common stock. The Rights Offering was completed on April 9, 2015. We issued an aggregate of 3,137,305 shares of common stock and Series M warrants to purchase a like number of shares. Net proceeds, after deduction of fees and expenses, including dealer-manager fees, were $12.1 million. On September 1, 2015, we entered into a Stock Purchase Agreement with certain purchasers party thereto pursuant to which we sold in tranche one of a private placement 113,636 shares of common stock for a per share purchase price of $4.40 and issued Series N warrants to purchase a like number of shares, for a total purchase price of $499,999. We also agreed to sell and the purchasers agreed to purchase an additional aggregate of $4.5 million of common stock in four additional tranches upon our achievement of certain milestones to further the clinical development of OPX-212. We also granted the purchasers certain registration rights with respect to the securities sold in the September 1, 2015 private placement transaction. This Stock Purchase Agreement was amended on March 14, 2016 to extend by six months the timeframes for achieving the milestones relating to funding under subsequent tranches and to extend by six months the expiration date for the Series N warrants issued to the purchasers.

Sales of additional shares of our common stock, as well as securities convertible into or exercisable for common stock, could result in substantial dilution to our shareholders and cause the market price of our common stock to decline. An aggregate of 6,982,909 shares of common stock were outstanding as of December 31, 2015. As of such date, another (i) 417,404 shares of common stock were issuable upon exercise of outstanding options and (ii) 3,662,954 shares of common stock were issuable upon the exercise of outstanding warrants. A substantial majority of the outstanding shares of our common stock and warrants (as well as a substantial majority of the shares of common stock issuable upon exercise of outstanding options and warrants) are freely tradable without restriction or further registration under the Securities Act of 1933.

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

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

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

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

Our charter allows us to issue up to 150,000,000 shares of our common stock and to issue and designate the rights of, without shareholder approval, up to 10,000,000 shares of preferred stock. In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share paid by other investors, and dilution to our shareholders could result. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors, and investors purchasing shares or other securities in the future could have rights superior to existing shareholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by other investors.

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

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

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

In addition to general corporate purposes (including working capital, research and development, business development and operational purposes), we currently intend to use our available cash (i) to continue funding the ongoing Abili-T clinical study of Tcelna in patients with SPMS, and (ii) to continue preclinical and manufacturing activities for OPX-212 in patients with NMO, and if such activities are successful, to file an IND application with the FDA to initiate a Phase 1/2 proof-of-concept study. We reached our enrollment target for the Abili-T trial in June 2014, and a total of 190 patients have been enrolled in this two-year study. We expect top-line data for Tcelna to be available early in the fourth quarter of 2016. While we believe we have sufficient resources to complete the trial and support our operations during the pendency of the trial, if our projections prove to be inaccurate or we encounter additional costs to complete the trial or to sustain our operations, we may need to raise additional capital or modify either the Abili-T clinical study, our development of OPX-212 in NMO, or other aspects of our current business plan.

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

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

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

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

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

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

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

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

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

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

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

Item 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 2020 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. [Note: we implemented a one-for-eight reverse split of our common stock on September 28, 2015, and all sales prices in the table below have been adjusted to reflect the reverse split.]

	Price Ranges	
	High	Low
Fiscal Year Ended December 31, 2014		
First Quarter	$ 17.60	$ 13.12
Second Quarter	15.44	10.08
Third Quarter	13.68	6.80
Fourth Quarter	8.56	5.60
Fiscal Year Ended December 31, 2015		
First Quarter	$ 8.64	$ 4.24
Second Quarter	5.84	2.64
Third Quarter	4.24	2.33
Fourth Quarter	5.10	2.75

As of March 10, 2016, there were approximately 216 registered holders 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, 2015, 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	417,404	$ 18.04	60,810
Equity Compensation Plans Not Approved by Stockholders	—	—	—
Total	417,404	$ 18.04	60,810

Refer to Note 11 "Options and Warrants" in the Notes to our financial statements for the fiscal year ended December 31, 2015, included elsewhere in the annual report for a description of our 2010 Stock Incentive Plan and 2004 Compensatory Stock Option Plan.

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

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

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

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

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

Stock-Based Compensation. On January 1, 2006, we adopted the provisions of FASB ASC 718 which establishes accounting for equity instruments exchanged for employee service. We utilize the Black-Scholes option pricing model to estimate the fair value of employee stock based compensation at the date of grant, which requires the input of highly subjective assumptions, including expected volatility and expected life. Changes in these inputs and assumptions can materially affect the measure of estimated fair value of our share-based compensation. These assumptions are subjective and generally require significant analysis and judgment to develop. When estimating fair value, some of the assumptions will be based on, or determined from, external data and other assumptions may be derived from our historical experience with stock-based payment arrangements. The appropriate weight to place on historical experience is a matter of judgment, based on relevant facts and circumstances.

We estimated volatility by considering historical stock volatility. We have opted to use the simplified method for estimating 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, 2015 with the Year Ended December 31, 2014

Net Sales. Revenues related to the $5 million upfront payment from Merck Serono in connection with the Merck Serono Agreement and the $3 million payment from Merck Serono in connection with the Merck Serono Amendment (see Revenue Recognition) was $2,556,329 for the year ended December 31, 2015, compared to $1,271,895 for the year ended December 31, 2014. We recorded no commercial revenues for the years ended December 31, 2015 and December 31, 2014. The increase in 2015 is primarily due to the revenue recognized in relation to the $3 million payment made in March 2015 upon execution of the Merck Serono Amendment.

Research and Development Expenses. Research and development expenses were $10,039,496 for the year ended December 31, 2015, compared to $12,118,629 for the year ended December 31, 2014. The decrease in expenses were primarily due to decreases in the need for supplies used both in our research and clinical trial product manufacturing operations and decreased clinical investigator costs associated with a decreased number 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 $4,258,147 for the year ended December 31, 2015, compared to $3,833,370 for the year ended December 31, 2014. The increase in expense is due to an increase in staff compensation expenses, higher professional service fees and higher insurance premiums. These increases were partially offset by lower stock option expenses.

Depreciation and Amortization Expenses. Depreciation and amortization expenses were $351,403 for the year ended December 31, 2015, compared to $387,779 for the year ended December 31, 2014. The decrease in depreciation is mainly due to laboratory equipment, software and leasehold improvements becoming fully depreciated. There were also fewer fixed asset additions in 2015 compared to the previous year.

Interest Expense. Interest expense was $2,315 for the year ended December 31, 2015, compared to $1,983 for the year ended December 31, 2014. Interest expense is primarily related to the financing of insurance premiums.

Interest Income. Interest income was $8,226 for the year ended December 31, 2015, compared to $15,456 for the year ended December 31, 2014, and related to the cash balances in our savings facility.

Net Loss. We had a net loss for the year ended December 31, 2015 of $12,019,278, or $2.05 per share (basic and diluted), compared with a net loss of $15,052,263, or $4.33 per share (basic and diluted), for the year ended December 31, 2014.

Liquidity and Capital Resources

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of December 31, 2015, we had cash and cash equivalents of approximately $12.6 million. Our operating cash burn rate during the 12 months ended December 31, 2015 was approximately $1.1 million per month.

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

We believe that we have sufficient liquidity to support our current clinical activities for the Abili-T trial of Tcelna in SPMS, to continue planned preclinical development and manufacturing activities for OPX-212 in NMO, and for general operations to sustain the Company and support such activities into the first quarter of 2017. We expect top-line data for the Abili-T trial to be available early in the fourth quarter of 2016, and thus believe we have sufficient resources to complete the trial. However, if our projections prove to be inaccurate, or if we encounter additional costs to complete the trial or to sustain our operations, or if we incur other costs such as those associated with pursuing additional disease indications for our T-cell technology or pursuing clinical development of OPX-212 in NMO following an IND filing in the absence of funding under the Stock Purchase Agreement entered into on September 1, 2015 described below, we would need to raise additional capital to complete the Abili-T trial.

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

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

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

While the additional proceeds anticipated to be received from the sale of the additional securities under the September 1, 2015 Stock Purchase Agreement, as amended, are anticipated to provide sufficient funding for a potential Phase 1/2 proof of concept study, assuming an IND is filed with and accepted by the FDA and that the applicable milestones under the Stock Purchase Agreement are achieved and/or such funding is otherwise available, such amounts would not be sufficient to pay our general operations during the pendency of such proof of concept study. Depending upon the specific timing for any such study, we may need to secure additional resources to support our operations during the course of such study. We may also need to secure additional resources to pay for the costs of any such study if we are unable to obtain funding under the Stock Purchase Agreement, as amended, including as a result of failing to meet the associated milestones.

On September 6, 2012, we entered into a Sales Agreement with Brinson Patrick Securities Corporation as sales agent, which was subsequently amended March 5, 2014 and assumed by Meyers Associates, L.P. (doing business at the time as Brinson Patrick, a division of Meyers Associates, L.P.), pursuant to which we can offer and sell shares of our common stock from time to time depending upon market demand, in transactions deemed to be an "at the market" offering. Brinson Patrick is now a division of IFS Securities, Inc. We previously registered up to 312,500 shares for potential sale under the ATM facility, and 58,191 registered shares remain available for future sale. From March 5, 2014 through December 31, 2015, we generated gross and net proceeds including amortization of deferred financing costs of $1,397,902 and $1,335,001, respectively, on sales of an aggregate 254,308 shares of our common stock at average prices ranging from $3.20 to $13.47 per share. We will need to keep current our shelf registration statement and the offering prospectus relating to the ATM facility in order to use the program to sell shares of common stock in the future.

Given our need for additional amounts of capital to support our current business plan, we intend to continue to explore potential opportunities and alternatives to obtain additional resources, including one or more additional financing transactions. There can be no assurance that any such financings or potential opportunities and alternatives can be consummated on acceptable terms, if at all.

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

If Merck Serono does not exercise the Option and acquire the exclusive, worldwide (excluding Japan) license of our Tcelna program for MS, or if we are not successful in attracting another partner and entering into a collaboration on acceptable terms, we may not be able to complete development of or commercialize any product candidate, including Tcelna. In particular, we may be unable to undertake, or complete, any Phase III clinical study of Tcelna in SPMS, assuming the results of the Abili-T Phase IIb study warrant such a further study. In such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered and we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations.

We do not maintain any external lines of credit or have any sources of debt or equity capital committed for funding, other than our at-the-market program and the September 1, 2015 Stock Purchase Agreement, as amended, which may result in our sale of an additional $4.5 million in shares of common stock, subject to achievement of certain milestones to further the clinical development of OPX-212. Should we need any additional capital in the future beyond these sources, management will be reliant upon "best efforts" debt or equity financings. As our prospects for funding, if any, develop during the fiscal year, we will assess our business plan and make adjustments accordingly. Although we have successfully funded our operations to date by attracting additional investors in our equity and debt securities, there is no assurance that our capital raising efforts will be able to attract additional necessary capital for our operations in the future.

Off-Balance Sheet Arrangements

None.

Inflation

We believe that inflation has not had a material impact on our results of operations for the two years ended December 31, 2015 and 2014, since inflation rates have generally remained at relatively low levels and our operations are not otherwise uniquely affected by inflation concerns.

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 Acting 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 Acting Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2015 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 Acting 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, 2015 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 current executive officers are as follows:

Name	Age	Position
Neil K. Warma	53	President, Chief Executive Officer, Acting Chief Financial Officer and Director
Don Healey, Ph.D.	54	Chief Scientific Officer
Donna R. Rill	62	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.

Don Healey, Ph.D has served as our Chief Scientific Officer since April 2013. Dr. Healey has over 25 years of experience in cellular immunology and immune regulation in both academic and biotech environments. Prior to joining Opexa in April 2010, Dr. Healey was Director of Immunology for Argos Therapeutics from 2003 to 2010, and was responsible for the development of novel autologous dendritic cell therapies for the treatment of renal carcinoma and HIV. Dr Healey was Group Leader for Immunotherapy for ML Laboratories, UK (formerly Cobra Biotherapeutics) from 2001 to 2003, where he developed autologous dendritic cell therapies for the treatment of Melanoma. Dr. Healey was a member of Council of the British Society for Immunology from 1996 to 1998. He is a former lecturer in immunology at the University of Leicester, UK, and held post-doctoral positions in the Department of Pathology, Cambridge University, UK, conducting studies on immunoregulation in animal models of autoimmunity, including Type I Diabetes and Multiple Sclerosis. Dr. Healey obtained his Ph.D. at the Hunterian Institute in London, UK, and BSc in the Department of Pathology, Bristol University, UK.

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, M.D.	61	Director
Gail J. Maderis	58	Director
Michael S. Richman	54	Director
Scott B. Seaman	60	Director
Neil K. Warma	53	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 boards of: ArQule, Inc., a Boston-based, NASDAQ-listed biotech company; Vigilant Biosciences, Inc., a private medical device company; Veeva Systems Inc., a cloud based software company focusing on the life sciences industry; 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 the President and Chief Executive Officer of Antiva Biosciences, Inc. since July 2015. Formerly, Ms. Maderis 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, from October 2009 to March 2015, and also served on BayBio's board from 2004 to March 2015. 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 NextCure, Inc. since December 2015. Mr. Richman served as president and chief executive officer of Amplimmune, Inc. from July 2008 to July 2015. 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, (iv) 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, and (v) 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. 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 Audit Committee of the Board currently consists of Messrs. Seaman (chair) and Barabe and Ms. Maderis, each of whom is an independent, non-employee director. 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 reports to be filed with the SEC, and oversees management's identification, evaluation, and mitigation of major risks to Opexa. The Audit Committee operates pursuant to a written charter. During the last fiscal year, the Audit Committee held four meetings.

All of the members of the Audit Committee are non-employee directors who: (1) met the criteria for independence as required by NASDAQ listing standards and as set forth in Rule 10A-3(b)(1) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"); (2) did not participate in preparation of our financial statements during the past three years; and (3) are able to read and understand fundamental financial statements, including a balance sheet, income statement, and cash flow statement. The Board has determined that Messrs. Seaman and Barabe and Ms. Maderis each, individually, 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, 2015.

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, 2015. 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.

2015 Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards(1)	Options Awards(2)	All Other Compensation	Total
Neil K. Warma	2015	$ 416,625	$ -	$ -	$ 92,112	$ 0	$ 508,737
President and Chief Executive Officer	2014	$ 406,464	$ 172,747	$ 94,181	$ 1,137,357	$ 0	$ 1,810,749
Don Healey, Ph.D. (3)	2015	$ 266,240	$ -	$ -	$ 46,056	$ 0	$ 312,296
Chief Scientific Officer							
Karthik Radhakrishnan (4)	2015	$ 271,250	-	$ -	$ 38,380	$ 0	$ 309,630
Chief Financial Officer	2014	$ 246,000	$ 71,033	$ 30,319	$ 232,417	$ 0	$ 579,769

(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. Healey was appointed as an executive officer on October 26, 2015.

(4) Mr. Radhakrishnan's employment terminated on March 2, 2016 as part of a restructuring initiative and reduction-in-force which occurred on that date.

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 $416,625 per annum. 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 781shares of our common stock to be issued if and when the closing bid price of our common stock equals or exceeds $128.00 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 our 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.

Don Healey. We entered into an employment agreement with Don Healey on March 4, 2010, pursuant to which Mr. Healey serves as our Chief Scientific Officer. Mr. Healey is currently compensated at the rate of $270,000 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. Healey receives 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. Mr. Healey's employment may be terminated at any time voluntarily by him or without cause (as defined in the agreement) by the Board. If his employment is terminated by the Board without cause, Mr. Healey will be entitled to receive a severance payment equal to six months of his base salary. The severance benefits are subject to Mr. Healey 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 Mr. Healey under the employment agreement is subject to applicable requirements of Section 409A of the Code and the related Treasury Regulations.

Karthik Radhakrishnan. Mr. Radhakrishnan was employed as our Chief Financial Officer from March 29, 2013 until his employment terminated on March 2, 2016 as part of a restructuring initiative and reduction-in-force which occurred on that date. Pursuant to the terms of his March 2013 offer letter, he will be entitled to receive severance payments equal to six months of his base salary and vesting for any unvested stock options will accelerate by six additional months. In addition, Mr. Radhakrishnan will have a period of 12 months following his termination of employment within which to exercise any vested options, as opposed to the three months otherwise available for terminating employees. The severance benefits are subject to Mr. Radhakrishnan executing and delivering a general release and waiver of claims in favor of the Company, not being in breach of the offer letter or the Company's proprietary information and inventions agreement, and not engaging in any activity which is competitive with the Company while receiving the severance benefits. Mr. Radhakrishnan's salary at the time of his termination was $275,000 per annum. The timing of any payments to Mr. Radhakrishnan is subject to applicable requirements of Section 409A of the Code and the related Treasury Regulations.

2015 Outstanding Equity Awards at Fiscal Year-End

The following table presents information regarding outstanding equity awards at December 31, 2015 for each of the Named Executive Officers.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date
Neil K. Warma	7,812	—	$ 32.32	06/16/18
	4,687	—	$ 7.04	01/16/19
	3,125	—	$ 65.60	11/30/19
	2,343	—	$ 49.92	01/04/21
	5,452	—	$ 30.40	01/06/22
	11,919	77(1)	$ 30.40	01/06/22
	5,452	—	$ 30.40	01/06/22
	6,250	—	$ 15.04	11/08/23
	17,294	22,237(2)	$ 14.56	02/28/24
	—	39,531(3)	$ 14.56	02/28/24
	—	15,000(2)	$ 6.56	03/02/25
Don Healey, Ph.D.	937	—	$ 72.00	04/30/20
	937	—	$ 49.92	01/04/21
	1,308	—	$ 30.40	01/06/22
	2,600	17(1)	$ 30.40	01/06/22
	1,199	—	$ 30.40	01/06/22
	2,084	416(4)	$ 14.00	04/29/23
	3,533	4,545(2)	$ 14.56	02/28/24
	—	8,078(3)	$ 14.56	02/28/24
	—	7,500(2)	$ 6.56	03/02/25
Karthik Radhakrishnan (5)	14,323	1,302(4)	$ 18.72	03/29/23
	3,533	4,545(2)	$ 14.566	02/28/24
	—	8,078(3)	$ 14.56	02/28/24
	—	6,250(2)	$ 6.56	03/02/25

(1) The performance-based options began vesting quarterly over a three year-period upon achievement of certain key milestone events. 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.

(2) 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.

(3) 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 it's designated study endpoints.

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

(5) As a result of his employment termination on March 2, 2016, vesting for any unvested stock options will accelerate by six additional months. In addition, Mr. Radhakrishnan will have a period of 12 months following his termination of employment within which to exercise any vested options, as opposed to the three months otherwise available for terminating employees.

2015 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, 2015.

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

(1) In lieu of $15,000 cash, Messrs. Barabe and Richman and Ms. Maderis elected to receive 4,459 shares of restricted common stock, of which 852 shares vested on March 31, 2015, 1,053 shares vested on June 30, 2015, 1,200 shares vested on September 30, 2015, and 1,354 shares vested on December 31, 2015.

(2) In lieu of $15,000 cash, Mr. Seaman elected to receive an option to purchase 4,463 shares of common stock on March 30, 2015 at an exercise price of $4.24 per share, with 25% vesting on each of March 31, 2015, June 30, 2015, September 30, 2015 and December 31, 2015.

(3) 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 11 to our financial statements included in our annual report on Form 10-K for assumptions underlying the valuation of equity awards.

(4) The aggregate number of shares underlying outstanding option awards as of December 31, 2015 was: Mr. Barabe, 14,050 shares; Dr. Hartung, 14,856 shares; Ms. Maderis, 19,301 shares; Mr. Richman, 23,005 shares; and Mr. Seaman, 28,806 shares

(5) As compensation for Board services, our non-employee directors were issued the following two options on March 30, 2015 to purchase shares of common stock at an exercise price of $4.24 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 8,926 shares, with 50% vesting immediately upon grant and the remaining 50% vesting on December 31, 2015; and (ii) an option, with a term of ten years, to purchase 2,975 shares, with 50% vesting immediately upon grant and the remaining 50% vesting on March 30, 2016.

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 29, 2016, 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 29, 2016, there were 6,982,909 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]	264,296[3]	3.71%
Neil K. Warma	94,143[4]	1.33%
Karthik Radhakrishnan	43,058[5]	*
Don Healey, Ph.D.	19,457[6]	*
Michael S. Richman	30,555[7]	*
Gail J. Maderis	26,851[8]	*
Timothy Barabe	24,509[9]	*
Hans-Peter Hartung, M.D.	14,856[10]	*
All directors and current executive officers as a group (8 persons)	498,696[11]	6.84%

* Less than 1%

(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) 129,676 shares of common stock held by Ventures; (ii) 21,972 shares of common stock underlying Series I warrants held by Ventures; (iii) 2,868 shares of common stock underlying Series K warrants held by Ventures; (iv) 64,838 shares of common stock underlying Series M warrants held by Ventures; (v) 10,625 shares of common stock held by Mr. Seaman; and (vi) 5,510 shares of common stock underlying Series M warrants; (vii) 28,806 shares of common stock underlying currently exercisable stock options held by Mr. Seaman.

(4) Consisting of: (i) 18,110 shares of common stock; (ii) 659 shares of common stock underlying Series I Warrants; (iii) 86 shares of common stock underlying Series K Warrants; (iv) 4,656 shares of common stock underlying Series M warrants; and (v) 70,632 shares of common stock underlying currently exercisable stock options.

(5) Consisting of: (i) 15,582 shares of common stock; (ii) 6,250 shares of common stock underlying Series M warrants; and (iii) 21,226 shares of common stock underlying currently exercisable stock options. Mr. Radhakrishnan's employment terminated on March 2, 2016 as part of a restructuring initiative and reduction-in-force which occurred on that date.

(6) Consisting of: (i) 4,045 shares of common stock; and (ii) 15,412 shares of common stock underlying currently exercisable stock options.

(7) Consisting of: (i) 6,520 shares of common stock; (ii) 1,030 shares of common stock underlying Series M warrants; and (iii) 23,005 shares of common stock underlying currently exercisable stock options.

(8) Consisting of: (i) 6,520 shares of common stock; (ii) 1,030 shares of common stock underlying Series M warrants; and (iii) 19,301 shares of common stock underlying currently exercisable stock options.

(9) Consisting of: (i) 8,459 shares of common stock; (ii) 2,000 shares of common stock underlying Series M warrants; and (iii) 14,050 shares of common stock underlying currently exercisable stock options.

(10) Consisting of: 14,856 shares of common stock underlying currently exercisable stock options.

(11) Consisting of: 188,049 shares of common stock; (ii) 104,650 shares of common stock underlying warrants; and (iii) 205,996 shares of common stock underlying stock options. Includes only current directors and executive officers serving in such capacity on the date of this report.

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

Transactions with Related Persons

Since January 1, 2015, 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,	
	2015	2014
Audit fees(1)(2)(3)	$ 65,000	$ 75,000
Tax fees	—	—
All other fees(4)	31,500	16,500
	$ 96,500	$ 91,500

(1) Audit fees include professional services rendered for (i) the audit of our annual financial statements for the fiscal years ended December 31, 2015 and 2014, and (ii) the reviews of the financial statements included in our quarterly reports on Form 10-Q for such years.
(2) Audit fees paid in 2015 include $20,000 for the 2014 fiscal year audit.
(3) Audit fees paid in 2014 include $30,000 for the 2013 fiscal year audit.
(4) We have not engaged MaloneBailey, LLP for any consulting services. "All other fees" reflect payments to provide consent for financing activities such as registration statements on Forms S-1, S-3 and S-8 filings.

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

INDEX TO FINANCIAL STATEMENTS

Audited Financial Statements for years ended December 31, 2015 and December 31, 2014

2. Financial Statement Schedules

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

3. List of Exhibits

See the Exhibit Index immediately preceding the exhibits filed with this Annual Report on Form 10-K.

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
Date: March 15, 2016

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, Acting Chief Financial Officer and Director *(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)*	March 15, 2016
/s/Timothy Barabe Timothy Barabe	Director	March 15, 2016
/s/Hans-Peter Hartung Hans-Peter Hartung	Director	March 15, 2016
/s/Gail J. Maderis Gail J. Maderis	Director	March 15, 2016
/s/Michael S. Richman Michael S. Richman	Director	March 15, 2016
/s/Scott B. Seaman Scott B. Seaman	Director	March 15, 2016

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, 2015 and 2014 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, 2015 and 2014 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
March 15, 2016

OPEXA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
As of December 31, 2015 and 2014

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 12,583,764	$ 9,906,373
Other current assets	995,067	758,943
Total current assets	13,578,831	10,665,316
Property & equipment, net of accumulated depreciation of $2,443,600 and $2,099,389, respectively	837,867	1,098,104
Other long term assets	—	38,939
Total assets	$ 14,416,698	$ 11,802,359
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 739,850	$ 702,494
Accrued expenses	1,008,077	1,049,513
Deferred revenue	2,905,165	1,230,746
Notes payable – Insurance	148,344	149,671
Total current liabilities	4,801,436	3,132,424
Long term liability:		
Deferred revenue	—	1,230,748
Total liabilities	$ 4,801,436	$ 4,363,172
Stockholders' equity:		
Preferred stock, no par value, 10,000,000 shares authorized, none issued and outstanding	—	—
Common stock, $0.01 par value, 150,000,000 shares authorized, 6,982,909 and 3,529,344 shares issued and outstanding	69,829	35,293
Additional paid in capital	162,884,919	148,724,102
Accumulated deficit	(153,339,486)	(141,320,208)
Total stockholders' equity	9,615,262	7,439,187
Total liabilities and stockholders' equity	$ 14,416,698	$ 11,802,359

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

OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
Years ended December 31, 2015 and 2014

	2015	2014
Revenue:		
Option revenue	$ 2,556,329	$ 1,271,895
Research and development	10,039,496	12,118,629
General and administrative	4,258,147	3,833,370
Depreciation and amortization	351,403	387,779
Loss on disposal of fixed assets	1,167	—
Operating loss	(12,093,884)	(15,067,883)
Interest income, net	5,911	13,473
Other income and expense, net	68,695	2,147
Net loss	$ (12,019,278)	$ (15,052,263)
Basic and diluted loss per share	$ (2.05)	$ (4.33)
Weighted average shares outstanding	5,854,438	3,477,628

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, 2015 and 2014

	Common Stock		Additional Paid in	Accumulated	
	Shares	Par	Capital	Deficit	Total
Balances at December 31, 2013	3,443,257	$ 34,433	$ 146,810,786	$ (126,267,945)	$ 20,577,274
Shares issued for service	21,285	212	305,891	—	306,103
Shares sold for cash	64,802	648	647,527	—	648,175
Option expense	—	—	959,898	—	959,898
Net loss	—	—	—	(15,052,263)	(15,052,263)
Balances at December 31, 2014	3,529,344	$ 35,293	$ 148,724,102	$ (141,320,208)	$ 7,439,187
Shares issued for services	13,379	134	78,079	—	78,213
Cancellation of fractional shares	(1,365)	(13)	(5,015)	—	(5,028)
Shares sold for cash	3,440,448	34,404	13,247,631	—	13,282,035
Exercise of warrants	1,103	11	4,399	—	4,410
Option expense	—	—	835,723	—	835,723
Net loss	—	—	—	(12,019,278)	(12,019,278)
Balances at December 31, 2015	6,982,909	$ 69,829	$ 162,884,919	$ (153,339,486)	$ 9,615,262

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

OPEXA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2015 and 2014

	2015	2014
Cash flows from operating activities		
Net loss	$ (12,019,278)	$ (15,052,263)
Adjustments to reconcile net loss to net cash used in operating activities		
Shares issued for services	78,213	306,103
Depreciation	351,403	387,779
Option expense	835,723	959,898
Loss on disposal of equipment	1,167	—
Changes in:		
Other current assets	(87,780)	513,304
Accounts payable	37,356	6,339
Accrued expenses	(191,107)	(183,477)
Deferred revenue	443,671	138,727
Other long-term assets	38,939	(1,271,895)
Net cash used in operating activities	(10,511,693)	(14,195,485)
Cash flows from investing activities		
Purchase of property & equipment	(92,333)	(190,859)
Net cash used in investing activities	(92,333)	(190,859)
Cash flows from financing activities		
Common stock and warrants sold for cash, net of offering costs	13,282,035	648,175
Cash generated from exercise of warrants	4,410	—
Repurchase of fractional shares	(5,028)	—
Net cash provided by financing activities	13,281,417	648,175
Net change in cash and cash equivalents	2,677,391	(13,738,169)
Cash and cash equivalents at beginning of period	9,906,373	23,644,542
Cash and cash equivalents at end of period	$ 12,583,764	$ 9,906,373
Cash paid for:		
Income tax	$ —	$ —
Interest	$ 2,315	$ 1,983

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.

Reverse Stock Split. On September 28, 2015, Opexa effected a one-for-eight reverse stock split of its common stock (the "1:8 Reverse Stock Split") which decreased the number of common shares issued and outstanding from approximately 54.3 million shares to approximately 6.8 million shares. The number of authorized shares of common stock and preferred stock remained the same following the 1:8 Reverse Stock Split.

Unless otherwise noted, impacted amounts included in the consolidated financial statements and notes thereto have been retroactively adjusted for the stock splits as if such stock splits occurred on the first day of the first period presented. Impacted amounts include shares of common stock issued and outstanding, shares underlying warrants and stock options, shares reserved, exercise prices of warrants and options, and loss per share. There was no impact on the amount of preferred or common stock authorized resulting from the 1:8 Reverse Stock Split.

Principles of Consolidation. 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, 2015. 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, 2015, Opexa Hong Kong reported cash and cash equivalents of $9,999 in converted U.S. dollars and does not have any reported liabilities in the consolidated balance sheets.

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

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

Opexa received an upfront payment of $5 million for granting the option. 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 straight-line basis over the estimated option exercise period which coincides with the expected completion term of Opexa's current Phase IIb clinical trial for Tcelna in patients with SPMS. 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. No changes to estimates for the option exercise milestone were made in 2015. The expected completion term for revenue recognition is December 2016.

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

- Opexa will create a detailed Pre-Phase III Plan (including a GANTT chart containing key tasks, decision points, timing, budget and milestones) documenting all of the activities necessary for laboratory facilities both in the U.S. and Europe to reach operational readiness by the end of December 2016 (e.g., review and identification of a preferred contract manufacturing organization in Europe; set-up, identification and qualification of third parties for raw materials; validation of laboratory facilities in the U.S. and Europe; and a hiring plan for key personnel). For Europe, the Pre-Phase III Plan would address the creation of a dedicated lab to support a Phase III trial, and for the U.S., the Pre-Phase III Plan would address the expansion of existing capabilities and infrastructure for a Phase III trial. The Joint Steering Committee ("JSC") established pursuant to the Merck Serono Agreement will be responsible for reviewing, approving and ultimately overseeing Opexa's completion of the Pre-Phase III Plan, which approval may not be unreasonably withheld or delayed. The JSC will meet at least quarterly to advise and make specific recommendations with respect to the Pre-Phase III Plan. In the event the JSC has not approved the Pre-Phase III Plan prior to the end of the Option Period (as defined in the Merck Serono Agreement), the Option Period will be extended for 60 days following approval of the Pre-Phase III Plan by the JSC.

- Opexa will provide Merck Serono updates and analysis on a blinded basis, grouped in patient batches according to Opexa's analysis timetable, on the progress of Opexa's immune monitoring program (the "Program") being conducted in conjunction with Opexa's ongoing Abili-T clinical trial, with such updates and analysis to be shared with Merck Serono within 30 days of Opexa's initial assessment of such information. Opexa will inform Merck Serono of any existing or future external bioinformatics vendor used by Opexa for the Program, and Merck Serono will have the right, at its expense, to review current and future data storage and integrity measures for the on-going Abili-T clinical trial.

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

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 during 2014 and 2015 included 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 expenses 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. During 2015, a single custom reagent that will be used primarily for the NMO program and other Pre-Phase III activities is captured as custom reagents and reported under Other Current Assets due to its material cost and three-year shelf life. Upon consumption, the cost of this reagent will be amortized to research and development expenses in the consolidated statements of operations.

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. Any remaining deferred offering costs that exist upon the expiration of the equity offering (or ATM program) are written off to expense.

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 4 year period). Additionally, Opexa accounts for share-based awards to non-employees in accordance with FASB ASC 505, and such awards 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, 2015 and 2014 was $10,039,496 and $12,118,629, 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.

Reclassifications. Certain comparative amounts from prior periods have been reclassified to conform to the current year's presentation. These changes did not affect previously reported net loss.

NOTE 2—CASH AND CASH EQUIVALENTS

As of December 31, 2015, Opexa invested approximately $11.7 million in a savings account. For the year ended December 31, 2015, the savings account recognized an average market yield of 0.07%. Interest income of $8,203 from the savings account was recognized for the year ended December 31, 2015 in the consolidated statements of operations.

As of December 31, 2015 and 2014, 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, 2015 and 2014, the money market fund recognized an average market yield of 0.01%. Interest income of $3 was recognized for the year ended December 31, 2015 in the consolidated statements of operations.

NOTE 3—OTHER CURRENT ASSETS

Other current assets consisted of the following at December 31, 2015 and 2014:

Description	2015	2014
Custom reagents	$ 496,269	$ -
Deferred offering costs	28,876	259,989
Prepaid expenses	469,922	498,954
Total Other Current Assets	$ 995,067	$ 758,943

Custom reagents include a single custom reagent that will be used primarily for the NMO program and other Pre-Phase III research activities. Upon consumption, the cost of this reagent will be amortized to research and development expenses in the consolidated statements of operations.

Deferred offering costs at December 31, 2015 include $28,876 in costs incurred from third parties in connection with the renewal of the Company's shelf registration statement. Deferred offering costs at December 31, 2014 included $238,154 in costs incurred from third parties in connection with the implementation of a $1.5 million & $15 million purchase agreement in November 2012 pursuant to which Opexa had the right (now terminated) to sell to Lincoln Park Capital Fund, LLC ("Lincoln Park") shares of its common stock, subject to certain conditions and limitations. Deferred offering costs at December 31, 2014 also included unamortized costs of $21,835 incurred in establishment of the ATM sales agreement in 2013. These deferred offering costs from 2014 were expensed in 2015 in tandem with the use of the ATM facility and expiration of the respective stock purchase agreements. The unamortized portion of the ATM deferred offering cost was written off to expense with the expiration of the 2012 shelf registration statement.

Prepaid expenses at December 31, 2015 and 2014 also include costs incurred from third parties in connection with the Merck Serono Agreement (see Note 1). As of December 31, 2015, the remaining costs of $38,938 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. There are no remaining costs in connection with the Merck Serono Agreement that are expected to be amortized beyond the upcoming twelve month period. Also included in prepaid expenses is an advance to Pharmaceutical Research Associates, Inc. ("PRA"), a contract research organization providing services to Opexa, in the amount of $45,365 as well as $31,250 remaining from a prior payment to PRA of $75,000 upon execution of an amendment to Opexa's agreement with PRA. The remaining balance in prepaid expenses is attributable to various service and maintenance contracts.

NOTE 4—PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31, 2015 and 2014:

Description	Life	2015	2014
Computer equipment	3 years	$ 193,596	$ 168,209
Office furniture and equipment	5-7 years	247,679	247,679
Software	3 years	125,412	116,022
Laboratory equipment	7 years	1,120,693	1,100,559
Leasehold improvements	5 years	683,295	675,672
Manufacturing equipment	7 years	910,792	889,352
Subtotal		3,281,467	3,197,493
Less: accumulated depreciation		(2,443,600)	(2,099,389)
Property and equipment, net		$ 837,867	$ 1,098,104

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 seven 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 $351,403 and $387,779 for the years ended December 31, 2015 and 2014, respectively.

NOTE 5—OTHER LONG TERM ASSETS

Other long term assets include costs incurred from third parties in connection with the Merck Serono Agreement (see Note 1). At December 31, 2015 and December 31, 2014 the unamortized costs that are expected to be amortized beyond the upcoming twelve month period amounted to $0 and $38,939, respectively.

NOTE 6—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, 2015 and 2014, 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, 2015 and 2014, capitalized R&D amounted to $35.3 million and $25.9 million, respectively.

At December 31, 2015 and 2014, 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, 2015	December 31, 2014
Net Operating Loss	$ 24,806,175	$ 24,531,026
Research and development tax credits	2,593,792	1,778,030
Capitalized research and development costs	11,900,122	8,803,914
Subtotal	39,300,089	35,112,970
Less valuation allowance	(39,300,089)	(35,112,970)
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 7—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. In May 2015, we exercised the option for an additional five year lease. Rent expense in the consolidated statements of operations for the years ended December 31, 2015 and 2014 was approximately $153,000 and $136,000 respectively. The future minimum lease payments are:

Year	Amount
2016	$ 200,000
2017	200,000
2018	201,250
2019	206,250
2020	157,500
Total future minimum lease payments	$ 965,000

NOTE 8—SIGNIFICANT CONTRACTUAL SERVICE AND MILESTONE AGREEMENTS

In February 2012, Opexa entered into an agreement with PRA pursuant to which PRA provides 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, 2015 and 2014, which were charged to research and development expense on the consolidated statements of operations, amounted to $1,115,868 and $1,557,824, 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, 2015, 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 and conduct of preclinical activities.

NOTE 9—EQUITY

Summary information regarding equity related transactions for the years ended December 31, 2014 and December 31, 2015 is as follows:

During 2014, equity related transactions were as follows:

- On February 28, 2014, 13,700 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 $31,090 and $168,412 related to these shares for the year ended December 31, 2015 and 2014 respectively. The restricted shares issued to management vested 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 vested in four quarterly increments beginning on March 31, 2014.

- On March 19, 2014, 750 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 $2,123 and $9,877 related to these shares for the year ended December 31, 2015 and 2014 respectively. The restricted shares vested in three quarterly increments beginning on June 30, 2014.

- In the third quarter of 2014, Opexa settled sales of 64,801 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 facility.

- In the fourth quarter of 2014, Opexa issued 6,833 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.

During 2015, equity related transactions were as follows:

- In February 2015, Opexa recognized stock-based compensation expense of $33,213 related to vested shares of restricted common stock issued, on February 28, 2014, to certain members of Opexa's management and non-employee directors.

- On March 31, 2015, 2,557 shares of restricted common stock with an aggregate fair value of $11,250 were issued to certain non-employee directors for service on Opexa's Board. Opexa recognized stock-based compensation of $11,250 related to these shares. The shares vested immediately upon grant.

- On April 9, 2015, Opexa issued 3,137,305 shares of common stock and Series M warrants to purchase a like number of shares upon the closing of a rights offering. Opexa raised $13,804,140 in gross proceeds, before expenses, through subscriptions for 3,137,305 units at a price of $4.40 per unit. Net proceeds were $12,095,210 after deduction of related fees and expenses, including dealer-manager fees, totaling $ 1,708,930.

- In June 2015, Opexa issued 953 shares of common stock and received gross proceeds of $3,810 upon the exercise of Series M warrants to purchase 953 shares of common stock.

- On June 30, 2015, 3,160 shares of restricted common stock with an aggregate fair value of $11,250 were issued to certain non-employee directors for service on Opexa's Board. Opexa recognized stock-based compensation of $11,250 related to these shares. The shares vested immediately upon grant.

- July 2015, Opexa issued 150 shares of common stock and received gross proceeds of $600 upon the exercise of Series M warrants to purchase 150 shares of common stock.

- At Opexa's annual meeting on August 28, 2015, shareholders approved an amendment to the Company's Restated Certificate of Formation to increase the number of authorized shares of common stock from 100 million to 150 million, and the amendment was effect as of September 9, 2015.

- On September 1, 2015, Opexa sold 113,636 shares of common stock for $4.40 per share and issued Series N warrants to purchase a like number of shares for gross and net proceeds of $499,999 upon the closing of tranche one of a private placement. Opexa also agreed to sell and the purchasers agreed to purchase an additional aggregate of $4.5 million of common stock in four additional tranches upon Opexa's achievement of certain milestones to further the clinical development of OPX-212, Opexa's autologous T-cell immunotherapy being developed for the treatment of neuromyelitis optica.

- On September 28, 2015, Opexa effected the 1:8 Reverse Stock Split. An aggregate of 1,365 shares of common stock were identified as fractional shares, and cash in the amount of $5,028 was paid in lieu of these fractional shares. Unless otherwise noted, impacted amounts included in the consolidated financial statements and notes thereto have been retroactively adjusted for the stock splits as if such stock splits occurred on the first day of the first period presented. Impacted amounts include shares of common stock issued and outstanding, shares underlying warrants and stock options, shares reserved, exercise prices of warrants and options, and loss per share. There was no impact on the amount of preferred or common stock authorized resulting from the 1:8 Reverse Stock Split.

- On September 30, 2015, 3,600 shares of restricted common stock with an aggregate fair value of $11,250 were issued to certain non-employee directors for service on Opexa's Board. Opexa recognized stock-based compensation of $11,250 related to these shares. The shares vested immediately upon grant.

- On September 30, 2015 Opexa sold an aggregate of 75,000 shares of common stock under the ATM facility for gross and net proceed of $240,143 and $232,934, respectively. These sales settled and shares were issued in October 2015.

- In November 2015, Opexa sold an aggregate of 114,507 shares of common stock under the ATM facility for gross and net proceed of $483,634 and $469,116, respectively. These sales settled and shares were issued in December 2015.

- On December 31, 2015, 4,062 shares of restricted common stock with an aggregate fair value of $11,250 were issued to certain non-employee directors for service on Opexa's Board. Opexa recognized stock-based compensation of $11,250 related to these shares. The shares vested immediately upon grant.

NOTE 10—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 375,000 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 71,875 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 453,125 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 64,152 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.

Opexa accounts for stock-based compensation, including options and nonvested shares, according to the provisions of FASB ASC 718, "Share Based Payment." During the 12 months ended December 31, 2015, Opexa recognized stock-based compensation expense of $835,723. Unamortized stock-based compensation expense as of December 31, 2015 amounted to $1,897,092.

Stock Option Activity

A summary of the stock option activity for the years 2014 and 2015 are presented below:

	Number of Shares	Weighted Avg. Exercise Price	Weighted Average Remaining Contract Term (# years)	Intrinsic Value
Outstanding at December 31, 2013	145,233	$ 34.39		
Granted	175,417	14.27		
Exercised	-	-		
Forfeited and canceled	(17,816)	23.86		
Outstanding at December 31, 2014	302,834	$ 23.34	8.0	$ -
Exercisable at December 31, 2014	120,485	$ 36.52	6.4	$ -
Granted	135,430	5.22		
Exercised	-	-		
Forfeited and canceled	(20,860)	13.35		
Outstanding at December 31, 2015	417,404	$ 18.04	7.7	$ -
Exercisable at December 31, 2015	231,071	$ 23.58	7.0	$ -

Employee Options:

Option awards are granted with an exercise price equal to the market price of Opexa's stock at the date of issuance, generally have a ten-year life, and have various vesting dates that range from no vesting or partial vesting upon date of grant to full vesting on a specified date. Opexa estimates the fair value of stock options using the Black-Scholes option-pricing model and records the compensation expense ratably over the service period.

During 2014, performance-based options to purchase an aggregate of 63,765 shares at an exercise price of $14.56 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 96,609 shares were granted to employees, at exercise prices ranging from $6.88 to $14.56. 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 13,110 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.

During 2015, time-based options to purchase an aggregate of 71,462 shares at exercise prices ranging from $3.04 to $6.56 were granted to employees. These options have a term of ten years and have a vesting schedule of the earlier of four years or termination of employment without cause following a change of control. Fair value of $406,713 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 1.95% to 2.19%, (2) expected term of 6.25 years, (3) expected volatility range of 134.18% to 144.83% and (4) zero expected dividends.

During 2015, options to purchase 20,860 shares were forfeited and cancelled.

Opexa recognized stock based compensation expense of $623,040 for grants made to employees during 2015. Unamortized stock compensation expense as of December 31, 2015 amounted to $1,890,846.

Non-Employee Options:

During 2014, options to purchase an aggregate of 15,055 shares were granted to directors for service on Opexa's Board at an exercise price ranging from $14.56 to $16.00. Options to purchase an aggregate of 3,286 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 9,857 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 1,106 shares has a term of 10 years, with quarterly vesting ending on December 31, 2014. An option to purchase the remaining 806 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 4,718 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.

During 2015, options to purchase an aggregate of 63,968 shares at an exercise price of $4.24 were granted to non-employee directors for service on Opexa's Board. Options to purchase an aggregate of 44,630 shares will expire on the earlier of 10 years or a change in control of Opexa, with 50% of the shares vesting immediately and 50% vesting on December 31, 2015. Options to purchase an aggregate of 14,875 shares have terms of 10 years, with 50% of the shares vesting immediately and 50% vesting on March 30, 2016. An option to purchase 4,463 shares will expire on the earlier of 10 years or a change in control of Opexa, with vesting in four quarterly increments beginning on June 30, 2015. Fair value of $214,844 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 1.95%, (2) expected term of 5.25 years, (3) expected volatility of 107.33% and (4) zero expected dividends.

Opexa recognized stock based compensation expense of $212,683 for grants made to non-employee directors during 2015. Unamortized stock compensation expense as of December 31, 2015 amounted to $6,246.

Warrant Activity

A summary of warrant activity for 2015 and 2014 is presented below:

	Number of Shares	Weighted Avg. Exercise Price	Weighted Average Remaining Contract Term (# years)	Intrinsic Value
Outstanding at January 1, 2014	383,603	$ 32.96	2.46	-
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited and canceled	(2,789)	80.00	-	-
Outstanding at December 31, 2014	380,814	29.92	2.21	-
Exercisable at December 31, 2014	380,814	29.92	2.21	-
Outstanding at January 1, 2015	380,814	$ 29.92	2.21	-
Granted	3,311,128	4.16	-	-
Exercised	(1,103)	4.00	-	-
Forfeited and canceled	(27,885)	74.96	-	-
Outstanding at December 31, 2015	3,662,954	6.30	2.17	-
Exercisable at December 31, 2015	3,662,954	6.30	2.17	-

On April 9, 2015, the Company issued Series M warrants to purchase an aggregate of 3,137,305 shares of common stock upon the closing of a rights offering. The Series M warrants entitle the holders to purchase common stock at an exercise price of (i) $4.00 per share from the date of issuance (April 9, 2015) through June 30, 2016 and (ii) $12.00 per share from July 1, 2016 through their expiration on April 9, 2018. Pursuant to the anti-dilution provisions of certain of the Company's outstanding warrants and as a result of the rights offering (i) the per share exercise prices of the Series A, J, K and L warrants were adjusted to $74.96, $8.24, $8.00 and $12.72, respectively, and (ii) Series L warrants to purchase an aggregate of an additional 60,187 shares of common stock were issued. The Series A warrants expired on June 15, 2015.

On September 1, 2015, the Company issued Series N warrants to purchase an aggregate of 113,636 shares of common stock at an exercise price of (i) $4.00 per share from the date of issuance through June 30, 2016 and (ii) $12.00 per share from July 1, 2016 through their original expiration on April 9, 2018.

NOTE 11—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.

NOTE 12—SUBSEQUENT EVENTS

On March 2, 2016, the Company announced implementation of a restructuring initiative which included a reduction of approximately 30% of its then full-time workforce of 36 employees in order to reduce operating expenses and conserve cash resources.

On March 14, 2016, the Company entered into an amendment to the September 1, 2015 Stock Purchase Agreement with the purchasers party thereto to extend by six months the original dates for the milestones relating to the subsequent tranches. As part of the amendment, the expiration date of the Series N warrants issued pursuant thereto was extended from April 9, 2018 to October 9, 2018.

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	Certificate of Amendment to the Restated Certificate of Formation of Opexa Therapeutics, Inc., effective as of September 9, 2015 (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed on November 10, 2015).
3.5	Certificate of Amendment to the Restated Certificate of Formation of Opexa Therapeutics, Inc., effective as of September 28, 2015 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on September 28, 2015).
3.6	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).
4.10	Form of Series M Warrant issued on April 9, 2015 (incorporated by reference to Exhibit 4.11 to the Company's Registration Statement on Form S-1, as amended (File No. 333-201731), originally filed on January 28, 2015).

4.11	Warrant Agreement, dated February 25, 2015, by and between Opexa Therapeutics, Inc. and Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2015).
4.12	Subscription Agent Agreement, dated February 25, 2015, by and between Opexa Therapeutics, Inc. and Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2015).
4.13*	Amended and Restated Series N Warrants issued on March 14, 2016.
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).
10.17	First Amendment of Option and License Agreement, dated March 9, 2015, by and between Opexa Therapeutics, Inc. and Ares Trading S.A. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 9, 2015).
10.18	First Amendment to Lease Agreement, dated May 11, 2015, by and between Opexa Therapeutics, Inc. and Dirk D. Laukien (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2015).
10.19	Form of restricted stock agreement for awards to be made under the Opexa Therapeutics, Inc. 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2015).
10.20	Stock Purchase Agreement by and between Opexa Therapeutics, Inc. and the purchasers party thereto, dated September 1, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 1, 2015).
10.21*	Amendment to Stock Purchase Agreement by and between Opexa Therapeutics, Inc. and the purchasers party thereto, dated March 14, 2016.
10.22+*	Offer Letter, dated March 2, 2010, by and between Opexa Therapeutics, Inc. and Don Healey.
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.
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Acting Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Acting Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Annual Report on Form 10-K of the Company as of and for the period ended December 31, 2015, 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 4.13

EXECUTION VERSION

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 AS AMENDED (THE "ACT"), OR ANY STATE SECURITIES LAWS. SUCH SECURITIES MAY NOT BE SOLD OR OTHERWISE TRANSFERRED EXCEPT AS PERMITTED UNDER THE ACT AND THE APPLICABLE STATE SECURITIES LAWS, PURSUANT TO REGISTRATION OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL (WHICH MAY BE COUNSEL FOR THE COMPANY) IN FORM AND SUBSTANCE REASONABLY SATISFACTORY TO THE ISSUER TO THE EFFECT THAT ANY PROPOSED TRANSFER OR RESALE IS IN COMPLIANCE WITH THE ACT.

N-3 March 14, 2016

Note: This Amended and Restated Warrant supersedes and replaces in its entirety that certain Warrant N-1 issued on September 1, 2015. The only changes intended by this Amended and Restated Warrant, as compared with Warrant N-1, are (i) an extension of the reference date for the definition of the Expiration Date (as defined below) from April 9, 2018 to October 9, 2018, and (ii) modification of the amount of the Warrant Price (as defined below) and the amount of the Warrant Shares (as defined below) to reflect a 1-for-8 reverse split of the Common Stock (as defined below) which was effective as of September 28, 2015.

OPEXA THERAPEUTICS, INC.

AMENDED AND RESTATED WARRANT TO PURCHASE SHARES

OF COMMON STOCK, PAR VALUE $0.01 PER SHARE

For VALUE RECEIVED, William R. Guthy Separate Property Trust ("***Warrantholder***") is entitled to purchase, subject to the provisions of this Amended and Restated Warrant (this "***Warrant***"), from Opexa Therapeutics, Inc., a Texas corporation ("***Company***"), at any time after the date hereof (the "***Initial Exercise Date***") and not later than 5:00 P.M., Central time, on the Expiration Date (as defined below), at an exercise price per share equal to (i) Four Dollars ($4.00) if this Warrant is exercised on or before June 30, 2016, or (ii) Twelve Dollars ($12.00) if this Warrant is exercised after June 30, 2016 (the applicable exercise price in effect being herein called the "***Warrant Price***"), Fifty-Six Thousand Eight Hundred Eighteen (56,818) shares ("***Warrant Shares***") of the Company's Common Stock, par value $0.01 per share ("***Common Stock***"). The number of Warrant Shares purchasable upon exercise of this Warrant and the Warrant Price shall be subject to adjustment from time to time as described herein. The "***Expiration Date***" shall mean October 9, 2018; provided, however, that upon a merger, consolidation, sale of substantially all assets or similar transaction involving the Company, at the option of the Company and upon at least ten (10) days prior written notice to Warrantholder, this Warrant must be exercised no later than immediately prior to the closing of any such transaction or it shall automatically expire upon such closing (in which event such closing shall be the Expiration Date). If not exercised on or before the Expiration Date, this Warrant shall become void.

1. Registration. The Company shall maintain books for the transfer and registration of the Warrant. Upon the initial issuance of this Warrant, the Company shall issue and register the Warrant in the name of the Warrantholder.

2. Transfers. This Warrant may be transferred only pursuant to a registration statement filed under the Securities Act of 1933, as amended (the "***Securities Act***"), or an exemption from such registration. Subject to such restrictions, the Company shall transfer this Warrant from time to time upon the books to be maintained by the Company for that purpose, upon surrender hereof for transfer, properly endorsed or accompanied by appropriate instructions for transfer and such other documents as may be reasonably required by the Company, including, if required by the Company, an opinion of counsel to the effect that such transfer is exempt from the registration requirements of the Securities Act, to establish that such transfer is being made in accordance with the terms hereof, and a new Warrant shall be issued to the transferee (who shall thereafter be the Warrantholder hereunder) and the surrendered Warrant shall be canceled by the Company.

3. Exercise of Warrant. The Warrantholder may exercise this Warrant, in whole or in part, at any time after the Initial Exercise Date and prior to 5:00 p.m. Central Time on the Expiration Date upon (i) written notice, in the form attached hereto as **APPENDIX A** (the "***Exercise Notice***"), of the Warrantholder's election to exercise this Warrant, and (ii) payment by cash, certified check or wire transfer of funds for the aggregate Warrant Price for that number of Warrant Shares then being purchased, to the Company during normal business hours on any business day at the Company's principal executive offices (or such other office or agency of the Company as it may designate by notice to the Warrantholder). The Warrant Shares so purchased shall be deemed to be issued to the Warrantholder or the Warrantholder's designee, as the record owner of such shares, as of the close of business on the date on which the Warrant Price shall have been paid and the completed Exercise Notice shall have been delivered. The Warrantholder shall not be required to deliver the original Warrant in order to effect an exercise hereunder. Certificates for the Warrant Shares so purchased shall be delivered to the Warrantholder within a reasonable time, not exceeding three (3) business days, after this Warrant shall have been so exercised. The certificates so delivered shall be in such denominations as may be requested by the Warrantholder and shall be registered in the name of the Warrantholder. If this Warrant shall have been exercised only in part, then, unless this Warrant has expired, the Company shall, at its expense, at the time of delivery of such certificates, deliver to the Warrantholder a new Warrant representing the right to purchase the number of shares with respect to which this Warrant shall not then have been exercised. As used herein, "business day" means a day, other than a Saturday or Sunday, on which banks in Houston, Texas are open for the general transaction of business. The Warrantholder's acceptance of this Warrant as well as each exercise hereof shall each constitute the affirmation by the Warrantholder that the representations and warranties contained in **APPENDIX B** attached hereto are true and correct in all material respects with respect to the Warrantholder as of the time of such acceptance and as of the time of each exercise. The Warrantholder shall promptly physically surrender this Warrant to the Company in the event the Warrant is exercised. The Warrantholder and the Company shall maintain records showing the amount exercised and the dates of such exercise. The Warrantholder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provision of this paragraph, following exercise of a portion of the Warrant, the number of Warrant Shares of this Warrant may be less than the amount stated on the face hereof.

4. Compliance with Securities Laws. This Warrant may only be exercised by the Warrantholder in accordance with applicable securities laws. The Company may cause the legend set forth on the first page of this Warrant to be set forth on each Warrant, and a similar legend on any security issued or issuable upon exercise of this Warrant, unless counsel for the Company is of the opinion as to any such security that such legend is unnecessary.

5. Payment of Taxes. The Company will pay any documentary stamp taxes attributable to the initial issuance of Warrant Shares issuable upon the exercise of the Warrant; provided, however, that the Company shall not be required to pay any tax or taxes which may be payable in respect of any transfer involved in the issuance or delivery of any certificates for Warrant Shares in a name other than that of the Warrantholder in respect of which such shares are issued, and in such case, the Company shall not be required to issue or deliver any certificate for Warrant Shares or any Warrant until the person requesting the same has paid to the Company the amount of such tax or has established to the Company's reasonable satisfaction that such tax has been paid. The Warrantholder shall be responsible for income taxes due under federal, state or other law, if any such tax is due.

6. Mutilated or Missing Warrants. In case this Warrant shall be mutilated, lost, stolen, or destroyed, the Company shall issue in exchange and substitution of and upon surrender and cancellation of the mutilated Warrant, or in lieu of and substitution for the Warrant lost, stolen or destroyed, a new Warrant of like tenor and for the purchase of a like number of Warrant Shares, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction of the Warrant, and with respect to a lost, stolen or destroyed Warrant, reasonable indemnity or bond with respect thereto, if requested by the Company.

7. Reservation of Common Stock. The Company represents and warrants that on the date hereof, it has duly authorized and reserved, and covenants that at any time when this Warrant is exercisable, the Company shall at all applicable times keep reserved until issued (if necessary) as contemplated by this Section 7, out of the authorized and unissued shares of Common Stock, at least a number of shares of Common Stock as shall from time to time be necessary to effect the exercise of all of this Warrant then outstanding. The Company covenants that all Warrant Shares issued upon due exercise of the Warrant shall be, at the time of delivery of the certificates for such Warrant Shares, duly authorized, validly issued, fully paid and non-assessable shares of Common Stock of the Company.

8. Adjustments.

(a) If the Company shall, at any time or from time to time while this Warrant is outstanding, pay a dividend or make a distribution on its Common Stock in shares of Common Stock, subdivide its outstanding shares of Common Stock into a greater number of shares or combine its outstanding shares of Common Stock into a smaller number of shares, then (i) the Warrant Price in effect immediately prior to the date on which such change shall become effective shall be adjusted by multiplying such Warrant Price by a fraction, the numerator of which shall be the number of shares of Common Stock outstanding immediately prior to such change and the denominator of which shall be the number of shares of Common Stock outstanding immediately after giving effect to such change and (ii) the number of Warrant Shares purchasable upon exercise of this Warrant shall be adjusted by multiplying the number of Warrant Shares purchasable upon exercise of this Warrant immediately prior to the date on which such change shall become effective by a fraction, the numerator of which is shall be the Warrant Price in effect immediately prior to the date on which such change shall become effective and the denominator of which shall be the Warrant Price in effect immediately after giving effect to such change, calculated in accordance with clause (i) above. Such adjustments shall be made successively whenever any event listed above shall occur.

(b) Unless the Expiration Date occurs coincident therewith (as provided in the first paragraph of this Warrant): (i) if any capital reorganization, reclassification of the capital stock of the Company, consolidation or merger of the Company with another corporation in which the Company is not the survivor, or sale, transfer or other disposition of all or substantially all of the Company's assets to another corporation shall be effected, then, as a condition of such reorganization, reclassification, consolidation, merger, sale, transfer or other disposition, lawful and adequate provision shall be made whereby each Warrantholder shall thereafter have the right to purchase and receive upon the basis and upon the terms and conditions herein specified and in lieu of the Warrant Shares immediately theretofore issuable upon exercise of the Warrant, such shares of stock, securities or assets as would have been issuable or payable with respect to or in exchange for a number of Warrant Shares equal to the number of Warrant Shares immediately theretofore issuable upon exercise of the Warrant, had such reorganization, reclassification, consolidation, merger, sale, transfer or other disposition not taken place, and in any such case appropriate provision shall be made with respect to the rights and interests of each Warrantholder to the end that the provisions hereof (including, without limitation, provision for adjustment of the Warrant Price) shall thereafter be applicable, as nearly equivalent as may be practicable in relation to any shares of stock, securities or assets thereafter deliverable upon the exercise hereof; and (ii) the Company shall not effect any such consolidation, merger, sale, transfer or other disposition unless prior to or simultaneously with the consummation thereof the successor corporation (if other than the Company) resulting from such consolidation or merger, or the corporation purchasing or otherwise acquiring such assets or other appropriate corporation or entity shall assume the obligation to deliver to the Warrantholder, at the last address of the Warrantholder appearing on the books of the Company, such shares of stock, securities or assets as, in accordance with the foregoing provisions, the Warrantholder may be entitled to purchase, and the other obligations under this Warrant. The provisions of this paragraph (b) shall similarly apply to successive reorganizations, reclassifications, consolidations, mergers, sales, transfers or other dispositions.

(c) In case the Company shall fix a payment date for the making of a distribution to all holders of Common Stock (including any such distribution made in connection with a consolidation or merger in which the Company is the continuing corporation) of evidences of indebtedness or assets (other than cash dividends or cash distributions payable out of consolidated earnings or earned surplus or dividends or distributions referred to in Section 8(a)), or subscription rights or warrants, the Warrant Price to be in effect after such payment date shall be determined by multiplying the Warrant Price in effect immediately prior to such payment date by a fraction, the numerator of which shall be the total number of shares of Common Stock outstanding multiplied by the Market Price (as defined below) per share of Common Stock immediately prior to such payment date, less the fair market value (as determined by the Company's Board of Directors (the "***Board of Directors***") in good faith) of said assets or evidences of indebtedness so distributed, or of such subscription rights or warrants, and the denominator of which shall be the total number of shares of Common Stock outstanding multiplied by such Market Price per share of Common Stock immediately prior to such payment date. "***Market Price***" of a share of Common Stock on any date shall mean, (i) if the shares of Common Stock are listed on the NASDAQ Stock Market, the official closing price reported on that date; (ii) if the shares of Common Stock are no longer listed on the NASDAQ Stock Market and are listed on any other national securities exchange, the last sale price of the Common Stock reported by such exchange on that date; (iii) if the shares of Common Stock are not listed on any such exchange and the shares of Common Stock are traded in the over-the-counter market, the last price reported on such day by the OTC Bulletin Board; (iv) if the shares of Common Stock are not listed on any such exchange or quoted on the OTC Bulletin Board, then the last price quoted on such day in the over-the-counter market as reported by the National Quotation Bureau Incorporated (or any similar organization or agency succeeding its functions of reporting prices); or (v) if none of clauses (i)-(iv) are applicable, then as determined in good faith by the Board of Directors.

(d) An adjustment to the Warrant Price shall become effective immediately after the payment date in the case of each dividend or distribution and immediately after the effective date of each other event which requires an adjustment.

(e) In the event that, as a result of an adjustment made pursuant to this Section 8, the Warrantholder shall become entitled to receive any shares of capital stock of the Company other than shares of Common Stock, the number of such other shares so receivable upon exercise of this Warrant shall be subject thereafter to adjustment from time to time in a manner and on terms as nearly equivalent as practicable to the provisions with respect to the Warrant Shares contained in this Warrant.

9. Fractional Interest. The Company shall not be required to issue fractions of Warrant Shares upon the exercise of this Warrant. If any fractional share of Common Stock would, except for the provisions of the first sentence of this Section 9, be deliverable upon such exercise, the Company, in lieu of delivering such fractional share, shall pay to the exercising Warrantholder an amount in cash equal to the fair market value of such fractional share of Common Stock on the date of exercise.

10. Benefits. Nothing in this Warrant shall be construed to give any person, firm or corporation (other than the Company and the Warrantholder) any legal or equitable right, remedy or claim, it being agreed that this Warrant shall be for the sole and exclusive benefit of the Company and the Warrantholder.

11. Notices to Warrantholder.

(a) Upon the happening of any event requiring an adjustment of the Warrant Price, the Company shall promptly give written notice thereof to the Warrantholder at the address appearing in the records of the Company, stating the adjusted Warrant Price and the adjusted number of Warrant Shares resulting from such event and setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based. Failure to give such notice to the Warrantholder or any defect therein shall not affect the legality or validity of the subject adjustment.

(b) The Company hereby covenants to the Warrantholder that, from the date hereof and for so long as this Warrant remains not fully exercised, it shall give written notice promptly to the Warrantholder upon the happening of any of the following events: (i) the admission in writing by the Company of its insolvency; (ii) the commission of any voluntary act of bankruptcy by the Company; (iii) the execution by the Company of a general assignment for the benefit of creditors; (iv) the filing by or against the Company of any petition in bankruptcy or any petition for relief under the provisions of the federal bankruptcy act or any other state or federal law for the relief of debtors and the continuation of such petition without dismissal for a period of sixty (60) days or more; (v) the appointment of a receiver or trustee to take possession of the property or assets of the Company; (vi) any dissolution of the Company; (vii) the adoption by the Company of any plan of liquidation; or (viii) the commencement against the Company of any case, proceeding or other action seeking issuance of a warrant of attachment, execution, distraint or similar process against all or any substantial part of its assets which results in the entry of an order for any such relief which shall not have been vacated, discharged, or stayed or bonded pending appeal within sixty (60) days from the entry thereof.

12. Identity of Transfer Agent. The Transfer Agent for the Common Stock is Continental Stock Transfer & Trust, 17 Battery Place, New York, New York 10004. Upon the appointment of any subsequent transfer agent for the Common Stock or other shares of the Company's capital stock issuable upon the exercise of the rights of purchase represented by the Warrant, the Company will mail to the Warrantholder a statement setting forth the name and address of such transfer agent.

13. Notices. Unless otherwise provided, any notice required or permitted under this Warrant shall be given in writing and shall be deemed effectively given and received as hereinafter described (i) if given by personal delivery, then such notice shall be deemed received upon such delivery, (ii) if given by facsimile, then such notice shall be deemed received upon receipt of confirmation of complete transmittal, (iii) if given by certified mail return receipt requested, then such notice shall be deemed received upon the day such return receipt is signed, and (iv) if given by an internationally recognized overnight air courier, then such notice shall be deemed given one business day after delivery to such carrier. Copies of such notices shall also be transmitted by email. All notices shall be addressed as follows: if to the Warrantholder, at the address as follows, or at such other address as the Warrantholder may designate by ten days' advance written notice to the Company:

William R. Guthy Separate Property Trust
Guthy-Renker LLC
1018 Pamela Drive
Beverly Hills, California 90210
Fax: (310) 581-3443
Email: BGuthy@guthy-renker.com

if to the Company, at the address as follows, or at such other address as the Company may designate by ten days' advance written notice to the Warrantholder:

Opexa Therapeutics, Inc.
2635 Technology Forest Blvd.
The Woodlands, Texas 77381
Attention: President
Fax: (281) 872-8585

14. Successors. All the covenants and provisions hereof by or for the benefit of the Warrantholder shall bind and inure to the benefit of its respective successors and permitted assigns hereunder.

15. Governing Law; Consent to Jurisdiction; Waiver of Jury Trial. This Warrant shall be governed by, and construed in accordance with, the internal laws of the State of Texas, without reference to the choice of law provisions thereof. The Company and, by accepting this Warrant, the Warrantholder, each irrevocably submits to the exclusive jurisdiction of the courts of the State of Texas located in Harris County and the United States District Court for the Southern District of Texas for the purpose of any suit, action, proceeding or judgment relating to or arising out of this Warrant and the transactions contemplated hereby. Service of process in connection with any such suit, action or proceeding may be served on each party hereto anywhere in the world by the same methods as are specified for the giving of notices under this Warrant. The Company and, by accepting this Warrant, the Warrantholder, each irrevocably waives any objection to the laying of venue of any such suit, action or proceeding brought in such courts and irrevocably waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. **EACH OF THE COMPANY AND, BY ITS ACCEPTANCE HEREOF, THE WARRANTHOLDER HEREBY WAIVES ANY RIGHT TO REQUEST A TRIAL BY JURY IN ANY LITIGATION WITH RESPECT TO THIS WARRANT AND REPRESENTS THAT COUNSEL HAS BEEN CONSULTED SPECIFICALLY AS TO THIS WAIVER.**

16. No Rights as Shareholder. Prior to the exercise of this Warrant, the Warrantholder shall not have or exercise any rights as a shareholder of the Company by virtue of its ownership of this Warrant.

17. Amendment; Waiver. Any term or provision of this Warrant may be amended or waived upon the written consent of the Company and the Warrantholder.

18. Remedies; Other Obligations; Breaches and Injunctive Relief. The remedies provided in this Warrant shall be cumulative and in addition to all other remedies available under this Warrant, at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the right of the Warrantholder right to pursue actual damages for any failure by the Company to comply with the terms of this Warrant. The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the Warrantholder and that the remedy at law for any such breach may be inadequate. The Company therefore agrees that, in the event of any such breach or threatened breach, the Warrantholder shall be entitled, in addition to all other available remedies, an injunction restraining any breach, without the necessity of showing economic loss and without any bond or other security being required.

19. Authorized Shares. The Company covenants that during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of executing stock certificates to execute and issue the necessary certificates for the Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the trading market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Warrantholder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Warrantholder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (a) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (b) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (c) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof as may be necessary to enable the Company to perform its obligations under this Warrant.

20. Section Headings. The section headings in this Warrant are for the convenience of the Company and the Warrantholder and in no way alter, modify, amend, limit or restrict the provisions hereof.

[signature page follows]

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed as of the date first written above.

OPEXA THERAPEUTICS, INC.

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

APPENDIX A

EXERCISE NOTICE
OPEXA THERAPEUTICS, INC.

The undersigned holder hereby exercises the right to purchase _____ of the shares of Common Stock ("***Warrant Shares***") of Opexa Therapeutics, Inc., a Texas corporation (the "***Company***"), evidenced by the attached Amended and Restated Warrant (the "***Warrant***"). Capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Warrant.

1. Payment of Warrant Price. The holder shall pay the aggregate Warrant Price in the sum of $_____ to the Company in accordance with the terms of the Warrant.

2. Delivery of Warrant Shares. The holder requests that the Company deliver the Warrant Shares in the name of the undersigned holder by physical delivery of a certificate to:

_____
_____
_____

Date: _____ __, 20____

_____
Name of Registered Holder

By: _____
Printed Name:_____
Title (if applicable): _____
Entity Name (if applicable):_____

APPENDIX B

Representations and Warranties

The Warrantholder represents and warrants to the Company that:

- Purchase Entirely for Own Account. The Warrant and the securities to be received by the Warrantholder pursuant to the Warrant (the "***Securities***") is being/will be acquired for the Warrantholder's own account, not as nominee or agent, and not with a view to the resale or distribution of any part thereof in violation of the Securities Act, and the Warrantholder has no present intention of selling, granting any participation in, or otherwise distributing the same in violation of the Securities Act without prejudice, however, to the Warrantholder's right at all times to sell or otherwise dispose of all or any part of the Securities in compliance with applicable federal and state securities laws.

- Investment Experience. The Warrantholder acknowledges that it can bear the economic risk and complete loss of its investment in the Securities and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of an investment in the Securities.

- Disclosure of Information. The Warrantholder has had an opportunity to receive all information related to the Company requested by it and to ask questions of and receive answers from the Company regarding the Company, its business and the terms and conditions of the Securities.

- Restricted Securities. The Warrantholder understands that the Securities are characterized as "***restricted securities***" under the U.S. federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances. The Warrantholder represents that it is familiar with Rule 144, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act. The Warrantholder acknowledges that the Securities have not been registered under the Securities Act or registration or qualified under any applicable blue sky laws in reliance, in part, on the representations and warranties herein.

- Legends. The Warrantholder understands that certificates evidencing the Securities may bear the following or any similar legend:

"THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 AS AMENDED (THE "*ACT*"), OR ANY STATE SECURITIES LAWS. SUCH SECURITIES MAY NOT BE SOLD OR OTHERWISE TRANSFERRED EXCEPT AS PERMITTED UNDER THE ACT AND THE APPLICABLE STATE SECURITIES LAWS, PURSUANT TO REGISTRATION OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL (WHICH MAY BE COUNSEL FOR THE COMPANY) IN FORM AND SUBSTANCE REASONABLY SATISFACTORY TO THE ISSUER TO THE EFFECT THAT ANY PROPOSED TRANSFER OR RESALE IS IN COMPLIANCE WITH THE ACT."

- If required by the authorities of any state in connection with the issuance or sale of the Securities, the legend required by such state authority.

- Accredited Investor. The Warrantholder is an accredited investor as defined in Rule 501(a) of Regulation D, as amended, under the Securities Act.

- No General Advertisement. The Warrantholder did not learn of the investment in the Securities as a result of any public solicitation or advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or similar media or broadcast over television, radio or internet or presented at any seminar or other general advertisement.

- Brokers and Finders. No person or entity will have any valid right, interest or claim against or upon the Company or the Warrantholder for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of the Warrantholder.

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 AS AMENDED (THE "ACT"), OR ANY STATE SECURITIES LAWS. SUCH SECURITIES MAY NOT BE SOLD OR OTHERWISE TRANSFERRED EXCEPT AS PERMITTED UNDER THE ACT AND THE APPLICABLE STATE SECURITIES LAWS, PURSUANT TO REGISTRATION OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL (WHICH MAY BE COUNSEL FOR THE COMPANY) IN FORM AND SUBSTANCE REASONABLY SATISFACTORY TO THE ISSUER TO THE EFFECT THAT ANY PROPOSED TRANSFER OR RESALE IS IN COMPLIANCE WITH THE ACT.

N-4 March 14, 2016

Note: This Amended and Restated Warrant supersedes and replaces in its entirety that certain Warrant N-2 issued on September 1, 2015. The only changes intended by this Amended and Restated Warrant, as compared with Warrant N-2, are (i) an extension of the reference date for the definition of the Expiration Date (as defined below) from April 9, 2018 to October 9, 2018, and (ii) modification of the amount of the Warrant Price (as defined below) and the amount of the Warrant Shares (as defined below) to reflect a 1-for-8 reverse split of the Common Stock (as defined below) which was effective as of September 28, 2015.

OPEXA THERAPEUTICS, INC.

AMENDED AND RESTATED WARRANT TO PURCHASE SHARES

OF COMMON STOCK, PAR VALUE $0.01 PER SHARE

For VALUE RECEIVED, Victoria Jackson Revocable Trust ("***Warrantholder***") is entitled to purchase, subject to the provisions of this Amended and Restated Warrant (this "***Warrant***"), from Opexa Therapeutics, Inc., a Texas corporation ("***Company***"), at any time after the date hereof (the "***Initial Exercise Date***") and not later than 5:00 P.M., Central time, on the Expiration Date (as defined below), at an exercise price per share equal to (i) Four Dollars ($4.00) if this Warrant is exercised on or before June 30, 2016, or (ii) Twelve Dollars ($12.00) if this Warrant is exercised after June 30, 2016 (the applicable exercise price in effect being herein called the "***Warrant Price***"), Fifty-Six Thousand Eight Hundred Eighteen (56,818) shares ("***Warrant Shares***") of the Company's Common Stock, par value $0.01 per share ("***Common Stock***"). The number of Warrant Shares purchasable upon exercise of this Warrant and the Warrant Price shall be subject to adjustment from time to time as described herein. The "***Expiration Date***" shall mean October 9, 2018; provided, however, that upon a merger, consolidation, sale of substantially all assets or similar transaction involving the Company, at the option of the Company and upon at least ten (10) days prior written notice to Warrantholder, this Warrant must be exercised no later than immediately prior to the closing of any such transaction or it shall automatically expire upon such closing (in which event such closing shall be the Expiration Date). If not exercised on or before the Expiration Date, this Warrant shall become void.

1. Registration. The Company shall maintain books for the transfer and registration of the Warrant. Upon the initial issuance of this Warrant, the Company shall issue and register the Warrant in the name of the Warrantholder.

2. Transfers. This Warrant may be transferred only pursuant to a registration statement filed under the Securities Act of 1933, as amended (the "***Securities Act***"), or an exemption from such registration. Subject to such restrictions, the Company shall transfer this Warrant from time to time upon the books to be maintained by the Company for that purpose, upon surrender hereof for transfer, properly endorsed or accompanied by appropriate instructions for transfer and such other documents as may be reasonably required by the Company, including, if required by the Company, an opinion of counsel to the effect that such transfer is exempt from the registration requirements of the Securities Act, to establish that such transfer is being made in accordance with the terms hereof, and a new Warrant shall be issued to the transferee (who shall thereafter be the Warrantholder hereunder) and the surrendered Warrant shall be canceled by the Company.

3. Exercise of Warrant. The Warrantholder may exercise this Warrant, in whole or in part, at any time after the Initial Exercise Date and prior to 5:00 p.m. Central Time on the Expiration Date upon (i) written notice, in the form attached hereto as **APPENDIX A** (the "***Exercise Notice***"), of the Warrantholder's election to exercise this Warrant, and (ii) payment by cash, certified check or wire transfer of funds for the aggregate Warrant Price for that number of Warrant Shares then being purchased, to the Company during normal business hours on any business day at the Company's principal executive offices (or such other office or agency of the Company as it may designate by notice to the Warrantholder). The Warrant Shares so purchased shall be deemed to be issued to the Warrantholder or the Warrantholder's designee, as the record owner of such shares, as of the close of business on the date on which the Warrant Price shall have been paid and the completed Exercise Notice shall have been delivered. The Warrantholder shall not be required to deliver the original Warrant in order to effect an exercise hereunder. Certificates for the Warrant Shares so purchased shall be delivered to the Warrantholder within a reasonable time, not exceeding three (3) business days, after this Warrant shall have been so exercised. The certificates so delivered shall be in such denominations as may be requested by the Warrantholder and shall be registered in the name of the Warrantholder. If this Warrant shall have been exercised only in part, then, unless this Warrant has expired, the Company shall, at its expense, at the time of delivery of such certificates, deliver to the Warrantholder a new Warrant representing the right to purchase the number of shares with respect to which this Warrant shall not then have been exercised. As used herein, "business day" means a day, other than a Saturday or Sunday, on which banks in Houston, Texas are open for the general transaction of business. The Warrantholder's acceptance of this Warrant as well as each exercise hereof shall each constitute the affirmation by the Warrantholder that the representations and warranties contained in **APPENDIX B** attached hereto are true and correct in all material respects with respect to the Warrantholder as of the time of such acceptance and as of the time of each exercise. The Warrantholder shall promptly physically surrender this Warrant to the Company in the event the Warrant is exercised. The Warrantholder and the Company shall maintain records showing the amount exercised and the dates of such exercise. The Warrantholder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provision of this paragraph, following exercise of a portion of the Warrant, the number of Warrant Shares of this Warrant may be less than the amount stated on the face hereof.

4. Compliance with Securities Laws. This Warrant may only be exercised by the Warrantholder in accordance with applicable securities laws. The Company may cause the legend set forth on the first page of this Warrant to be set forth on each Warrant, and a similar legend on any security issued or issuable upon exercise of this Warrant, unless counsel for the Company is of the opinion as to any such security that such legend is unnecessary.

5. Payment of Taxes. The Company will pay any documentary stamp taxes attributable to the initial issuance of Warrant Shares issuable upon the exercise of the Warrant; provided, however, that the Company shall not be required to pay any tax or taxes which may be payable in respect of any transfer involved in the issuance or delivery of any certificates for Warrant Shares in a name other than that of the Warrantholder in respect of which such shares are issued, and in such case, the Company shall not be required to issue or deliver any certificate for Warrant Shares or any Warrant until the person requesting the same has paid to the Company the amount of such tax or has established to the Company's reasonable satisfaction that such tax has been paid. The Warrantholder shall be responsible for income taxes due under federal, state or other law, if any such tax is due.

6. Mutilated or Missing Warrants. In case this Warrant shall be mutilated, lost, stolen, or destroyed, the Company shall issue in exchange and substitution of and upon surrender and cancellation of the mutilated Warrant, or in lieu of and substitution for the Warrant lost, stolen or destroyed, a new Warrant of like tenor and for the purchase of a like number of Warrant Shares, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction of the Warrant, and with respect to a lost, stolen or destroyed Warrant, reasonable indemnity or bond with respect thereto, if requested by the Company.

7. Reservation of Common Stock. The Company represents and warrants that on the date hereof, it has duly authorized and reserved, and covenants that at any time when this Warrant is exercisable, the Company shall at all applicable times keep reserved until issued (if necessary) as contemplated by this Section 7, out of the authorized and unissued shares of Common Stock, at least a number of shares of Common Stock as shall from time to time be necessary to effect the exercise of all of this Warrant then outstanding. The Company covenants that all Warrant Shares issued upon due exercise of the Warrant shall be, at the time of delivery of the certificates for such Warrant Shares, duly authorized, validly issued, fully paid and non-assessable shares of Common Stock of the Company.

8. Adjustments.

(a) If the Company shall, at any time or from time to time while this Warrant is outstanding, pay a dividend or make a distribution on its Common Stock in shares of Common Stock, subdivide its outstanding shares of Common Stock into a greater number of shares or combine its outstanding shares of Common Stock into a smaller number of shares, then (i) the Warrant Price in effect immediately prior to the date on which such change shall become effective shall be adjusted by multiplying such Warrant Price by a fraction, the numerator of which shall be the number of shares of Common Stock outstanding immediately prior to such change and the denominator of which shall be the number of shares of Common Stock outstanding immediately after giving effect to such change and (ii) the number of Warrant Shares purchasable upon exercise of this Warrant shall be adjusted by multiplying the number of Warrant Shares purchasable upon exercise of this Warrant immediately prior to the date on which such change shall become effective by a fraction, the numerator of which is shall be the Warrant Price in effect immediately prior to the date on which such change shall become effective and the denominator of which shall be the Warrant Price in effect immediately after giving effect to such change, calculated in accordance with clause (i) above. Such adjustments shall be made successively whenever any event listed above shall occur.

(b) Unless the Expiration Date occurs coincident therewith (as provided in the first paragraph of this Warrant): (i) if any capital reorganization, reclassification of the capital stock of the Company, consolidation or merger of the Company with another corporation in which the Company is not the survivor, or sale, transfer or other disposition of all or substantially all of the Company's assets to another corporation shall be effected, then, as a condition of such reorganization, reclassification, consolidation, merger, sale, transfer or other disposition, lawful and adequate provision shall be made whereby each Warrantholder shall thereafter have the right to purchase and receive upon the basis and upon the terms and conditions herein specified and in lieu of the Warrant Shares immediately theretofore issuable upon exercise of the Warrant, such shares of stock, securities or assets as would have been issuable or payable with respect to or in exchange for a number of Warrant Shares equal to the number of Warrant Shares immediately theretofore issuable upon exercise of the Warrant, had such reorganization, reclassification, consolidation, merger, sale, transfer or other disposition not taken place, and in any such case appropriate provision shall be made with respect to the rights and interests of each Warrantholder to the end that the provisions hereof (including, without limitation, provision for adjustment of the Warrant Price) shall thereafter be applicable, as nearly equivalent as may be practicable in relation to any shares of stock, securities or assets thereafter deliverable upon the exercise hereof; and (ii) the Company shall not effect any such consolidation, merger, sale, transfer or other disposition unless prior to or simultaneously with the consummation thereof the successor corporation (if other than the Company) resulting from such consolidation or merger, or the corporation purchasing or otherwise acquiring such assets or other appropriate corporation or entity shall assume the obligation to deliver to the Warrantholder, at the last address of the Warrantholder appearing on the books of the Company, such shares of stock, securities or assets as, in accordance with the foregoing provisions, the Warrantholder may be entitled to purchase, and the other obligations under this Warrant. The provisions of this paragraph (b) shall similarly apply to successive reorganizations, reclassifications, consolidations, mergers, sales, transfers or other dispositions.

(c) In case the Company shall fix a payment date for the making of a distribution to all holders of Common Stock (including any such distribution made in connection with a consolidation or merger in which the Company is the continuing corporation) of evidences of indebtedness or assets (other than cash dividends or cash distributions payable out of consolidated earnings or earned surplus or dividends or distributions referred to in Section 8(a)), or subscription rights or warrants, the Warrant Price to be in effect after such payment date shall be determined by multiplying the Warrant Price in effect immediately prior to such payment date by a fraction, the numerator of which shall be the total number of shares of Common Stock outstanding multiplied by the Market Price (as defined below) per share of Common Stock immediately prior to such payment date, less the fair market value (as determined by the Company's Board of Directors (the "***Board of Directors***") in good faith) of said assets or evidences of indebtedness so distributed, or of such subscription rights or warrants, and the denominator of which shall be the total number of shares of Common Stock outstanding multiplied by such Market Price per share of Common Stock immediately prior to such payment date. "***Market Price***" of a share of Common Stock on any date shall mean, (i) if the shares of Common Stock are listed on the NASDAQ Stock Market, the official closing price reported on that date; (ii) if the shares of Common Stock are no longer listed on the NASDAQ Stock Market and are listed on any other national securities exchange, the last sale price of the Common Stock reported by such exchange on that date; (iii) if the shares of Common Stock are not listed on any such exchange and the shares of Common Stock are traded in the over-the-counter market, the last price reported on such day by the OTC Bulletin Board; (iv) if the shares of Common Stock are not listed on any such exchange or quoted on the OTC Bulletin Board, then the last price quoted on such day in the over-the-counter market as reported by the National Quotation Bureau Incorporated (or any similar organization or agency succeeding its functions of reporting prices); or (v) if none of clauses (i)-(iv) are applicable, then as determined in good faith by the Board of Directors.

(d) An adjustment to the Warrant Price shall become effective immediately after the payment date in the case of each dividend or distribution and immediately after the effective date of each other event which requires an adjustment.

(e) In the event that, as a result of an adjustment made pursuant to this Section 8, the Warrantholder shall become entitled to receive any shares of capital stock of the Company other than shares of Common Stock, the number of such other shares so receivable upon exercise of this Warrant shall be subject thereafter to adjustment from time to time in a manner and on terms as nearly equivalent as practicable to the provisions with respect to the Warrant Shares contained in this Warrant.

9. Fractional Interest. The Company shall not be required to issue fractions of Warrant Shares upon the exercise of this Warrant. If any fractional share of Common Stock would, except for the provisions of the first sentence of this Section 9, be deliverable upon such exercise, the Company, in lieu of delivering such fractional share, shall pay to the exercising Warrantholder an amount in cash equal to the fair market value of such fractional share of Common Stock on the date of exercise.

10. Benefits. Nothing in this Warrant shall be construed to give any person, firm or corporation (other than the Company and the Warrantholder) any legal or equitable right, remedy or claim, it being agreed that this Warrant shall be for the sole and exclusive benefit of the Company and the Warrantholder.

11. Notices to Warrantholder.

(a) Upon the happening of any event requiring an adjustment of the Warrant Price, the Company shall promptly give written notice thereof to the Warrantholder at the address appearing in the records of the Company, stating the adjusted Warrant Price and the adjusted number of Warrant Shares resulting from such event and setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based. Failure to give such notice to the Warrantholder or any defect therein shall not affect the legality or validity of the subject adjustment.

(b) The Company hereby covenants to the Warrantholder that, from the date hereof and for so long as this Warrant remains not fully exercised, it shall give written notice promptly to the Warrantholder upon the happening of any of the following events: (i) the admission in writing by the Company of its insolvency; (ii) the commission of any voluntary act of bankruptcy by the Company; (iii) the execution by the Company of a general assignment for the benefit of creditors; (iv) the filing by or against the Company of any petition in bankruptcy or any petition for relief under the provisions of the federal bankruptcy act or any other state or federal law for the relief of debtors and the continuation of such petition without dismissal for a period of sixty (60) days or more; (v) the appointment of a receiver or trustee to take possession of the property or assets of the Company; (vi) any dissolution of the Company; (vii) the adoption by the Company of any plan of liquidation; or (viii) the commencement against the Company of any case, proceeding or other action seeking issuance of a warrant of attachment, execution, distraint or similar process against all or any substantial part of its assets which results in the entry of an order for any such relief which shall not have been vacated, discharged, or stayed or bonded pending appeal within sixty (60) days from the entry thereof.

12. Identity of Transfer Agent. The Transfer Agent for the Common Stock is Continental Stock Transfer & Trust, 17 Battery Place, New York, New York 10004. Upon the appointment of any subsequent transfer agent for the Common Stock or other shares of the Company's capital stock issuable upon the exercise of the rights of purchase represented by the Warrant, the Company will mail to the Warrantholder a statement setting forth the name and address of such transfer agent.

13. Notices. Unless otherwise provided, any notice required or permitted under this Warrant shall be given in writing and shall be deemed effectively given and received as hereinafter described (i) if given by personal delivery, then such notice shall be deemed received upon such delivery, (ii) if given by facsimile, then such notice shall be deemed received upon receipt of confirmation of complete transmittal, (iii) if given by certified mail return receipt requested, then such notice shall be deemed received upon the day such return receipt is signed, and (iv) if given by an internationally recognized overnight air courier, then such notice shall be deemed given one business day after delivery to such carrier. Copies of such notices shall also be transmitted by email. All notices shall be addressed as follows: if to the Warrantholder, at the address as follows, or at such other address as the Warrantholder may designate by ten days' advance written notice to the Company:

Victoria Jackson Revocable Trust
Guthy-Renker LLC
1018 Pamela Drive
Beverly Hills, California 90210
Fax: (310) 581-3443
Email: BGuthy@guthy-renker.com

if to the Company, at the address as follows, or at such other address as the Company may designate by ten days' advance written notice to the Warrantholder:

Opexa Therapeutics, Inc.
2635 Technology Forest Blvd.
The Woodlands, Texas 77381
Attention: President
Fax: (281) 872-8585

14. Successors. All the covenants and provisions hereof by or for the benefit of the Warrantholder shall bind and inure to the benefit of its respective successors and permitted assigns hereunder.

15. Governing Law; Consent to Jurisdiction; Waiver of Jury Trial. This Warrant shall be governed by, and construed in accordance with, the internal laws of the State of Texas, without reference to the choice of law provisions thereof. The Company and, by accepting this Warrant, the Warrantholder, each irrevocably submits to the exclusive jurisdiction of the courts of the State of Texas located in Harris County and the United States District Court for the Southern District of Texas for the purpose of any suit, action, proceeding or judgment relating to or arising out of this Warrant and the transactions contemplated hereby. Service of process in connection with any such suit, action or proceeding may be served on each party hereto anywhere in the world by the same methods as are specified for the giving of notices under this Warrant. The Company and, by accepting this Warrant, the Warrantholder, each irrevocably waives any objection to the laying of venue of any such suit, action or proceeding brought in such courts and irrevocably waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. **EACH OF THE COMPANY AND, BY ITS ACCEPTANCE HEREOF, THE WARRANTHOLDER HEREBY WAIVES ANY RIGHT TO REQUEST A TRIAL BY JURY IN ANY LITIGATION WITH RESPECT TO THIS WARRANT AND REPRESENTS THAT COUNSEL HAS BEEN CONSULTED SPECIFICALLY AS TO THIS WAIVER.**

16. No Rights as Shareholder. Prior to the exercise of this Warrant, the Warrantholder shall not have or exercise any rights as a shareholder of the Company by virtue of its ownership of this Warrant.

17. Amendment; Waiver. Any term or provision of this Warrant may be amended or waived upon the written consent of the Company and the Warrantholder.

18. Remedies; Other Obligations; Breaches and Injunctive Relief. The remedies provided in this Warrant shall be cumulative and in addition to all other remedies available under this Warrant, at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the right of the Warrantholder right to pursue actual damages for any failure by the Company to comply with the terms of this Warrant. The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the Warrantholder and that the remedy at law for any such breach may be inadequate. The Company therefore agrees that, in the event of any such breach or threatened breach, the Warrantholder shall be entitled, in addition to all other available remedies, an injunction restraining any breach, without the necessity of showing economic loss and without any bond or other security being required.

19. Authorized Shares. The Company covenants that during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of executing stock certificates to execute and issue the necessary certificates for the Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the trading market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Warrantholder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Warrantholder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (a) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (b) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (c) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof as may be necessary to enable the Company to perform its obligations under this Warrant.

20. Section Headings. The section headings in this Warrant are for the convenience of the Company and the Warrantholder and in no way alter, modify, amend, limit or restrict the provisions hereof.

[signature page follows]

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed as of the date first written above.

OPEXA THERAPEUTICS, INC.

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

APPENDIX A

EXERCISE NOTICE
OPEXA THERAPEUTICS, INC.

The undersigned holder hereby exercises the right to purchase _____ of the shares of Common Stock ("***Warrant Shares***") of Opexa Therapeutics, Inc., a Texas corporation (the "***Company***"), evidenced by the attached Amended and Restated Warrant (the "***Warrant***"). Capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Warrant.

1. Payment of Warrant Price. The holder shall pay the aggregate Warrant Price in the sum of $_____ to the Company in accordance with the terms of the Warrant.

2. Delivery of Warrant Shares. The holder requests that the Company deliver the Warrant Shares in the name of the undersigned holder by physical delivery of a certificate to:

_____
_____
_____

Date: _____ __, 20____

_____
Name of Registered Holder

By: _____
Printed Name:_____
Title (if applicable): _____
Entity Name (if applicable):_____

APPENDIX B

Representations and Warranties

The Warrantholder represents and warrants to the Company that:

- Purchase Entirely for Own Account. The Warrant and the securities to be received by the Warrantholder pursuant to the Warrant (the "***Securities***") is being/will be acquired for the Warrantholder's own account, not as nominee or agent, and not with a view to the resale or distribution of any part thereof in violation of the Securities Act, and the Warrantholder has no present intention of selling, granting any participation in, or otherwise distributing the same in violation of the Securities Act without prejudice, however, to the Warrantholder's right at all times to sell or otherwise dispose of all or any part of the Securities in compliance with applicable federal and state securities laws.

- Investment Experience. The Warrantholder acknowledges that it can bear the economic risk and complete loss of its investment in the Securities and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of an investment in the Securities.

- Disclosure of Information. The Warrantholder has had an opportunity to receive all information related to the Company requested by it and to ask questions of and receive answers from the Company regarding the Company, its business and the terms and conditions of the Securities.

- Restricted Securities. The Warrantholder understands that the Securities are characterized as "***restricted securities***" under the U.S. federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances. The Warrantholder represents that it is familiar with Rule 144, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act. The Warrantholder acknowledges that the Securities have not been registered under the Securities Act or registration or qualified under any applicable blue sky laws in reliance, in part, on the representations and warranties herein.

- Legends. The Warrantholder understands that certificates evidencing the Securities may bear the following or any similar legend:

"THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 AS AMENDED (THE "*ACT*"), OR ANY STATE SECURITIES LAWS. SUCH SECURITIES MAY NOT BE SOLD OR OTHERWISE TRANSFERRED EXCEPT AS PERMITTED UNDER THE ACT AND THE APPLICABLE STATE SECURITIES LAWS, PURSUANT TO REGISTRATION OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL (WHICH MAY BE COUNSEL FOR THE COMPANY) IN FORM AND SUBSTANCE REASONABLY SATISFACTORY TO THE ISSUER TO THE EFFECT THAT ANY PROPOSED TRANSFER OR RESALE IS IN COMPLIANCE WITH THE ACT."

- If required by the authorities of any state in connection with the issuance or sale of the Securities, the legend required by such state authority.

- Accredited Investor. The Warrantholder is an accredited investor as defined in Rule 501(a) of Regulation D, as amended, under the Securities Act.

- No General Advertisement. The Warrantholder did not learn of the investment in the Securities as a result of any public solicitation or advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or similar media or broadcast over television, radio or internet or presented at any seminar or other general advertisement.

- Brokers and Finders. No person or entity will have any valid right, interest or claim against or upon the Company or the Warrantholder for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of the Warrantholder.

Exhibit 10.21

AMENDMENT TO STOCK PURCHASE AGREEMENT

THIS AMENDMENT TO STOCK PURCHASE AGREEMENT (this "***Amendment***") is made and effective as of March 14, 2016 (the "***Amendment Date***") by and between Opexa Therapeutics, Inc., a Texas corporation (the "***Company***"), and the William R. Guthy Separate Property Trust and the Victoria Jackson Revocable Trust (collectively, the "***Purchasers***"). The Company and the Purchasers shall be collectively referred to herein as the "***Parties***." This Amendment is made with reference to the following:

A. The Parties entered into that certain Stock Purchase Agreement effective as of September 1, 2015 (the "***Agreement***") with respect to the purchase by the Purchasers, and the sale and issuance by the Company, of certain securities of the Company. Defined terms used herein shall have their respective meanings as set forth in the Agreement.

B. The Parties desire to modify the following definitions in the Agreement, in each case to add six months to the specific date references set forth in such definitions: Tranche 2 Milestone; Tranche 3 Milestone; Tranche 4 Milestone; and Tranche 5 Milestone.

C. Concurrent with the effectiveness of this Amendment, the Company is issuing to the Purchasers an amended and restated Warrant which supersedes and replaces in its entirety the Warrant issued pursuant to the Agreement. Identical to the issuance of the Warrant, one-half of the amended and restated Warrant will be issued to each Purchaser. The only changes intended by such amended and restated Warrant are (i) an extension of the reference date for the definition of the Expiration Date in the Warrant from April 9, 2018 to October 9, 2018, and (ii) modification of the amount of the Warrant Price (as defined in the Warrant) and the amount of the Warrant Shares (as defined in the Warrant) to reflect a 1-for-8 reverse split of the Common Stock (as defined in the Warrant) which was effective as of September 28, 2015.

NOW, THEREFORE, the Parties hereby agree as follows:

1. Modification of Certain Definitions.

1.1 Tranche 2 Milestone. The reference in the definition of Tranche 2 Milestone to February 15, 2016 is hereby replaced and superseded for all purposes by a reference to August 15, 2016.

1.2 Tranche 3 Milestone. The reference in the definition of Tranche 3 Milestone to May 15, 2016 is hereby replaced and superseded for all purposes by a reference to November 15, 2016.

1.3 Tranche 4 Milestone. The reference in the definition of Tranche 4 Milestone to August 30, 2016 is hereby replaced and superseded for all purposes by a reference to February 28, 2017.

1.4 Tranche 5 Milestone. The reference in the definition of Tranche 5 Milestone to December 31, 2016 is hereby replaced and superseded for all purposes by a reference to June 30, 2017.

2. Amended and Restated Warrant. Concurrent with the effectiveness of this Amendment, the Company will issue to the Purchasers an amended and restated Warrant as contemplated by Recital C above, with one-half of such amended and restated Warrant being issued to each Purchaser. The Parties acknowledge and agree that such amended and restated Warrant supersedes and replaces in its entirety the Warrant issued pursuant to the Agreement. The Purchasers will promptly deliver to the Company for cancellation the original Warrant.

3. General Provisions.

3.1 Construction; Titles and Subtitles. The terms and conditions of this Amendment shall constitute a part of the Agreement as amended hereby, and shall be construed in accordance with the terms and conditions of the Agreement as amended. Except as expressly modified by this Amendment, the Agreement shall continue in full force and effect in accordance with its terms. The titles and subtitles used in this Amendment are used for convenience only and are not to be considered in construing or interpreting this Amendment.

3.2 Counterparts; Electronic Execution. This Amendment may be executed in one or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument. A signature to this Amendment transmitted electronically shall have the same authority, effect and enforceability as an original signature.

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Amendment Date.

THE COMPANY:

OPEXA THERAPEUTICS, INC.

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

Address:
2635 Technology Forest Blvd.
The Woodlands, Texas 77381
Fax: (281) 872-8585

PURCHASERS:

WILLIAM R. GUTHY SEPARATE PROPERTY TRUST

By: /s/ William R. Guthy, Trustee
William R. Guthy, Trustee

VICTORIA JACKSON REVOCABLE TRUST

By: /s/ Victoria Jackson, Trustee
Victoria Jackson, Trustee

Address:
William R. Guthy Separate Property Trust
Victoria Jackson Revocable Trust
Guthy-Renker LLC
1018 Pamela Drive
Beverly Hills, California 90210
Fax: (310) 581-3443

Exhibit 10.22

OPEXA THERAPEUTICS, INC.
2635 N. Crescent Ridge Drive
The Woodlands, TX 77381

March 2, 2010

Don Healey
402 Lookout Point
Rougemont, NC 27572
donboy@nc.rr.com

Dear Don:

On behalf of Opexa Therapeutics, Inc. (the "*Company*"), I am pleased to offer you the full-time position of Vice President, Scientific Development. This position currently reports to the Company's Chief Executive Officer (the "*CEO*"). This letter embodies the terms of our offer of employment to you. As explained in more detail below, your employment is contingent upon your assent to the terms and conditions set forth in this letter and the attachments hereto. Of course, the Company may change your duties, reporting relationship, compensation, benefits and place of employment from time to time as it deems necessary. If, after careful review, the terms discussed below and in the attachments hereto are acceptable to you, please sign this letter and the attached (i) Acknowledgement of At-Will Employment, (ii) Proprietary Information and Inventions Agreement and (iii) Agreement to Arbitrate where indicated and return them to me.

1. Compensation.

a. Salary. You will be compensated at a base rate of $200,000 per year, to be paid in accordance with the Company's standard payroll practices, as they may be changed from time to time. In addition, you will be eligible to receive an annual discretionary bonus of up to twenty percent (20%) of your base salary per 12-month period (pro rated for any partial period of less than 12 months), based upon a determination by the CEO and the Company's Board of Directors (the "*Board*") of the achievement of objectives to be set from time to time by the Board. The first measurement period for this purpose will end on approximately December 31, 2010.

b. Stock Plan. Subject to approval by the Board in its discretion, you will be granted the option (the "*Option*") to purchase 30,000 shares of the Company's common stock pursuant to the Company's stock option plan (the "*Plan*"). The Option will be subject to the terms and conditions (including, without limitation, vesting) set forth in a notice of stock option grant and an accompanying stock option agreement as well as the Plan. The exercise price for the shares at issue under the Option will be no less than their fair market value on the date of grant.

c. Vacation, Holidays and Sick-Leave. As a full-time employee, you will accrue vacation in accordance with the Company's standard policies and procedures. Holidays and sick-leave will likewise be provided in accordance with the Company's standard policies and procedures.

d . Benefits. As a full-time employee, you will be eligible to participate in and to receive benefits under such plans and benefits as may be adopted by the Company. The eligibility criteria and amount and extent of benefits to which you are entitled shall be governed by each specific benefit plan (as applicable) as it may be amended from time to time.

e . Relocation/Start Package. The Company will reimburse you for rent, for a period of up to three months and limited to $2,500 per month, for temporary housing while you complete your relocation to the greater Houston area ("*Relocation*"). In addition, assuming that your employment shall have been continuous with the Company from your start date, following Relocation the Company will pay you $10,000 for moving expenses (regardless of the actual amount of such expenses).

2 . Immigration Documentation. This offer is subject to your submission of an I-9 form and satisfactory documentation respecting your identification and right to work in the United States no later than three (3) days after your employment begins.

3. At-Will Employment. Your employment with the Company is "*at-will*." This means that your employment with the Company is not for a specific term, and can be terminated by yourself or by the Company at any time for any reason or no reason, with or without cause and with or without notice. Any contrary representations which may have been made or which may hereafter be made to you are superseded by this offer. Though your duties, compensation, benefits and place of employment may change over time and you may be subject to incremental discipline that does not include a termination, none of these events change the fact that you are an "at will" employee. In addition, the fact that the rate of your salary, vesting schedule or other compensation is stated in units of years or months and that your vacation and sick leave accrue annually or monthly does not alter the at-will nature of the employment, and does not mean and should not be interpreted to mean that you are guaranteed employment to the end of any period of time or for any period time. Your acceptance of this offer is contingent upon your execution of the Company's Acknowledgement of At-Will Employment, a copy of which is attached hereto as Exhibit A for your execution. This offer letter and the attached Acknowledgement of At-Will Employment constitute the full and complete agreement between the parties regarding the "*at-will*" nature of your employment, and can only be modified by written agreement signed by you and the CEO.

4. Severance for Termination Without Cause. Without limiting the provisions of the foregoing Paragraph 3, in the event that your employment with the Company is terminated by the Company without Cause (as defined below), you will be entitled to the continuation of your then-current base salary for a period of six (6) months following such termination; provided, however, that such benefit is contingent upon the following: (i) your employment with the Company shall have been continuous from your start date through the occurrence of the applicable event; (ii) you execute and deliver a general release (in a customary form provided by the Company) of all claims against the Company or persons affiliated with the Company (with any potential revocation periods having expired); and (iii) you are not in breach of any of the provisions of this Agreement or the attached Proprietary Information and Inventions Agreement. "*Cause*" as used herein shall mean: (i) you commit a felony or another crime involving moral turpitude; (ii) you fail to maintain an immigration status which allows you to work in the United States; (iii) you fail to complete a Relocation within six (6) months of your start date; (iv) you materially violate any of the Company's rules and regulations (including, without limitation, the rules of conduct) or any other policies and practices established by the Board; (v) you materially violate this Agreement or the attached Proprietary Information and Inventions Agreement; (vi) you fail to exercise reasonable efforts to perform duties consistent with your position with the Company (including, without limitation, as reasonably instructed by the CEO) and such failure has not been cured within ten (10) days of notice to such effect from the Company; or (vii) you commit any breach of fiduciary duty or misconduct that is likely to cause a material adverse effect upon the financial condition or business operations of the Company.

5 . Proprietary Information and Inventions Agreement. Your acceptance of this offer is contingent upon your execution of the Company's Proprietary Information and Inventions Agreement, a copy of which is attached hereto as Exhibit B for your execution.

6. Non-Compete and Outside Activities. As more fully set forth in the Company's Proprietary Information and Inventions Agreement (attached hereto as Exhibit B), you agree that, while serving as a full-time employee of the Company and during any period in which you are receiving any payments pursuant to Paragraph 4 above, you will not engage in any activity which is competitive with the Company. In addition, during your employment with the Company, you shall devote your best efforts and your full business time, skill and attention to the performance of your duties on behalf of the Company. The foregoing, however, shall not preclude you from engaging in appropriate civic, charitable, professional or trade association activities or from serving on one or more boards of directors of public or private companies, so long as such activities and service do not (i) interfere with the performance of your duties for the Company, (ii) involve any assets, information or other resources proprietary or confidential to the Company or any of its licensors or (iii) involve any third party that is competitive, directly or indirectly, with the Company.

7 . Arbitration. Your acceptance of this offer is contingent upon your execution of the Company's Agreement to Arbitrate, a copy of which is attached hereto as Exhibit C for your execution. As more fully set forth in the Agreement to Arbitrate, both you and the Company agree that any controversy, claim or dispute arising out of, concerning or relating in any way to your employment with the Company or the termination thereof shall be submitted exclusively to final and binding arbitration.

8 . Company Rules. As an employee of the Company, you will be expected to abide by the Company's rules and regulations. You will be required to sign an acknowledgement that you have read and understand the Company rules of conduct as provided in the Company's Employee Handbook, which the Company will distribute.

9. Integrated Agreement. This offer, if accepted, supersedes any prior agreements, representations or promises of any kind, whether written, oral, express or implied between the parties hereto with respect to the subject matters herein. Likewise, the terms of this offer shall constitute the full, complete and exclusive agreement between you and the Company with respect to the subject matters herein. This Agreement may only be changed by a writing, signed by you and an authorized representative of the Company.

10. Withholding. Any payments or other compensation provided to you or for our benefit from the Company will be subject to (and thus reduced by) all applicable deductions and withholdings.

11. Severability. If this offer is accepted, and any term herein is held to be invalid, void or unenforceable, the remainder of the terms herein shall remain in full force and effect and shall in no way be affected; and, the parties shall use their best efforts to find an alternative way to achieve the same result.

If you wish to accept employment at the Company under the terms set out above and in the enclosed Acknowledgement of At-Will Employment, Proprietary Information and Inventions Agreement and Agreement to Arbitrate, please sign and date this letter and the enclosed documents, and return them to me. If you accept our offer, your first day of employment will be on a date within the next several weeks as mutually determined (but no later than April 12, 2010).

This offer, if not accepted, will expire on March 5, 2010.

We look forward to your favorable reply and to a productive and exciting work relationship.

Sincerely,

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

Approved and Accepted:

/s/ Don Healey Date: March 4, 2010
Name: Don Healey

EXHIBIT A

ACKNOWLEDGEMENT OF AT-WILL EMPLOYMENT

I understand and acknowledge that my employment with Opexa Therapeutics, Inc. (the "*Company*") is at-will and for no specified term. I understand that I may resign at any time, for any reason or no reason, with or without cause and with or without notice. I further understand and agree that the Company may terminate my employment at any time, for any reason or no reason, with or without cause and with or without notice. I understand and acknowledge that this policy may only be modified in a signed, written document executed by the CEO of the Company.

Date: March 4, 2010

Name: Don Healey

Signature: /s/ Don Healey

EXHIBIT B

OPEXA THERAPEUTICS, INC.

PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT
(Don Healey)

Opexa Therapeutics, Inc.
2635 N. Crescent Ridge Drive
The Woodlands, TX 77381

Ladies and Gentlemen:

I recognize that Opexa Therapeutics, Inc., a Texas corporation ("*Opexa*"), possesses a body of existing technology and intellectual property rights and is engaged in a continuous program of research, development and production with respect to its business (present and future).

I understand that:

A. As part of my employment by Opexa (with the term "*employment*", as used herein, to include any consulting relationship as well as any service as a member of the Board of Directors), I am expected to make new contributions and inventions of value to Opexa.

B. My employment creates a relationship of confidence and trust between me and Opexa and that my position places me in a unique position of access to the proprietary technology, trade secrets and research, development and business information:

(1) applicable to the business of Opexa; or

(2) applicable to the business of any client, partner or customer of Opexa,

which may be made known to me by Opexa or by any client, partner or customer of Opexa, or learned by me during the period of my employment.

C. Opexa possesses and will continue to possess information that has been or will be created, discovered or developed, or has or will otherwise become known to Opexa (including, without limitation, information created, discovered, developed or made known by or to me during the period of or arising out of my employment by Opexa), and/or in which property rights have been or will be assigned or otherwise conveyed to Opexa, which information has commercial value in the business in which Opexa is engaged. All of the aforementioned information is hereinafter called "*Confidential Information*." By way of illustration, but not limitation, Confidential Information includes all data, compilations, blueprints, plans, audio and/or video recordings and/or devices, information on computer disks, software, tapes, printouts and other printed, typewritten or handwritten documents, specifications, strategies, systems, schemas, methods, business and marketing development plans, customer, employee and supplier lists, budgets and unpublished financial statements, licenses and license agreements, research projections, processes, techniques, designs, sequences, components, programs, technology, ideas, know-how, improvements, inventions (whether or not patentable or copyrightable), information about operations and maintenance, trade secrets, formulae, models, patent disclosures, information regarding the skills and compensation of other employees of Opexa and other information concerning the actual or anticipated business, research or development of Opexa or its actual or potential customers, suppliers or partners or which is or has been generated or received in confidence by or for Opexa by or from any person; and all tangible and intangible embodiments thereof of any kind whatsoever including, where appropriate and without limitation, all compositions, machinery, apparatus, records, reports, drawings, copyright applications, patent applications, documents, samples, prototypes, models, products and the like.

In consideration of my employment or continued employment, as the case may be, and the compensation received by me from Opexa from time to time, I hereby agree as follows:

1. All Confidential Information shall be the sole property of Opexa and its assigns, and Opexa and its assigns shall be the sole owner of all trade secrets, patents, copyrights and other rights in connection therewith. I hereby assign to Opexa any rights I may have or acquire in all Confidential Information. At all times during my employment by Opexa and at all times after termination of my employment by me or Opexa for any reason ("*Termination*"), I will hold in confidence and trust all Confidential Information, and I will not disclose, sell, use, lecture upon or publish any Confidential Information or anything relating to it without the prior written consent of Opexa, except as may be necessary in the ordinary course of performing my duties as an employee of (or consultant or Director to) Opexa.

2. Without limiting the terms of my employment with Opexa, I agree that during the period of my employment by Opexa I will not engage in any employment or activity in any business that is directly or indirectly competitive with Opexa or would otherwise conflict with my employment by Opexa.

3. All documents, data, records, apparatus, equipment, sequences, components, programs and other physical property, whether or not pertaining to Confidential Information, furnished to me by Opexa or produced by myself or others in connection with my employment shall be and remain the sole property of Opexa and shall be returned promptly to Opexa as and when requested by Opexa. Even should Opexa not so request, I shall return and deliver all such property upon Termination and I will not take with me any such property, any reproduction of such property or any materials or products derived from such property. I further agree that any property situated on Opexa's premises and owned by Opexa, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Opexa personnel at any time with or without notice.

4. I shall promptly disclose any outside activities or interests, including any ownership or participation in the development of Prior Inventions (as defined in Section 8 below), that conflict or may conflict with the interests of Opexa. I understand that I am required to make such disclosures promptly if the activity or interest is related, either directly or indirectly, to (i) an area of research, development or service of Opexa, (ii) a product candidate, product or product line of Opexa, (iii) a manufacturing, development or research methodology or process of Opexa or (iv) any activity that I may be involved with on behalf of Opexa.

5. I shall promptly disclose to Opexa, or any persons designated by it, all improvements, inventions, formulae, processes, programs, techniques, know-how, data and the like, whether or not patentable or copyrightable, made or conceived or reduced to practice or learned by me, either alone or jointly with others, during the period of my employment with Opexa which are related to the business of Opexa, or result from tasks assigned to me by Opexa, or result from use of premises owned, leased or contracted for by Opexa (all said improvements, inventions, formulae, processes, techniques, know-how, data and the like shall be collectively hereinafter called "*Inventions*"). Such disclosure shall continue for one year after Termination with respect to anything that would be an Invention if made, conceived, reduced to practice or learned prior to Termination.

6. I agree to keep and maintain adequate and current records (in the form of notes, sketches, documentation, drawings and in any other form that may be required by Opexa) of all Confidential Information developed by me and all Inventions made by me during the period of my employment at Opexa, which records shall be made available to and remain the sole property of Opexa at all times.

7. I agree that all Inventions shall be the sole property of Opexa and its assigns, and Opexa and its assigns shall be the sole owner of all trade secrets, patents, copyrights and other rights in connection therewith and all Confidential Information with respect thereto. I hereby assign to Opexa any and all rights I may have or acquire in all Inventions, including all rights that may be known as or referred to as "moral rights." I further agree as to all Inventions to assist Opexa in every proper way (but at Opexa's expense) to obtain and from time to time enforce patents and copyrights on Inventions in any and all countries, and to that end I will execute all documents for use in applying for and obtaining such patents and copyrights thereon and enforcing the same, as Opexa may desire, together with any assignments thereof to Opexa or persons designated by it. My obligation to assist Opexa in obtaining and enforcing patents and copyrights for the Inventions in any and all countries shall continue beyond Termination, but Opexa shall compensate me at a reasonable rate after Termination for time actually spent by me at Opexa's request on such assistance. In the event that Opexa is unable for any reason whatsoever to secure my signature to any lawful and necessary document required to apply for or execute any patent or copyright application with respect to Inventions (including renewals, extension, continuations, divisions, continuations in part or preservation of rights in respect thereof), I hereby irrevocably designate and appoint Opexa and its duly authorized officers and agents, as my agents and attorneys-in-fact to act for and in my behalf and instead of me, to execute and file any such application and to do all other lawfully permitted acts to further the prosecution and issuance of patents or copyrights thereon with the same legal force and effect as if executed by me.

8. As a matter of record I have identified on Annex 1 hereto a complete list of all inventions or improvements relevant to the subject matter of my employment by Opexa which have been made or conceived or first reduced to practice by me alone or jointly with others prior to my employment by Opexa (**"***Prior Inventions***"**) which I desire to remove from the operation of this Agreement. If disclosure of any such Prior Invention would cause me to violate any prior confidentiality agreement, I understand that I am not to list such Prior Invention on Annex 1 but am only to disclose a cursory name for each such Prior Invention, a listing of the party(ies) to whom it belongs and the fact that full disclosure as to such Prior Inventions has not been made for that reason. I represent that my list of Prior Inventions is complete. If no such list of Prior Inventions is identified, I represent that I have made no such Prior Inventions at the time of the commencement of my employment by Opexa. Notwithstanding the foregoing, and without limiting the other provisions of this Agreement, I agree that (i) any improvements or new inventions to the item(s) so identified on such list (if any) shall be treated as Inventions for purposes of this Agreement if the provisions of Section 5 above are otherwise applicable and (ii) if, in the course of my employment with Opexa, I incorporate a Prior Invention into an Opexa product, process, application, machine or invention, Opexa is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicensees) to make, have made, modify, use and sell such Prior Invention. Notwithstanding the foregoing, I agree that I will not incorporate, or permit to be incorporated, Prior Inventions in any Opexa product, process, application, machine or invention without Opexa's prior written consent.

9. I represent that my performance of all the terms of this Agreement and that my employment by Opexa does not and will not breach or constitute an event of default under any agreement (i) obligating me to keep in confidence proprietary information acquired by me in confidence or in trust prior to, or at any point throughout, my employment by Opexa, (ii) obligating me to assign to or protect for the benefit of any third party any proprietary information or any improvement, invention, formulae, process, program, technique, know-how or data or (iii) that is designed in any way to limit my employment or activity in any business in which I may compete, directly or indirectly, with any other business, or which might by application have such an effect. I have not entered into, and I agree that I will not enter into, any agreement (either written or oral) in conflict herewith.

10. I understand, acknowledge and agree that, as part of the consideration for my employment or continued employment by Opexa, I have not brought and will not bring with me to Opexa or use in the performance of my responsibilities at or for Opexa any equipment, supplies, facilities, trade secrets or other proprietary information of any former employer which are not generally available to the public, unless I have obtained (and provide herewith to Opexa a copy of) written authorization for their possession and use.

11. I also understand that, during the course of my employment by Opexa, I am not to breach any obligation of confidentiality that I have to others, and I agree that I shall fulfill all such obligations during my employment by Opexa. A copy of any document reflecting any such obligation, or a description thereof if no document is available, is provided herewith to Opexa.

12. I agree that during the term of my employment with Opexa and for a period of twelve (12) months after Termination, I will not directly or indirectly: (i) induce or attempt to induce any employee or consultant of Opexa to leave the employ of Opexa or to otherwise end such employee's or consultant's relationships with Opexa or (ii) other than on behalf of Opexa, induce or attempt to induce any other person to terminate a relationship with Opexa.

13. After Termination, I hereby consent to the notification of my new employer (if any) of my rights and obligations under this Agreement.

14. I acknowledge that, due to the uniqueness of my relationship with Opexa, Opexa would not have an adequate remedy at law for money damages in the event that this Agreement is not fully performed in accordance with its terms. I agree that in addition to any other rights and remedies available to Opexa for any breach by me of my obligations hereunder, Opexa shall be entitled to enforcement of my obligations hereunder by court injunction (without the posting of a bond or other security), specific performance or other appropriate equitable relief.

15. If any one or more of the provisions of this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect the other provisions of this Agreement and this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein. If, moreover, any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it shall be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it shall then appear.

16. If applicable, this Agreement does not apply to ideas or inventions for which no equipment, supplies, facility or trade secret information of Opexa were used and which were developed entirely on my own time, and (i) which do not relate at the time of conception or reduction to practice of the invention (a) to the actual business of Opexa, or (b) to Opexa's actual or demonstrably anticipated research or development, or (ii) which do not result from any work performed by me for Opexa. Notwithstanding the foregoing, I shall disclose in confidence to Opexa any invention in order to permit Opexa to make a determination as to compliance by me with the terms and conditions of this Agreement.

17. This Agreement shall be effective as of the first day of my employment by Opexa and shall survive Termination. The term "*employment*" and the term or duration of my employment, as used herein and for purposes of this Agreement, shall include, without limitation, any consulting relationship or service pursuant to a directorship between myself and Opexa (including, if applicable, any such relationship which may follow the termination of my status as an employee of Opexa or which may precede my status as an employee of Opexa). Accordingly, notwithstanding any other provision of this Agreement to the contrary (and without limitation), a "*Termination*" shall not be deemed to have occurred if a consulting relationship or directorship persists following the termination of my status as an employee of Opexa (if applicable).

18. The term Opexa, as used herein, shall include (i) Opexa, (ii) any predecessor or successor to Opexa or its business or assets, (iii) any subsidiary or affiliate of Opexa or any such predecessor or successor and (iv) any predecessor or successor to any such subsidiary or affiliate or its business or assets.

19. This Agreement shall be binding upon me, my heirs, executors, assigns and administrators and shall inure to the benefit of Opexa, its successors and assigns.

20. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Texas, without regard to the conflicts of law principles thereof.

I have read this Agreement carefully and understand its terms. The list of Prior Inventions attached on Annex 1 is complete.

Dated as of: March 4, 2010

Signature: /s/ Don Healey
Don Healey

Accepted and Agreed to:

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma
Name: Neil K. Warma
Its: President and CEO

Annex 1

(Don Healey)

Prior Inventions

(a) Prior Inventions. Except as set forth in part (b) below, the following is a complete list of all Prior Inventions (as defined in Section 8 of the Proprietary Information and Inventions Agreement to which this Exhibit is attached) relevant to the present business of Opexa:

❒ None.

❒ See below.

_____

_____

_____

_____

_____

_____

_____

_____

_____

❒ Additional sheets attached.

(b) Confidential Prior Inventions. Due to a prior confidentiality agreement, I cannot complete the disclosure with respect to the inventions or improvements generally listed below, the proprietary rights and duty of confidentiality with respect to which I owe to the following party(ies):

	Invention or Improvement	Party(ies)	Relationship
1.			
2.			
3.			
4.			
5.			

❒ Additional Sheets Attached.

EXHIBIT C

AGREEMENT TO ARBITRATE

I, Don Healey (the "*Employee*"), and Opexa Therapeutics, Inc. (the "*Company*"), hereby enter into this agreement to arbitrate (the "*Agreement*").

The parties hereto agree that, except as noted below, any controversy, claim or dispute arising out of, concerning or relating in any way to the Employee's employment with the Company or the termination thereof, whether arising in tort, contract or pursuant to a statute, regulation or ordinance now in existence or which may in the future be enacted or recognized (the "*Claims*") shall be submitted exclusively to final and binding arbitration. **The parties hereto understand and agree that by entering into this Agreement they are waiving their respective right to bring such Claims to court, including any right to a jury trial.**

The Claims subject to this Agreement include, but are not limited to: (a) claims for fraud, promissory estoppel, fraudulent inducement of contract or breach of contract or contractual obligation, whether such alleged contract or obligation be oral or written, express or implied by fact or law; (b) claims for wrongful termination of employment, wrongful termination in violation of public policy and constructive discharge, infliction of emotional distress, misrepresentation, interference with contract or prospective economic advantage, defamation, unfair business practices, and any other tort or tort-like causes of action relating to or arising from the employment relationship; (c) claims for discrimination, harassment, or retaliation under any and all federal, state, or municipal statutes, regulations, or ordinances (including, but not limited to, Title VII of the Civil Rights Act of 1965, the Americans With Disabilities Act and the Age Discrimination in Employment Act) as well as claims for violation of any other federal, state, or municipal statute, regulation, or ordinance, except as set forth herein; (d) claims for wages, commissions, bonuses, severance, employee benefits, stock options and the like, whether such claims are based on alleged express or implied contract or obligation, equity, the Texas Labor Code, the Fair Labor Standards Act, the Employee Retirement Income Securities Act or any other federal, state, or municipal laws concerning wages, compensation or employee benefits; (e) claims arising out of or relating to the grant, exercise, vesting and/or issuance of equity in the Company or options to purchase equity in the Company; and (f) claims concerning the validity, infringement, enforceability or misappropriation of any trade secret, patent right, copyright, trademark, or any other intellectual or confidential property held or sought by the Employee or the Company, including claims alleged by Employee or the Company that arise under the Company's Proprietary Information and Inventions Agreement regarding such intellectual or confidential property.

Notwithstanding the above: (a) nothing in this Agreement shall be construed as limiting the Employee's right to file a claim with or seek the assistance of the Equal Employment Opportunity Commission, or any similar state agency, however, any claim that cannot be resolved administratively shall be subject to this Agreement; (b) the following disputes and claims are not covered by this Agreement and shall therefore be resolved by both parties in any appropriate forum, including courts of law, as required by the laws then in effect: (i) claims for workers' compensation benefits; (ii) claims for unemployment insurance benefits; and (iii) claims for state or federal disability insurance benefits; and (c) neither party waives the right to seek through judicial process, preliminary injunctive relief to preserve the status quo or prevent irreparable injury before the matter can be heard in arbitration.

The arbitration provided under this Agreement shall be conducted by a single arbitrator in accordance with the then-current rules issued by the American Association (" *AAA*") for the resolution of employment disputes, which rules are incorporated herein by reference. The parties understand and agree that the arbitration shall take place in The Woodlands, Texas, or, at the Employee's option, in the county in which the Employee primarily worked with the Company at the time the arbitrable dispute or claim arose.

Both the Employee and the Company have the right to be represented by counsel of their choice. Each party shall be responsible for his/her/its own attorneys' fees, except as provided by law. The Company will pay the arbitrator's fee for the proceeding, as well as any administrative, room or other charges required by AAA. However, each party shall be responsible for all costs associated with discovery which that party initiates, *e.g.*, depositions, except that a party or third-party witness being deposed shall be responsible for the cost of a copy of the transcript if he/she/it chooses to order a copy.

The arbitrator shall issue a written arbitration decision or award stating the arbitrator's essential findings and conclusions upon which the decision or award is based. The decision or award of the arbitrator shall be final and binding upon the parties. The arbitrator shall have the power to award any type of legal or equitable relief that would be available in a court of competent jurisdiction including, but not limited to, costs, attorneys' fees, and punitive damages when such damages and fees are available under the applicable statute and/or judicial authority. Either party may file pre-hearing motions directed at the legal sufficiency of a claim or defense equivalent to a demurrer or summary judgment prior to the arbitration hearing. The arbitrator's decision or award may be entered as a judgment or order in any court of competent jurisdiction.

The parties agree to file any demand for arbitration within the time limit established by the applicable statute of limitations for the asserted claims or within one year of the conduct that forms the basis of the claim if no statutory limitation is applicable. Failure to demand arbitration within the prescribed time period shall result in waiver of said claims. The parties further agree that nothing in this Agreement relieves either of them from any obligation they may have to exhaust certain administrative remedies before arbitrating any claims or disputes under this Agreement.

The parties understand and agree that neither the terms nor the conditions described in this Agreement are intended to create a contract of employment for a specific duration of time or to limit the circumstances under which the Employee's employment may be terminated.
This is the complete agreement between the Employee and the Company on the subject of the arbitration of disputes. This Agreement supersedes any prior or contemporaneous oral or written understanding on the subject. This Agreement shall be governed by and shall be interpreted in accordance with the laws of the State of Texas. The terms of this Agreement may not be orally modified. This Agreement can be modified only by a written document signed by the CEO of the Company and the Employee. The parties hereto further agree that this Agreement shall survive the termination of the Employee's employment.

In the event that any provision of this Agreement is determined by the arbitrator or by a court of competent jurisdiction to be illegal, invalid, or unenforceable to any extent, such term or provision shall be enforced to the extent permissible under the law and all remaining terms and provisions hereof shall continue in full force and effect.

Both parties acknowledge, represent and warrant that they are knowingly and voluntarily entering into this Agreement, that they have or may consult with an attorney concerning the terms of this Agreement, and understand that by entering into this Agreement they are agreeing to waive a jury trial as to all Claims.

EMPLOYEE	OPEXA THERAPEUTICS, INC.
/s/ Don Healey Signature	/s/ Neil K. Warma Signature
March 4, 2010 Date	March 2, 2010 Date
Don Healey Print Name	Neil K. Warma Print Name
	President and CEO Title

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), Form S-3 (File No. 333-191655, 333-185003, 333-185001 and 333-208314) and Form S-8 (File No. 333-192215, 333-176934 and 333-139196) of our report dated March 15, 2016 with respect to the audited consolidated financial statements of Opexa Therapeutics, Inc. as of December 31, 2015 and 3014 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
March 15, 2016

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: March 15, 2016

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, 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: March 15, 2016

By: /s/ Neil K. Warma
Neil K. Warma
Acting Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Annual Report of Opexa Therapeutics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2015 (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: March 15, 2016

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, 2015 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Neil K. Warma, Acting Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

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

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

Date: March 15, 2016

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