**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, 2016

☐ **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 |
| Warrants to purchase common stock | 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 acceleratedfiler ☐ Acceleratedfiler ☐ Non-accelerated filer (Do not check if a smaller reporting company) ☑ Smaller reportingcompany

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, 2016 based upon the closing price as of such date was $27,500,691.

As of March 10, 2017, 7,657,332 shares of the registrant's common stock, par value $0.01 per share, were outstanding.

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**Forward-Looking Statements**

This Annual Report on Form 10-K contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements contained in this report, other than statements of historical fact, constitute "forward-looking statements." The words "expects," "believes," "hopes," "anticipates," "estimates," "may," "could," "intends," "exploring," "evaluating," "progressing," "proceeding" and similar expressions are intended to identify forward-looking statements. These forward-looking statements do not constitute guarantees of future performance. Investors are cautioned that statements which are not strictly historical statements, including, without limitation, statements regarding current or future financial payments, costs, returns, royalties, performance and position, plans and objectives for future operations, plans and objectives for product development, plans and objectives for present and future clinical trials and results of such trials, plans and objectives for regulatory approval, litigation, intellectual property, product development, manufacturing plans and performance, management's initiatives and strategies, and the development of Opexa's product candidates, including 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:

- the continued development of Tcelna for the treatment of secondary progressive multiple sclerosis "SPMS"), the continued development of OPX-212 for neuromyelitis optica ("NMO"), or any continued research or development;
- 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 outcome of our clinical trials;
- the efficacy of Tcelna for any particular indication, such as for relapsing remitting multiple sclerosis or SPMS, and the efficacy of OPX-212 for 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 that has historically focused on developing personalized immunotherapies with the potential to treat major illnesses, including multiple sclerosis (MS) as well as other autoimmune diseases such as neuromyelitis optica (NMO). These therapies are based on our proprietary T-cell technology. 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.

On October 28, 2016, we announced that our Phase IIb clinical trial ("Abili-T") of our lead product candidate, Tcelna, in patients with secondary progressive MS (SPMS) did not meet its primary endpoint of reduction in brain volume change (atrophy), nor did it meet the secondary endpoint of reduction of the rate of sustained disease progression. Abili-T is a 183-patient, randomized, double-blind, placebo-controlled Phase IIb study that was conducted at 35 clinical trial sites in the U.S. and Canada and designed to evaluate the safety and efficacy of Tcelna (imilecleucel-T) in patients with SPMS. Patients in the Tcelna arm of the study received two annual courses of Tcelna treatment consisting of five subcutaneous injections per year. We completed enrollment of the Abili-T study in May 2014 and un-blinded the results from the study in late October 2016.

The primary endpoint for the Abili-T study was the percentage of whole brain volume change as measured by magnetic resonance imaging ("MRI") at two years. The analysis was conducted using a mixed model of repeated measures to include data from months 6, 12 and 24, relative to baseline normalized brain volume values. The mean percentage (and standard deviation) brain volume loss at two years for placebo-treated subjects was -0.657 (0.7598), and for Tcelna-treated subjects was -0.886 (0.7519) [p=0.043]. Further analysis of the data may be conducted to evaluate the potential for pseudo-atrophy to be a primary driver in the change in whole brain atrophy for Tcelna versus placebo-treated subjects.

Secondary endpoints included percentage of subjects with confirmed disease progression of disability in one or more of the Expanded Disability Status Scale ("EDSS"), Timed 25-foot Walk ("T25FW"), or 9-Hole Peg Test ("9HPT"). For each test, the following definitions were applied: EDSS score increased from baseline by at least 1 point if baseline EDSS <6.0, or by at least 0.5 points if baseline EDSS ≥6 sustained for 12 weeks; for T25FW, time increased by at least 20% of the baseline walk sustained for six months; and for 9HPT, time increased by at least 20% of the time taken at baseline sustained for six months. After two years on study, 32.2% of placebo-treated subjects were scored as progressed, compared to 33.3% of Tcelna-treated subjects [p=0.873]. A further secondary endpoint monitored time to sustained progression of disability by EDSS confirmed over three months, but not associated with an acute relapse. 17.8% of placebo subjects versus 20.4% of Tcelna-treated subjects were scored as progressed by EDSS after two years on study. Time (in months) to sustained progression by Kaplan-Meier analysis generated values for the 25% quartile of 24.9 for placebo, versus 25.0 for Tcelna [p=0.697].

The overall summary of adverse events ("AEs") in the safety population consisting of 93 placebo subjects and 96 Tcelna-treated subjects found no difference in treatment-emergent adverse events ("TEAE") possibly, probably or definitely related to study treatment. The number of subjects with a TEAE leading to early study termination was 9 (9.7%) in the placebo treatment arm, versus 6 (6.3%) in the Tcelna treatment arm. Tcelna was considered safe and well tolerated.

An immune monitoring program was conducted on blood samples collected over time to detect Tcelna-induced immune modulation. The analysis of the differentiation and functional status of various anti-inflammatory/regulatory CD4+ T-cells showed no difference between Tcelna and placebo-treated subjects. A statistically significant increase in CD4+ T-cells displaying a Th17 (IL-17+) and Th1 (IFNg+) profile was recorded in Tcelna-treated subjects. This inflammatory response to the Tcelna product may correlate with priming of the immune response to target myelin-reactive T-cells (MRTC). A correlation analysis of immune monitoring T-cell phenotypes to MRTC bio-activity has not yet been conducted.

After further analysis of the data from the Abili-T trial, we have determined that we will not move forward with further studies of Tcelna in SPMS at this time. We are conducting a review of our other research and development programs, including our preclinical program for OPX-212 in NMO, to assess the viability of continuing to pursue one or more of these programs. We are also exploring our strategic alternatives. We cannot fully predict our future cash needs until we complete this analysis.

We implemented a reduction in workforce of 40% of our then 20 full-time employees, announced on November 2, 2016, while we reevaluated our programs and various strategic alternatives in light of the disappointing Abili-T study data. On December 14, 2016, a further workforce reduction was implemented to conserve cash, reducing the number of full-time employees by an additional 25% of the then 12 employees. As of December 31, 2016, we had nine full-time employees. On January 31, 2017, an additional workforce reduction of seven full-time employees was implemented to conserve cash.

On February 1, 2017, we assigned to a third party all of our rights and obligations under the lease for our 10,200 square foot corporate headquarters facility located in The Woodlands, Texas. In light of our continuing evaluation of our strategic alternatives following the release of data from the Abili-T clinical study, management deemed it advisable to reduce our office, R&D and manufacturing space and corresponding rent obligations.

To date, we have devoted substantially all of our resources to research and development efforts relating to Tcelna, including conducting clinical trials and developing manufacturing capabilities, providing general and administrative support for these operations, and protecting our intellectual property. We do not have any products approved for sale and have never generated any commercial revenues, nor do we expect to generate any commercial revenues for the foreseeable future or other revenues in the near term that will result in cash receipts. From inception, we have funded our operations primarily through the sales of equity and debt securities.

We have incurred net losses in each year since our inception. As of December 31, 2016, we had an accumulated deficit of approximately $161.3 million. Substantially all of our net losses, including those incurred during the periods presented in this report, have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We cannot predict whether and to what extent we will resume drug development activities. If we determine to continue the development of one or more of our programs, we expect to continue to incur significant expenses and increasing losses for at least the next several years. We would need to raise additional capital in order to conduct further development. We continue to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to support our ongoing operations through and beyond the next 12 months, including raising additional capital through either private or public equity or debt financing as well as using our ATM facility and cutting expenses where possible. However, given the disappointing results of our Abili-T trial, we believe our ability to issue equity securities or obtain debt financing in the future on favorable terms, or at all, has been substantially impaired, particularly if the intended use of proceeds would be for the continued development of Tcelna.

If we are unable to obtain additional funding to support our current or proposed activities and operations, we may not be able to continue our operations as proposed, which may require us to suspend or terminate any ongoing development activities, 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 substantial portion or even all of their investment.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to the results of our identification and evaluation of potential strategic alternatives and the extent to which we elect to pursue drug development activities in the future.

If we are unable to seek an appropriate use for our remaining assets, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our shareholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

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.

**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 the option to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna program for the treatment of MS (the "Option"). The Option was exercisable 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. The agreement provided that upon exercise, 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. We would have also been entitled to receive certain milestone and royalty payments upon the achievement of development milestones by Merck Serono for Tcelna in SPMS. On March 9, 2015, we entered into a First Amendment of Option and License Agreement with Merck Serono pursuant to which we received a payment of $3 million in consideration for performing certain activities in connection with pre-Phase III planning and providing updates and analysis to Merck Serono with respect to our immune monitoring program conducted in conjunction with the Abili-T clinical trial.

On November 23, 2016, we received notice from Merck Serono that it would not be exercising the Option. As a result of receiving the notice from Merck Serono, our Option and License Agreement with Merck Serono automatically expired upon receipt. If we are not successful in attracting another partner, we may not be able to complete development of or commercialize any product candidate. 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. In such event, our shareholders may lose a substantial portion or even all of their investment.

**License Agreement with Baylor College of Medicine**

In 2001, we entered into an agreement with Baylor College of Medicine for the exclusive worldwide license to a patient-specific, autologous T-cell immunotherapy for the treatment of MS, which is the initial T-cell technology on which Tcelna is based, including rights to certain patents held by Baylor. In consideration for the right and license to commercially exploit such technology, we agreed to pay the following (per scenario 1 of the license agreement): (i) a 2% royalty on net sales of licensed patented products sold by Opexa or its affiliates where annual gross sales of such products is less than or equal to $500 million; (ii) a 1% royalty on net sales of licensed patented products sold by Opexa or its affiliates where annual gross sales of such products exceed $500 million; (iii) a 1% royalty on net sales of licensed patent pending products sold by Opexa or its affiliates; and (iv) a 1% royalty on net sales of licensed patented products or licensed patent pending products sold by any sublicensees of Opexa. Unless earlier terminated, the Baylor license agreement expires in 2025 upon expiration of the last of the licensed patent rights.

**NMO – OPX-212**

In addition to our clinical development program for Tcelna, we have been developing OPX-212 as an autologous T-cell immunotherapy for the treatment of NMO. This program is currently in the preclinical development stage and we have been conducting IND-enabling activities. 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.

OPX-212 could be manufactured 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. Assuming it advances to clinical development, we believe OPX-212 for NMO would qualify for Orphan drug designation, and we would 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.

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, 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 included 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. However, we did not meet any of the milestones in 2016 or the first milestone in 2017 that would have allowed for the sale of additional shares to the purchasers, and we do not currently expect to meet the last milestone, and therefore no further shares are anticipated to be sold under this agreement.

**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 has been on the development of Tcelna in SPMS, as well as our development plans for OPX-212 in NMO, it is possible that the T-cell platform could be expanded into other autoimmune diseases as well as used in connection with potentially in-licensing 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 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**

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 years ended December 31, 2016 and 2015 were approximately $6.5 million and $10.0 million, respectively, 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. To date, we have focused on developing our T-cell technology for MS and NMO and have not generated any commercial revenues from operations.

**Employees**

During 2016, we implemented a number of restructuring initiatives and workforce reductions as the operational demands associated with completing the Abili-T clinical trial for Tcelna in patients with SPMS were completed, and then subsequently, as a result of the disappointing results from the data release from the trial. On March 2, 2016, we announced the 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. On November 2, 2016, another restructuring initiative was announced which included an additional reduction of approximately 40% of our then 20 full-time employees. A further workforce reduction was implemented on December 14, 2016 of an additional 25% of the then 12 employees, and as of December 31, 2016, we had nine full-time employees. On January 31, 2017, an additional workforce reduction of seven full-time employees was implemented to conserve cash, and as of March 27, 2017, we have two full-time employees. 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**

***Our business to date has been almost entirely dependent on the development of Tcelna, which recently failed to show a treatment effect in the Phase IIb clinical trial known as the Abili-T study. We are continuing to assess the viability of our other research and development programs and conduct a review of strategic alternatives, and it is possible that we may ultimately decide not to pursue any further drug development of Tcelna or our other programs. Although we have decreased our cash burn substantially, our cash needs over the next few months may be unpredictable.***

On October 28, 2016, we announced that the Phase IIb Abili-T clinical trial designed to evaluate the efficacy and safety of Tcelna (imilecleucel-T) in patients with SPMS did not meet its primary endpoint of reduction in brain volume change (atrophy), nor did it meet the secondary endpoint of reduction of the rate of sustained disease progression. We had previously devoted substantially all of our research, development, clinical efforts and financial resources toward the development of Tcelna. We implemented a reduction in workforce of 40% of our then 20 full-time employees, announced on November 2, 2016, while we reevaluated our programs and various strategic alternatives in light of the disappointing Abili-T study data. On December 14, 2016, a further workforce reduction was implemented to conserve cash, reducing the number of full-time employees by an additional 25% of the then 12 employees. As of December 31, 2016 we had nine full-time employees. On January 31, 2017, an additional workforce reduction of seven full-time employees was implemented to conserve cash. After further analysis of the data from the Abili-T trial, we have determined that we will not move forward with further studies of Tcelna in SPMS at this time. We are conducting a review of our other research and development programs, including our preclinical program for OPX-212 in NMO, to assess the viability of continuing to pursue one or more of these programs. We are also exploring our strategic alternatives. We cannot fully predict whether or to what extent we will resume drug development activities, and we cannot predict our future cash needs until we complete this analysis and while we are evaluating strategic alternatives.

***If we decide to continue one or more of our development programs, we will be required to raise additional capital, and our ability to obtain funding in light of the disappointing results from the Abili-T study is likely to be challenging. If sufficient capital is not available, we may not be able to continue our operations, which may require us to suspend or terminate any ongoing development activities, modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws.***

As of December 31, 2016, we had cash and cash equivalents of $3.4 million as well as accounts payable, short-term notes payable and accrued expenses aggregating $1.2 million. Our operating cash burn rate during the 12 months ended December 31, 2016 was approximately $767,000 per month, which was mainly for the completion and wind down of the Phase IIb Abili-T clinical study in SPMS.

We believe that we have sufficient liquidity to support our current activities in winding down the Abili-T trial and for general operations to sustain the Company and support such activities into the second quarter of 2017. However, if our projections prove to be inaccurate, or if we encounter additional costs to wind down the trial or to sustain our operations, or if we incur other costs such as those associated with pursuing further research and development, we would need to raise additional capital to continue our operations.

If we decide to continue the development of one or more of our programs, we expect to continue to incur significant expenses and increasing losses for at least the next several years. We would need to raise additional capital in order to conduct additional clinical trials of Tcelna or any other product candidates. Given the disappointing results of our Abili-T trial, we believe our ability to issue equity securities or obtain debt financing in the future on favorable terms, or at all, has been substantially impaired, particularly if the intended use of proceeds would be for the continued development of Tcelna.

We continue to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to support our ongoing operations through and beyond the next 12 months, including raising additional capital through either private or public equity or debt financing as well as using our ATM facility and cutting expenses where possible. However, in light of the Abili-T study results, there can be no assurance that we will be able to secure additional funds or, if such funds are available, that the terms or conditions would be acceptable to us. If we are unable to obtain additional funding to support our current activities and operations, we may not be able to continue our operations as proposed, which may require us to suspend or terminate any development activities, 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 substantial portion or even all of their investment.

If we are not successful in attracting another partner, we may not be able to complete development of or commercialize any product candidate. 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. In such event, our shareholders may lose a substantial 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 ATM facility. 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;
- 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.

***There is substantial doubt as to our ability to continue as a going concern, which may make it more difficult for us to raise capital.***

The report of our independent auditors in respect of the 2016 fiscal year expressed substantial doubt about our ability to continue as a going concern. Specifically, it noted our recurring losses, negative operating cash flows and accumulated deficit. Our consolidated financial statements as of December 31, 2016 and for the 12-month period then ended were prepared assuming that we will continue as a going concern, meaning that we will continue in operation for the foreseeable future and will be able to realize assets and discharge liabilities in the ordinary course of operations. While we have historically recognized revenue related to the $5 million and $3 million payments from Merck Serono received in February 2013 and March 2015 in connection with the Option and License Agreement and the Amendment over the exclusive option period based on the expected completion term of the Abili-T clinical trial, we have never generated any commercial revenues, nor do we expect to generate any commercial revenues for the foreseeable future or other revenues in the near term that will result in cash receipts. As of December 31, 2016, we had cash and cash equivalents of $3.4 million as well as accounts payable, short-term notes payable and accrued expenses aggregating $1.2 million.

On October 28, 2016, we announced that the Abili-T trial did not meet its primary or secondary endpoints, and, in order to conserve cash resources while we reevaluated our programs and explored various strategic alternatives, during the fourth quarter of 2016 and the first quarter of 2017 we implemented several reductions in workforce totaling 90% of our then 20 full-time employees. After further analysis of the data from the Abili-T trial, we have determined that we will not move forward with further studies of Tcelna in SPMS at this time, and we are conducting a review of our other research and development programs. We believe that we have sufficient liquidity to support our current activities in winding down the Abili-T trial and for general operations to sustain the Company and support such activities into the second quarter of 2017.

We continue to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to support our ongoing operations through and beyond the next 12 months, including raising additional capital through either private or public equity or debt financing as well as using our ATM facility and cutting expenses where possible. In the absence of significant additional funding to support our operations, there is substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Additionally, in light of the disappointing Abili-T study results, there can be no assurance that we will be able to secure additional funds, or if such funds are available, that the terms or conditions would be acceptable to us. If we are unable to obtain additional funding to support our current activities and operations, we may not be able to continue our operations as proposed, which may require us to suspend or terminate any development activities, 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 substantial portion or even all of their investment.

***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. To date, we have devoted substantially all of our resources to research and development efforts relating to Tcelna.***

Our business is at an early stage of development. We do not 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. To date, we have devoted substantially all of our resources to research and development efforts relating to Tcelna, including conducting clinical trials and developing manufacturing capabilities, providing general and administrative support for these operations and protecting our intellectual property. The disappointing results of from our Abili-T trial have resulted, at a minimum, in a development delay of at least a few years. If we decide to continue the development of one or more of our programs, we will need to commence and complete additional clinical trials, manage clinical and manufacturing activities, and obtain necessary regulatory approvals from the FDA in the United States and from foreign regulatory authorities in other jurisdictions. Additionally, our second pipeline candidate, OPX-212 is currently in preclinical development for the treatment of NMO. Any of our potential products will require regulatory approval prior to marketing in the United States and other countries. Obtaining such approval requires significant research and development and preclinical and clinical testing. We may not be able to develop any products, obtain regulatory approvals, enter clinical trials (or any development activities) for any product candidates, or commercialize any products. Any of our potential products may prove to have undesirable or unintended side effects or other characteristics adversely affecting their safety, efficacy or cost-effectiveness that could prevent or limit their use. Any product using any of our technology may fail to provide the intended therapeutic benefits or to achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production.

***The Abili-T trial results cast doubt about the probative value of our results in earlier clinical trials of Tcelna.***

Trial designs and results from previous trials are not necessarily predictive of our future clinical trial designs or results. For example, although the results of prior clinical trials of Tcelna for the treatment of MS included evidence of efficacy, the Abili-T trial for the treatment of patients with SPMS failed to meet either its primary or secondary endpoints.

There is a high failure rate for drug candidates proceeding through clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

***We will need regulatory approvals for any product candidate 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 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. Failure can occur at any stage of the trials, and problems could be encountered that would cause us to be unable to initiate a trial, or to abandon or repeat a clinical trial.

The commencement and completion of clinical trials 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 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, 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, will be limited by any failure to obtain or limitation on necessary regulatory approvals.

***As a result of the disappointing data from the Abili-T trial and the reductions in our workforce during 2016 and early 2017, our workforce has been reduced substantially. If we are unable to retain our remaining employees, or rebuild our workforce if we decide to continue one or more of our development programs, our business will be seriously jeopardized. It will be difficult to grow or operate our business with the limited number of employees we currently have.***

On November 2, 2016, we announced a reduction of 40% of our then full-time workforce of 20 employees as a result of the disappointing data from the Abili-T study. On December 14, 2016, a further workforce reduction was implemented to conserve cash, reducing the number of full-time employees by an additional 25% of the then 12 employees. As of December 31, 2016, we had nine full-time employees. On January 31, 2017, an additional workforce reduction of seven full-time employees was implemented to conserve cash, leaving us at this point with only two full-time employees. Our Chief Development Officer resigned in November 2016 after announcement of the Abili-T trial results and the employment of our Chief Scientific Officer was terminated as part of the January 2017 reduction. We have only one officer remaining, who is our President, Chief Executive Officer and Acting Chief Financial Officer.

Our exploration of strategic alternatives and cash conservation activities may yield unintended consequences, such as attrition beyond our planned reductions in workforce and reduced employee morale which may cause our remaining employees to seek alternate employment. In such event, we may be unable on a timely basis to hire suitable replacements to operate our business effectively. The loss of the services of any of our employees could have a material adverse effect on our business and results of operations. Our restructuring initiatives have caused disruption in our business operations, and we may not be able to effectively realize the savings anticipated by any restructuring initiative and reductions-in-force. Additionally, there may be future 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 any workforce reduction, including the possibility that we may incur unanticipated charges or make cash payments that are not contemplated.

Additionally, if we ultimately decide to pursue one or more of our development programs, we will need to rebuild our workforce and management team. We may be unable on a timely basis to hire and train suitable new employees to continue to operate our business and further any such development programs. It will be difficult to grow or operate our business with the small number of employees we currently have.

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

We conducted an immune monitoring program on blood samples collected over time to detect Tcelna-induced immune modulation. While certain data has been analyzed to date, a correlation analysis of immune monitoring T-cell phenotypes to MRTC bio-activity has not been conducted. 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, or we may elect not to proceed with certain analyses, and these changes may result in either increased or decreased expenses for the study.

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

***We would need to 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.***

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. We would need to rely on contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct any clinical trials and to perform data collection and analysis.

Any clinical trials we may conduct could 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. While we believe that there are numerous alternative sources to provide these services, we might not be able to enter into replacement arrangements without delays or additional expenditures if we were to seek such alternative sources.

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

We have focused on MS as the first disease to be pursued off our T-cell platform technology, and in 2014, we initiated development activities for OPX-212, our drug candidate for NMO, as the second disease we are pursuing. As a platform technology, there exists the potential to address other autoimmune diseases with the technology. While preclinical development and manufacturing activities have been conducted for OPX-212 in NMO, such work is modest compared to the effort that has been committed to Tcelna for the lead MS indication. However, inasmuch as the Abili-T study of Tcelna in SPMS did not meet either its primary or secondary endpoints, we have determined that we will not move forward with further studies of Tcelna in SPMS at this time and are assessing whether to continue our development activities. 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.

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

Our business depends on licenses from third parties. These third party license agreements impose obligations on us, such as payment obligations and obligations diligently to pursue development of commercial products under the licensed patents. If applicable, we may also need to seek additional licenses to move into Phase III trials or 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.

***We no longer lease a research and manufacturing facility in which to conduct development or manufacture product candidates for our programs or clinical trial activities or, if any such clinical trials were to be successful, commercial applications.***

Through January 2017, we conducted our research and development in a 10,200 square foot facility in The Woodlands, Texas, which included an approximately 1,200 square foot suite of three rooms for the manufacture of T-cell therapies. On February 1, 2017, we assigned the facility lease to a third party, who assumed from us all of our remaining rights and obligations under the lease. In connection with the lease assignment, we also sold certain furniture, fixtures and equipment (including laboratory and manufacturing equipment) as well as our laboratory supplies located at our corporate headquarters to the third party for cash consideration. In light of the continuing evaluation of our strategic alternatives following the release of data from the Abili-T clinical study, we deemed it advisable to reduce our office, R&D and manufacturing space and corresponding rent obligations. As a result, we are currently using temporary office space in the same facility but no longer have the capacity for any research and development or for any manufacturing operations. If we decide to continue to pursue development of any of our product candidates, we would need to locate and obtain a new facility, arrange for R&D and manufacturing staff, contract with corporate collaborators or other third parties to assist with future drug production and commercialization, or defer to a collaborative partner or third party to address these needs.

In the event that we decide to again establish a R&D or manufacturing facility, we would require substantial additional funds and would 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 an R&D or manufacturing facility, and we may not be able to build a facility that both meets regulatory requirements and is sufficient for our needs.

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 any of our product candidates. 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 any of our product candidates 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 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 was 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.***

Tcelna was based on our novel T-cell immunotherapy platform, ImmPath, which produces an autologous T-cell immunotherapy utilizing a patient's own blood. OPX-212 may 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 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 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 is approved, commercialization.

Regulatory approval of product candidates 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 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.***

Our ability to successfully commercialize any product we may eventually have, to the extent applicable, and/or our ability to receive any revenue 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, 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 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. We currently have a very limited workforce, and it may be difficult to adhere to appropriate internal controls over financial reporting or disclosure controls with such limited staffing. 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, especially in light of the fact that we currently have a very limited workforce. 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 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 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 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, which could delay development and commercialization.***

We, our third-party contractors and suppliers, and our product candidates 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 and our product candidates 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 and our product candidates. 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 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 may not be approved for all indications that we request, which would limit uses and adversely impact our potential royalties and product sales. Such approval may be subject to limitations on the indicated uses for which any potential product may be marketed or require costly, post-marketing follow-up studies.

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

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

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

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

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

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

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 may be rendered obsolete or uneconomical by new discoveries before we recover any expenses incurred in connection with their development. If our product candidates 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, 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 to other available therapies. If reimbursement of any product candidate 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 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. 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; the ability to set a price that we believe is fair for any product candidate; 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.

**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. In the past we have received staff deficiency letters from NASDAQ but we are currently compliant with NASDAQ listing requirements.

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. For example, as a consequence of our announcement on October 28, 2016 that the Abili-T trial did not meet either its primary or secondary endpoints, our stock has traded below $1.00 per share at times. If our stock price does not increase in the future, we may receive a notice 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 disappointing results recently announced on October 28, 2016 for the Abili-T clinical study of Tcelna in SPMS;
- announcements of significant changes in our business or operations, including the decision not to pursue one or more of our drug development programs or the decision to implement restructurings such as reductions in our workforce;
- the development status of any drug candidates, such as Tcelna, including clinical study results and determinations by regulatory authorities with respect thereto;
- the initiation, termination or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;
- our inability to obtain additional funding;
- 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. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. Moreover, following the announcement on October 28, 2016 of disappointing results for the Abili-T study, our stock price decreased substantially, which may portend securities class action litigation against us. If 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.***

On March 25, 2016, we entered into a new Sales Agreement with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.) as sales agent, pursuant to which we can offer and sell shares of our common stock from time to time depending upon market demand, in transactions deemed to be an "at the market" offering. We registered up to 1,000,000 shares of common stock for potential sale under the new ATM facility. From August 17, 2016 through December 31, 2016, we sold an aggregate of 66,184 shares of our common stock under our ATM facility. We generated gross and net proceeds, including amortization of deferred offering costs, of $293,345 and $276,912, respectively, with the average share price ranging from $4.12 to $4.73 per share. During January 2017, we further sold an aggregate of 516,278 shares of common stock for gross proceeds of $490,098, with the average share price ranging from $0.90 to $0.97. 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.

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 7,141,054 shares of common stock were outstanding as of December 31, 2016. As of such date, another (i) 481,947 shares of common stock were issuable upon exercise of outstanding options and (ii) 3,596,625 shares of common stock were issuable upon the exercise of outstanding warrants. A substantial majority of the outstanding shares of our common stock and warrants (as well as a substantial majority of the shares of common stock issuable upon exercise of outstanding options and warrants) are freely tradable without restriction or further registration under the Securities Act of 1933.

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

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

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

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

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

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

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

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

In addition to general corporate purposes (including working capital, research and development, business development and operational purposes), we currently intend to use our available cash to continue to assess the viability of pursuing one or more of our research and development programs, including our preclinical program for OPX-212 in NMO, and to explore our strategic alternatives. We cannot fully predict our future cash needs until we complete this analysis. However, after further analysis of the data from the Abili-T trial, we have determined that we will not move forward with further studies of Tcelna in SPMS at this time.

Depending on future developments and circumstances, we may use some of our available cash for other purposes which may have the potential to decrease our 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 our Series M warrants, 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. 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. 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.***

The Series M warrants issued in April 2015 will expire on April 9, 2018. The warrants entitle the holders to purchase shares of common stock at an exercise price of $12.00 per share through their expiration. 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 may be redeemed on short notice. This may have an adverse impact on their price.***

We may redeem the Series M warrants for $0.01 per warrant if 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, 2016, we had net operating loss carryforwards (NOLs) for federal income tax purposes of approximately $74 million. These NOLs are generally carried forward to reduce taxable income in future years. If unused, the NOLs will begin to expire December 31, 2024. 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. 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.

***The employment agreement with our President and Chief Executive Officer may require us to pay severance benefits if he is terminated under specified circumstances, including in connection with a change of control of us, which could harm our financial condition or results.***

The employment agreement with our President and Chief Executive Officer contains change of control and severance provisions providing for the payment of severance and other benefits, including accelerated vesting of stock options, in the event of a termination of employment under specified circumstances, including in connection with a change of control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of severance benefits could harm our financial condition and results of operation. In addition, these potential severance payments and benefits may discourage or prevent third parties from seeking a business combination with us.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

Through January 2017, we leased a 10,200 square foot facility located on three acres at 2635 Technology Forest Boulevard in The Woodlands, Texas. This location provided 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 remained available for future build-out. We leased the facility for a term ending in September 2020 with two options for an additional five years each at the then prevailing market rate.

On February 1, 2017, we assigned the facility lease to a third party, who assumed from us all of our remaining rights and obligations under the lease. In connection with the lease assignment, we also sold certain furniture, fixtures and equipment (including laboratory and manufacturing equipment) as well as our laboratory supplies located at our corporate headquarters to the third party for cash consideration. In light of the continuing evaluation of our strategic alternatives following the release of data from the Abili-T clinical study, we deemed it advisable to reduce our office, R&D and manufacturing space and corresponding rent obligations. As a result, we are currently using temporary office space in the same facility but do not have any long-term arrangements.

**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. All sales prices in the table below have been adjusted to reflect the one-for-eight reverse split of our common stock implemented on September 28, 2015.

| | Price Ranges | |
|---|---|---|
| | High | Low |
| **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 |
| | | |
| **Fiscal Year Ended December 31, 2016** | | |
| First Quarter | $ 2.87 | $ 1.69 |
| Second Quarter | 4.29 | 2.05 |
| Third Quarter | 4.93 | 2.92 |
| Fourth Quarter | 4.38 | .50 |

As of March 10, 2017, there were approximately 206 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, 2016, 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 (A) | Weighted Average Exercise Price of Outstanding Options (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 | 481,947 | $ 12.14 | 568,807 |
| Equity Compensation Plans Not Approved by Stockholders | — | — | — |
| Total | 481,947 | $ 12.14 | 568,807 |

Refer to Note 11 "Options and Warrants" in the Notes to our financial statements for the fiscal year ended December 31, 2016, 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.

On February 4, 2013, we entered into an Option and License Agreement (the "Merck Serono Agreement") with Ares Trading SA ("Merck Serono"). Pursuant to the terms, Merck Serono had an option to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna® program for the treatment of MS (the "Option"). The Option was exercisable by Merck Serono prior to or upon our completion of the Abili-T Phase IIb clinical trial for Tcelna in patients with secondary progressive MS. We received an upfront payment of $5 million for granting the Option and recognized revenues from the nonrefundable, up-front Option fee on a straight-line basis over the estimated Option exercise period which coincided with the expected completion term of the Abili-T trial. The expected completion term for revenue recognition was December 2016.

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 $3 million in consideration for certain activities to be conducted in connection with preparation for operational readiness for further clinical studies of Tcelna and for providing Merck Serono with updates and analysis with respect to our immune monitoring program that was conducted in conjunction with the Abili-T clinical trial. We evaluated the Merck Serono Amendment and determined that the $3 million payment from Merck Serono had stand-alone value due to our performance obligations thereunder. The $3 million payment was determined to be a single unit of accounting and was recognized as revenue on a straight-line basis over the period equivalent to the expected completion of the performance obligations in December 2016.

On October 28, 2016, we announced that the Abili-T clinical trial designed to evaluate the efficacy and safety of Tcelna in patients with SPMS did not meet its primary or secondary endpoints. On November 23, 2016, we received notice from Merck Serono that Merck Serono would not be exercising the Option, and as a result of such notice, the Merck Serono Agreement automatically expired.

**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, 2016 with the Year Ended December 31, 2015**

**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 $2,905,165 for the year ended December 31, 2016, compared to $2,556,329 for the year ended December 31, 2015. We recorded no commercial revenues for the years ended December 31, 2016 and 2015. 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 $6,497,531 for the year ended December 31, 2016, compared to $10,039,496 for the year ended December 31, 2015. 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. Also contributing to this decrease was the reduction in staff compensation expenses due to the reductions-in-force implemented during 2016. Offsetting these decreases in research and development expense was an increase in the stability testing of our custom reagent during 2016. We expense research and development costs as incurred. Property and equipment for research and development that has an alternative future use is capitalized and the related depreciation is expensed.

**General and Administrative Expenses.** Our general and administrative expenses were $3,122,337 for the year ended December 31, 2016, compared to $4,258,147 for the year ended December 31, 2015. The decrease is mainly due to a reduction in professional service fees, corporate governance expenses and a decrease in staff compensation due to the 2016 workforce reductions. Further reducing our general and administrative expense is the decrease in our option expense, driven by the factors used to evaluate the Black Scholes pricing model. These decreases were partially offset by an increase in directors' fees and the valuation of their stock-based compensation.

**Depreciation and Amortization Expenses** . Depreciation and amortization expenses were $238,127 for the year ended December 31, 2016, compared to $351,403 for the year ended December 31, 2015. 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 2016 compared to the previous year.

**Impairment loss** . Loss on the impairment of fixed assets for the year ended December 31, 2016 was $548,638. This is in connection with the assignment of our corporate headquarters lease and sale of certain assets which was effective as of February 1, 2017 (see Note 13). Based on the cash consideration received being less than the carrying value of the assets, management determined it was appropriate to write-down the carrying value of the property and equipment to a net book value of $50,000. Also included in the impairment loss at December 31, 2016 was the 100% write-down of the asset value of our custom reagent to account for the uncertainty of its future use amounting to $487,829.

**Interest Expense.** Interest expense was $3,314 for the year ended December 31, 2016, compared to $2,315 for the year ended December 31, 2015. Interest expense is primarily related to the financing of insurance premiums.

**Interest Income.** Interest income was $4,188 for the year ended December 31, 2016, compared to $8,226 for the year ended December 31, 2015, and related to the cash balances in our savings facility.

**Net Loss.** We had a net loss for the year ended December 31, 2016 of $7,980,114, or $1.13 per share (basic and diluted), compared with a net loss of $12,019,278, or $2.05 per share (basic and diluted), for the year ended December 31, 2015.

**Liquidity and Capital Resources**

Historically, we have financed our operations primarily through the sale of debt and equity securities. The report of our independent auditors in respect of the 2016 fiscal year expressed substantial doubt about our ability to continue as a going concern. Specifically, it noted our recurring losses, negative operating cash flows and accumulated deficit. The accompanying audited consolidated financial statements for the 12 months ended December 31, 2016 have been prepared assuming that Opexa will continue as a going concern, meaning Opexa will continue in operation for the foreseeable future and will be able to realize assets and discharge liabilities in the ordinary course of operations. As of December 31, 2016, we had cash and cash equivalents of $3.4 million as well as accounts payable, short-term notes payable and accrued expenses aggregating $1.2 million. While we have historically recognized revenue related to certain upfront payments received from Ares Trading SA (“Merck Serono”), a wholly owned subsidiary of Merck Serono S.A., in connection with the Option and License Agreement and an amendment thereto, we have never generated any commercial revenues, nor do we expect to generate any commercial revenues for the foreseeable future or other revenues in the near term that will result in cash receipts.

We believe that we have sufficient liquidity to support our current activities in winding down the Abili-T trial and for general operations to sustain the Company and support such activities into the second quarter of 2017. However, if our projections prove to be inaccurate, or if we encounter additional costs to wind down the trial or to sustain our operations, or if we incur other costs such as those associated with pursuing further research and development, we would need to raise additional capital to continue our operations.

On March 25, 2016, we entered into a new Sales Agreement with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.) as sales agent, pursuant to which we can offer and sell shares of our common stock from time to time depending upon market demand, in transactions deemed to be an “at the market” offering. We registered up to 1,000,000 shares of common stock for potential sale under the new ATM facility. From August 17, 2016 through December 31, 2016, we sold an aggregate of 66,184 shares of our common stock under our ATM facility. We generated gross and net proceeds, including amortization of deferred offering costs, of $293,345 and $276,912, respectively, with the average share price ranging from $4.12 to $4.73 per share. During January 2017, we further sold an aggregate of 516,278 shares of common stock for gross proceeds of $490,098, with the average share price ranging from $0.90 to $0.97. 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.

If we determine to continue the development of one or more of our programs, we expect to continue to incur significant expenses and increasing losses for at least the next several years. We would need to raise additional capital in order to conduct further development. Given the disappointing results of our Abili-T trial, we believe our ability to issue equity securities or obtain debt financing in the future on favorable terms, or at all, has been substantially impaired, particularly if the intended use of proceeds would be for the continued development of Tcelna.

We continue to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to support our ongoing operations through and beyond the next 12 months, including raising additional capital through either private or public equity or debt financing as well as using our ATM facility and cutting expenses where possible. However, in light of the Abili-T study results, there can be no assurance that we will be able to secure additional funds or, if such funds are available, that the terms or conditions would be acceptable to us. If we are unable to obtain additional funding to support our current or proposed activities and operations, we may not be able to continue our operations as proposed, which may require us to suspend or terminate any ongoing development activities, 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 substantial 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 ATM facility. Should we need any additional capital in the future beyond the ATM facility, management will be reliant upon "best efforts" debt or equity financings. As our prospects for funding, if any, develop, 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, given the disappointing results of our Abili-T study, there is no assurance that our capital raising efforts will be able to attract additional capital necessary for future operations.

**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, 2016 and 2015, 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, 2016 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, 2016 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**

We have one executive officer that is elected by the Board of Directors and serves at the discretion of the Board. Our current executive officer is as follows:

| Name | Age | Position |
|---|---|---|
| Neil K. Warma | 54 | President, Chief Executive Officer, Acting Chief Financial Officer and Director |

Biographical information for our executive officer 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 has served as our Acting Chief Financial Officer since March 2016, and previously served in such role 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.

**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 | 64 | Director |
| Hans-Peter Hartung, M.D. | 62 | Director |
| Gail J. Maderis | 59 | Director |
| Michael S. Richman | 56 | Director |
| Neil K. Warma | 54 | Director, President, Chief Executive Officer and Acting Chief Financial 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. Mr. Barabe has been on the Board of Selecta Biosciences (SELB) since August 2016 and is a member of their Audit Committee. Selecta is based in Watertown, MA and is listed on NASDAQ. 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.

**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. Richman (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. Richman 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, 2016.

**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, 2016. Our Named Executive Officers include persons who (i) served as our principal executive officer or acted in a similar capacity during 2016, (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.

***2016 Summary Compensation Table***

| Name and Principal Position | Year | Salary | Options Awards [1] | All Other Compensation | Total |
|---|---|---|---|---|---|
| Neil K. Warma | 2016 | $ 416,625 | $ 201,846 | $ 0 | $ 618,471 |
| *President, Chief Executive Officer and Acting Chief Financial Officer* | 2015 | $ 416,625 | $ 92,112 | $ 0 | $ 508,737 |
| Don Healey, Ph.D. (2) | 2016 | $ 270,000 | $ 96,125 | $ 0 | $ 366,125 |
| *Former Chief Scientific Officer* | 2015 | $ 266,240 | $ 46,056 | $ 0 | $ 312,296 |
| Donna R. Rill (3) | 2016 | $ 218,377 | $ 96,125 | $ 0 | $ 314,502 |
| *Former Chief Development Officer* | 2015 | $ 261,917 | $ 38,380 | $ 0 | $ 300,297 |

(1) Amounts in this column represent the aggregate grant date fair value of option awards computed in accordance with FASB ASC 718. Mr. Warma was granted two options on May 16, 2016, 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. Dr. Healey and Ms. Rill were each granted a time-based option on May 16, 2016. See Note 11 to our financial statements included in our annual report on Form 10-K for assumptions underlying the valuation of equity awards.

(2) Dr. Healey was appointed as an executive officer on October 26, 2015 and his employment terminated on January 31, 2017 as part of a reduction-in-force which occurred on that date.

(3) Ms. Rill resigned as Chief Development Officer on November 4, 2016.

***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. Mr. Warma also became our Acting Chief Financial Officer on March 2, 2016. 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 781 shares 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, Ph.D .*** Dr. Healey was employed as our Chief Scientific Officer pursuant to the terms of an employment agreement dated March 4, 2010 until his employment terminated on January 31, 2017 as part of a reduction-in-force which occurred on that date. Pursuant to the terms of his March 2010 employment agreement, he is entitled to receive severance payments equal to six months of his base salary. The severance benefits are subject to Dr. Healey 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 while receiving the severance benefits. Dr. Healey's salary at the time of his termination was $270,000 per annum. The timing of any payments to Dr. Healey is subject to applicable requirements of Section 409A of the Code and the related Treasury Regulations.

***Donna R. Rill.*** Ms. Rill was employed as our Chief Development Officer pursuant to the terms of an employment agreement dated April 1, 2010 until she resigned from her position on November 4, 2016. Ms. Rill was not entitled to receive any severance benefits as a result of her resignation. Ms. Rill's salary at the time of her resignation was $252,150 per annum.

***2016 Outstanding Equity Awards at Fiscal Year-End***

The following table presents information regarding outstanding equity awards at December 31, 2016 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 |
| | 5,452 | — | $ 30.40 | 01/06/22 |
| | 11,996 | — | $ 30.40 | 01/06/22 |
| | 6,250 | — | $ 15.04 | 11/08/23 |
| | 27,178 (1) | 12,353 | $ 14.56 | 02/28/24 |
| | 6,562 (1) | 8,438 | $ 6.56 | 03/02/25 |
| | 18,750 (1) | 31,250 | $ 2.13 | 05/16/26 |
| | | | | |
| Don Healey, Ph.D. | 937 | — | $ 72.00 | 04/30/20 |
| | 937 | — | $ 49.92 | 01/04/21 |
| | 1,308 | — | $ 30.40 | 01/06/22 |

| | | | | | |
|---|---|---|---|---|---|
| | 2,617 | — | $ | 30.40 | 01/06/22 |
| | 1,199 | — | $ | 30.40 | 01/06/22 |
| | 2,500 | — | $ | 14.00 | 04/29/23 |
| | 5,554 | 2,524 | $ | 14.56 | 02/28/24 |
| | 3,281 (1) | 4,219 | $ | 6.56 | 03/02/25 |
| | 18,750 (1) | 31,250 | $ | 2.13 | 05/16/26 |
| | | | | | |
| | 1,000 | — | $ | 175.04 | 06/18/25 |
| Donna Rill | 93 | — | $ | 34.88 | 05/06/18 |
| | 1,031 | — | $ | 37.44 | 06/26/18 |
| | 1,250 | — | $ | 7.04 | 01/16/19 |
| | 262 | — | $ | 15.04 | 02/06/19 |
| | 1,562 | — | $ | 65.60 | 11/30/19 |
| | 781 | — | $ | 49.92 | 01/04/21 |
| | 1,199 | — | $ | 30.40 | 01/06/22 |
| | 1,308 | — | $ | 30.40 | 01/06/22 |
| | 2,617 | — | $ | 30.40 | 01/06/22 |
| | 2,500 | — | $ | 14.00 | 04/29/23 |
| | 5,049 | — | $ | 14.56 | 02/28/24 |
| | 2,344 | — | $ | 6.56 | 03/02/25 |
| | 15,625 | — | $ | 2.13 | 05/16/26 |

(1) 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.

***2016 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, 2016.

| Name | Fees Earned or Paid in Cash | Stock Awards (1) | Option Awards (2) | All Other Compensation | Total |
|---|---|---|---|---|---|
| Timothy C. Barabe | $ 13,750 (3) | $ 41,247 (4) | -- | $ 0 | $ 54,997 |
| Hans-Peter Hartung, M.D. | $ 55,000 | -- | -- | $ 0 | $ 55,000 |
| Gail J. Maderis | $ 13,750 (3) | $ 41,247 (4) | -- | $ 0 | $ 54,997 |
| Michael S. Richman | $ 13,750 (3) | $ 41,247 (4) | -- | $ 0 | $ 54,997 |
| Scott B. Seaman (5) | $ 0 | $ 41,248 (4) | -- | $ 0 | $ 41,248 |

(1) Amount represents the aggregate grant date fair value of equity awards computed in accordance with FASB ASC 718. The fair value of restricted stock awards is based on the closing price of our common stock on the grant date. See Note 11 to our financial statements included in our annual report on Form 10-K for assumptions underlying the valuation of equity awards.

(2) The aggregate number of shares underlying outstanding option awards as of December 31, 2016 was: Mr. Barabe, 14,050 shares; Dr. Hartung, 14,856 shares; Ms. Maderis, 19,301 shares; Mr. Richman, 21,912 shares; and Mr. Seaman, 27,713 shares.

(3) For the fourth quarter of 2016, Board compensation to US-based directors was paid in cash in arrears in lieu of restricted stock awards.

(4) As compensation for Board services for the first three quarters of 2016, Messrs. Barabe, Richman and Seaman and Ms. Maderis each received an aggregate of 19,365 shares of restricted common stock.

(5) Mr. Seaman resigned from the Board on October 31, 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. During 2016, our annual compensation arrangements for our non-employee directors was valued at $55,000 and consisted of (i) for US-based directors, shares of restricted stock issued on a quarterly basis and immediately vested for the first three quarters of 2016, and cash compensation paid in arrears for the fourth quarter of 2016 and (ii) for the Company's one non-US-based director, cash compensation paid in arrears. In December 2016, the Board modified our standard annual compensation arrangements for non-employee directors to provide for quarterly cash payments of $13,750 in lieu of any equity awards, totaling the same $55,000 annual compensation, with such cash payments made in advance rather than in arrears.

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

The following table sets forth, as of March 1, 2017, 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 March 1, 2017, there were 7,657,332 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:*** | | | | |
| Neil K. Warma | (2) | 129,651 | % | 1.67 |
| Don Healey, Ph.D. | (3) | 41,128 | | * |
| Donna R. Rill | (4) | 0 | | * |
| Michael S. Richman | (5) | 48,826 | | * |
| Gail J. Maderis | (6) | 46,215 | | * |
| Timothy Barabe | (7) | 26,960 | | * |
| Hans-Peter Hartung, M.D. | (8) | 14,856 | | * |
| All current directors and executive officers as a group (5 persons) | (9) | 266,508 | % | 3.40 |

* 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) 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) 106,140 shares of common stock underlying currently exercisable stock options.

(3) Consisting of: (i) 4,045 shares of common stock; and (ii) 37,083 shares of common stock underlying currently exercisable stock options. Dr. Healey's employment terminated on January 31, 2017 as part of a reduction-in-force which occurred on that date.

(4) Ms. Rill resigned from her position on November 4, 2016.

(5) Consisting of: (i) 25,884 shares of common stock; (ii) 1,030 shares of common stock underlying Series M warrants; and (iii) 21,912 shares of common stock underlying currently exercisable able stock options.

(6) Consisting of: (i) 25,884 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.

(7) Consisting of: (i) 12,910 shares of common stock held by Barabe Consulting, Inc., for which Mr. Barabe has sole voting and disposition authority and may be deemed the beneficial owner as the president, sole director and sole stockholder; and (ii) 14,050 shares of common stock underlying currently exercisable stock options held by Mr. Barabe.

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

(9) Consisting of: (i) 82,788 shares of common stock; (ii) 7,461 shares of common stock underlying warrants; and (iii) 176,259 shares of common stock underlying stock options. Includes only current directors and executive officers serving in such a capacity on the date of this report.

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

**Transactions with Related Persons**

Since January 1, 2016, 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 and Richman 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 | X |
| Hans-Peter Hartung | X | | | |
| Gail J. Maderis | X | X | X | X |
| Michael S. Richman | X | 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, | |
|---|---|---|
| | 2016 | 2015 |
| Audit fees [1][2][3] | $ 80,046 | $ 65,000 |
| Tax fees | — | — |
| All other fees [4] | 5,500 | 31,500 |
| | $ 85,546 | $ 96,500 |

(1) Audit fees include professional services rendered for (i) the audit of our annual financial statements for the fiscal years ended December 31, 2016 and 2015, 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 2016 include $35,046 for the 2015 fiscal year audit.
(3) Audit fees paid in 2015 include $20,000 for the 2014 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, 2016 and December 31, 2015**



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.

**Item 16. Form 10-K Summary**

Not Applicable.

**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.**

Date **:** March 28, 2017

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

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<br>Neil K. Warma | President, Chief Executive Officer, Acting Chief Financial Officer and Director<br>*(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)* | March 28, 2017 |
| /s/ Timothy Barabe<br>Timothy Barabe | Director | March 28, 2017 |
| /s/ Hans-Peter Hartung<br>Hans-Peter Hartung | Director | March 28, 2017 |
| /s/ Gail J. Maderis<br>Gail J. Maderis | Director | March 28, 2017 |
| /s/ Michael S. Richman<br>Michael S. Richman | Director | March 28, 2017 |

## 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, 2016 and 2015 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for 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, 2016 and 2015 and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses, negative operating cash flows and an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ MALONEBAILEY, LLP
www.malonebailey.com
Houston, Texas
March 28, 2017

**OPEXA THERAPEUTICS, INC.**

**CONSOLIDATED BALANCE SHEETS**
**As of December 31, 2016 and 2015**

| | December 31, 2016 | December 31, 2015 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 3,444,952 | $ 12,583,764 |
| Other current assets | 371,562 | 498,798 |
| Total current assets | 3,816,514 | 13,082,562 |
| Property & equipment, net of accumulated depreciation of $3,194,029 and $2,443,600, respectively | 50,000 | 837,867 |
| Other long-term assets | — | 496,269 |
| Total assets | $ 3,866,514 | $ 14,416,698 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 377,956 | $ 739,850 |
| Accrued expenses | 625,890 | 1,008,077 |
| Deferred revenue . | — | 2,905,165 |
| Notes payable – Insurance | 156,642 | 148,344 |
| Total current liabilities | 1,160,488 | 4,801,436 |
| Total liabilities | $ 1,160,488 | $ 4,801,436 |
| Stockholders' equity: | | |
| Preferred stock, no par value, 10,000,000 shares authorized, none issued and outstanding | — | — |
| Common stock, $0.01 par value, 150,000,000 shares authorized, 7,141,054 and 6,982,909 shares issued and outstanding | 71,411 | 69,829 |
| Additional paid in capital | 163,954,215 | 162,884,919 |
| Accumulated deficit | (161,319,600) | (153,339,486) |
| Total stockholders' equity | 2,706,026 | 9,615,262 |
| Total liabilities and stockholders' equity | $ 3,866,514 | $ 14,416,698 |

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

**OPEXA THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**
**Years ended December 31, 2016 and 2015**

| | 2016 | 2015 |
|---|---|---|
| Revenue: | | |
| Option revenue | $ 2,905,165 | $ 2,556,329 |
| Research and development | 6,497,531 | 10,039,496 |
| General and administrative | 3,122,337 | 4,258,147 |
| Depreciation and amortization | 238,127 | 351,403 |
| Impairment loss | 1,036,467 | — |
| Loss on disposal of fixed assets | 2,320 | 1,167 |
| Operating loss | (7,991,617) | (12,093,884) |
| Interest income, net | 874 | 5,911 |
| Other income and expense, net | 10,629 | 68,695 |
| Net loss | $ (7,980,114) | $ (12,019,278) |
| Basic and diluted loss per share | $ (1.13) | $ (2.05) |
| Weighted average shares outstanding | 7,048,661 | 5,854,438 |

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, 2016 and 2015**

| | Common Stock | | | | |
|---|---|---|---|---|---|
| | Shares | Par | Additional Paid in Capital | Accumulated Deficit | Total |
| 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 |
| Shares issued for services | 77,460 | 775 | 164,215 | — | 164,990 |
| Shares sold for cash | 66,184 | 662 | 276,250 | — | 276,912 |
| Exercise of warrants | 14,501 | 145 | 57,840 | — | 57,985 |
| Option expense | — | — | 570,991 | — | 570,991 |
| Net loss | — | — | — | (7,980,114) | (7,980,114) |
| Balance at December 31, 2016 | 7,141,054 | $ 71,411 | $ 163,954,215 | $ (161,319,600) | 2,706,026 |

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

**OPEXA THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**Years ended December 31, 2016 and 2015**

| | 2016 | 2015 |
|---|---|---|
| Cash flows from operating activities | | |
| Net loss | $ (7,980,114) | $ (12,019,278) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Shares issued for services | 164,990 | 78,213 |
| Depreciation | 238,127 | 351,403 |
| Option expense | 570,991 | 835,723 |
| Loss on disposal of property and equipment | 2,320 | 1,167 |
| Impairment loss | 1,036,467 | — |
| Changes in: | | |
| Other current assets | 405,005 | (547,606) |
| Accounts payable | (361,894) | 37,356 |
| Accrued expenses | (382,187) | (41,436) |
| Deferred revenue | (2,905,165) | 443,671 |
| Other long-term assets | 8,440 | 535,208 |
| Net cash used in operating activities | (9,203,020) | (10,325,579) |
| | | |
| Cash flows from investing activities | | |
| Purchase of property & equipment | (1,221) | (92,333) |
| Net cash used in investing activities | (1,221) | (92,333) |
| | | |
| Cash flows from financing activities | | |
| Common stock and warrants sold for cash, net of offering costs | 276,912 | 13,282,035 |
| Cash generated from exercise of warrants | 57,985 | 4,410 |
| Repurchase of fractional shares | — | (5,028) |
| Note payable – insurance | (186,706) | (186,114) |
| Payment of deferred offering cost | (82,762) | — |
| Net cash provided by financing activities | 65,429 | 13,095,303 |
| | | |
| Net change in cash and cash equivalents | (9,138,812) | 2,677,391 |
| Cash and cash equivalents at beginning of period | 12,583,764 | 9,906,373 |
| Cash and cash equivalents at end of period | $ 3,444,952 | $ 12,583,764 |

| | | |
|---|---|---|
| Cash paid for: | | |
| Income tax | $ — | $ — |
| Interest | $ 3,314 | $ 2,315 |
| | | |
| Non-cash transactions: | | |
| Insurance premium financed through issuance of notes | $ 195,004 | $ 184,787 |

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

## NOTE 1—BUSINESS OVERVIEW, GOING CONCERN AND SUMMARY OF ACCOUNTING POLICIES

**Description of Business** . Opexa Therapeutics, Inc. ("Opexa" 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.

Opexa is a biopharmaceutical company developing personalized immunotherapies with the potential to treat major illnesses, including multiple sclerosis (MS) as well as other autoimmune diseases such as neuromyelitis optica ("NMO"). These therapies are based on the Company's proprietary T-cell technology. Information related to its 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.

On October 28, 2016, the Company announced that the Abili-T trial did not meet its primary endpoint of reduction in brain volume change (atrophy), nor did it meet the secondary endpoint of reduction of the rate of sustained disease progression. Abili-T is a 183-patient, randomized, double-blind, placebo-controlled Phase IIb study that was conducted at 35 clinical trial sites in the U.S. and Canada and designed to evaluate the safety and efficacy of Tcelna (imilecleucel-T) in patients with secondary progressive MS (SPMS). Patients in the Tcelna arm of the study received two annual courses of Tcelna treatment consisting of five subcutaneous injections per year. The Company completed enrollment of the Abili-T study in May 2014 and un-blinded the results from the study in late October 2016. Previously, in September 2008, the Company completed a Phase IIb clinical study of Tcelna in the relapsing-remitting MS (RRMS) indication.

The Company 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.

**Going Concern.** The accompanying audited consolidated financial statements for the 12 months ended December 31, 2016 have been prepared assuming that the Company will continue as a going concern, meaning the Company will continue in operation for the foreseeable future and will be able to realize assets and discharge liabilities in the ordinary course of operations. As of December 31, 2016, the Company had cash and cash equivalents of $3.4 million as well as accounts payable, short-term notes payable and accrued expenses aggregating $1.2 million. While the Company has historically recognized revenue related to certain upfront payments received from Ares Trading SA ("Merck Serono"), a wholly owned subsidiary of Merck Serono S.A., in connection with the Option and License Agreement and an amendment thereto between Merck Serono and the Company, the Company has never generated any commercial revenues, nor does it expect to generate any commercial revenues for the foreseeable future or other revenues in the near term that will result in cash receipts. Opexa continues to incur net losses, negative operating cash flows and has an accumulated deficit of $161,319,600 as of December 31, 2016.

Following the October 28, 2016 announcement that the Abili-T trial did not meet its primary or secondary endpoints, and in order to conserve cash resources while it reevaluated its programs and explored various strategic alternatives, during the fourth quarter of 2016 and first quarter of 2017 the Company implemented several reductions in workforce totaling 90% of its then 20 full-time employees. After further analysis of the data from the Abili-T trial, the Company has determined that it will not move forward with further studies of Tcelna in SPMS at this time and is conducting a review of its other research and development programs, including the preclinical program for OPX-212 in NMO, to assess the viability of continuing to pursue one or more of these programs. The Company is also exploring its strategic alternatives. The Company cannot fully predict its future cash needs until it completes this analysis. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company continues to explore potential opportunities and alternatives to obtain the additional resources that will be necessary to support its ongoing operations through and beyond the next 12 months, including raising additional capital through either private or public equity or debt financing as well as using its at-the-market offering program and cutting expenses where possible. However, in light of the disappointing Abili-T study results, there can be no assurance that the Company will be able to secure additional funds or, if such funds are available, whether the terms or conditions would be acceptable to the Company.

**Reverse Stock Split.** On September 28, 2015, the Company 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, 2016. 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, 2016, Opexa Hong Kong reported cash and cash equivalents of $9,875 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 Merck Serono. Pursuant to the terms, Merck Serono had an option to acquire an exclusive, worldwide (excluding Japan) license of Opexa's Tcelna® program for the treatment of MS. The option was exercisable by Merck Serono prior to or upon Opexa's completion of its Abili-T Phase IIb clinical trial for Tcelna in patients with secondary progressive MS. Opexa received an upfront payment of $5 million for granting the option and recognized revenues from the nonrefundable, up-front option fee on a straight-line basis over the estimated option exercise period which coincided with the expected completion term of the Abili-T trial. The expected completion term for revenue recognition was 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 certain activities to be conducted in connection with preparation for operational readiness for further clinical studies of Tcelna and for providing Merck Serono with updates and analysis with respect to Opexa's immune monitoring program that was conducted in conjunction with the Abili-T clinical trial. Opexa evaluated the Merck Serono Amendment and determined that the $3 million payment from Merck Serono had stand-alone value due to Opexa's performance obligations thereunder. The $3 million payment was determined to be a single unit of accounting and was recognized as revenue on a straight-line basis over the period equivalent to the expected completion of the performance obligations in December 2016.

On October 28, 2016, Opexa announced that the Abili-T clinical trial designed to evaluate the efficacy and safety of Tcelna in patients with SPMS did not meet its primary or secondary endpoints. On November 23, 2016, Opexa received notice from Merck Serono that Merck Serono would not be exercising the option, and as a result of such notice, the Merck Serono Agreement automatically expired.

**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 2016 and 2015 included reagents and supplies that were used to manufacture Tcelna and placebo product in Opexa's Phase IIb clinical study. These prepaid reagents and supplies are amortized to research and development expenses in the consolidated statements of operations over the period that these supplies were used. A single custom reagent that was used primarily for the NMO program and other Pre-Phase III activities is captured as custom reagents and reported under Other Long-Term 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 expense in the consolidated statement 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, 2016 and 2015 was $6,497,531 and $10,039,496, 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.

**Recently Issued Accounting Pronouncements.** The Company has implemented all new accounting pronouncements that are in effect and that may impact its consolidated financial statements and does not believe that there are any other new pronouncements that have been issued that might have a material impact on its financial position or results of operations.

**NOTE 2—CASH AND CASH EQUIVALENTS**

As of December 31, 2016, Opexa invested approximately $2.8 million in a savings account. For the year ended December 31, 2016, the savings account recognized an average market yield of 0.06%. Interest income of $4,188 from the savings account was recognized for the year ended December 31, 2016 in the consolidated statements of operations.

**NOTE 3—OTHER CURRENT ASSETS**

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

| Description | 2016 | 2015 |
|---|---|---|
| Deferred offering costs | 111,641 | 28,876 |
| Prepaid expenses | 259,921 | 469,922 |
| Total Other Current Assets | $ 371,562 | $ 498,798 |

Deferred offering costs at December 31, 2016 include $111,641 in costs incurred from third parties in connection with the renewal of the Company's shelf registration statement. Deferred offering costs at December 31, 2015 included $28,876 in costs incurred from third parties in connection with the implementation of a $1.5 million and $15 million purchase agreement in November 2012 pursuant to which Opexa had the right (now terminated) to sell to Lincoln Park Capital Fund, LLC shares of its common stock, subject to certain conditions and limitations.

As of December 31, 2015, the remaining costs of $38,938 in connection with the Merck Serono Agreement were included in other current assets (see Note 1). Such costs were amortized during 2016 and no balance remained at December 31, 2016. 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 $174,400 of prepaid insurance for Opexa's directors' and officers' liability insurance. 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, 2016 and 2015:

| Description | Life | 2016 | 2015 |
|---|---|---|---|
| Computer equipment | 3 years | $ 173,147 | $ 193,596 |
| Office furniture and equipment | 5-7 years | 238,661 | 247,679 |
| Software | 3 years | 125,412 | 125,412 |
| Laboratory equipment | 7 years | 1,117,173 | 1,120,693 |
| Leasehold improvements | 5 years | 684,515 | 683,295 |
| Manufacturing equipment | 7 years | 905,121 | 910,792 |
| Subtotal: | | 3,244,029 | 3,281,467 |
| Less: accumulated depreciation and impairment | ) | (3,194,029 ) | (2,443,600 ) |
| Property and equipment, net | | $ 50,000 | $ 837,867 |

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 $238,127 and $351,403 for the years ended December 31, 2016 and 2015, respectively.

In connection with the assignment of the Company's corporate headquarters lease and sale of certain assets which was effective as of February 1, 2017 (see Note 13), and based on the consideration received being less than the carrying value of the assets, management determined it was appropriate to write-down the carrying value of the property and equipment to its recoverable value of $50,000 as of December 31, 2016. The Company recorded an impairment loss of $548,638 for the year ended December 31, 2016.

**NOTE 5—OTHER LONG-TERM ASSETS**

Other long-term assets consists solely of a single custom reagent that was available to be used for the development of the Company's product candidate OPX-212 for NMO, other Pre-Phase III research activities or potentially for other treatment options or autoimmune diseases utilizing the T-cell technology platform. Upon consumption, the costs of this reagent are amortized to research and development expenses in the consolidated statements of operations. The custom reagent has a three-year shelf life and its expiration is November 2018. At December 31, 2016 and 2015, other long-term assets consist solely of a single custom reagent with a carrying value of $0 and $496,269, respectively, which included a 100% write-down of the asset value at December 31, 2016 to account for the uncertainty in future use of the custom reagent.

**NOTE 6 – NOTES PAYABLE**

Notes payable consists of a commercial insurance premium finance agreement - promissory note with AFCO of which $136,038 was outstanding as of December 31, 2016. The loan has an interest rate of 3.5% per annum and matures July 1, 2017. The second note is also a commercial insurance premium finance agreement – promissory note with AFCO of which $20,604 was outstanding as of December 31, 2016. The loan has an interest rate of 3.5% per annum and matures September 1, 2017. Payments on the above notes are due and payable monthly until maturity.

**NOTE 7—INCOME TAXES**

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

At December 31, 2016 and 2015 Opexa had approximately $74 million and approximately $70 million of unused net operating losses (NOLs), respectively, available for carry forward to future years. For tax purposes, Opexa elects to capitalize research and development expenses and amortize them over a 10-year period. The unused NOLs begin to expire at December 31, 2024. At December 31, 2016 and 2015, capitalized R&D amounted to $41.2 million and $35.3 million, respectively.

At December 31, 2016 and 2015, 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, 2016 | December 31, 2015 |
|---|---|---|
| Net operating loss | $ 25,050,750 | $ 24,806,175 |
| Research and development tax credits | 2,896,079 | 2,593,792 |
| Capitalized research and development costs | 13,568,440 | 11,900,122 |
| Subtotal | 41,515,269 | 39,300,089 |
| Less valuation allowance | (41,151,269) | (39,300,089) |
| 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. At December 31, 2016, the tax returns open for examination by the Internal Revenue Service are 2013, 2014, 2015 and 2016 (not yet filed).

**NOTE 8—COMMITMENTS AND CONTINGENCIES**

In October 2005, Opexa entered into a ten-year lease for its office and research facilities. The facility including the property was 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, Opexa exercised the option for an additional five year lease. Rent expense in the consolidated statements of operations for the years ended December 31, 2016 and 2015 was approximately $203,000 and $153,000 respectively.

As of December 31, 2016, the future minimum lease payments were:

| Year | Amount |
|---|---|
| 2017 | 200,000 |
| 2018 | 201,250 |
| 2019 | 206,250 |
| 2020 | 157,500 |
| Total future minimum lease payments | $ 765,000 |

Subsequent to December 31, 2016, Opexa entered into an Assignment and Assumption of Lease with KBI Biopharma, Inc. on February 1, 2017, pursuant to which Opexa assigned to KBI, and KBI assumed from Opexa, all of Opexa's remaining rights and obligations under the lease for Opexa's office and research facilities. See Note 13.

**NOTE 9—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 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, 2016 and 2015, which were charged to research and development expense on the consolidated statements of operations, amounted to $1,679,973 and $1,115,868, 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 (Abili-T), and each of the Institutions will provide appropriate resources and facilities so the Institution's Investigator can conduct the Abili-T 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 Abili-T study.

On October 28, 2016, Opexa announced that the Abili-T trial did not meet its primary endpoint of reduction in brain volume change (atrophy), nor did it meet the secondary endpoint of reduction of the rate of sustained disease progression. Abili-T was a 183-patient, randomized, double-blind, placebo-controlled Phase IIb study that was conducted at 35 clinical trial sites in the U.S. and Canada and designed to evaluate the safety and efficacy of Tcelna (imilecleucel-T) in patients with SPMS. Patients in the Tcelna arm of the study received two annual courses of Tcelna treatment consisting of five subcutaneous injections per year. Opexa completed the enrollment of the Abili-T study in May 2014 and un-blinded the results from the study in late October 2016.

**NOTE 10—EQUITY**

Summary information regarding equity related transactions for the years ended December 31, 2015 and December 31, 2016 is as follows:

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, pursuant to a Stock Purchase Agreement, 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 pursuant to the September 1, 2016 Stock Purchase Agreement 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.

During 2016, equity related transactions were as follows:

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

- On May 16, 2016, a total of 103,280 shares of common stock with an aggregate fair value of $219,986 were granted to certain non-employee directors for service on Opexa's Board of Directors. Of these common stock awards, 25% vested immediately and the shares were issued on such date, and 25% vested and the shares were issued on each of June 30, 2016 and September 30, 2016. Opexa recognized stock-based compensation expense relating to these issued shares of an aggregate of $164,990. While the remaining 25% of the shares were originally scheduled to vest and be issued on December 31, 2016, the fourth increment of 25,820 shares did not vest and the shares were not issued because before the vesting date one non-employee director had resigned and the Board determined to instead pay cash to the non-employee directors for their Board service compensation.

- In June 2016, Opexa issued 14,501 shares of common stock upon the exercise of Series M warrants for net proceeds of $57,985 collected on July 5, 2016.

- From August 17, 2016 through September 13, 2016, Opexa sold an aggregate of 66,184 shares of common stock under the ATM facility, with the new Sales Agreement entered into with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.). Gross and net proceeds, including amortization of deferred offering costs, were $293,345 and $276,912, respectively. The average share price ranged from $4.12 to $4.73 per share. These sales settled and shares were issued by December 31, 2016.

**NOTE 11—OPTIONS AND WARRANTS**

The Board initially adopted the Opexa Therapeutics, Inc. 2010 Stock Incentive Plan (the "2010 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. Subsequently, on September 25, 2013, the Board amended 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 was further amended by the Board on March 29, 2016 and approved by the Company's shareholders on May 16, 2016, in order to (i) further increase the number of shares of common stock reserved for issuance by 650,000 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 1,103,125 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. At December 31, 2016, 568,807 shares of common stock remained available for grant of awards 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, 2016, Opexa recognized stock-based compensation expense of $570,991. Unamortized stock-based compensation expense as of December 31, 2016 amounted to $523,381 .

**Stock Option Activity**

A summary of the stock option activity for the years 2016 and 2015 are presented below:

| | Number of Shares | Weighted Avg. Exercise Price | Weighted Average Remaining Contract Term (# years) | Intrinsic Value |
|---|---|---|---|---|
| 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 | $ - |
| Granted | 290,000 | $ 2.14 | | |
| Exercised | - | - | | |
| Forfeited and canceled | (225,457) | $ 10.52 | | |
| Outstanding at December 31, 2016 | 481,947 | $ 12.14 | 7.6 | $ - |
| Exercisable at December 31, 2016 | 352,096 | $ 14.95 | 7.1 | $ - |

***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 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.

During the 12 months ended December 31, 2016, time-based options to purchase an aggregate of 290,000 shares at exercise prices ranging from $2.13 to $4.13 were granted to employees. These options have a term of ten years and have a vesting schedule of the earlier of three years or termination of employment without cause following a change of control. Fair value of $638,779 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 1.57% to 1.75%, (2) expected term of 5.56 to 10 years, (3) expected volatility range of 134.40% to 167.77% and (4) zero expected dividends.

During 2016, options to purchase 223,271 shares were forfeited and cancelled.

During 2016, Opexa recognized stock based compensation expense of $564,746 for grants made to employees. Unamortized stock compensation expense as of December 31, 2016 amounted to $523,381.

***Non-Employee Options:***

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 $6,245.

During the 12-month period ended December 31, 2016, no options to purchase shares were granted to non-employee directors for service on Opexa's Board.

During 2016, options to purchase 2,186 shares were forfeited and cancelled.

During 2016, Opexa recognized stock based compensation expense of $6,245 for grants made to non-employee directors. Unamortized stock compensation expense as of December 31, 2016 amounted to $0.

**Warrant Activity**

A summary of warrant activity for 2016 and 2015 is presented below:

| | Number of Shares | Weighted Avg. Exercise Price | Weighted Average Remaining Contract Term (# years) | Intrinsic Value |
|---|---|---|---|---|
| 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 | - |
| Outstanding January 1, 2016 | 3,662,954 | 6.30 | 2.17 | - |
| Granted | - | - | | |
| Exercised | (14,501) | 4.00 | | |
| Forfeited and cancelled | (51,828) | 83.52 | | |
| Outstanding at December 31, 2016 | 3,596,625 | 12.39 | 1.21 | - |
| Exercisable at December 31, 2016 | 3,596,625 | 12.39 | 1.21 | - |

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 $12.00 per share through their expiration on April 9, 2018, although such warrants offered an exercise price of $4.00 per share until June 30, 2016. 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 $12.00 per share through their expiration on April 9, 2018, although such warrants offered an exercise price of $4.00 per share until June 30, 2016. Subsequently on March 14, 2016, Opexa entered into an amendment to the September 1, 2015 Stock Purchase Agreement with the purchasers party thereto, to extend by nine months the original dates for the milestones relating to the subsequent tranches. As part of the amendment, the expiration date of the Series N warrants issued pursuant to the Stock Purchase Agreement was also extended from April 9, 2018 to October 9, 2018. The Company determined that there is no accounting impact to the modification of the Series N warrants since these are investor warrants

On February 11, 2016, Series H warrants to purchase 51,823 shares of common stock expired and were cancelled.

During June 2016, 14,501 shares of common stock were issued upon the exercise of Series M warrants.

**NOTE 12—LICENSES**

**License Agreement with Baylor College of Medicine**

In 2001, Opexa entered into an agreement with Baylor College of Medicine for the exclusive worldwide license to a patient-specific, autologous T-cell immunotherapy for the treatment of MS, which is the initial T-cell technology on which Tcelna is based, including rights to certain patents held by Baylor. In consideration for the right and license to commercially exploit such technology, Opexa agreed to pay the following (per scenario 1 of the license agreement): (i) a 2% royalty on net sales of licensed patented products sold by Opexa or its affiliates where annual gross sales of such products is less than or equal to $500 million; (ii) a 1% royalty on net sales of licensed patented products sold by Opexa or its affiliates where annual gross sales of such products exceed $500 million; (iii) a 1% royalty on net sales of licensed patent pending products sold by Opexa or its affiliates; and (iv) a 1% royalty on net sales of licensed patented products or licensed patent pending products sold by any sublicensees of Opexa. Unless earlier terminated, the Baylor license agreement expires in 2025 upon expiration of the last of the licensed patent rights.

**NOTE 13—SUBSEQUENT EVENTS**

During January 2017, Opexa sold an aggregate of 516,278 shares of common stock under its ATM facility with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.) as sales agent, for gross proceeds of $490,098. Opexa paid compensation and fees totaling $14,714 to the sales agent with respect to the shares sold.

As part of its continuing efforts to reduce operating expenses and conserve cash following the release of data from the Abili-T clinical trial, on January 31, 2017 Opexa further reduced its workforce by terminating the employment of seven full-time employees. Opexa incurred total costs of approximately $219,000 associated with this workforce reduction.

On February 1, 2017, Opexa entered into an Assignment and Assumption of Lease with KBI Biopharma, Inc., pursuant to which Opexa assigned to KBI, and KBI assumed from Opexa, all of Opexa's remaining rights and obligations under the lease for Opexa's 10,200 square foot corporate headquarters facility located in The Woodlands, Texas. The facility was originally leased by Opexa from Dirk D. Laukien, as landlord, pursuant to a lease dated August 19, 2005 as amended by that certain First Amendment to Lease Agreement dated May 11, 2015. In light of Opexa's continuing evaluation of its strategic alternatives following the release of the data from the Abili-T clinical study, management deemed it advisable to reduce the office, R&D and manufacturing space and corresponding rent obligations. The lease had a remaining term through September 2020 and current monthly base rental payments of $16,666.67 with payment escalations to $17,500 over the remaining term. In connection with the lease assignment, Opexa also sold certain furniture, fixtures and equipment (including laboratory and manufacturing equipment) as well as its laboratory supplies located at its corporate headquarters to KBI for cash consideration in the amount of $50,000.

**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, File No. 001-33004). |
| 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 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). |
| 4.3 | 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). |
| 4.4 | 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). |
| 4.5 | 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). |
| 4.6 | 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). |
| 4.7 | 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). |
| 4.8 | 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). |
| 4.9 | 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). |
| 4.10 | Amended and Restated Series N Warrants issued on March 14, 2016 (incorporated by reference to Exhibit 4.13 to the Company's Annual Report on Form 10-K filed on March 15, 2016). |
| 10.1+ | 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, File No. 001-33004). |
| 10.3+ | Opexa Therapeutics, Inc. 2010 Stock Incentive Plan, as amended and restated (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed on April 11, 2016). |
| 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, File No. 001-33004). |
| 10.6 | License Agreement dated September 5, 2001 by and between Opexa Therapeutics, Inc. (as successor) and Baylor College of Medicine (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed August 11, 2016). |
| 10.7 | 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). |
| 10.8 | 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). |
| 10.9 | 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). |
| 10.10 | 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). |
| 10.11 | 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). |
| 10.12 | Amendment to Stock Purchase Agreement by and between Opexa Therapeutics, Inc. and the purchasers party thereto, dated March 14, 2016 (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed on March 15, 2016). |
| 10.13+ | Offer Letter, dated March 2, 2010, by and between Opexa Therapeutics, Inc. and Don Healey (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed on March 15, 2016). |
| 10.14 | Sales Agreement, dated March 25, 2016, by and between Opexa Therapeutics, Inc. and IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 25, 2016). |
| 10.15 | Assignment and Assumption of Lease, dated February 1, 2017, by and between Opexa Therapeutics, Inc. and KBI Biopharma, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 1, 2017). |
| 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, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations; (iii) Consolidated Statements of Changes in Stockholders' Equity; (iv) Consolidated Statements of Cash Flows; and (v) Notes to Consolidated Financial Statements. |

* Filed herewith

\+ Management contract or compensatory plan or arrangement.

\# Confidential treatment was granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

**EXHIBIT 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statements on Form S-1 (File No. 333-201731), Form S-3 (File No. 333-191655, 333-185003, 333-185001 and 333-208314) and Form S-8 (File No. 333-192215, 333-176934, 333-139196 and 333-213090) of our report dated March 28, 2017 with respect to the audited consolidated financial statements of Opexa Therapeutics, Inc. as of December 31, 2016 and 2015 and for the years then ended. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

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 28, 2017

**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 28, 2017

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 28, 2017

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, 2016 (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 28, 2017

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, 2016 (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 28, 2017

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