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, 2012

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

Commission File Number: 001-33004

Opexa Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

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

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

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

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

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

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

☐ Large accelerated filer	☐ Accelerated filer	☐ Non-accelerated filer	☑ Smaller reporting company
		(Do not check if a smaller reporting company)	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 29, 2012 based upon the closing price as of such date was $6,356,733.

As of March 15, 2013, 7,991,559 shares of the registrant's common stock, par value $0.01 per share, were outstanding.

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We implemented a one-for-four reverse stock split of our common stock on December 14, 2012. All share numbers and prices have been adjusted to reflect the reverse stock split.

Forward Looking Statements

Statements contained in this report, other than statements of historical fact, constitute "forward-looking statements." The words "expects," "believes," "anticipates," "estimates," "may," "could," "intends," and similar expressions are intended to identify forward-looking statements. In particular, these forward-looking statements may be found, among other places, under the headings "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." These forward-looking statements do not constitute guarantees of future performance. Investors are cautioned that statements which are not strictly historical statements, including, without limitation, statements regarding current or future financial payments, returns, royalties, performance and position, management's strategy, plans and objectives for future operations, plans and objectives for product development, plans and objectives for present and future clinical trials and results of such trials, plans and objectives for regulatory approval, litigation, intellectual property, product development, manufacturing plans and performance, and management's initiatives and strategies, constitute forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated. These risks and uncertainties include, but are not limited to, those risks discussed in "Risk Factors," as well as, without limitation, risks associated with: market conditions; our capital position; the rights and preferences provided to the Series A convertible preferred stock and investors in the convertible secured notes we issued in July 2012 (including a secured interest in all of our assets); 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), including in this regard our ability to satisfy various conditions required to access the financing potentially available under the purchase agreements with Lincoln Park Capital Fund, LLC (such as the minimum closing price for our common stock, the registration of the underlying shares of common stock under the Securities Act of 1933, as amended, and the requirement for an ongoing trading market for our stock); our ability to regain and maintain compliance with NASDAQ listing standards; the success of our clinical trials (including the Phase IIb trial for Tcelna in secondary progressive multiple MS which, depending upon results, may determine whether Merck elects to exercise its Option); whether Merck exercises its Option and, if so, whether we receive any development or commercialization milestone payments or royalties from Merck pursuant to the Option; our dependence (if Merck exercises its Option) on the resources and abilities of Merck for the further development of Tcelna; the efficacy of Tcelna for any particular indication, such as for relapsing remitting MS or secondary progressive MS; our ability to develop and commercialize products; our ability to obtain required regulatory approvals; our compliance with all Food and Drug Administration regulations; our ability to obtain, maintain and protect intellectual property rights (including for Tcelna); 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 Securities and Exchange Commission. These forward-looking statements speak only as of the date of this report. We assume no obligation or undertaking to update or revise any forward-looking statements contained herein to reflect any changes in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in the reports we file with the SEC.

PART I

Item 1. Business.

Overview

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

We are a biopharmaceutical company developing personalized cellular therapies with the potential to treat major illnesses, including multiple sclerosis (MS). These therapies are based on our proprietary T-cell technology. Information related to our product candidate is preliminary and investigative. Our product candidate has not been approved by the U.S. Food and Drug Administration (FDA).

Our product candidate, Tcelna™, is a personalized T-cell therapeutic vaccine licensed from Baylor College of Medicine, which is in clinical development for the treatment of MS.

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.

T-Cell Therapy and Tcelna™

Tcelna™ is a novel T-cell immunotherapy in Phase IIb clinical development for the treatment of patients with secondary progressive MS (SPMS). It is also positioned to enter Phase III clinical development for the treatment of patients with relapsing remitting MS (RRMS), subject to the availability of sufficient resources. Tcelna is a personalized therapy that is specifically tailored to each patient's disease profile. Tcelna is manufactured using ImmPath™, our proprietary method for the production of a patient-specific T-cell immunotherapy, which encompasses the collection of blood from the MS patient, isolation of peripheral blood mononuclear cells, generation of an autologous pool of myelin-reactive T-cells (MRTCs) raised against selected peptides from myelin basic protein (MBP), myelin oligodendrocyte glycoprotein (MOG) and proteolipid protein (PLP), and the return of these expanded, irradiated T-cells back to the patient. These attenuated T-cells are reintroduced into the patient via subcutaneous injection to trigger a therapeutic immune system response.

Initiation of Phase IIb Clinical Study in Patients with SPMS

In September 2012, we announced the initiation of a Phase IIb clinical trial of Tcelna in patients with SPMS. The trial is entitled: *A Phase II Double-Blind, Placebo Controlled Multi-Center Study to Evaluate the Efficacy and Safety of Tcelna in Subjects with Secondary Progressive Multiple Sclerosis* and has been named the "Abili-T" trial. The newly-initiated Phase IIb trial is a double-blind, 1:1 randomized, placebo-controlled study in SPMS patients who demonstrate evidence of disease progression without associated relapses. The trial is expected to enroll 180 patients at approximately 30 leading clinical sites in the U.S. and Canada. According to the study protocol, patients will receive two annual courses of Tcelna treatment consisting of five subcutaneous injections per year at weeks 0, 4, 8, 12 and 24. The primary efficacy endpoint of the trial is the percentage of brain volume change (atrophy) at 24 months. Study investigators will also measure several important secondary outcomes commonly associated with MS including disease progression as measured by Expanded Disability Status Scale (EDSS), annualized relapse rate (ARR) and changes in disability as measured by EDSS and the Multiple Sclerosis Functional Composite (MSFC). The Phase IIb clinical study in North America of Tcelna is expected to complete enrollment of 180 patients by late 2013 or early 2014, with the resulting top-line data expected to be available in the first half of 2016.

Tcelna is the first ever personalized T-cell therapy for MS patients and has received Fast Track designation from the FDA in SPMS. The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical need.

The estimated future costs of our Phase IIb clinical study of Tcelna in SPMS, as well as the ongoing expenses of our operations through the expected completion date of such study and release of top-line data, are estimated to be between $33-35 million as of January 1, 2013. Our existing resources are not adequate to permit us to complete such study or the majority of it. We will need to secure significant additional resources to continue and complete the trial and support our operations during the pendency of the trial. We believe we have sufficient liquidity to support our clinical trial activities into the fourth quarter of 2013. Given our need for substantial amounts of capital to continue the Phase IIb clinical study in North America of Tcelna in SPMS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources, including one or more additional financings, that will be necessary to complete the Phase IIb study and to support our operations during the pendency of such study. There can be no assurance that any such financings or potential opportunities and alternatives can be consummated on acceptable terms, if at all.

Option and License Agreement with Merck Serono

On February 4, 2013, we entered into an Option and License Agreement with Ares Trading SA ("Merck"), a wholly owned subsidiary of Merck Serono S.A. Pursuant to the agreement, Merck has an option (the "Option") to acquire an exclusive, worldwide (excluding Japan) license of our Tcelna program for the treatment of MS. The Option may be exercised by Merck prior to or upon completion of our ongoing Phase IIb trial of Tcelna in patients with SPMS.

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

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

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

SPMS Overview

SPMS is characterized by a steady accrual of irreversible disability, despite, in some cases, reversible relapses, remissions or clinical plateaus. Older age at onset of MS diagnosis is the strongest predictor of conversion to SPMS. Males have a shorter time to conversion to SPMS compared with females. Available immunomodulating and immunosuppressive therapies used for RRMS have not been effective in SPMS. In clinical trials, these therapies have demonstrated anti-inflammatory properties as measured by the reduction in number and volume of contrast-enhancing or acutely inflammatory central nervous system (CNS) lesions most commonly seen in patients with RRMS. The typical SPMS patient, however, has little or no radiographic evidence of acute inflammation. It is commonly observed that contrast-enhancing CNS lesions are uncommon among these patients, despite a clearly deteriorating neurologic course. The lack of effect of conventional MS therapeutics in SPMS suggests that the cerebral deterioration characterizing progressive disease may be driven by factors other than acute inflammation. For instance, the immunopathology of SPMS is more consistent with a transition to a chronic T-cell dependent inflammatory type, which may encompass the innate immune response and persistent activation of microglia cells. Radiographic features that stand out among patients with SPMS include significantly more atrophy of gray matter compared with RRMS patients. Of note, long-term disability in MS in general appears more closely correlated to gray matter atrophy than to white matter inflammation. Such atrophy may be suggestive of progressive clinical disability. Both clinically and radiographically, SPMS represents a disease process with certain features distinct from those of RRMS, and one with extremely limited treatment options.

Current Treatment Options for SPMS

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

Tcelna Clinical Overview in SPMS

In multiple previously conducted clinical trials for the treatment of patients with MS (which have been weighted significantly toward patients with RRMS), Tcelna has demonstrated one of the safest side effect profiles for any marketed or development-stage MS therapy, as well as encouraging efficacy signals. A total of 142 MS patients have received Tcelna in previously conducted trials for RRMS and SPMS. The therapy has been well tolerated in all subjects and has demonstrated an excellent overall safety profile. The most common side effect is mild to moderate irritation at the site of injection, which is typically resolved in 24 hours. Tcelna has been administered to a total of 36 subjects with SPMS across three previous clinical studies. Based on preliminary data suggesting stabilized or improved disability among SPMS subjects receiving Tcelna, Opexa believes that further development of this product candidate in SPMS is warranted.

Summary of TERMS Phase IIb Clinical Trial Data in RRMS

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

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

- In the modified intent to treat patient population (n=142), the ARR for Tcelna-treated patients was 0.214 as compared to 0.339 for placebo-treated patients, which represented a 37% decrease in ARR for Tcelna as compared to placebo in the general population;

- In a prospective group of patients with more active disease (ARR>1, n=50), Tcelna demonstrated a 55% reduction in ARR as compared to placebo, and a 73% reduction in relapse rate was observed in Tcelna patients in this population compared to placebo during the 24-week period following the administration of the full course of treatment; and

- In a retrospective analysis in patients naïve to previous disease modifying treatment (*i.e.*, patients who had not previously used any drugs other than steroids to treat their disease), the results showed that patients, when treated with Tcelna, had a 64% reduction in ARR versus placebo (p=0.046, n=70).

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

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 and other relevant peptides to be used to treat MS patients.

We have developed (and, in part, in licensed from the University of Chicago) a proprietary adult stem cell technology to produce monocyte-derived stem cells (MDSC) from blood. These MDSC can be derived from a patient's monocytes, expanded *ex vivo*, and then administered to the same patient. Our initial focus for this technology is the further development of this monocyte-derived stem cell technology as a platform for the *in vitro* generation of highly specialized cells for potential application in autologous cell therapy for patients with diabetes mellitus. The diabetes program is in an early (pre-clinical) development stage.

Our T-Cell Platform

Multiple Sclerosis—Background

Multiple sclerosis is a chronic, often disabling disease that attacks the central nervous system (CNS), which is made up of the brain, spinal cord, and optic nerves. Symptoms may be mild, such as numbness in the limbs, or severe, such as paralysis or loss of vision. The progress, severity and specific symptoms of MS are unpredictable and vary from one person to another. There are approximately 450,000 MS patients in North America and an estimated 2.5 million patients worldwide. Of these, approximately 85% have RRMS, one-half of whom will develop steadily progressive disease, SPMS, within 10 years, increasing to 90% within 25 years of MS diagnosis. The MS drug market was approximately $13 billion in 2012 and is forecasted to reach as much as $16 billion by 2015.

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

In recent years, the understanding of MS pathogenesis has evolved to comprise an initial, T-cell-mediated inflammatory activity followed by selective demyelination (erosion of the myelin coating of the nerve fibers) and then neurodegeneration. The discovery of disease-relevant immune responses has accelerated the development of targeted therapeutic products for the treatment of the early stages of MS.

Some subjects, who have the appropriate genetic background, have increased susceptibility for the *in vivo* activation and expansion of myelin autoreactive T-cells. These myelin autoreactive T-cells may remain dormant, but at some point they are activated in the periphery, thus enabling them to cross the blood-brain barrier (BBB) and infiltrate the healthy tissue of the brain and spinal cord. The cascade of pathogenic events leads to demyelination of protrusions from nerve cells called axons, which causes nerve impulse transmissions to diffuse into the tissue resulting in disability to the individual.

Tcelna for MS

We believe that Tcelna works selectively on the myelin autoreactive T-cells by harnessing the body's natural immune defense system and feedback mechanisms to deplete these T-cells and induce favorable immune regulatory responses by rebalancing the immune system. Tcelna is manufactured by isolating the MRTCs from the blood, expanding them to a therapeutic dose *ex-vivo*, and attenuating them with gamma irradiation to prevent DNA replication. These attenuated MRTCs are then injected subcutaneously into the body in therapeutic dosages. The body recognizes specific T-cell receptor molecules of these MRTCs as foreign and initiates an immune response reaction against them, not only destroying the injected attenuated MRTCs, but also the circulating, myelin autoreactive T-cells carrying the peptide-specific T-cell receptor molecules. In addition, T-cell activation molecules on the surface of the activated MRTCs used as vaccine induce favorable immune regulatory responses, which promote anti-inflammatory responses. Because the therapy uses an individual's own cells, the only directly identifiable side effect observed thus far is injection site reactions which typically are minor and generally clear within 24 hours.

We believe that this technology platform may have applications in other T-cell mediated autoimmune diseases such as Crohn's disease, psoriasis, rheumatoid arthritis and Type 1 diabetes.

Tcelna Manufacturing

We manufacture Tcelna in our own current Good Manufacturing Practice (cGMP) facility. The technology used to produce Tcelna is similar to that of traditional microbial vaccine technology, where the pathogen (or the attenuated derivative) is used to derive the protective antigens necessary to induce protective immune responses.

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

Personalized Therapy

The clinical symptoms of MS are the result of an immune attack against the myelin sheaths that insulate nerves in the brain and spinal cord that constitute the CNS. A subset of white cells, called T-cells, is the primary orchestrator of this immunity. Tcelna is an immunotherapy representing an enriched source of the patient's own MRTCs that are used to invoke a protective response to limit further damage to the myelin sheaths within the patient's CNS. Immunity to myelin in terms of the specificity of T-cells for myelin proteins varies between individuals. Therefore, Tcelna is further personalized by screening the immune response, and detecting those proteins that are preferentially targeted by T-cells on a per patient basis. This is achieved using protein fragments, called peptides, from the three major myelin proteins (MOG, MBP and PLP) as targets to finely map immunity to myelin. A limited number of peptides are chosen to which immunity appears greatest, and the Tcelna product is manufactured against these peptides. Thus, Tcelna is not only manufactured for each patient, but it is also tailored against each patient's personalized T-cell immune response to myelin. In preparing Tcelna for a patient, the patient-specific MRTCs are expanded from a unit of whole blood using the selected myelin peptides in the presence of growth factors. Once sufficient numbers of T-cells have been propagated to support the clinical dosing regimen, they are frozen down as individual Tcelna doses. Prior to clinical use, a frozen Tcelna dose is thawed, formulated, and attenuated (by irradiation) to render the T-cells unable to replicate, but viable for therapy. After quality control and quality assurance, each dose is shipped overnight to the clinical site for administration over a defined schedule of five subcutaneous injections. Patients will be treated with a new vaccine series (five subcutaneous injections) each year based on their altered disease profile or epitope shift.

Tcelna Safety and Tolerability

We believe that Tcelna treatment selectively targets and depletes the pathogenic T-cell population. It is not a general immune suppressant and, accordingly, it is not associated with the serious side effects seen by those MS treatments that function by systemically suppressing the immune system. In clinical trials conducted to date, there have been no serious adverse events associated with Tcelna treatment. We believe that this favorable safety profile may be an important advantage as patient compliance represents a significant challenge due to serious side effects associated with many currently available and in development MS treatments.

Licenses, Patents and Proprietary Rights

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

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

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

Competition

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

Sales and Marketing

If Merck exercises its Option to acquire an exclusive, worldwide license for our Tcelna program for the treatment of MS and pays us an upfront license fee, Merck would be solely responsible for funding future commercialization activities for Tcelna in MS, although we would retain an option to co-fund certain development in exchange for increased royalty rates. We would also retain rights to Tcelna in Japan, certain rights with respect to the manufacture of Tcelna, and rights outside of MS. We would consider partnering with large biotech and pharmaceutical companies, if and when applicable, to assist with marketing and sales of an MS T-cell therapy in Japan as well as to assist with marketing and sales in indications beyond MS.

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

Government Regulation

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

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

FDA Approval Process

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

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

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

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

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

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

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

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

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

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

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

Ongoing Compliance Requirements

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

- Registration and listing;
- Regulatory submissions relating to changes in an NDA or BLA (such as the manufacturing process or labeling) and annual reports;

- Adverse event reporting;
- Compliance with advertising and promotion restrictions that relate to drugs and biologics; and
- Compliance with GMP and biological product standards (subject to FDA inspection of facilities to determine compliance).

Other Regulations

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

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

Research and Development

Research and development expenses for the year ended December 31, 2012 were approximately $6.3 million, mainly reflecting the costs of preparation, initiation and operation of the Abili-T clinical trial for Tcelna in MS. Research and development expenses for the year ended December 31, 2011 were approximately $3.3 million, mainly reflecting the costs of preparation for the Abili-T clinical trial for Tcelna.

Organizational History

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

Employees

As of March 15, 2013, we had 26 full-time employees. We believe that our relations with our employees are good. None of our employees is represented by a union or covered by a collective bargaining agreement.

Available Information

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

Financial and other information about Opexa is available on our website (**www.opexatherapeutics.com**). Information on our website is not incorporated by reference into this report. We make available on our website, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. Copies are available in print to any Opexa stockholder 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 common stock and warrants 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 common stock or warrants. The following factors affect our business, our intellectual property, the industry in which we operate and our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known or which we currently consider immaterial may also have an adverse effect on our business. If any of the matters discussed in the following risk factors were to occur, our business, financial condition, results of operations, cash flows, or prospects could be materially adversely affected, the market price of our common stock could decline and you could lose all or part of your investment in our securities.

Risks Related to Our Business

We will be required to raise significant additional capital, or secure a development partner, in the near-term, and our ability to obtain funding is uncertain. If sufficient capital is not available, we may not be able to continue our operations as proposed (including any Phase IIb clinical trial initiated or ongoing for Tcelna), which may require us to modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws.

As of December 31, 2012, we had cash and cash equivalents of $592,004. During 2012, we closed a private offering in July 2012 consisting of convertible secured notes and warrants to purchase common stock which generated approximately $4.1 million in gross proceeds (of which $500,000 is held in a controlled account, and $500,000 was released to us in January 2013). These convertible secured notes are due July 25, 2014, and to date, notes in the aggregate principal amount of $900,000 have been converted into shares of Series A convertible preferred stock, which in turn, have been converted into an aggregate of 288,229 shares of common stock. From November 2012 through January 2013, we sold an aggregate of 390,000 shares of our common stock to Lincoln Park Capital Fund, LLC ("Lincoln Park") for gross proceeds of $523,709 pursuant to our $1.5 million purchase agreement with Lincoln Park. To date in 2013, we closed a private offering of unsecured convertible promissory notes and warrants to purchase common stock in January 2013 which generated $650,000 in gross proceeds. Upon receipt of the upfront payment from Merck in February 2013, we repaid $550,000 principal amount plus accrued interest of the January 2013 notes and converted the remaining $100,000 principal amount into shares of common stock pursuant to the investor's election to convert into equity. In February 2013, we sold an aggregate of 167,618 shares of our common stock pursuant to a sales agreement executed on September 6, 2012 with Brinson Patrick Securities Corporation acting as sales agent under an "at-the-market" program, for gross proceeds of $536,417. On February 4, 2013, we entered into an Option and License Agreement with Merck pursuant to which we granted the Option to Merck to acquire an exclusive, worldwide (excluding Japan) license to our Tcelna program for the treatment of MS in consideration for an upfront payment of $5 million. On February 11, 2013, we closed on an offering of 1,083,334 shares of common stock and warrants to purchase shares of common stock for gross proceeds of $3,250,002. As part of this offering, we agreed not to sell shares pursuant to our purchase agreements with Lincoln Park or under our "at-the-market" program for a period of 120 days following the offering.

Our burn rate during 2012, inclusive of the cost of preparations to commence the Phase IIb clinical study of Tcelna in patients with SPMS, was approximately $830,000 per month. Significant activities in the conduct of the clinical trial will result in substantial increases in our monthly cash burn during 2013. We believe we have sufficient liquidity to support our current clinical trial activities into the fourth quarter of 2013. However, the Phase IIb clinical study in North America of Tcelna is expected to complete enrollment of 180 patients by late 2013 or early 2014, with the resulting top line data expected to be available in the first half of 2016. The estimated future costs of the study, as well as the ongoing expenses of our operations through the expected completion date of the study and release of top line data, are estimated to be between $33-35 million as of January 1, 2013. Our existing resources are not adequate to permit us to complete such study or the majority of it. We will need to secure significant additional resources to continue and complete the trial and support our operations during the pendency of the trial.

Given our need for substantial amounts of capital to continue and complete the Phase IIb clinical study for Tcelna in SPMS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to continue and complete the Phase IIb study and to support our operations during the pendency of such study. These opportunities and alternatives may include one or more additional financing transactions. There can be no assurance that any such financings can be consummated on acceptable terms, if at all. If we are unable to obtain additional funding for operations in the immediate future, we will be forced to suspend or terminate our current ongoing clinical trial for Tcelna, which may require us to modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws.

Assuming we are able to achieve financing which is sufficient to support the Phase IIb study of Tcelna in SPMS and to support our operations during the pendency of such study, we are also exploring a pivotal Phase III clinical study of Tcelna in RRMS. Any such study of Tcelna in RRMS would also depend upon the availability of sufficient resources.

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

- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- the accuracy of the assumptions underlying our estimates for capital needs in 2013 and beyond as well as for the clinical study of Tcelna;
- scientific progress in our research and development programs;

- the magnitude and scope of our research and development programs;
- our progress with preclinical development and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- the number and type of product candidates that we pursue.

If we raise additional funds by issuing equity securities (including pursuant to the $1.5 million purchase agreement and the $15.0 million purchase agreement with Lincoln Park), stockholders 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 stockholders. There is no assurance that our capital raising efforts will be able to attract the capital needed to execute on our business plan and sustain our operations.

If we are unable to obtain additional funding, we may not be able to continue or complete the Phase IIb clinical study of Tcelna in SPMS or otherwise continue our operations as proposed, which may require us to modify our business plan or curtail various aspects of our operations. If we are unable to maintain an adequate level of capital, it may be necessary to cease operations or seek relief under applicable bankruptcy laws. In such event, our stockholders may lose a portion or even all of their investment.

Funding from our purchase agreements with Lincoln Park may be limited or be insufficient to fund our operations or to implement our strategy. As part of our February 2013 common stock and warrant offering, we agreed not to sell shares to Lincoln Park for a period of 120 days following that offering.

Under our purchase agreements with Lincoln Park, we may direct Lincoln Park to purchase up to $1.5 million of shares of common stock subject to certain limitations over a 30-month period, and, upon effectiveness of a registration statement for resale of the applicable shares under the $15.0 million purchase agreement, and subject to other conditions, we also may direct Lincoln Park to purchase up to $15.0 million of our shares of common stock over a 30-month period. However, in connection with our February 2013 common stock and warrant offering, we agreed not to sell shares under the purchase agreements with Lincoln Park for a period of 120 days after the offering. From November 2012 through January 2013, we sold an aggregate of 390,000 shares to Lincoln Park pursuant to the $1.5 million purchase agreement, and we issued an aggregate of 56,507 initial commitment shares and 3,585 additional commitment shares in connection therewith. There can be no assurance that we will be able to receive any or all of the additional funds from Lincoln Park because the $1.5 million purchase agreement and the $15.0 million purchase agreement contain limitations, restrictions, requirements, events of default and other provisions that could limit our ability to cause Lincoln Park to buy common stock from us, including that the closing price of our stock is at least $1.00 and that Lincoln Park own no more than 4.99% of our common stock under the $1.5 million purchase agreement or no more than 9.99% of our common stock under the $15.0 million purchase agreement. In addition, under the applicable rules of the NASDAQ Capital Market, if we seek to issue shares which may be aggregated with shares sold to Lincoln Park under the $1.5 million purchase agreement and the $15.0 million purchase agreement in excess of 1,151,829 shares or 19.99% of the total common stock outstanding as of the date of the $15.0 million purchase agreement, we may be required to seek shareholder approval in order to be in compliance with the NASDAQ Capital Market rules.

The extent to which we rely on Lincoln Park as a source of funding will depend on a number of factors, including the amount of working capital needed, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we would need to secure another source of funding. Even if we sell all $16.5 million of common stock under the purchase agreements with Lincoln Park, we will still need additional capital to fully implement our current business, operating plans and development plans, including to complete the Phase IIb clinical study of Tcelna in patients with SPMS and to conduct our operations through the expected completion date of such study.

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.

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.

Our audited consolidated financial statements as of December 31, 2012 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. We do not currently generate revenues, and our burn rate during the 12 months ended December 31, 2012, inclusive of the cost preparations to commence the Phase IIb clinical study of Tcelna in patients with SPMS, was approximately $830,000 per month. Significant activities in the conduct of the clinical trial will

result in substantial increases in our monthly cash burn during 2013. We believe we have sufficient liquidity to support our current clinical trial activities into the fourth quarter of 2013. In the absence of significant additional funding, there is substantial doubt about our ability to continue as a going concern. This may make it more difficult for us to raise funds. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures or to generate revenue. If we are unable to obtain additional financing for our operations, we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations, cease operations or seek relief under applicable bankruptcy laws. In such event, investors may lose a portion or all of their investment. Our consolidated financial statements contain no adjustment for the outcome of this uncertainty.

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

Our business is at an early stage of development. We do not have any product candidates that have completed late-stage clinical trials nor do we have any products on the market. We have only one product candidate, Tcelna, which has progressed to the stage of being studied in human clinical trials in the United States. In September 2012, we announced the initiation of a Phase IIb study of Tcelna in patients with SPMS. We are still in the very early stages of identifying and conducting research on any other potential products. Tcelna, and any other potential products, will require regulatory approval prior to marketing in the United States and other countries. Obtaining such approval requires significant research and development and preclinical and clinical testing. We may not be able to develop any products, to obtain regulatory approvals, to continue clinical development of Tcelna, to enter clinical trials (or any development activities) for any other product candidates or to commercialize any products. Tcelna, and any other potential products, may prove to have undesirable or unintended side effects or other characteristics adversely affecting their safety, efficacy or cost-effectiveness that could prevent or limit their use. Any product using any of our technology may fail to provide the intended therapeutic benefits or to achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production.

We might be unable to service our current debt due to a lack of cash flow or otherwise fail to comply with terms of the convertible secured promissory notes or related agreements and might be subject to default. The convertible secured promissory notes are secured by a pledge of all of our assets. The issuance of securities upon the conversion of such notes and/or the exercise of warrants issued in tandem with such notes will result in significant dilution for our shareholders.

On July 25, 2012, we closed a private offering consisting of convertible secured notes and warrants to purchase shares of common stock which generated approximately $4.1 million in gross proceeds ($500,000 of which is held in a controlled account). The notes mature on July 25, 2014 and accrue interest at the rate of 12% per annum, compounded annually. Interest is payable semi-annually in either cash or registered shares of common stock at our election. The notes are secured by substantially all of our assets and are convertible into a new class of non-voting Series A convertible preferred stock. The notes can be converted into Series A convertible preferred stock at the option of the investors at a price of $100.00 per share, subject to certain limitations and adjustments. Additionally, we can elect to convert the notes into Series A convertible preferred stock if (i) our common stock closes at or above $10.00 per share for 20 consecutive trading days or (ii) we achieve certain additional funding milestones to continue our clinical trial program. These milestones include (x) executing a strategic agreement with a partner or potential partner by which we will receive a minimum of $5 million to partially fund, or an option to partner with us for, our Phase II clinical trial for Tcelna in patients with SPMS and (y) receiving a minimum of $25 million in additional capital (including the note offering proceeds) from any partner, potential partner or any other source. The Series A convertible preferred stock accrues dividends at the rate of 8% per annum, which are cumulative and payable semi-annually in either cash or registered shares of the common stock at our election. The Series A convertible preferred stock is convertible into shares of our common stock at the option of the holders at a price of $3.1225 per share, subject to certain limitations and adjustments. Additionally, we can elect to convert the Series A convertible preferred stock into common stock if our common stock closes at or above $16.00 per share for 20 consecutive trading days. To date, secured promissory notes in the aggregate principal amount of $900,000 have been converted into shares of Series A convertible preferred stock which, in turn, have been converted into an aggregate of 288,229 shares of common stock. No shares of Series A convertible preferred stock are currently outstanding.

The warrants have an exercise price of $2.56 per share, a five-year term and are exercisable for 112.5% of the number of shares of common stock into which the initial principal amount of the notes is ultimately convertible, subject to certain limitations and adjustments. We can redeem the warrants at $0.01 per share if our common stock closes at or above $10.00 per share for 20 consecutive trading days.

As a result of anti-dilution adjustments since the closing of the July 2012 secured promissory note financing, up to 1,020,007 shares of common stock are issuable if all currently outstanding convertible secured promissory notes are converted to Series A convertible preferred stock and such stock is then converted into shares of our common stock. The noteholders were granted certain registration rights for the shares of common stock underlying the notes and the warrants issued in July 2012.

As part of the security interest in all of our assets granted to the noteholders, $500,000 of the proceeds is currently maintained in a controlled account. This amount was previously $1 million; however, in January 2013 we issued the noteholders five-year warrants to acquire an aggregate of 187,500 shares of our common stock at an exercise price of $1.21 per share in exchange for the reduction of such amount.

If we do not make the required payments when due, either at maturity, or at applicable installment payment dates, or if we breach other terms of the convertible secured notes or related agreements, the noteholders could elect to declare all amounts outstanding, together with accrued and unpaid interest, to be immediately due and payable. Even if we were able to prepay the full amount in cash, any such repayment could leave us with little or no working capital for our business. If we are unable to repay those amounts, the noteholders will have a first claim on our assets pledged under the convertible secured notes. If the noteholders should attempt to foreclose on the collateral, it is unlikely that there would be any assets remaining after repayment in full of such secured indebtedness. Any default under the convertible secured notes and resulting foreclosure would have a material adverse effect on our financial condition and our ability to continue our operations.

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

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

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

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

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

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

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

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous FDA requirements, and must otherwise comply with federal, state and local requirements and policies of the medical institutions where they are conducted. The clinical trial process is also time-consuming. We estimate that the Phase IIb clinical trial in North America of our lead product candidate, Tcelna, in SPMS will complete enrollment by late 2013 or early 2014, with the resulting top-line data expected to be available in the first half of 2016. In addition, we anticipate that a pivotal Phase III clinical trial would be necessary before an application could be submitted for approval of Tcelna for SPMS. Failure can occur at any stage of the trials, and problems

could be encountered that would cause us or Merck (in the event the Option is exercised) to be unable to initiate a trial, or to abandon or repeat a clinical trial.

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

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

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

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

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

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

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

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

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

- any third party upon whom we rely does not successfully carry out its contractual duties or regulatory obligations or meet expected deadlines;
- any such third party needs to be replaced; or

- the quality or accuracy of the data obtained by the third party is compromised due to its failure to adhere to clinical protocols or regulatory requirements or for other reasons.

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

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

We have targeted MS as the first disease to be pursued off our T-cell platform technology. As a platform technology, there exists the potential to address other autoimmune diseases with the technology. Minimal work has been done outside the lead MS indication. Our business over the long term is substantially dependent on our ability to develop, license or acquire product candidates and further develop them for commercialization. The success of this strategy depends upon our ability to expand our existing platform or identify, select and acquire the right product candidates. We have limited experience identifying, negotiating and implementing economically viable product candidate acquisitions or licenses, which is a lengthy and complex process. Also, the market for licensing and acquiring product candidates is intensely competitive, and many of our competitors have greater resources than we do. We may not have the requisite capital resources to consummate product candidate acquisitions or licenses that we identify to fulfill our strategy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Under the corporate governance standards of NASDAQ, a majority of our Board of Directors and each member of our Audit Committee must be an independent director. If any vacancies on our Board or our Audit Committee 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.

Risks Related to Our Intellectual Property

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

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

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

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

For our licensed intellectual property, we have limited control over the amount or timing of resources that are devoted to the prosecution of such intellectual property. Due to this lack of control and general uncertainties in the patent prosecution process, we cannot be sure that any licensed patents will result from licensed applications or, if they do, that they will be maintained. Issued U.S. patents require the payment of maintenance fees to continue to be in force. We rely on licensors to do this and their failure to do so could result in the forfeiture of patents not timely maintained. Many foreign patent offices also require the payment of periodic annuities to keep patents and patent applications in good standing. As we do not maintain control over the payment of annuities, we cannot assure you that our licensors will timely pay such annuities and that the granted patents and pending patent applications will not become abandoned. In addition, our licensors may have selected a limited amount of foreign patent protection, and therefore applications have not been filed in, and foreign patents may not have been perfected in, all commercially significant countries.

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

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

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

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

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

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

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

the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

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

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

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

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

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

Risks Related to Our Industry

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

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

In addition, both before and after regulatory approval, we, our partners and our product candidates, such as Tcelna, are subject to numerous FDA requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising,

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

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

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

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

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

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

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing of qui tam actions has increased significantly in recent years, causing greater numbers of healthcare companies to have to

defend a False Claims Act action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties. Various states have also enacted laws modeled after the federal False Claims Act.

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

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

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

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

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

Rapid technological change could make our products obsolete.

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

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

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

In the event that any of our product candidates becomes an approved product and is commercialized, consumers may make product liability claims directly against us and/or our partners (such as Merck, in the event the Option is exercised, with respect to Tcelna), and our partners or others selling these products may seek contribution from us if they incur any loss or expenses related to such claims. We have insurance that covers clinical trial activities. We believe our current insurance coverage 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.

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

Risks Related to Our Securities

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

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

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

We are required to meet certain qualitative and financial tests (including a minimum stockholders' equity requirement of $2.5 million and bid price for our common stock of $1.00 per share) to maintain the listing of our common stock on the NASDAQ Capital Market, and our common stock is in jeopardy of being delisted. On November 26, 2012, we received a staff deficiency letter from NASDAQ notifying us that the stockholders' equity of $2,339,285 as reported in our Quarterly Report on Form 10-Q for the period ended September 30, 2012 was below the minimum stockholders' equity of $2.5 million required for continued listing on NASDAQ. We were provided 45 calendar days, or until January 10, 2013, to submit a plan to regain compliance with the minimum stockholders' equity standard. We submitted such a plan and it was accepted, with NASDAQ thus granting us an extension until May 15, 2013 to evidence compliance with the minimum stockholders' equity standard. If we fail to evidence compliance upon filing our Quarterly Report on Form 10-Q for the period ending March 31, 2013, we may be subject to delisting. As of the date of this Annual Report on Form 10-K, we believe we have regained compliance with the stockholders' equity requirement based on our stockholders' equity balance of $2,883,332 as of December 31,2012 and the equity capital we have raised subsequent to December 31, 2012.

While we are exercising diligent efforts to maintain the listing of our common stock on NASDAQ, there can be no assurance that we will be able to maintain compliance with the stockholder's equity standard.

It is also possible that we could fail to satisfy another NASDAQ requirement for continued listing of our stock, such as the minimum bid price, the market value or number of publicly held shares or number of shareholders, or a corporate governance requirement. For example, during portions of 2008 and 2009, our stockholders' equity was below the continued listing standard requirement of $2.5 million and the bid price for our common stock was below $1.00 per share for periods of time, and our common stock was in jeopardy of being delisted. Additionally, during 2010 and 2011, the trading price of our common stock was minimally above $1.00 per share for certain periods of time, and our stock closed below $1.00 per share from December 2011 through part of December 2012. In February 2012, we received a staff deficiency letter from NASDAQ indicating that our common stock failed to comply with the minimum bid price requirement because it traded below the $1.00 minimum closing bid price for 30 consecutive trading days, and after an initial and an extended grace period, and implementation of a one-for-four reverse stock split of our common stock on December 14, 2012, we regained compliance with the $1.00 minimum closing bid price listing standard and NASDAQ notified us that the matter was closed in January 2013. However, there is no assurance that the closing bid price of our common stock will continue to stay above the minimum continued listing standard.

We may receive additional future notices from NASDAQ that we have failed to meet its requirements, and proceedings to delist our stock could be commenced. In such event, NASDAQ rules permit us to appeal any delisting determination to a NASDAQ Hearings Panel. If we are unable to maintain or regain compliance in a timely manner and our common stock is delisted, it could be more difficult to buy or sell our common stock and obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting may also impair our ability to raise capital.

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

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

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

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

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

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

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

Our articles of incorporation authorize the issuance of "blank check" preferred stock with such designations, rights and preferences as may be determined by our Board of Directors without stockholder 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 stockholders from receiving a premium for their shares in connection with a change of control.

Future sales of our common stock in the public market could lower our stock price.

In July 2012, we closed a private offering consisting of convertible secured notes and warrants to purchase common stock which generated approximately $4.1 million in gross proceeds, of which notes in the aggregate principal amount of $900,000 have been converted into shares of Series A convertible preferred stock which, in turn, have been converted into an aggregate of 288,229 shares of common stock. From November 2012 through January 2013, we sold an aggregate of 390,000 shares to Lincoln Park pursuant to the $1.5 million purchase agreement and issued an additional 56,507 shares as initial commitment shares and 3,585 shares as additional commitment shares. In January 2013, we issued $650,000 principal amount of unsecured convertible promissory notes of which $100,000 was converted into 77,034 shares of common stock at $1.298125 per share and the remaining $550,000 of principal amount plus accrued interest was repaid. Purchasers of such notes also received five-year warrants to acquire an aggregate of 243,750 shares of our common stock at an exercise price of $1.24 per share. Pursuant to a Sales Agreement executed on September 6, 2012, we have registered for sale up to 1,000,000 shares of common stock through Brinson Patrick Securities Corporation acting as sales agent in an "at-the-market" program. In February 2013, we sold an aggregate of 167,618 shares of our common stock pursuant to

such at-the-market program for gross proceeds of $536,417. On February 11, 2013, we closed on an offering of 1,083,334 shares of common stock and warrants to purchase shares of common stock, for gross proceeds of $3,250,002. 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.

Sales of a substantial number of additional shares of our common stock in the public market could cause the market price of our common stock to decline. An aggregate of 7,991,559 shares of common stock were outstanding as of March 15, 2013. As of such date, another (i) 816,432 shares were issuable upon exercise of outstanding options, (ii) 3,422,652 shares of common stock were issuable upon the exercise of outstanding warrants, and (iii) 1,020,007 shares were issuable if all outstanding 12% convertible secured promissory notes were converted to Series A convertible preferred stock which was then ultimately converted into common stock.

A substantial majority of the outstanding shares of our common stock are freely tradable without restriction or further registration under the Securities Act of 1933. We may sell additional shares of common stock, as well as securities convertible into or exercisable for common stock, in subsequent public or private offerings. We may also issue additional shares of common stock, as well as securities convertible into or exercisable for common stock, to finance future acquisitions. Among other requirements, we will need to raise significant additional capital in order to continue and complete the Phase IIb clinical study of Tcelna in SPMS, and this may require us to issue a substantial amount of securities (including common stock as well as securities convertible into or exercisable for common stock). 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 adversely affect prevailing market prices for our common stock.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

Under the purchase agreements with Lincoln Park, we may direct Lincoln Park to purchase up to $1.5 million of shares of common stock subject to certain limitations over a 30-month period, and, upon effectiveness of a registration statement for resale of the applicable shares pursuant to the $15.0 million purchase agreement, and subject to other conditions, we may also direct Lincoln Park to purchase up to $15.0 million of our shares of common stock over a 30-month period. However, in conjunction with our February 2013 offering of common stock and warrants, we agreed not to sell shares under the purchase agreements with Lincoln Park for a period of 120 days after the offering. We have sold an aggregate of 390,000 shares to date under the $1.5 million purchase agreement. Additionally, we issued Lincoln Park 56,507 shares of common stock as initial commitment shares and have issued an aggregate of 3,586 additional commitment shares, and may in the future issue up to an additional 109,428 shares of common stock as additional commitment shares, as a fee for its commitment to purchase the shares under the $1.5 million purchase agreement and the $15.0 million purchase agreement. The number of shares ultimately offered for sale by Lincoln Park is dependent upon the number of shares purchased by Lincoln Park under the purchase agreements. Depending on market liquidity at the time, sales of shares we issue to Lincoln Park may cause the trading price of our common stock to decline.

Subject to certain conditions, we generally have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of our agreements with Lincoln Park, we would be unable to sell shares to Lincoln Park if and when the market price of our common stock is below $1.00 per share or if Lincoln Park would own more than 4.99% of our common stock for stock sold to it under the $1.5 million purchase agreement or 9.99% of our common stock for stock sold to it under the $15.0 million purchase agreement. The purchase price for the shares that we may sell to Lincoln Park will fluctuate based on the price of our common stock and other factors determined by us. As such, Lincoln Park may ultimately purchase all, some or none of the shares of our common stock and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Therefore, sales to Lincoln Park by us pursuant to either or both of the purchase agreements could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could cause the trading price of our common stock to decline and could make it more difficult for us to sell equity or equity-related securities in the future.

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

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

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

Our charter allows us to issue up to 100,000,000 shares of our common stock and to issue and designate the rights of, without stockholder approval, up to 10,000,000 shares of preferred stock. In connection with the July 25, 2012 convertible note financing,

80,000 shares of preferred stock were designated as non-voting Series A convertible 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 stockholders 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 stockholders. 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.

For example, on July 25, 2012, we closed a private offering consisting of convertible secured notes and warrants to purchase common stock which generated approximately $4.1 million in gross proceeds. The notes mature on July 25, 2014 and accrue interest at the rate of 12% per annum, compounded annually, payable in either cash or registered shares of common stock. The notes are secured by substantially all of our tangible and intangible assets, and $500,000 of the proceeds from the note offering is being held in a controlled account as part of the security interest granted to the noteholders. This amount was previously $1 million; however, in January 2013 we issued the noteholders five-year warrants to acquire an aggregate of 187,500 shares of our common stock at an exercise price of $1.21 per share in exchange for the reduction of such amount. The notes are convertible into a new class of non-voting Series A convertible preferred stock at a conversion price of $100.00, subject to certain limitations and adjustments. The Series A convertible preferred stock accrues cumulative dividends at the rate of 8% per annum, payable in either cash or registered shares of common stock, and carries a $100.00 per share liquidation preference. The Series A convertible preferred stock is convertible into common stock at a conversion price of $3.1225, subject to certain limitations and adjustments. As a result of antidilution adjustments since the closing of the July 2012 financing: (i) up to 1,020,007 shares of common stock are issuable if all the current outstanding principal balance of $3,185,000 of convertible secured promissory notes are converted to Series A convertible preferred stock and such stock is then converted into common stock; and (ii) the warrants issued to the purchasers of the convertible secured promissory notes are exercisable at an adjusted exercise price of $2.56 per share for an aggregate of 1,436,121 shares of common stock. As of March 15, 2013, secured promissory notes with an aggregate principal amount of $900,000 have been converted into shares of Series A convertible preferred stock which, in turn, have been converted into an aggregate of 288,229 shares of our common stock.

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

In addition to general corporate purposes (including working capital and operational purposes), we currently intend to use our available cash, including the $5 million proceeds received from Merck in February 2013 as well as the approximately $3.25 million in gross proceeds from the February 2013 registered offering of common stock and warrants, to continue our ongoing Phase IIb clinical study of Tcelna in SPMS. The Phase IIb clinical study in North America of Tcelna is expected to complete enrollment of 180 patients by late 2013 or early 2014, with the resulting top-line data expected to be available in the first half of 2016. The estimated future costs of the study, as well as the ongoing expenses of our operations through the expected completion date of the study and release of top-line data, are estimated to be between $33-35 million as of January 1, 2013. We used the $650,000 gross proceeds from the January 2013 private offering of convertible unsecured promissory notes and warrants as bridge financing to continue our Phase IIb clinical study while continuing discussions with Merck regarding the February 2013 Option and License Agreement. We repaid the principal balance of the January 2013 notes with $550,000 in cash and $100,000 was converted into 77,034 shares of common stock. Our existing resources are not adequate to permit us to complete our ongoing phase IIb clinical study of Tcelna in SPMS or the majority of it. We will need to secure significant additional resources to complete the trial and support our operations during the pendency of the trial.

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

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

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information and Holders

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

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

	Price Ranges	
	High	Low
Fiscal Year Ended December 31, 2011		
First Quarter	$ 11.20	$ 6.08
Second Quarter	8.04	6.36
Third Quarter	6.56	4.44
Fourth Quarter	5.60	3.60
Fiscal Year Ended December 31, 2012		
First Quarter	$ 4.36	$ 2.84
Second Quarter	3.04	1.28
Third Quarter	3.08	1.28
Fourth Quarter	3.28	1.12

The closing price of our common stock on March 15, 2013 was $2.13 per share, and there were approximately 200 holders of record of our common stock. This number does not include stockholders 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, 2012, with respect to our compensation plans under which common stock is authorized for issuance, which consist of our 2010 Stock Incentive Plan and its predecessor, our June 2004 Compensatory Stock Option Plan. We believe that the exercise price for all of the options granted under these plans reflect at least 100% of fair market value on the dates of grant for the options at issue.

Equity Compensation Plan Information

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (A)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column A) (C)
Equity Compensation Plans Approved by Stockholders	824,620	$ 5.54	313,600
Equity Compensation Plans Not Approved by Stockholders	—	—	—
Total	824,620	$ 5.54	313,600

Refer to Note 12 "Options and Warrants" in the Notes to our financial statements for the fiscal year ended December 31, 2012, included elsewhere in the annual report for a description of our 2010 Stock Incentive Plan and 2004 Compensatory Stock Option Plan.

Recent Sales of Unregistered Securities and Equity Purchases by Company

None.

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

Critical Accounting Policies

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

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

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

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

Results of Operations

Comparison of Year Ended December 31, 2012 with the Year Ended December 31, 2011

Net Sales. We recorded no commercial revenues for the years ended December 31, 2012 and 2011.

Research and Development Expenses. Research and development expenses were $6,318,476 for the year ended December 31, 2012, compared to $3,340,038 for the year ended December 31, 2011. The increase in expenses was primarily due to an increases in staff to conduct increased development activities, the procurement and use of supplies used in both our laboratory and product manufacturing operations, the engagement of consultants and the costs of subject participation in our Phase IIb clinical study, facilities costs and stock compensation expense, and was partially offset by a decrease in legal costs. We have made and expect to continue to make substantial investments in research and development in order to develop and market our technology. We expense research and development costs as incurred. Acquired research and development that has no alternative future use is expensed when acquired. Property, plant 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 $2,508,541 for the year ended December 31, 2012, as compared to $2,406,269 for the year ended December 31, 2011. The increase in expense is due to increases in legal expense, capital financing activities, stock compensation expense and facilities costs, and was partially offset by a reduction in professional service fees.

Depreciation and Amortization Expenses. Depreciation and amortization expenses were $303,677 for the year ended December 31, 2012, as compared to $210,252 for the year ended December 31, 2011. The increase in expense is due to an increase in depreciation for facility build-out costs incurred during the first half of 2011, an increase in depreciation for laboratory and manufacturing equipment acquired during 2011 and 2012 to support increased development activities and an increase in depreciation for information technology equipment to replace and upgrade obsolete equipment.

Interest Expense. Interest expense was $350,300 for the year ended December 31, 2012, compared to $3,135 for the year ended December 31, 2011. The increase in interest expense was primarily related to the non-cash amortized debt discount and interest on the July 25, 2012 convertible notes and the amortization of the financing fees over the life of the notes. Interest expense for the year ended December 31, 2011 related solely to the financing costs on insurance policies and the loan payable on an equipment line.

Interest Income. Interest income was $280 for the year ended December 31, 2012, compared to $932 for the year ended December 31, 2011.

Net Loss. We had a net loss for the year ended December 31, 2012 of $8,930,833, or $1.54 per share (basic and diluted), compared with a net loss of $5,968,448, or $1.06 per share (basic and diluted), for the year ended December 31, 2011. The increase in net loss is primarily due to increases in research and development, general and administrative, depreciation and interest expenses.

Liquidity and Capital Resources

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of December 31, 2012, we had cash and cash equivalents of $592,004. Our financing activities generated approximately $4.0 million for the year ended December 31, 2012, compared to approximately $8.6 million for the year ended December 31, 2011. The cash generated in 2012 was proceeds from a July convertible secured note financing and sales of shares of our common stock to Lincoln Park Capital Fund, LLC ("Lincoln Park"), as discussed below.

During July 2012, we issued an aggregate of $4,085,000 of convertible secured promissory notes for net proceeds of $2,815,779 (excluding $1 million of the gross proceeds held in a controlled account, $500,000 of which was released to us in January 2013). We issued 163,224 shares of common stock on December 31, 2012 in payment of the semi-annual accrued interest on these promissory notes.

On September 6, 2012, we entered into a sales agreement with Brinson Patrick Securities Corporation in connection with the implementation of an "at-the-market" offering program pursuant to which we may sell shares of our common stock directly into the open market from time to time depending upon market demand, through our sales agent, in transactions deemed to be an "at-the-market" offering as defined in Rule 415 of the Securities Act of 1933. We have registered up to 1,000,000 shares of our common stock for potential sale under this program, and in February 2013, we sold an aggregate of 167,618 shares of our common stock, for gross proceeds of $536,417.

On November 2, 2012, we entered into a $15.0 million purchase agreement and registration rights agreement, and on November 5, 2012, we entered into a $1.5 million purchase agreement, each with Lincoln Park pursuant to which we have the right to sell to Lincoln Park an aggregate of up to $16.5 million in shares of our common stock, subject to certain conditions and limitations. Under the terms and subject to the conditions of the purchase agreements, Lincoln Park is obligated to purchase up to an aggregate of $16.5 million in shares of common stock (subject to certain limitations) from time to time over a 30-month period (which, as it relates to the $15.0 million purchase agreement, commences on the date that a registration statement is declared effective by the SEC and a final prospectus in connection therewith is filed). We may direct Lincoln Park, at our sole discretion and subject to certain conditions, to purchase up to 100,000 shares of common stock in regular purchases, increasing to amounts of up to 300,000 shares depending upon the closing sale price of our common stock. In addition, we may direct Lincoln Park to purchase additional amounts as accelerated purchases. The purchase price of shares of common stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to 12 business days leading up to such time), but in no event will shares be sold to Lincoln Park on a day the common stock closing price is less than the adjusted minimum floor price of $1.00. During November and December 2012, we raised proceeds of $381,309 through the sale of our common stock to Lincoln Park. In January 2013, we sold an additional $142,400 in shares of common stock to Lincoln Park. As of March 15, 2013, we have a remaining commitment amount of $15,976,291 available to us through Lincoln Park purchase agreements (subject to effectiveness of a registration statement and other closing conditions for the $15.0 million purchase agreement). However, there can be no assurance that we will be able to receive any or all of the additional funds from Lincoln Park because the purchase agreements contain limitations, restrictions, requirements, events of default and other provisions that could limit our ability to cause Lincoln Park to buy common stock from us.

Additionally, in January 2013 we closed a private offering of unsecured convertible promissory notes and warrants to purchase common stock , which generated $650,000 in gross proceeds.

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

Upon receipt of the upfront payment from Merck in February 2013, we repaid $550,000 principal amount plus accrued interest on the January 2013 unsecured convertible promissory notes and converted the remaining $100,000 principal amount into shares of our common stock pursuant to the investor's election to convert into equity.

On February 11, 2013, we closed an offering of 1,083,334 shares of common stock and warrants to purchase shares of common stock, for gross proceeds of $3,250,002. As part of this offering, we agreed not to sell shares pursuant to our purchase agreements with Lincoln Park or under our "at-the-market" program for a period of 120 days following the February 2013 offering.

Our burn rate during 2012, inclusive of the costs of preparations to commence our Phase IIb clinical trial, was approximately $830,000 per month. Significant activities in the conduct of the clinical trial will result in substantial increases in our monthly cash burn during 2013. We will need to raise additional capital to fund our current business plan and support our clinical trial operations. Based on our current burn rate, we believe we have sufficient liquidity to support our current clinical trial activities into the fourth quarter of 2013.

We currently intend to continue to use our available cash to fund general corporate purposes (including working capital and operational purposes) and continue the Phase IIb clinical study of Tcelna in SPMS. The Phase IIb clinical study in North America of Tcelna is expected to complete enrollment of 180 patients by late 2013 or early 2014, with resulting top-line data expected to be available in the first half of 2016. The estimated future costs of the study, as well as the ongoing expenses of our operations through the expected completion date of the study and release of top-line data, are estimated to be between $33-35 million as of January 1, 2013. Our existing resources are not adequate to permit us to complete such study or the majority of it. We will need to secure significant additional resources to continue and complete the trial and support our operations during the pendency of the trial. If we are unable to obtain additional funding for operations, we will be forced to suspend or terminate our current ongoing clinical trial for Tcelna, which may require us to modify our current business plan and curtail various aspects of our operations, as well as implement significant cost-reduction measures or potentially cease operations.

Given our need for substantial amounts of capital to continue the Phase IIb clinical study in North America of Tcelna in SPMS, we intend to continue to explore potential opportunities and alternatives to obtain the additional resources, including one or more additional financings, that will be necessary to complete the Phase IIb study and to support our operations during the pendency of such study. There can be no assurance that any such financings or potential opportunities and alternatives can be consummated on acceptable terms, if at all.

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

We do not maintain any external lines of credit. Should we need any additional capital in the future beyond the purchase agreements with Lincoln Park and our at-the-market program, management will be reliant upon "best efforts" debt or equity financings. As our prospects for funding, if any, develop during the fiscal year, we will assess our business plan and make adjustments accordingly. Although we have successfully funded our operations to date by attracting additional investors in our equity and debt securities, there is no assurance that our capital raising efforts will be able to attract additional necessary capital for our operations in the future.

Assuming we are able to achieve financing which is sufficient to continue our Phase IIb study of Tcelna in SPMS in North America and to support our operations during the pendency of such study, we are also able to concurrently manage a pivotal Phase III clinical study in RRMS in North America in our present facility. However, any such study would also depend upon the availability of sufficient resources.

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, 2012 and 2011, since inflation rates have generally remained at relatively low levels and our operations are not otherwise uniquely affected by inflation concerns.

Recently Issued Accounting Pronouncements

On July 1, 2009, the FASB officially launched the FASB Accounting Standards Codification, which has become the single official source of authoritative, nongovernmental U.S. Generally Accepted Accounting Principles, in addition to guidance issued by the Securities and Exchange Commission. The codification supersedes all prior FASB, AICPA, EITF, and related literature. The codification, which is effective for interim and annual periods ending after September 15, 2009, is organized into approximately 90 accounting topics. The FASB no longer issues new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts. Instead, amendments to the codification are made by issuing "Accounting Standards Updates."

There were various other accounting standards and interpretations issued during 2012 and 2011, none of which are expected to have a material impact on our financial position, operations or cash flows.

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, 2012 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, 2012 in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

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

Changes in Internal Control over Financial Reporting

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

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers

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

Name	Age	Position
Neil K. Warma	50	President, Chief Executive Officer, and Director
David E. Jorden	50	Acting Chief Financial Officer and Director
Jaye L. Thompson	47	Senior Vice President of Clinical Development and Regulatory Affairs
Donna R. Rill	59	Senior Vice President of Operations and Quality Systems

Biographical information for our executive officers is set forth below:

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

David E. Jorden has served as Acting Chief Financial Officer since August 2012 and a Director since August 2008. Mr. Jorden has also served as Executive Chairman for Cytomedix, Inc. since February 2012 and previously as an executive board member since October 2008. Mr. Jorden previously served as vice president with Morgan Stanley in its Wealth Management group where he was responsible for equity portfolio management for high net worth individuals since 2003. Prior to Morgan Stanley, Mr. Jorden served as vice president and chief financial officer of Genometrix, Inc., a private genomics/life sciences company focused on high-throughput microarray applications from March 2000 to September 2002. Mr. Jorden was a principal with Fayez Sarofim & Co. prior to joining Genometrix. Mr. Jorden earned a MBA from Kellogg School of Management at Northwestern University in 1989 and a BBA from the University of Texas/Austin in 1984. He currently serves as a director of Cytomedix, Inc. and PLx Pharma, Inc. Mr. Jorden is a Chartered Financial Analyst and Certified Public Accountant. He has extensive experience in various aspects of corporate finance and accounting for public companies including capital formation and deployment.

Jaye L. Thompson, Ph.D., has served as Senior Vice President of Clinical Development and Regulatory Affairs since November 2009. From April 2006 to September 2009, Dr. Thompson served as Senior Vice President of Regulatory and Emerging Technologies for inVentiv Clinical Solutions, LLC, a subsidiary of inVentiv Heath, Inc., a publicly traded company providing a wide range of services to the pharmaceutical industries. inVentiv Health acquired SYNERGOS, Inc., the company founded in 1991 by Dr. Thompson. SYNERGOS was a contract research organization helping companies move through the clinical and regulatory hurdles of product development. She currently serves as a director of Repros Therapeutics, Inc. Dr. Thompson received a doctorate and masters degree in Biostatistics from the University of Texas Health Science Center, School of Public Health, and a B.S. in Applied Mathematics from Texas A&M University.

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

Directors

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

Name	Age	Position
David E. Jorden	50	Director and Acting Chief Financial Officer
Gail J. Maderis	55	Director
Michael S. Richman	52	Director
Scott B. Seaman	57	Director
Neil K. Warma	50	Director, President and Chief Executive Officer

David E. Jorden—refer to "Executive Officers" section above for Mr. Jorden's biographical information.

Gail J. Maderis has served as a Director since October 2011. Ms. Maderis has served as President and CEO of BayBio (Bay Area Bioscience Association), an independent, non-profit trade association serving the life sciences industry in Northern California, since October 2009 and joined BayBio's board in 2004. From July 2003 to June 2009, Ms. Maderis served as President and CEO of FivePrime 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 been a member of several private company boards, and currently serves on The Mayor's Biotech Advisory Council of San Francisco, as well as the HBS Healthcare Initiative board. Ms. Maderis received a B.S. degree in business from the University of California at Berkeley and an M.B.A. from Harvard Business School. Ms. Maderis has extensive experience as a senior executive of life sciences companies, giving her valuable operational and industry experience and leadership skills, as well as an extensive network of contacts related to financing, partnering and support services in the biotech industry and visibility into business and policy trends that impact the biopharmaceutical industry.

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

Scott B. Seaman has served as a Director of since April 2006. Mr. Seaman has served for over five years as the executive director and treasurer of the Albert and Margaret Alkek Foundation of Houston, Texas, a private foundation primarily supporting institutions in the Texas Medical Center in Houston, Texas. Since January 1996 to present, Mr. Seaman has served as the chief financial officer of Chaswil Ltd., an investment management company. Since September 1986, Mr. Seaman has served as secretary and treasurer of M & A Properties Inc., a ranching and real estate concern. In April 2009, Mr. Seaman became the Managing Member of ICT Development LLC which is the Managing Member of ICT Holdings LLC, an energy services supplier. From January 2003 to April 2009, Mr. Seaman served as chairman and from July 2004 to April 2009, as president of ICT Management Inc., the general partner of Impact Composite Technology Ltd., a composite industry supplier. From October 2007 to December 2010, Mr. Seaman served on the board of GeneExcel, Inc., a privately held biotechnology company. From May 2004 to December 2010, Mr. Seaman served as a Member of the Investment Committee of Global Hedged Equity Fund LP, a hedge fund. Mr. Seaman received a bachelor's degree in business administration from Bowling Green State University and is a certified public accountant. Mr. Seaman has extensive experience in overall financial management and corporate development, combined with operational and corporate governance experience.

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

Audit Committee

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

Code of Ethics

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who beneficially own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership. These reporting persons are required by SEC regulations to furnish us with copies of all such reports they file. To our knowledge, based solely on our review of the copies of such reports furnished to us and written representations from certain insiders that no other reports were required, we believe all of the reporting persons complied with all applicable Section 16(a) filing requirements applicable to them with respect to transactions during the fiscal year ended December 31, 2012, except with respect to the following reports that were filed late: two reports by Mr. Warma reporting one transaction for each report; and one report by each Messrs. Jorden and Seaman, Dr. Thompson and Ms. Rill reporting one transaction each.

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, 2012. Our Named Executive Officers include persons who (i) served as our principal executive officer or acted in a similar capacity during 2012, (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.

2012 Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Options Awards[1]	All Other Compensation	Total
Neil K. Warma	2012	$ 396,550	$ 50,000	$ 688,684	$ 100	$ 1,135,334
President, Chief Executive Officer, Acting Chief Financial Officer[2]	2011	$ 385,000	$ 50,000	$ 115,051	—	$ 550,051
Donna R. Rill	2012	$ 220,000	$ 15,000	$ 154,152	$ 250	$ 389,402
Senior Vice President of Operations and Quality Systems	2011	$ 200,000	$ 15,000	$ 38,350	—	$ 253,350
Jaye L. Thompson, Ph.D.	2012	$ 220,000	$ 10,000	$ 154,152	$ 50	$ 384,202
Senior Vice President of Clinical Development and Regulatory Affairs	2011	$ 200,000	$ 15,000	$ 38,350	—	$ 253,350

(1) Amounts in this column represent the aggregate grant date fair value of awards computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 ("FASB ASC 718"). Each executive officer was granted two options on January 6, 2012, and the fair value of each was calculated using the Black-Scholes option-pricing model. The first option is based on the achievement of future performance-based, strategic milestone objectives, and the grant date fair value is based upon the probable outcome of the performance conditions. See Note 12 to our financial statements included in this annual report on Form 10-K for assumptions underlying the valuation of equity awards.

(2) Mr. Warma served as Acting Chief Financial officer until August 15, 2012.

Executive Employment Agreements

We entered into an employment agreement on June 16, 2008 with Neil K. Warma pursuant to which he serves as our President and Chief Executive Officer. Pursuant to the agreement, which automatically renews for 12-month periods, Mr. Warma is currently paid $396,550 per year. In addition, Mr. Warma is entitled to the following: (i) an annual cash bonus of up to 50% of his base salary based upon milestones to be agreed upon; and (ii) a one-time payment of $50,000 cash and 6,250 shares of our common stock to be issued if and when the closing bid price of our common stock equals or exceeds $16.00 for 20 consecutive trading days. In addition, we provide Mr. Warma with our standard benefits and insurance coverage as generally provided to our management, as well as contractual indemnification rights by reason of his service as an officer and employee. If his employment is terminated by the Board without cause, as defined in the agreement, Mr. Warma will be entitled to receive a severance payment equal to 12 months of his base salary plus a payment equal to 30% of base salary in lieu of any potential bonus, in addition any earned but unpaid bonus. In addition, vesting of stock options will accelerate in full. We will also reimburse Mr. Warma for COBRA expenses for a 12-month period, subject to a cap equal to Opexa's standard contribution to employee health benefits. Upon the effectiveness of a change in control, as defined in the agreement, Mr. Warma will receive 18 months of salary and COBRA reimbursement and a payment equal to 45% of base salary in lieu of any potential bonus, in addition to any earned but unpaid bonus. In addition, all vesting of options will accelerate in full. Any payment or benefit Mr. Warma might receive upon a change of control which would constitute a "parachute payment" under Section 280G of the Internal Revenue Code will be reduced so as not to trigger excise tax under Section 4999 of such Code. Mr. Warma's agreement also provides that for a 12-month period following his termination of employment, he will not engage or participate in any competitive business or solicit or recruit any of Opexa's employees. The severance and change of control benefits are subject to Mr. Warma executing and delivering a general release and waiver of claims in favor of Opexa.

We entered into an amended and restated employment agreement with Donna R. Rill on April 21, 2010 which is effective as of April 1, 2010, pursuant to which Ms. Rill serves as our Senior Vice President of Operations and Quality Systems. This agreement superseded Ms. Rill's prior agreement. Ms. Rill is currently compensated at the rate of $220,000 per annum and is eligible to receive an annual discretionary bonus of up to 20% of her base salary per 12-month period, based on the achievement of objectives as determined by Opexa's Board and Chief Executive Officer. In addition, Ms. Rill receives our standard benefits and insurance coverage as generally provided to our management, as well as contractual indemnification rights by reason of her service as an officer and employee. Ms. Rill's employment may be terminated at any time voluntarily by her or without cause (as defined in the agreement) by the Board. If her employment is terminated by the Board without cause, Ms. Rill will be entitled to receive a severance payment equal to six months of her base salary and vesting for any unvested stock options will accelerate by six additional months. The severance benefits are subject to Ms. Rill having been continuously employed through the termination event, executing and delivering a general release and waiver of claims in favor of Opexa, not being in breach of the employment agreement or Opexa's proprietary information and inventions agreement, and not engaging in any activity which is competitive with Opexa during the term of the employment agreement or while receiving the severance benefits. The timing of any payments to Ms. Rill under the employment agreement is subject to applicable requirements of Section 409A of the Code and the related Treasury Regulations.

We entered into an amended and restated employment agreement with Jaye L. Thompson, Ph.D., on June 27, 2011, pursuant to which Dr. Thompson serves as our Senior Vice President of Clinical Development and Regulatory Affairs. This agreement superseded Dr. Thompson's prior agreement dated November 16, 2009. Dr. Thompson is currently compensated at the rate of $220,000 per annum and is eligible to receive an annual discretionary bonus of up to 20% of her base salary per 12-month period, based upon the achievement of objectives as determined by Opexa's Board and Chief Executive Officer. In addition, Dr. Thompson receives our standard benefits and insurance coverage as generally provided to our management. Dr. Thompson's employment may be terminated at any time voluntarily by her or without cause (as defined in the agreement) by the Board. If her employment is terminated by the Board without cause, Dr. Thompson will be entitled to receive a severance payment equal to six months of her base salary. In addition, in the event of a change of control (as defined in the agreement) and Dr. Thompson's employment is terminated without cause or Dr. Thompson resigns for good reason (as defined in the agreement) within 12 months of such change of control, Dr. Thompson will be entitled to receive a severance payment equal to six months of her base salary and all unvested equity awards will immediately vest in full and become exercisable pursuant to their terms. The severance benefits are subject to Dr. Thompson having been continuously employed through the termination event, executing and delivering a general release and waiver of claims in favor of Opexa, not being in material breach of the employment agreement or Opexa's proprietary information and inventions agreement, and not engaging in any activity which is competitive with Opexa during the term of the employment agreement or while receiving the severance benefits. The timing of any payments to Dr. Thompson under the employment agreement is subject to applicable requirements of Section 409A of the Code and the related Treasury Regulations.

2012 Grants of Plan Based Awards

The following table presents information regarding stock options granted during the fiscal year ended December 31, 2012 pursuant to our 2010 Stock Incentive Plan to our Named Executive Officers.

		Estimated Future Payouts Under Equity Incentive Plan Awards[1]					
Name	Grant Date	Threshold	Target	Maximum	All Other Option Awards: Number of Securities Underlying Options[4]	Exercise Price of Option Awards	Grant Date Fair Value of Options
Neil K. Warma	01/06/12	-	139,593 [2]	139,593 [2]		$3.80	$ 528,612[3]
	01/06/12				43,623	$3.80	$ 160,071[5]
Donna R. Rill.....	01/06/12	-	31,408	31,408		$3.80	$ 118,937[3]
	01/06/12				9,597	$3.80	$ 35,215[5]
Jaye L. Thompson .	01/06/12	-	31,408	31,408		$3.80	$ 118,937[3]
	01/06/12				9,597	$3.80	$ 35,215[5]

(1) The Target and Maximum amounts represent the number of shares of common stock underlying performance-based options that begin vesting, if at all, in two tranches commencing upon achievement of certain key milestone events. So long as the identified key milestones are achieved prior to their respective expiration dates, the applicable portion of the performance options thereupon commence vesting quarterly over a three-year period. Generally, (i) the first tranche of one-third of the performance option shares commences three-year quarterly vesting upon achievement of the first key milestone, which is Opexa initiating a clinical trial for Tcelna in SPMS, and (ii) the second tranche of two-thirds of the performance option shares commences three-year quarterly vesting upon achievement of the second key milestone, which is Opexa entering into a collaboration, partnership or other strategic arrangement involving rights in the United States for Tcelna. The performance options have a term of ten years, but potentially expire in two tranches, with (i) the first tranche to have expired on December 31, 2012 if the first key milestone was not achieved and (ii) the second tranche expiring on June 30, 2013 if the second key milestone is not achieved. On September 12, 2012, the first key milestone objective was met and vesting commenced for the first tranche of one-third of the performance option shares.

(2) Three-year quarterly vesting for an increment of 8,724 shares of Mr. Warma's second performance option tranche may commence earlier if Opexa enters into a collaboration, partnership or other strategic arrangement involving any rights proprietary to Opexa in any country in Asia or Europe.

(3) Amount represents the aggregate grant date fair value of the option award computed in accordance with FASB ASC 718. The fair value was calculated using the Black-Scholes option-pricing model, and the grant date fair value is based upon the probable outcome of the performance conditions. See Note 12 to our financial statements included in this annual report on Form 10-K for assumptions underlying the valuation of equity awards.

(4) These options are time-based, have a term of ten years and vest quarterly over a three-year period commencing on the date of grant.

(5) Amount represents the aggregate grant date fair value of the option award computed in accordance with FASB ASC 718. The fair value was calculated using the Black-Scholes option-pricing model. See Note 12 to our financial statements included in this annual report on Form 10-K for assumptions underlying the valuation of equity awards.

2012 Outstanding Equity Awards at Fiscal Year-End

The following table presents information regarding outstanding equity awards at December 31, 2012 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	62,500	—	$ 4.04	06/16/18
	37,500	—	$ 0.88	01/16/19
	25,000	—	$ 8.20	11/30/19
	10,937	7,813[(1)]	$ 6.24	01/04/21
	10,906	32,717[(1)]	$ 3.80	01/06/22
	3,635	135,958[(2)(3)]	$ 3.80	01/06/22
Donna R. Rill	1,500	—	$ 28.00	12/05/15
	5,845	—	$ 20.00	04/20/16
	8,000	—	$ 21.88	06/18/17
	750	—	$ 4.36	05/06/18
	8,250	—	$ 4.68	06/26/18
	10,000	—	$ 0.88	01/16/19
	2,099	—	$ 1.88	02/06/19
	12,500	—	$ 8.20	11/30/19
	3,646	2,604[(1)]	$ 6.24	01/04/21
	2,399	7,198[(1)]	$ 3.80	01/06/22
	872	30,536[(2)]	$ 3.80	01/06/22
Jaye L. Thompson	12,500	—	$ 8.20	11/30/19
	3,646	2,604[(1)]	$ 6.24	01/04/21
	2,399	7,198[(1)]	$ 3.80	01/06/22
	872	30,536[(2)]	$ 3.80	01/06/22

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

(2) The performance-based options begin vesting, if at all, in two tranches commencing upon achievement of certain key milestone events. So long as the identified key milestones are achieved prior to their respective expiration dates, the applicable portion of the performance options thereupon commence vesting quarterly over a three-year period. Generally, (i) the first tranche of one-third of the performance option shares commences three-year quarterly vesting upon achievement of the first key milestone, which is Opexa initiating a clinical trial for Tcelna in SPMS, and (ii) the second tranche of two-thirds of the performance option shares commences three-year quarterly vesting upon achievement of the second key milestone, which is Opexa entering into a collaboration, partnership or other strategic arrangement involving rights in the United States for Tcelna. The performance options have a term of ten years, but potentially expire in two tranches, with (i) the first tranche to have expired on December 31, 2012 if the first key milestone was not achieved and (ii) the second tranche expiring on June 30, 2013 if the second key milestone is not achieved. On September 12, 2012, the first key milestone objective was met and vesting commenced for the first tranche of one-third of the performance option shares.

(3) Three-year quarterly vesting for an increment of 8,724 shares of Mr. Warma's second performance option tranche may commence earlier if Opexa enters into a collaboration, partnership or other strategic arrangement involving any rights proprietary to Opexa in any country in Asia or Europe.

2012 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, 2012.

Name	Fees Earned or Paid in Cash	Options Awards[1]	Total
David E. Jorden[2]	$ 37,500 [3]	$27,857 [4][5]	$ 65,357
Gail J. Maderis	—	$27,857[4][5]	$ 27,857
Michael S. Richman	—	$27,857[4][5]	$ 27,857
Scott B. Seaman	—	$27,857[4][5]	$ 27,857

(1) Amounts in this column represent the aggregate grant date fair value of awards computed in accordance with FASB ASC 718. The fair value was calculated using the Black-Scholes option-pricing model. See Note 12 to our financial statements included in this annual report on Form 10-K for assumptions underlying the valuation of equity awards.

(2) Mr. Jorden was appointed as Acting Chief Financial Officer on August 15, 2012.

(3) Compensation for services as chair of the Audit Committee until August 15, 2012.

(4) As compensation for Board services, Messrs. Jorden, Richman and Seaman and Ms. Maderis were issued the following two options on March 1, 2012 to purchase shares of common stock at an exercise price of $3.76 per share, the market value on the date of grant: (i) an option, with a term of ten years, to purchase 2,500 shares, with 50% vesting immediately upon grant and the remaining 50% vesting on March 1, 2013; and (ii) an option, with a term of the earlier of ten years or upon a change of control of Opexa, to purchase 5,150 shares in lieu of cash compensation for services, with 50% vesting immediately upon grant and the remaining 50% vesting on December 31, 2012.

(5) The aggregate number of shares underlying outstanding option awards as of December 31, 2012 was: Mr. Jorden, 46,717 shares; Ms. Maderis, 13,505 shares; Mr. Richman, 43,159 shares; and Mr. Seaman, 45,034 shares.

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. As compensation for their services on our Board, in 2012 our non-employee directors were issued options to purchase shares of Opexa common stock in lieu of cash compensation. Each option is granted with an exercise price equal to the fair market value of Opexa's common stock on the date of grant and is issued either fully vested or with a vesting schedule over a period of time up to one year (or up to two years in the case of an initial grant to a new director). In addition, we paid a quarterly retainer of $15,000 in cash to David E. Jorden while he served as the chair of our Audit Committee until August 15, 2012. As of August 15, 2012, we discontinued payment of a quarterly retainer to the Audit Committee chair.

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

The following table sets forth, as of March 15, 2013, 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 15, 2013, there were 7,991,559 shares of common stock issued and outstanding. All numbers in the table and the footnotes thereto have been adjusted to reflect the one-for-four reverse stock split of our common stock that was implemented December 14, 2012.

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
Beneficial Owners of more than 5%:		
Sabby Management, LLC [2]	750,000 [3]	9.4%
Albert and Margaret Alkek Foundation [4]	648,043 [5]	7.8%
Alkek & Williams Ventures Ltd.[6]	639,040 [7]	7.6%
DLD Family Investments, LLC [8]	624,985 [9]	7.4%
Charles E. Sheedy [10]	503,023 [11]	6.1%
Officers and Directors:		
Scott B. Seaman [6]	694,987 [12]	8.2%
David E. Jorden	412,597 [13]	5.0%
Neil K. Warma	186,433 [14]	2.3%
Donna R. Rill	59,778 [15]	*
Michael S. Richman	43,159 [16]	*
Jaye L. Thompson	24,010 [17]	*
Gail J. Maderis	11,838 [18]	*
All directors and executive officers as a group (7 persons)**	1,432,802 [19]	16.0%

* Less than 1%

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

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

(2) This information is based on the Schedule 13G filed with the SEC on February 11, 2013, by Sabby Healthcare Volatility Master Fund, Ltd. ("Sabby Healthcare Fund"), Sabby Volatility Warrant Master Fund, Ltd. ("Sabby Warrant Fund"), Sabby Management, LLC ("Sabby Management") and Hal Mintz. Sabby Management serves as the investment manager of Sabby Healthcare Fund and Sabby Warrant Fund, and Mr. Mintz serves as manager of Sabby Management. Sabby Healthcare Fund has shared voting and investment power over the shares held by it. Sabby Warrant Fund has shared voting and investment power over the shares held by it. Sabby Management and Mr. Mintz have shared voting and investment power of the shares held by Sabby Healthcare Fund and Sabby Warrant Fund. Sabby Management and Mr. Mintz disclaim beneficial ownership over the securities held by Sabby Healthcare Fund and Sabby Warrant Fund except to the extent of their pecuniary interest therein. The mailing address of Sabby Healthcare Fund and Sabby Warrant Fund is c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands. The mailing address of Sabby Management and Mr. Mintz is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458.

(3) Consisting of: (i) 500,000 shares of common stock held by Sabby Healthcare Fund; and (ii) 250,000 shares of common stock held by Sabby Warrant Fund. In addition to the shares beneficially owned reported in the table, Sabby Healthcare Fund and Sabby Warrant Fund hold Series L warrants to purchase 250,000 and 125,000 shares, respectively, of common stock that they are contractually prohibited from exercising to the extent the beneficial ownership of Sabby Healthcare Fund or Sabby Warrant Fund, together with their affiliates, would exceed 4.99% of the total number of issued and outstanding shares after such exercise, which beneficial ownership limitation can be increased to 9.99% upon 61 days prior notice to us.

(4) This information is based on the Schedule 13D/A filed with the SEC on August 23, 2012, by Albert and Margaret Alkek Foundation ("the Foundation"), Alkek & Williams Ventures, Ltd. ("Ventures"), Scott Seaman, DLD Family Investments, LLC ("DLD Family"), and the other reporting persons named therein ("the Foundation 13D") and other information available to us. The Foundation acts through an investment committee of its board of directors, which includes Mr. Charles Williams, Mr. Daniel Arnold, Mr. Joe Bailey, Mr. Scott Seaman and Ms. Randa Duncan Williams. Mr. Seaman is the executive director of the Foundation and chairman of the investment committee. The investment committee has sole voting and investment power over all of the shares of common stock beneficially owned by the Foundation. However, pursuant to the Foundation 13D, neither the executive director nor any member of the investment committee may act individually to vote or sell shares of common stock held by the Foundation; therefore, the Foundation has concluded that no individual committee member is deemed to beneficially own, within the meaning of Rule 13d-3 of the Exchange Act, any shares of common stock held by the Foundation solely by virtue of the fact that he or she is a member of the investment committee. Additionally, pursuant to the Foundation 13D, the Foundation has concluded that because Mr. Seaman, in his capacity as executive director or chairman of the investment committee, cannot act in such capacity to vote or sell shares of common stock held by the Foundation without the approval of the investment committee, he is not deemed to beneficially own, within the meaning of Rule 13d-3 of the

Exchange Act, any shares of common stock held by the Foundation by virtue of his position as executive director or chairman of the investment committee. The mailing address of the beneficial owner is 1100 Louisiana, Suite 5250, Houston, Texas 77002.

(5) Consisting of: (i) 370,228 shares of common stock; (ii) 62,500 shares of common stock underlying Series G warrants; (iii) 96,076 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (iv) 105,469 shares of common stock underlying Series I warrants; and (v) 13,770 shares of common stock underlying Series K warrants. Pursuant to the Foundation 13D, the Foundation and other reporting persons named therein may be deemed to constitute a group for purposes of Section 13(d) or Section 13(g) of the Exchange Act. However, the Foundation, Ventures, Chaswil, Ltd. and Mr. Seaman expressly disclaim (i) that, for purposes of Section 13(d) or Section 13(g) of the Exchange Act, they are a member of a group with respect to securities of Opexa held by DLD Family, Mr. Arnold, Mr. Bailey or Ms. Williams and (ii) that they have agreed to act together with DLD Family, Mr. Arnold, Mr. Bailey or Ms. Williams as a group other than as described in the Foundation 13D. Therefore, this does not include the following securities: (i) 221,126 shares of common stock held by DLD Family; (ii) 25,000 shares of common stock underlying Series G warrants held by DLD Family; (iii) 20,000 shares of common stock underlying Series H warrants held by DLD Family; (iv) 160,128 shares of common stock issuable if a 12% convertible secured promissory note held by DLD Family was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (v) 175,781 shares of common stock underlying Series I warrants held by DLD Family; (vi) 22,950 shares of common stock underlying Series K warrants held by DLD Family; (vii) 6,666 shares of common stock held by Mr. Arnold; (viii) 12,500 shares of common stock held by Mr. Bailey; (ix) 230,181 shares of common stock held by Ventures; (x) 50,000 shares of common stock underlying Series G warrants held by Ventures; (xi) 160,128 shares of common stock issuable if a 12% convertible secured promissory note held by Ventures was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (xii) 175,781 shares of common stock underlying Series I warrants held by Ventures; (xiii) 22,950 shares of common stock underlying Series K warrants held by Ventures; (xiv)10,913 shares of common stock held by Mr. Seaman; and (xv) 45,034 shares of common stock underlying currently exercisable stock options held by Mr. Seaman.

(6) Chaswil, Ltd. is the investment manager of Ventures and holds voting power and investment power with respect to Company securities held by Ventures pursuant to a written agreement. Scott B. Seaman is a principal of Chaswil, Ltd. and has shared voting power and shared investment power over all of the shares of common stock beneficially owned by Ventures. The information in this footnote is primarily based on the Foundation 13D and other information provided to us. The mailing address of the beneficial owner is 1100 Louisiana, Suite 5250, Houston, Texas 77002.

(7) Consisting of: (i) 230,181 shares of common stock; (ii) 50,000 shares of common stock underlying Series G warrants; (iii) 160,128 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (iv) 175,781 shares of common stock underlying Series I warrants; and (v) 22,950 shares of common stock underlying Series K warrants.

(8) Randa Duncan Williams is the principal of DLD Family and she may be deemed to exercise voting and investment power with respect to such shares. The information in this footnote is primarily based on the Foundation 13D and other information provided to us. The mailing address of the beneficial owner is P.O. Box 4735, Houston, Texas 77210-4735.

(9) Consisting of: (i) 221,126 shares of common stock; (ii) 25,000 shares of common stock underlying Series G warrants; (iii) 20,000 shares of common stock underlying Series H warrants; (iv) 160,128 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (v) 175,781 shares of common stock underlying Series I warrants; and (vi) 22,950 shares of common stock underlying Series K warrants.

(10) Charles E. Sheedy exercises sole voting and dispositive power over all of the shares of common stock beneficially owned. The information in this footnote is primarily based on information reported on the Schedule 13G/A filed with the SEC on February 14, 2013 by Charles E. Sheedy and other information available to us. The mailing address of the beneficial owner is Two Houston Center, 909 Fannin Street, Suite 2907, Houston, Texas 77010.

(11) Consisting of: (i) 259,594 shares of common stock; (ii) 12,500 shares of common stock underlying Series G warrants; (iii) 14,000 shares of common stock underlying Series H warrants; (iv) 80,064 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (v) 87,890 shares of common stock underlying Series I warrants; (vi) 37,500 shares of common stock underlying Series J warrants; and (vii) 11,475 shares of common stock underlying Series K warrants..

(12) Consisting of: (i) 230,181 shares of common stock held by Ventures; (ii) 50,000 shares of common stock underlying Series G warrants held by Ventures; (iii) 160,128 shares of common stock issuable if a 12% convertible secured promissory note held by Ventures was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (iv) 175,781 shares of common stock underlying Series I warrants held by Ventures; (v) 22,950 shares of common stock underlying Series K warrants held by Ventures; (vi) 45,034 shares underlying currently exercisable stock options held by Mr. Seaman; and

(vii) 10,913 shares of common stock held by Mr. Seaman. (See footnotes 6 and 7 for additional discussion of the information set forth in clauses (i) through (v) of the preceding sentence.) Pursuant to the Foundation 13D, this does not include the following shares which Mr. Seaman has determined he does not have beneficial ownership of or has disclaimed beneficial ownership: (i) 370,228 shares of common stock held by the Foundation; (ii) 62,500 shares of common stock underlying Series G warrants held by the Foundation; (iii) 96,076 shares of common stock issuable if a 12% convertible secured promissory note held by the Foundation was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (iv) 105,469 shares of common stock underlying Series I warrants held by the Foundation; and (v) 13,770 shares of common stock underlying Series K warrants held by the Foundation. (See footnotes 4 and 5 for additional discussion of the information set forth in clauses (i) through (v) of the preceding sentence.) The mailing address of the beneficial owner is 1100 Louisiana, Suite 5250, Houston, Texas 77002.

(13) Consisting of: (i) 227,094 shares of common stock; (ii) 25,000 shares of common stock underlying Series G warrants; (iii) 36,829 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (iv) 40,429 shares of common stock underlying Series I warrants; (v) 37,500 shares of common stock underlying the Series J warrants; (vi) 5,278 shares of common stock underlying the Series K warrants; and (vii) 40,467 shares of common stock underlying currently exercisable stock options.

(14) Consisting of: (i) 8,658 shares of common stock; (ii) 2,500 shares of common stock underlying Series G warrants; (iii) 4,803 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (iv) 5,273 shares of common stock underlying Series I warrants; (v) 688 shares of common stock underlying Series K warrants; and (vi) 164,511 shares of common stock underlying currently exercisable stock options.

(15) Consisting of: (i) 402 shares of common stock and (ii) 59,376 shares of common stock underlying currently exercisable stock options.

(16) Consisting of: 43,159 shares of common stock underlying currently exercisable stock options.

(17) Consisting of: (i) 1,078 shares of common stock and (ii) 22,932 shares of common stock underlying currently exercisable stock options.

(18) Consisting of: 11,838 shares of common stock underlying currently exercisable stock options.

(19) Consisting of: (a) the following held by Mr. Seaman or for which Mr. Seaman may be deemed to have voting and investment power: (i) 230,181 shares of common stock held by Ventures; (ii) 50,000 shares of common stock underlying Series G warrants held by Ventures; (iii) 160,128 shares of common stock issuable if a 12% convertible secured promissory note held by Ventures was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (iv) 175,781 shares of common stock underlying Series I warrants held by Ventures; (v) 22,950 shares of common stock underlying Series K warrants held by Ventures; (vi) 45,034 shares underlying currently exercisable stock options held by Mr. Seaman; and (vii) and 10,913 shares of common stock held by Mr. Seaman; (b) the following held by Mr. Jorden: (i) 227,094 shares of common stock; (ii) 25,000 shares of common stock underlying Series G warrants; (iii) 36,829 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (iv) 40,429 shares of common stock underlying Series I warrants; (v) 37,500 shares of common stock underlying the Series J warrants; (vi) 5,278 shares of common stock underlying the Series K warrants; and (vii) 40,467 shares of common stock underlying currently exercisable stock options; (c) the following held by Mr. Warma: (i) 8,658 shares of common stock; (ii) 2,500 shares of common stock underlying Series G warrants; (iii) 4,803 shares of common stock issuable if a 12% convertible secured promissory note was converted to Series A convertible preferred stock which was then ultimately converted into common stock; (iv) 5,273 shares of common stock underlying Series I warrants; (v) 164,511 shares of common stock underlying currently exercisable stock options; and (vi) 688 shares of common stock underlying Series K warrants; (d) 402 shares of common stock and 59,376 shares of common stock underlying currently exercisable stock options held by Ms. Rill; (e) 43,159 shares of common stock underlying currently exercisable stock options held by Mr. Richman; (f) 1,078 shares of common stock and 22,932 shares of common stock underlying currently exercisable stock options held by Dr. Thompson; and (g) 11,838 shares of common stock underlying currently exercisable stock options held by Ms. Maderis.

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

Transactions with Related Persons

Entities affiliated with director Scott B. Seaman invested an aggregate of $1.3 million principal amount in our 12% convertible secured promissory notes which were issued in a private offering of notes and warrants to purchase shares of our common stock pursuant to a Note Purchase Agreement dated July 25, 2012. An aggregate of $4.085 million in principal amount of notes was originally issued in the offering, of which $3.185 million is currently outstanding and $900,000 was converted into shares of Series A convertible preferred stock and such shares were then converted into 288,229 shares of common stock. The notes mature on July 25,

2014 and accrue interest at the rate of 12% per annum, compounded annually. Interest is payable semi-annually on June 30 and December 31, commencing December 31, 2012, in either cash or registered shares of our common stock at our election. The notes are secured by substantially all of our tangible and intangible assets, and $500,000 of the proceeds is presently held in a controlled account. Alkek & Williams Ventures Ltd. acts as the collateral agent for the noteholders. The notes are convertible into a new class of non-voting Series A convertible preferred stock, subject to certain limitations and adjustments, which is ultimately convertible into common stock. The warrants have an exercise price of $2.56 per share, a five-year term and are exercisable for 112.5% of the number of shares of common stock into which the notes are ultimately convertible, subject to certain limitations and adjustments. The investors have certain registration rights relating to the shares of common stock underlying the Series A convertible preferred stock and the warrants.

Convertible secured notes and warrants to purchase common stock were issued to investors affiliated with Mr. Seaman in the following amounts:

	Principal Amount of Note	Number of Shares Subject to Warrant
Alkek & Williams Ventures Ltd.	$500,000	175,781
Albert and Margaret Alkek Foundation	$300,000	105,469
DLD Family Investments, LLC	$500,000	175,781

See footnotes 4, 6 and 8 to the "Beneficial Ownership Table" for a description of the relationship between and among Mr. Seaman and each of these investors, each of whom is also a beneficial owner of more than 5% of our outstanding common stock.

Directors and executive officers David E. Jorden and Neil K. Warma also participated in the note offering and invested $115,000 and $15,000, respectively, and were issued warrants to purchase 40,429 and 5,273 shares, respectively.

While the Audit Committee of our Board of Directors is generally responsible for oversight and review of any related person transactions, an independent special committee of our Board reviewed and negotiated the terms of the convertible secured note offering and recommended that the offering be approved on behalf of Opexa and our Board of Directors.

We issued an aggregate of 163,224 shares of common stock to holders of the July 2012 notes in payment of accrued interest on December 31, 2012, of which entities affiliated with Mr. Seaman were issued an aggregate of 57,418 shares. Mr. Jorden and Mr. Warma were issued 5,080 and 663 shares, respectively.

We issued an aggregate of 163,224 shares of common stock to holders of the July 2012 notes in payment of accrued interest on December 31, 2012, of which entities affiliated with Mr. Seaman were issued an aggregate of 57,418 shares. Mr. Jorden and Mr. Warma were issued 5,080 and 663 shares, respectively.

Mr. Jorden and Charles E. Sheedy who is the beneficial owner of more than 5% of our outstanding common stock, participated in a private offering on January 23, 2013 with certain other accredited investors who purchased an aggregate of $650,000 in principal amount of our unsecured convertible promissory notes and warrants to purchase shares of our common stock. Messrs. Jorden and Sheedy each invested $100,000 in the offering and each received a warrant to purchase 37,500 shares of common stock. The notes were originally scheduled to mature on January 23, 2014 and accrued interest at the rate of 12% per annum, compounded annually. Interest was payable quarterly beginning March 31, 2013 in cash. The notes were convertible into common stock at the option of the investors at a price of $1.298125 per share, subject to certain limitations. Fifty percent of the initial principal amount (less any amount of such principal that has otherwise been prepaid or converted) was payable by us five business days following our receipt of an aggregate of at least $5 million in proceeds from the sale of our equity securities and/or as payments from one or more partners or potential partners in return for granting a license, other rights, or an option to license or otherwise acquire rights with respect to Tcelna. The remaining principal was payable five business days following our receipt of an aggregate of at least $7.5 million in proceeds from the sale of our equity securities and/or as payments from one or more partners or potential partners in return for granting a license, other rights, or an option to license or otherwise acquire rights with respect to Tcelna. Upon receipt of the upfront payment of $5 million from Merck in February 2013, we repaid $550,000 principal amount of the notes plus accrued interest and converted the remaining $100,000 principal amount into shares of our common stock pursuant to an investor's election to convert into equity. The warrants have an exercise price of $1.24 per share, a five-year term and are exercisable for a maximum of an aggregate of 243,750 shares of common stock, subject to certain limitations.

Pursuant to a waiver executed by the holders of in excess of two-thirds of the principal amount of the outstanding July 2012 notes and accepted by Opexa, the amount of the cash subject to the deposit control agreement was reduced to $500,000 on January 29, 2013. In exchange for such waiver, we issued warrants to the holders of the July 2012 notes to purchase an aggregate of 187,500 shares of our common stock. The warrants have an exercise price of $1.21 per share and a five-year term. Entities affiliated with Mr. Seaman were issued warrants to purchase an aggregate of 59,670 shares, and Messrs. Jorden and Warma were issued warrants to purchase 5,278 and 688 shares, respectively.

Pursuant to a waiver executed by the holders of in excess of two-thirds of the principal amount of the outstanding July 2012 notes and accepted by Opexa, the amount of the cash subject to the deposit control agreement was reduced to $500,000 on January 29, 2013. In exchange for such waiver, we issued warrants to the holders of the July 2012 notes to purchase an aggregate of 187,500 shares of our common stock. The warrants have an exercise price of $1.21 per share and a five-year term. Entities affiliated with Mr. Seaman were issued warrants to purchase an aggregate of 59,670 shares, and Messrs. Jorden and Warma were issued warrants to purchase 5,278 and 688 shares, respectively.

Director Independence

The Board determined that Ms. Maderis and Messrs. Richman and Seaman (and Mr. Jorden, prior to the time he was appointed as Acting Chief Financial Officer in August 2012), 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
Gail J. Maderis	X	X	X	X
Michael S. Richman	X	X	X	X
Scott B. Seaman	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,	
	2012	2011
Audit fees[(1)]	$ 60,000	$ 76,500
Tax fees[(2)]	2,250	3,750
All other fees[(3)]	19,775	16,522
	$ 82,025	$ 96,772

(1) Audit fees include professional services rendered for (i) the audit of our annual financial statements for the fiscal years ended December 31, 2012 and 2011, (ii) the reviews of the financial statements included in our quarterly reports on Form 10-Q for such years and (iii) the issuance of consents and other matters relating to registration statements filed by us.

(2) Tax fees include professional services relating to preparation of the annual tax return.

(3) Other fees include professional services for review of various filings and issuance of consents.

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

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

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) 1. Financial Statements

INDEX TO FINANCIAL STATEMENTS

Audited Financial Statements for years ended December 31, 2012 and 2011 and the period from January 22, 2003 (Inception) through December 31, 2012

2. Financial Statement Schedules

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

3. List of Exhibits

Exhibit No.	Description
2.1	Stock Purchase Agreement by and among Sportan United Industries, Inc., Jason G. Otteson, PharmaFrontiers Corp., Warren C. Lau and other PharmaFrontiers stockholders, dated May 5, 2004 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed June 4, 2004, File No. 000-25513).
2.2	Agreement and Plan of Reorganization by and among PharmaFrontiers Corp., Pharma Acquisition Corp and Opexa Pharmaceuticals, Inc. dated October 7, 2004 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on 8-K filed October 8, 2004, File No. 000-25513).
3.1	Restated Certificate of Formation of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 26, 2012).
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 26, 2012).
3.3	Certificate of Amendment of the Restated Certificate of Formation of Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 14, 2012).
3.4	Amended and Restated By-laws, as amended (incorporated by reference to Exhibit 3.3 to the Company's Annual Report on form 10-K filed on March 8, 2011).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-3 filed on November 13, 2009, File No. 333-163108).
4.2	Unit Purchase Agreement dated August 8, 2008 by and among Opexa Therapeutics, Inc. and the Investors named therein in connection with Unit offering of common stock and Series F Warrants (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 12, 2008).
4.3	Form of Series F Warrant issued in connection with August 8, 2008 financing (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed August 12, 2008).
4.4	Registration Rights Agreement dated August 8, 2008 between Opexa Therapeutics, Inc. and the Investors named therein in connection with common stock and Series F Warrants (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed August 12, 2008).

Exhibit No.	Description
4.5	Unit Purchase Agreement dated April 14, 2009 by and among Opexa Therapeutics, Inc. and the Investors party thereto for the 10% Convertible Notes and Series G Warrants (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed April 16, 2009).
4.6	Form of Series G Warrant issued on April 14, 2009 (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed April 16, 2009).
4.7	Form of Securities Purchase Agreement dated as of December 9, 2009 by and between Opexa Therapeutics, Inc. and each investor signatory thereto for Unit offering of Common Stock and Series A and Series B Warrants (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 10, 2009).
4.8	Form of Common Stock Purchase Warrant for Series A and Series B Warrants (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed December 10, 2009).
4.9	Form of Series H Warrant issued on February 11, 2011 (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed February 8, 2011).
4.10	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).
4.11	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).
4.12	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).
4.13	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).
4.14	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).
4.15	Placement Agent Agreement, dated February 7, 2013, by and between Opexa Therapeutics, Inc. and Dawson James Securities, Inc. (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on February 7, 2013).
10.1+	Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan (incorporated by reference to Exhibit B to the Company's Definitive Information Statement on Schedule 14C filed on June 29, 2004, File No. 000-25513).
10.2+	Certificate of Amendments to the Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan (incorporated by reference to Exhibit 10.15 of the Company's Annual Report on Form 10-K filed March 5, 2010).
10.3+	Employment Agreement dated June 16, 2008 by and between Opexa Therapeutics, Inc. and Neil K. Warma (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 18, 2008).
10.4+	Amended and Restated Employment Agreement entered into on April 21, 2010 by and between Opexa Therapeutics, Inc. and Donna R. Rill (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed April 27, 2010).
10.5+	Amended and Restated Employment Agreement entered into on June 27, 2011 by and between Opexa Therapeutics, Inc. and Jaye L. Thompson (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed June 30, 2011).
10.6	License Agreement dated September 5, 2001 by and between Opexa Therapeutics, Inc. and Baylor College of Medicine (incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-KSB filed April 15, 2005, File No. 000-25513).
10.7	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	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).
10.9	Fourth Amended and Restated License Agreement, dated November 2, 2011, by and between Opexa Therapeutics, Inc. and the University of Chicago (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed November 4, 2011).
10.10+	Opexa Therapeutics, Inc. 2010 Stock Incentive Plan (incorporated by reference to Appendix A to the Company's Schedule 14A definitive proxy statement filed September 14, 2010).
10.11+	Form of award agreement for awards to be made under the Opexa Therapeutics, Inc. 2010 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed October 22, 2010).
10.12	Form of Note Purchase Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.13	Form of 12% Convertible Secured Promissory Note issued to investors on July 25, 2012 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.14	Form of Security Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc., the investors signatory thereto, and Alkek & Williams Ventures, Ltd. as collateral agent for the investors (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.15	Deposit Account Control Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc., Alkek & Williams Ventures, Ltd. as collateral agent for the investors, and Wells Fargo Bank, National Association (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.16	Form of Registration Rights Agreement, dated July 25, 2012, by and among Opexa Therapeutics, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on July 26, 2012).
10.17	Sales Agreement, dated September 6, 2012, by and between Opexa Therapeutics, Inc. and Brinson Patrick Securities Corporation (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 7, 2012).
10.18	$15.0 million Purchase Agreement, dated as of November 2, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 5, 2012).
10.19	$1.5 million Purchase Agreement, dated as of November 5, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 5, 2012).
10.20	Registration Rights Agreement, dated as of November 2, 2012, by and between Opexa Therapeutics, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed November 5, 2012).
10.21	Form of unsecured 12% Convertible Promissory Note issued to investors on January 23, 2013 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 23, 2013).
10.22*	Form of Waiver and Omnibus Amendment, dated January 30, 2013, by and between Opexa Therapeutics, Inc. and certain investors.
10.23##	Option and License Agreement, dated February 4, 2013, by and between Ares Trading SA, a wholly owned subsidiary of Merck Serono S.A., and Opexa Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 5, 2013).
21.1*	List of Subsidiaries.

23.1*	Consent of Independent Registered Public Accounting Firm MaloneBailey, LLP, dated March 28, 2013 to the incorporation by reference of their report dated March 28, 2013 in the Company's Registration Statements on Form S-8 and S-3.
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*	Certificate 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 for the period ended December 31, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Expenses; (iii) Consolidated Statements of Changes in Stockholders' Equity; (iv) Consolidated Statements of Cash Flows; and (v) Notes to Consolidated Financial Statements.

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* Filed herewith

\+ Management contract or compensatory plan or arrangement.

Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

@ In accordance with Rule 406T under Regulation S-T, the XBRL-related information in Exhibit 101 shall be deemed to be "furnished" and not "filed."

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma

Neil K. Warma
President and Chief Executive Officer
Date: March 28, 2013

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

Signature	Title	Date
/s/ Neil K. Warma Neil K. Warma	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 28, 2013
/s/ David E. Jorden David E. Jorden	Acting Chief Financial Officer and Director *(Principal Financial and Accounting Officer)*	March 28, 2013
/s/ Gail J. Maderis Gail J. Maderis	Director	March 28, 2013
/s/ Michael S. Richman Michael S. Richman	Director	March 28, 2013
/s/ Scott B. Seaman Scott B. Seaman	Director	March 28, 2013

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors
Opexa Therapeutics, Inc.
(a development stage company)
The Woodlands, Texas

We have audited the accompanying consolidated balance sheets of Opexa Therapeutics, Inc., (a development stage company), as of December 31, 2012 and 2011 and the related consolidated statements of expenses, changes in stockholders' equity and cash flows for each of the years then ended and for the period from January 22, 2003 (Inception) through December 31, 2012. 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 as of December 31, 2012 and 2011 and the results of its operations and its cash flows for each of the years then ended and for the period from January 22, 2003 (Inception) through December 31, 2012 in conformity with accounting principles generally accepted in the United States of America.

/s/ MALONEBAILEY, LLP
www.malonebailey.com
Houston, Texas

March 28, 2013

OPEXA THERAPEUTICS, INC.
(a development stage company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 592,004	$ 7,109,215
Other current assets	1,077,546	124,773
Total current assets	1,669,550	7,233,988
Property & equipment, net of accumulated depreciation of $1,494,510 and $1,193,601, respectively	1,265,041	1,029,236
Restricted cash	1,000,000	—
Deferred financing costs, net of amortization of $58,639 and $0, respectively	211,479	—
Total assets	$ 4,146,070	$ 8,263,224
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 412,096	$ 491,315
Accrued expenses	473,879	576,545
Total current liabilities	885,975	1,067,860
Long term liabilities:		
Convertible debt, net of unamortized discount of $3,136,342 and $0, respectively	318,658	—
Convertible debt – related parties, net of unamortized discount of $571,895 and $0, respectively	58,105	—
Total liabilities	1,262,738	1,067,860
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, no par value, 10,000,000 shares authorized, none issued and outstanding	—	—
Common stock, $0.01 par value, 100,000,000 shares authorized, 6,249,369 and 5,762,028 shares issued and outstanding	62,494	57,621
Additional paid in capital	112,432,458	107,818,530
Deficit accumulated during the development stage	(109,611,620)	(100,680,787)
Total stockholders' equity	2,883,332	7,195,364
Total liabilities and stockholders' equity	$ 4,146,070	$ 8,263,224

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

OPEXA THERAPEUTICS, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF EXPENSES
Years ended December 31, 2012 and 2011 and the
Period from January 22, 2003 (Inception) to December 31, 2012

	2012	2011	Inception through 2012
Research and development	$ 6,318,476	$ 3,340,038	$ 76,497,351
General and administrative	2,508,541	2,406,269	30,117,616
Depreciation	303,677	210,252	1,650,158
Loss on disposal of fixed assets	3,097	9,686	513,345
Operating loss	(9,133,791)	(5,966,245)	(108,778,470)
Interest income	280	932	1,358,697
Other income and expense, net	—	—	661,146
Gain on extinguishment of debt	—	—	1,612,440
Gain on derivative instruments	552,978	—	1,941,826
Gain on sale of technology	—	—	3,000,000
Interest expense	(350,300)	(3,135)	(9,407,259)
Net loss	$ (8,930,833)	$ (5,968,448)	$ (109,611,620)
Basic and diluted loss per share	$ (1.54)	$ (1.06)	
Weighted average shares outstanding	5,785,372	5,633,124	

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

OPEXA THERAPEUTICS, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
Period from January 22, 2003 (Inception) through December 31, 2012

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Par			
Shares issued for cash	131,250	$ 65,625	$ (64,625)	$ —	$ 1,000
Shares repurchased and cancelled	(42,656)	(21,328)	21,003	—	(325)
Discount related to beneficial conversion feature	—	—	28,180	—	28,180
Discount on warrants attached to debt	—	—	28,180	—	28,180
Net loss	—	—	—	(126,003)	(126,003)
Balances at December 31, 2003	88,594	44,297	12,738	(126,003)	(68,968)
Shares issued for:					
cash	562	281	8,719	—	9,000
services	51,625	25,813	823,187	—	849,000
license	6,067	3,033	424,042	—	427,075
reverse merger with Sportan	24,934	12,467	(160,200)	—	(147,733)
acquisition of Opexa	62,500	31,250	23,718,750	—	23,750,000
additional shares attached to convertible debt	4,025	2,012	286,354	—	288,366
conversion of convertible notes	15,187	7,594	240,776	—	248,370
Shares cancelled	(2,000)	(1,000)	1,000	—	—
Discount related to beneficial conversion feature	—	—	855,849	—	855,849
Discount on warrants attached to debt	—	—	1,848,502	—	1,848,502
Option expense	—	—	123,333	—	123,333
Net loss	—	—	—	(31,411,736)	(31,411,736)
Balances at December 31, 2004	251,494	125,747	28,183,050	(31,537,739)	(3,228,942)
Shares issued for:					
cash, net of offering costs	97,362	48,681	5,297,536	—	5,346,217
convertible debt	152,756	76,378	7,573,068	—	7,649,446
debt	575	288	160,712	—	161,000
license	7,298	3,649	1,864,735	—	1,868,384
services	6,000	3,000	1,009,400	—	1,012,400
Discount related to beneficial conversion feature	—	—	831,944	—	831,944
Discount on warrants attached to debt	—	—	1,433,108	—	1,433,108
Option expense	—	—	2,487,741	—	2,487,741
Warrant expense	—	—	2,373,888	—	2,373,888
Transition of warrants from equity instruments to liability instruments	—	—	(10,658,496)	—	(10,658,496)
Net loss	—	—	—	(14,856,724)	(14,856,724)
Balances at December 31, 2005	515,485	257,743	40,556,686	(46,394,463)	(5,580,034)
Shares issued for:					
cash, net of offering costs	1,150,000	575,000	20,578,519	—	21,153,519
debt	8,707	4,354	175,646	—	180,000
Option expense	—	—	2,749,617	—	2,749,617
Warrant expense	—	—	1,568,966	—	1,568,966
Net loss	—	—	—	(12,649,170)	(12,649,170)
Balances at December 31, 2006	1,674,192	837,097	65,629,434	(59,043,633)	7,422,898

OPEXA THERAPEUTICS, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY—(Continued)
Period from January 22, 2003 (Inception) through December 31, 2012

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Par			
Cumulative change in derivative liability	—	—	10,658,496	(4,001,820)	6,656,676
Option expense	—	—	1,876,103	—	1,876,103
Warrant expense	—	—	845,275	—	845,275
Net loss	—	—	—	(14,667,367)	(14,667,367)
Balances at December 31, 2007	1,674,192	837,097	79,009,308	(77,712,820)	2,133,585
Shares issued for:					
cash, net of offering costs	1,375,968	687,984	7,963,595	—	8,651,579
services	11,300	5,650	43,315	—	48,965
Issuance of warrants for cash	—	—	603,850	—	603,850
Option expense	—	—	1,901,570	—	1,901,570
Net loss	—	—	—	(11,852,152)	(11,852,152)
Balances at December 31, 2008	3,061,460	1,530,731	89,521,638	(89,564,972)	1,487,397
Cumulative effect of change in accounting principle.			(1,976,457)	1,755,622	(220,835)
Par value adjustment	—	(1,500,117)	1,500,117	—	—
Reduction in derivative liability	—	—	587,609	—	587,609
Discount on convertible notes	—	—	439,493	—	439,493
Discount on warrants	—	—	37,453	—	37,453
Shares issued for:					
cash, net of offering costs	637,500	6,375	4,682,790	—	4,689,165
exercise of options	15,100	151	63,453	—	63,604
exercise of warrants	154,991	1,550	1,073,385	—	1,074,935
Option expense	—	—	650,249	—	650,249
Net loss	—	—	—	(1,433,922)	(1,433,922)
Balances at December 31, 2009	3,869,051	38,690	96,579,730	(89,243,272)	7,375,148
Conversion of convertible notes	690,045	6,900	1,373,191	—	1,380,091
Shares issued for:					
services	13,750	138	64,212	—	64,350
exercise of options	35,380	354	109,287	—	109,641
exercise of warrants	8,500	85	(85)	—	—
Option expense	—	—	508,550	—	508,550
Net loss	—	—	—	(5,469,067)	(5,469,067)
Balances at December 31, 2010	4,616,726	46,167	98,634,885	(94,712,339)	3,968,713
Shares issued for:					
cash, net of offering costs	1,132,726	11,328	8,606,829	—	8,618,157
services	12,576	126	86,902	—	87,028
Option expense	—	—	489,914	—	489,914
Net loss	—	—	—	(5,968,448)	(5,968,448)
Balances at December 31, 2011	5,762,028	57,621	107,818,530	(100,680,787)	7,195,364
Write off of derivative liability	—	—	1,761,657	—	1,761,657
Discount related to beneficial conversion feature	—	—	1,497,634	—	1,497,634
Shares issued for:					
initial commitment on Lincoln Park $1.5 million share purchase agreement	56,507	565	148,566	—	149,131
cash, net of offering costs	267,610	2,676	331,294	—	333,970
accrued interest	163,224	1,632	184,051		185,683
Option expense	—	—	690,726	—	690,726
Net loss	—	—	—	(8,930,833)	(8,930,833)
Balances at December 31, 2012	6,249,369	$ 62,494	$ 112,432,458	$ (109,611,620)	$ 2,883,332

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

OPEXA THERAPEUTICS, INC.
(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2012 and 2011 and the
Period from January 22, 2003 (Inception) to December 31, 2012

	2012	2011	Inception through 2012
Cash flows from operating activities			
Net loss	$ (8,930,833)	$ (5,968,448)	$ (109,611,620)
Adjustments to reconcile net loss to net cash used in operating activities			
Stock payable for acquired research and development	—	—	112,440
Stock issued for acquired research and development	—	—	26,286,589
Stock issued for services	—	87,028	2,061,743
Stock issued for debt in excess of principal	—	—	109,070
Amortization of discount on notes payable due to warrants and beneficial conversion feature	104,032	—	6,856,730
Gain on extinguishment of debt	—	—	(1,612,440)
Depreciation	303,677	210,252	1,650,158
Amortization of debt financing costs	58,639	—	583,017
Option and warrant expense	690,726	489,914	16,265,933
Gain on derivative instruments	(552,978)	—	(1,941,826)
Loss on disposal of fixed assets	3,097	9,686	513,345
Changes in:			
Other current assets	(611,607)	(39,248)	(1,153,053)
Accounts payable – third parties and related parties	(71,410)	(13,028)	(160,651)
Accrued expenses	83,018	234,923	605,238
Net cash used in operating activities	(8,923,639)	(4,988,921)	(59,435,327)
Cash flows from investing activities			
Purchase of property & equipment	(550,389)	(296,949)	(2,222,199)
Restricted cash	(1,000,000)	—	(1,000,000)
Net cash used in investing activities	(1,550,389)	(296,949)	(3,222,199)
Cash flows from financing activities			
Common stock and warrants sold for cash, net of offering costs	381,309	8,618,157	49,453,797
Common stock repurchased and canceled	—	—	(325)
Proceeds from exercise of warrants and options	—	—	1,248,588
Proceeds from third party debt	3,455,000	—	12,738,184
Proceeds from related party debt	630,000	—	630,000
Deferred financing and offering costs	(509,492)	—	(509,492)
Repayments on loan payable	—	(35,607)	(311,222)
Net cash provided by financing activities	3,956,817	8,582,550	63,249,530
Net change in cash and cash equivalents	(6,517,211)	3,296,680	592,004
Cash and cash equivalents at beginning of period	7,109,215	3,812,535	—
Cash and cash equivalents at end of period	$ 592,004	$ 7,109,215	$ 592,004
Cash paid for:			
Income tax	$ —	$ —	$ —
Interest	1,946	3,135	155,109
NON-CASH TRANSACTIONS			
Issuance of common stock to Sportan shareholders	—	—	147,733
Issuance of common stock for accrued interest	185,683	—	789,287
Issuance of warrants to placement agent	—	—	37,453
Conversion of notes payable to common stock	—	—	7,709,980
Conversion of accrued liabilities to common stock	—	—	197,176
Conversion of accounts payable to note payable	—	—	93,364
Discount on convertible notes relating to:			
Warrants	2,314,635	—	5,974,372
Beneficial conversion feature	1,497,634	—	3,303,153
Stock attached to notes	—	—	1,287,440
Fair value of derivative instrument	—	—	4,680,220
Derivative reclassified to equity	1,761,657	—	2,349,266
Unpaid additions to property and equipment	7,812	136,266	144,078
Amortization of deferred offering costs to paid-in capital	47,339	—	47,339
Shares issued as deferred offering costs	149,131	—	149,131

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

OPEXA THERAPEUTICS, INC.
(a development stage company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1—BUSINESS OVERVIEW 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. PharmaFrontiers' stockholders were issued Sportan shares in exchange for all of the outstanding common shares of PharmaFrontiers. Concurrent with the transaction, Sportan changed its name to PharmaFrontiers. During its development stage as a biopharmaceutical company, PharmaFrontiers acquired the worldwide exclusive license to a stem cell technology developed at Argonne National Laboratory, a U.S. Department of Energy Laboratory operated by the University of Chicago, in which adult multi-potent stem cells are derived from monocytes obtained from the patient's own blood (the "Stem Cell License"). A patent application was filed in November 2003 with the United States Patent and Trade Office regarding the technology involved in the Stem Cell License. The initial focus for this technology is the further development of this monocyte-derived stem cell technology as a platform for the *in vitro* generation of highly specialized cells for potential application in autologous cell therapy for patients with diabetes mellitus (the "Diabetes Program").

In October 2004, PharmaFrontiers acquired all of the outstanding stock of Opexa Pharmaceuticals, Inc. ("Opexa Pharmaceuticals"), a biopharmaceutical company that previously acquired the exclusive worldwide license from Baylor College of Medicine to an patient specific, autologous T-cell immunotherapy, Tcelna™ (formerly known as Tovaxin®), for the initial treatment of multiple sclerosis (MS). In June 2006, the Company changed its name to Opexa Therapeutics, Inc. from PharmaFrontiers Corp. and, in January 2007, Opexa Therapeutics, Inc., the parent, merged with its wholly owned subsidiary, Opexa Pharmaceuticals with Opexa Therapeutics, Inc. being the surviving company.

In August 2009, Opexa entered into an exclusive agreement with Novartis Institutes for BioMedical Research, Inc. ("Novartis") whereby Novartis acquired Opexa's rights to the Stem Cell License and associated technology platform and had full responsibility for funding and carrying out all research, development and commercialization activities. Opexa received an upfront cash payment of $3 million at the time the agreement was entered into and subsequently received $0.5 million as a technology transfer fee milestone. In November 2011, Opexa re-acquired the stem cell assets from Novartis in consideration for releasing Novartis with respect to any further payment obligations owed to Opexa by Novartis. In connection with the re-acquisition of the stem cell assets, a related license agreement with the University of Chicago was re-assigned to Opexa. Opexa and the University of Chicago entered into a Fourth Amended and Restated License Agreement in connection with such assignment to Opexa.

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

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

Development Stage Company. Opexa is considered to be in development stage and has had no commercial revenues to date.

Reverse Stock Split. In June, 2006, Opexa effected a one-for-ten reverse stock split of its common stock.

On December 14, 2012, Opexa effected a one-for-four reverse stock split of its common stock (the "1:4 Reverse Stock Split") which decreased the number of common shares issued and outstanding from approximately 23.6 million shares to approximately 5.9 million shares as of December 14, 2012. The number of authorized shares of common stock and preferred stock remained the same following the 1:4 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 convertible promissory notes, warrants and stock options, shares reserved, conversion prices of convertible securities, exercise prices of warrants or options, and loss per share. There was no impact on preferred or common stock authorized resulting from the 1:4 Reverse Stock Split.

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

The consolidated financial statements include the accounts of Opexa and its wholly owned subsidiary, Opexa Hong Kong Limited ("Opexa Hong Kong"). Opexa Hong Kong was formed in the Hong Kong Special Administrative Region during 2012 in order to facilitate potential development collaborations in the pan-Asian region. Presently, Opexa Hong Kong has not entered into any

agreements and has not recognized any revenues as of December 31, 2012. 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, 2012, Opexa Hong Kong reported cash and cash equivalents of $3,902 in converted U.S. dollars and does not have any reported liabilities in the consolidated balance sheets.

Cash and Cash Equivalents. For purposes of the 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. Reagents and supplies that will be used to manufacture Tcelna and placebo product in Opexa's Phase IIb clinical study are recorded as other current assets. The inventory of these reagents and supplies are determined at the lower of cost or market value with cost determined under the first-in first-out (FIFO) method.

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 Expenses. Additional paid in capital includes costs recorded as an offset to proceeds in connection with the completion of an equity offering.

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

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

Research and Development. Research and development expenses are expensed in the consolidated statements of expenses 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, 2012 and 2011 was $6,318,476 and $3,340,038, 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, except for intercompany transactions that are of a short-term nature with Opexa Hong Kong that are consolidated, combined or accounted for by the equity method in Opexa's consolidated financial statements. Opexa Hong Kong has transactions in Hong Kong dollars. Opexa records transaction gains and losses in its consolidated statements of operations related to the recurring measurement and settlement of such transactions. For the year ended December 31, 2012, Opexa did not record any gains and losses resulting from the translation of the functional currency into U.S. dollars and thus did not report any cumulative foreign currency translation adjustments in stockholders' equity in the consolidated balance sheets.

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, unvested share awards and convertible securities.

NOTE 2—CASH AND CASH EQUIVALENTS

At December 31, 2012, Opexa invested approximately $24,500 in a money market fund investing exclusively in high-quality, short-term money market instruments consisting of U.S. government obligations and repurchase agreements collateralized by the U.S. Government. While this fund seeks current income while preserving capital and liquidity, the fund is subject to risk, including U.S. government obligations risk, and is not federally insured or guaranteed by or obligations of the Federal Deposit Insurance Corporation or any other agency. For the 12 months ended December 31, 2012, the money market fund recognized an average market yield of 0.01%. Interest income of $280 was recognized for the year ended December 31, 2012 in the statements of expenses.

At December 31, 2011, Opexa invested approximately $7.0 million in a money market account with an average market yield of 0.01%. Interest income of $932 was recognized for the year ended December 31, 2011 in the statements of expenses.

Opexa issued a total of $4,085,000 in principal amount of convertible secured promissory notes to related parties and third parties on July 25, 2012 (see Note 6 and Note 7). As part of the security interest granted by Opexa to the investors, $1.0 million of the proceeds are required to be maintained in an account subject to a deposit account control agreement while the notes are outstanding. As of December 31, 2012, the $1.0 million balance in the controlled account is reported as restricted cash in the consolidated balance sheets. Subsequent to December 31, 2012, the restricted cash was reduced to $500,000 (see Note 14).

NOTE 3—OTHER CURRENT ASSETS

Other current assets consisted of the following at December 31, 2012 and 2011:

Description	2012	2011
Supplies inventory	$ 604,179	$ —
Deferred offering costs	341,166	—
Prepaid expenses	132,201	124,773
	$ 1,077,546	$ 124,773

Supplies inventory at December 31, 2012 includes reagents and supplies that will be used to manufacture Tcelna and placebo product in Opexa's Phase IIb clinical study. Opexa expects to amortize these prepaid reagents and supplies to research and development costs in the consolidated statements of expenses over the course of the clinical study.

Deferred offering costs at December 31, 2012 include costs incurred from third parties in connection with the implementation of an at-the-market program ("ATM Agreement") in September 2012 pursuant to which Opexa may sell shares of its common stock from time to time depending upon market demand through a sales agent in transactions deemed to be an "at-the-market" offering as defined in Rule 415 of the Securities Act of 1933. As of December 31, 2012, the costs of $101,972 in connection with the implementation of the ATM Agreement were capitalized and are included in other current assets in the consolidated balance sheets. Upon the sales of any shares of common stock under the ATM Agreement, the capitalized costs will be offset against the proceeds of such sales of shares of common stock.

Deferred offering costs at December 31, 2012 also include costs incurred from third parties in connection with the implementation of a $1.5 million Purchase Agreement and a $15 million Purchase Agreement (collectively, the "Purchase Agreements") in November 2012 pursuant to which Opexa has the right to sell to Lincoln Park Capital Fund, LLC ("Lincoln Park") an aggregate of up to $16.5 million in shares of its common stock, subject to certain conditions and limitations. As of December 31, 2012, the remaining costs of $216,198 in connection with the implementation of the Purchase Agreements remained capitalized and are included in other current

assets in the consolidated balance sheets. Upon the sales of shares of common stock under the Purchase Agreements, the capitalized costs are offset against the proceeds of such sales of shares of common stock.

Deferred offering costs at December 31, 2012 also include costs incurred from third parties in connection with the Option and License Agreement entered into with Ares Trading SA ("Merck"), a wholly owned subsidiary of Merck Serono S.A., on February 4, 2013. Under the terms of the Agreement, the Company received an upfront payment of $5 million on February 20, 2013. As of December 31, 2012, the remaining costs of $22,996 in connection with the Option and License Agreement remained capitalized and are included in other current assets in the consolidated balance sheets.

NOTE 4—PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31, 2012 and 2011:

Description	Life	2012	2011
Computer equipment	3 years	$ 121,129	$ 99,603
Office furniture and equipment	5-7 years	274,438	251,170
Software	3 years	149,867	96,097
Laboratory equipment	7 years	1,020,158	994,994
Leasehold improvements	10 years	622,772	603,445
Manufacturing equipment	7 years	571,187	177,528
Subtotal		2,759,551	2,222,837
Less: accumulated depreciation		(1,494,510)	(1,193,601)
Property and equipment, net		$ 1,265,041	$ 1,029,236

Property and equipment is carried at cost less accumulated depreciation. Depreciation is calculated by the straight-line method over the estimated useful life of three to ten years, depending upon the type of equipment, except for leasehold improvements which are amortized using the straight-line method over the remaining lease term or the life of the asset, whichever is shorter. The cost of repairs and maintenance is charged as an expense as incurred. Depreciation expense totaled $303,677 and $210,252 for the years ended December 31, 2012 and 2011, respectively.

NOTE 5—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, 2012 and 2011, Opexa had approximately $69 million and approximately $61 million of unused net operating losses, respectively, available for carry forward to future years. The unused net operating losses begin to expire at December 31, 2024. At December 31, 2012 and 2011, Opexa's deferred tax asset resulting from its cumulative NOLs amounted to $23,678,228 and $20,876,592, respectively 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.

NOTE 6—CONVERTIBLE PROMISSORY NOTES

On July 25, 2012, Opexa issued a total of $4,085,000 in principal amount of secured convertible promissory notes ("Notes") to third parties and related parties (collectively, the "Noteholders"), of which an aggregate of $630,000 was issued to related parties (See Note 7). The Notes mature on July 25, 2014 and accrue interest at the rate of 12% per annum, compounded annually. Interest is payable semi-annually on June 30 and December 31 in either cash or registered shares of common stock, at Opexa's election. The Notes are secured by substantially all of Opexa's assets and are convertible into a new class of non-voting Series A convertible preferred stock. The Notes can be converted into Series A convertible preferred stock at the option of the investors at a price of $100.00 per share, subject to certain limitations and adjustments. Additionally, Opexa can elect to convert the Notes into Series A convertible preferred stock if (i) Opexa's common stock closes at or above $10.00 per share for 20 consecutive trading days or (ii) Opexa achieves certain additional funding milestones to continue its clinical trial program. These milestones include (x) executing a strategic agreement with a partner or potential partner by which Opexa will receive a minimum of $5 million to partially fund, or an option to partner with Opexa for, its Phase II clinical trial for Tcelna in patients with SPMS and (y) receiving a minimum of $25 million in additional capital (including the Note offering proceeds) from any partner, potential partner or any other source.

The Series A convertible preferred stock accrues dividends at the rate of 8% per annum, which are cumulative and payable semi-annually on June 30 and December 31 in either cash or registered shares of common stock at Opexa's election. The Series A convertible preferred stock has a liquidation preference of $100.00 per share, entitling holders to payment from the assets of the Company available for distribution to its shareholders before any payment is made to the holders of the common stock. The Series A

convertible preferred stock participates in any dividends or other distributions on shares of common stock (other than dividends payable in shares of common stock) along with the common stock. As a result of anti-dilution adjustments following the November 2012 sale of shares of Opexa's common stock, the Series A convertible preferred stock is convertible into shares of the Company's common stock at a price of $3.12 per share (the floor price), subject to certain limitations and conditions, and up to 1,308,236 shares of common stock were issuable if all 12% convertible secured promissory notes issued in the July 2012 financing and outstanding at December 31, 2012 were converted to Series A convertible preferred stock and such stock is then converted into common stock. Additionally, Opexa can elect to convert the Series A convertible preferred stock into common stock if the Company's common stock closes at or above $16.00 per share for 20 consecutive trading days. As of December 31, 2012, no shares of Series A convertible preferred stock were currently outstanding. Subsequent to December 31, 2012, $900,000 in principal amount of the notes were converted into shares of Series A convertible preferred stock and such shares were then converted into common stock (see Note 14).

As part of the security interest in all of the Company's assets granted to the Noteholders, $1.0 million of the proceeds is maintained in a controlled account (see Note 2). Subsequent to December 31, 2012, the restricted cash was reduced to $500,000 (see Note 14). The Noteholders were granted certain registration rights for the shares of underlying common stock.

If the Company does not make the required payments when due, either at maturity, or at applicable installment payment dates, or if the Company breaches other terms of the convertible secured notes or related agreements, the Noteholders could elect to declare all amounts outstanding, together with accrued and unpaid interest, to be immediately due and payable. Even if the Company was able to prepay the full amount in cash, any such repayment could leave the Company with little or no working capital for its business. If the Company is unable to repay those amounts, the Noteholders will have a first claim on Opexa's assets pledged under the convertible secured notes. If the Noteholders should attempt to foreclose on the collateral, it is unlikely that there would be any assets remaining after repayment in full of such secured indebtedness. Any default under the convertible secured notes and resulting foreclosure would have a material adverse effect on Opexa's financial condition and the Company's ability to continue its operations.

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

In connection with the issuance of the Notes, Opexa also issued Series I warrants to the Noteholders to initially purchase an aggregate of 957,422 shares of Opexa's common stock at $5.00 per share, subject to certain limitations and adjustments. The warrants have a five-year term and are exercisable six months from the date of issuance, or January 25, 2013. As a result of anti-dilution adjustments, the number of warrant shares for which the Series I warrants are exercisable increased to an aggregate increase of 1,436,121 shares of Opexa's common stock at an adjusted exercise price of $2.56 per share, subject to further certain limitations and adjustments. As a result, Opexa accounted for these reset provisions in accordance with FASB ASC 815-40, which requires Opexa to record the warrants as a derivative liability at the grant date and to record changes in fair value relating to the warrants at each subsequent balance sheet date (see Note 8). Opexa can redeem the warrants at $0.01 per share if its common stock closes at or above $10.00 per share for 20 consecutive trading days.

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

The following table provides a summary of the changes in convertible debt – third parties, net of unamortized discount, during 2012:

Balance at December 31, 2011	$ —
July 25, 2012 Notes, face value	3,455,000
Discount on beneficial conversion feature of Notes at issuance	(1,266,665)
Discount on fair value of Series I warrant liability at issuance	(1,957,665)
Amortization of debt discount to interest expense through December 31, 2012	87,988
Balance at December 31, 2012	$ 318,658

NOTE 7—RELATED PARTY TRANSACTIONS

Investors in the July 25, 2012 Note offering included two members of Opexa's Board of Directors and entities affiliated with a third director. Opexa issued an aggregate of $630,000 in principal amount of Notes to the two directors and an entity for which a third director reports beneficial ownership of Opexa securities. In connection with the issuance of such Notes, Opexa also issued warrants to purchase an aggregate of 221,483 shares of common stock. The fair value of the warrants was $356,969. Opexa also determined the

Notes contained a beneficial conversation feature with fair value of $230,969. Opexa recorded a total of $587,939 as debt discount associated with the Notes issued to the related parties and amortized $16,044 as interest expense in the consolidated statements of expenses for the year ended December 31, 2012.

On August 15, 2012, Opexa appointed director David E. Jorden as its Acting Chief Financial Officer. As a non-employee officer of Opexa, Mr. Jorden receives cash compensation of $100,000 per annum for his service. For the period of August 15, 2012 through December 31, 2012, cash compensation totaling $37,500 was earned by Mr. Jorden and is reported in general and administrative expense in the consolidated statements of expenses. As of December 31, 2012, cash compensation totaling $8,333 was due to Mr. Jorden and is included in accounts payable in the consolidated balance sheets.

The following table provides a summary of the changes in convertible debt – related parties, net of unamortized discount, during 2012:

Balance at December 31, 2011	$	—
July 25, 2012 Notes, face value		630,000
Discount on beneficial conversion feature of Notes at issuance		(230,970)
Discount on fair value of Series I warrant liability at issuance		(356,969)
Amortization of debt discount to interest expense through December 31, 2012		16,044
Balance at December 31, 2012	$	58,105

NOTE 8—FAIR VALUE OF DERIVATIVE FINANCIAL INSTRUMENTS

The carrying value of cash and cash equivalents, receivables, accounts payable and accrued expenses in the consolidated balance sheets approximates their fair values because of the short-term nature of these instruments. The carrying value of the Notes in the consolidated balance sheets approximates fair value since the related rate of interest approximates current market rates. Management believes Opexa is not exposed to significant interest or credit risks arising from these financial instruments.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. Opexa utilizes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable.

- Level 1 — Quoted prices in active markets for identical assets or liabilities. These are typically obtained from real-time quotes for transactions in active exchange markets involving identical assets.

- Level 2 — Quoted prices for similar assets and liabilities in active markets; quoted prices included for identical or similar assets and liabilities that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets. These are typically obtained from readily-available pricing sources for comparable instruments.

- Level 3 — Unobservable inputs, where there is little or no market activity for the asset or liability. These inputs reflect the reporting entity's own beliefs about the assumptions that market participants would use in pricing the asset or liability, based on the best information available in the circumstances.

FASB ASC 815, "Accounting for Derivatives and Hedging Activities" ("FASB ASC 815") specifies that a contract that would otherwise meet the definition of a derivative, but is both (a) indexed to its own stock and (b) classified in stockholders' equity in the statement of financial position would not be considered a derivative financial instrument. FASB ASC 815 provides a new two-step model to be applied in determining whether a financial instrument or an embedded feature is indexed to an issuer's own stock, including evaluating the instrument's contingent exercise and settlement provisions, and thus able to qualify for the FASB ASC 815-10 scope exception. It also clarifies the impact of foreign-currency-denominated strike prices and market-based employee stock option valuation instruments on the evaluation. Initially, Opexa evaluated all of its financial instruments and determined that the Series I warrants associated with the July 2012 Note financing (see Note 6) qualified for treatment under FASB ASC 815. Consequently, the Company recorded a derivative liability of $2,314,635 upon issuance of the warrants and a corresponding discount on the convertible debt. On November 8, 2012, it was determined that the floor for resetting the exercise price was met and no further adjustments to the exercise price of the Series I warrants would occur. Therefore, the Series I warrants were considered indexed to the company's stock and qualified for the scope exception under FASB ASC 815-10 allowing for a transfer from liability classification to equity classification. Consequently, the remaining derivative liability of $1,761,657 at November 8, 2012 was written off to additional paid in capital.

The following table provides a summary of the changes in fair value, including net transfers in and/or out, of the derivative financial instruments, measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

Balance at December 31, 2011	$ —
Fair value of warrant derivative liabilities at issuance	2,314,635
Realized derivative gains included in other income (expense)	(552,978)
Write off of warrant derivative liability to additional paid in capital	(1,761,657)
Balance at December 31, 2012	$ —

The fair value of the derivative liabilities are calculated at the time of issuance using the Lattice option pricing model with Monte Carlo simulation. Opexa records a derivative liability for the calculated value. Changes in the fair value of the derivative liabilities are reported in other income (expense) in the consolidated statements of expenses. The variables used in the Lattice option pricing model for the derivative liabilities during the year ended December 31, 2012 include:

	July 25, 2012	September 30, 2012	November 8, 2012
Market value of common stock on measurement date	$2.56	$2.70	$1.96
Projected exercise price	$5.00	$4.52	$4.56
Risk free interest rate	0.56%	0.56%	0.72%
Warrant lives in years	5	4.88	4.71
Expected volatility	193%	193%	194%
Expected dividend yield	0%	0%	0%
Offering price range	$2.56-$6.56	$2.72-$6.72	$2.56-$6.56

NOTE 9—COMMITMENTS AND CONTINGENCIES

In October 2005, Opexa entered into a ten-year lease for its office and research facilities. The facility including the property is leased for a term of ten years with two options for an additional five years each at the then prevailing market rate. Future minimum lease payments under the non-cancellable operating lease are $157,896 for 2013, $157,896 for 2014 and $118,422 for 2015. Rent expense in the consolidated statements of expenses was approximately $136,000 for each of the years ended December 31, 2012 and 2011.

NOTE 10—SIGNIFICANT CONTRACTUAL SERVICE AND MILESTONE AGREEMENTS

In February 2012, Opexa entered into an agreement with Pharmaceutical Research Associates, Inc. ("PRA"), a contract research organization, in which PRA will provide Opexa with services related to the design, implementation and management of Opexa's ongoing Phase IIb clinical trial program in SPMS (the "PRA Agreement"). Under the terms of the PRA Agreement, Opexa made upfront cash payments to PRA of $543,766. Future 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. In December 2012, Opexa entered into an Amendment #1 to Task Order #1 (the "Amendment") with PRA in which Opexa agreed to reimburse PRA for additional services and pass-through expenses incurred while performing out-of-scope work. Under the terms of the Amendment, an upfront cash payment of $37,605 is to be made to PRA as payment for certain out-of-scope tasks performed by PRA and future payments by Opexa to PRA under the PRA Agreement on the achievement of certain time milestones in the Amendment. Total payments to PRA during 2012, which were charged to expense, amounted to $1,382,236. 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.

During 2012, Opexa entered into individual Clinical Trial Agreements with 18 clinical institutions (the "Institutions") across the U.S. and 18 principal investigators (the "Investigators") acting within their employment or agent positions within their clinical institution. Under the terms of each Clinical Trial Agreement, each of the Investigators will identify and recruit subjects with SPMS meeting certain enrollment requirements and conduct clinical research in conjunction with Opexa's Phase IIb clinical study, and each of the Institutions will provide appropriate resources and facilities so the Institution's Investigator can conduct Opexa's Phase IIb clinical study in a timely and professional manner and according to the terms of the Clinical Trial Agreement. Under the terms of each Clinical Trial Agreement, Opexa paid an upfront cash payment to each Institution for start-up and other costs which were charged directly to expense. Future payments by Opexa to the Institutions during the term of each Clinical Trial Agreement are based on the achievement of certain performance milestones as presented in each Clinical Trial Agreement. Unless terminated by Opexa without cause with 30 days notice, or unless terminated by the Institution, Investigator or Opexa for health or safety reasons, the initial term of the Clinical Trial Agreements with each Institution and Investigator is for the duration of their enrolled subjects in the Phase IIb clinical study.

NOTE 11—EQUITY

Summary information regarding equity related transactions for the years ended December 31, 2011 and December 31, 2012 is as follows:

During 2011, equity related transactions were as follows:

- In January 2011, 96,189 shares of common stock were sold under the Continuous Offering Program Agreement dated May 14, 2010 (the "2010 ATM Agreement") for net proceeds of $1,066,286. Compensation and fees totaling $10,826 was paid to the placement agent with respect to the shares sold. The 2010 ATM Agreement was subsequently terminated by Opexa on February 7, 2011.
- In February 2011, an aggregate of 1,036,622 units were sold in a public offering, with each unit consisting of one share of common stock and a warrant to purchase four-tenths (0.40) of a share of common stock, at a price to the public of $2.05 per unit, for gross proceeds of $8,500,325. The shares of common stock and warrants were immediately separable and were issued separately such that no units were issued. The warrants were exercisable immediately upon issuance, have a five-year term and an exercise price of $10.44 per share. Net proceeds from this offering were approximately $7,551,891 after deducting underwriting discounts and commissions and other estimated offering expenses. The offering closed on February 11, 2011.
- 12,576 shares of common stock valued at their fair value of $87,028 were issued to a consultant in exchange for services.

During 2012, equity related transactions were as follows:

- In November 2012, Opexa entered into two purchase agreements with Lincoln Park pursuant to which the Company has the right to sell to Lincoln Park an aggregate of up to $16.5 million in shares of common stock, subject to certain conditions and limitations. As consideration for its commitment to purchase shares of common stock pursuant to the $1.5 million purchase agreement, Opexa issued to Lincoln Park 56,507 shares of common stock with a fair value of $149,131.
- In November and December 2012, 265,000 shares of common stock were sold and 2,610 additional commitment shares were issued to Lincoln Park for net proceeds of $333,970.
- In December 2012, 163,224 shares of common stock were issued to the Noteholders of the July 2012 Notes as payment of accrued interest.

NOTE 12—OPTIONS AND WARRANTS

On September 2, 2010, the Board adopted the Opexa Therapeutics, Inc. 2010 Stock Incentive Plan ("the 2010 Plan") for the granting of equity incentive awards to employees, directors and consultants of Opexa. The 2010 Plan was approved by the Company's stockholders on October 19, 2010. The 2010 Plan is the successor to and continuation of Opexa's June 2004 Compensatory Stock Option Plan (the "2004 Plan"). The 2004 Plan reserved a maximum of 575,000 shares of common stock for issuance pursuant to incentive stock options and nonqualified stock options granted to employees, directors and consultants. Awards were made as either incentive stock options or nonqualified stock options, with the Board having discretion to determine the number, term, exercise price and vesting of grants made under the 2004 Plan. All outstanding equity awards granted under the 2004 Plan continue to be subject to the terms and conditions as set forth in the agreements evidencing such stock awards and the terms of the 2004 Plan, but no additional awards will be granted under the 2004 Plan subsequent to approval of the 2010 Plan. Under the 2010 Plan, the total number of shares of common stock reserved for issuance consists of 625,000 shares 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 793,204 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 stockholder approval, the Board or Compensation Committee, as applicable, may also determine the exercise price of options granted under the 2010 Plan.

Employee Options:

During 2011, options to purchase 43,750 shares of common stock were granted by Opexa to its employees at an exercise price of $6.24. These options have a term of ten years and vest over three years. Fair value of $268,451 was recorded using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for options issued during the year ended

December 31, 2011 include (1) discount rate of 3.36%, (2) expected term of six years, (3) expected volatility of 192% and (4) zero expected dividends.

During 2011, options to purchase 18,750 shares were forfeited and cancelled.

Opexa recorded $304,024 stock-based compensation expense to management and employees during 2011. Unamortized stock-based compensation expense as of December 31, 2011 amounted to $364,064.

During 2012, options to purchase an aggregate of 107,832 shares were granted to employees, at exercise prices ranging from $1.80 to $3.80. These options have terms of ten years and have a vesting schedule of three years. Fair value of $381,020 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 1.40% and 1.98%, (2) expected term of 5.25 to 7 years, (3) expected volatility range of 180% and 183% and (4) zero expected dividends.

During 2012, options to purchase an aggregate of 254,756 shares were granted to senior management, based on the achievement of future performance-based, strategic milestone objectives, at an exercise price of $3.80. These options have terms of ten years and have vesting schedules of three years commencing after the two specific milestone objectives have been individually met. Fair value of $964,715 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 1.98%, (2) expected term of ten years, (3) expected volatility of 183% and (4) zero expected dividends. As of December 31, 2012, one of the two specific milestone objectives had been individually met and an aggregate of 82,009 shares granted to senior management commenced vesting during 2012.

During 2012, options to purchase 4,678 shares were forfeited and cancelled.

Opexa recorded $549,150 stock-based compensation expense to management and employees during 2012, which included the related expense for the options that are expected to vest based on achievement of their related performance conditions. Unamortized stock compensation expense as of December 31, 2012 amounted to $1,142,135.

Non-Employee Options:

During 2011, options to purchase 32,407 shares of common stock were granted by Opexa to its consultants and directors at exercise prices ranging from $3.80 to $7.12. These options have terms of two to ten years, and have vesting dates that vary from either full or partial vesting at date of grant to full vesting within one to two years of the date of grant. Fair value of $196,783 was recorded using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for options issued during the year ended December 31, 2011 include (1) discount rate range of 0.25% to 3.50%, (2) expected term of two to five and one-quarter years, (3) expected volatility of 85%—198% and (4) zero expected dividends.

Opexa recorded $185,890 stock-based compensation expense to consultants and directors during 2011. Unamortized stock-based compensation expense as of December 31, 2011 amounted to $19,658.

During 2012, an option to purchase an aggregate of 18,750 shares was granted to Opexa's non-employee Acting Chief Financial Officer at an exercise price of $2.04 in connection with his appointment. This option has a term of ten years, with one-third of the shares vesting immediately, one-third of the shares vesting on December 31, 2012 and the remaining one-third of the shares vesting at the earlier of June 30, 2013 or the appointment of a permanent chief financial officer. Fair value of $37,096 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for this option include (1) discount rate of 1.80%, (2) expected term of 5.25 years, (3) expected volatility of 185% and (4) zero expected dividends.

During 2012, options to purchase an aggregate of 30,600 shares were granted to directors for service on Opexa's Board at an exercise price of $3.76. Options to purchase an aggregate of 10,000 shares have terms of 10 years, with 50% of the shares vesting immediately and 50% vesting one year from the date of grant. Options to purchase the remaining 20,600 shares will expire on the earlier of 10 years or a change in control of the Company, with 50% of the shares vesting immediately and 50% vesting on December 31, 2012. Fair value of $111,428 was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for these options include (1) discount rate of 2.03%, (2) expected term of 5.25 years, (3) expected volatility of 186% and (4) zero expected dividends.

During 2012, options to purchase 25,563 shares were forfeited and cancelled.

Opexa recorded $141,576 of stock-based compensation expense to consultants and directors during 2012. Unamortized stock compensation expense as of December 31, 2012 amounted to $14,770.

Broker and Investor Warrants:

During 2011, warrants to purchase 671,972 shares were forfeited.

In connection with Opexa's February 2011 public offering, Opexa issued warrants to purchase an aggregate of 414,650 shares of common stock to the investors at an exercise price of $10.44 per share. These warrants have a term of five years and were immediately exercisable.

During 2012, warrants to purchase 464,584 shares were forfeited.

In connection with Opexa's July 25, 2012 private offering of the Notes (see Note 6), Opexa issued warrants to purchase an aggregate of 1,436,121 shares of common stock at a current adjusted exercise price of $2.56 per share, subject to certain limitations and adjustments. These warrants have a term of five years and are initially exercisable on January 25, 2013.

At December 31, 2011, the aggregate intrinsic value of the outstanding options and warrants was $227,567 and $435,913, respectively. At December 31, 2012, the aggregate intrinsic value of the outstanding options and warrants was $13,846 and $57,891, respectively.

Summary information regarding options and warrants from December 31, 2006 is as follows:

	Options	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2006	190,426	$ 45.92	917,590	$ 78.04
Year ended December 31, 2007:				
Granted	73,475	21.12	—	—
Forfeited and canceled	(4,336)	30.96	—	—
Outstanding at December 31, 2007	259,565	$ 39.16	917,590	$ 78.04
Year ended December 31, 2008:				
Granted	160,100	4.50	1,682,209	7.84
Forfeited and canceled	(31,617)	24.41	—	—
Outstanding at December 31, 2008	388,048	$ 25.88	2,599,799	$ 32.60
Year ended December 31, 2009:				
Granted	193,583	3.83	801,143	6.68
Exercised	(15,193)	4.21	(179,691)	6.64
Forfeited and canceled	(85,605)	42.22	(52,082)	20.00
Outstanding at December 31, 2009	480,833	$ 14.80	3,169,169	$ 27.72
Year ended December 31, 2010:				
Granted	38,138	8.34	1,966	8.00
Exercised	(36,284)	3.56	(17,102)	8.40
Forfeited and canceled	(97,171)	36.62	(289,160)	117.60
Outstanding at December 31, 2010	385,516	$ 8.60	2,864,873	$ 11.00
Year ended December 31, 2011:				
Granted	76,157	6.29	414,649	10.44
Exercised	—	—	—	—
Forfeited and canceled	(18,750)	20.00	(671,972)	23.72
Outstanding at December 31, 2011	442,923	$ 7.71	2,607,550	$ 6.66
Year ended December 31, 2012:				
Granted	411,938	3.68	1,436,121	2.56
Exercised	—	—	—	—
Forfeited and canceled	(30,241)	11.80	(464,584)	6.12
Outstanding at December 31, 2012	824,620	$ 5.54	3,579,087	$ 5.64

Summary of options outstanding and exercisable as of December 31, 2012 is as follows:

Range of Exercise Prices	Weighted Average Remaining Contractual Life (years)	Number of Options Outstanding	Number of Options Exercisable
$ 0.88 to $ 4.99	5.84	599,706	258,337
5.00 to 9.99	1.58	178,054	157,221
10.00 to 39.20	0.21	46,860	46,860
$ 0.88 to $39.20	7.63	824,620	462,418

Summary of warrants outstanding and exercisable as of December 31, 2012 is as follows:

Range of Exercise Prices	Weighted Average Remaining Contractual Life (years)	Number of Warrants Outstanding	Number of Warrants Exercisable
$ 0.18 to $ 4.99	1.86	1,850,102	413,981
5.00 to 9.99	0.04	1,068,905	1,068,905
10.00 to 10.44	0.53	660,080	660,080
$ 0.18 to $10.44	2.43	3,579,087	2,142,966

NOTE 13—LICENSES AND GAIN ON EXTINGUISHMENT OF DEBT

University of Chicago License Agreement

In 2004, Opexa entered into an agreement with the University of Chicago ("University") for the worldwide license to technology developed at Argonne National Laboratory, a U.S. Department of Energy Laboratory operated by the University. The license was later amended granting Opexa an exclusive, non-transferable worldwide license to the University's stem cell technology. In consideration for the license and amendment, Opexa paid the University a total of $232,742 and issued the University 53,462 shares of common stock valued at $2,295,461. Opexa also agreed to pay the University $1.5 million and to issue the University 21,623 shares of Opexa common stock. In April 2007, the $1.5 million cash payment obligation was extended until July 31, 2007 and the obligation to issue shares of Opexa's common stock was extended until July 31, 2007, with $112,440 accrued as of June 30, 2007.

In July 2007, Opexa entered into a second amended and restated license agreement with the University that eliminated the obligations under the prior agreement for the payment of $1.5 million due July 31, 2007 and the obligation to issue 21,623 shares of Opexa common stock. These obligations were recorded as an intangible asset, with the liabilities recorded as a notes payable—current portion of $1.5 million and a stock payable of $112,440. As a result of the amendment and restatement of the license agreement with the University, $1,612,440 was reported as a gain on extinguishment of liability. Opexa applied the accounting guidance related to transfers and servicing of financial assets and extinguishments of liabilities as well as the guidance on debtor's accounting for a modification or exchange of debt instruments. In August 2009, the University of Chicago license agreement was assigned to Novartis as part of Opexa's sale of its stem cell technology platform to Novartis, and effective November 2, 2011, the license agreement was re-assigned to Opexa and the license agreement was amended and restated, as further described below.

Stem Cell Technology Agreement

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

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

NOTE 14—SUBSEQUENT EVENTS

In January 2013, 125,000 shares of common stock were sold and 975 additional commitment shares were issued to Lincoln Park under the $1.5 million purchase agreement for net proceeds of $142,400.

On January 23, 2013, Opexa closed a private offering consisting of convertible notes (the "January 2013 Notes") and warrants to purchase shares of common stock for gross proceeds of $650,000 of which $100,000 was from a related party. The January 2013 Notes were scheduled to mature on January 23, 2014 and accrued interest at the rate of 12% per annum, compounded annually. The January 2013 Notes were convertible into common stock at the option of the investors at a price of $1.30 per share, subject to certain limitations. The principal balance plus accrued was payable within five business days of the receipt by Opexa of an aggregate of at least $7.5 million in proceeds from the sale of its equity securities and/or as payments from one or more partners or potential partners in return for granting a license, other rights, or an option to license or otherwise acquire rights with respect to Tcelna. On February 26, 2013, following the receipt of proceeds in excess of $7.5 million, Opexa paid principal and interest totaling $567,368 to holders of the January 2013 Notes and issued 77,034 shares of common stock to one holder of the January 2013 Notes who elected to convert the principal into common stock.

The warrants related to the January 2013 Notes financing have an exercise price of $1.24 per share, a five-year term and are exercisable for a maximum of 243,750 shares of common stock, subject to certain limitations. The Company can redeem the warrants at $0.01 per share if the Company's common stock closes at or above $10.00 per share for 20 consecutive trading days.

Pursuant to the convertible secured promissory note financing effected by Opexa on July 25, 2012 (the "July 2012 Notes"), $1.0 million of the gross proceeds are maintained in a segregated account and subject to a deposit control agreement while the July 2012 Notes are outstanding. Pursuant to a waiver executed by the holders of in excess of two-thirds (66-2/3%) of the principal amount of the outstanding July 2012 Notes and accepted by Opexa, the amount of the cash subject to the deposit control agreement was reduced to $500,000 on January 29, 2013. In exchange for such waiver, the Company issued warrants to the holders of the July 2012 Notes to purchase an aggregate of 187,500 shares of the Company's common stock. The warrants have an exercise price of $1.21 per share and a five-year term. The Company can redeem the warrants at $0.01 per underlying share of common stock if the common stock closes at or above $10.00 per share for 20 consecutive trading days.

In February 2013, three of the holders of the July 2012 Notes elected to convert an aggregate of $900,000 of the July 2012 Notes into shares of the Company's Series A convertible preferred stock with further immediate conversion into shares of the Company's common stock. Accordingly, the Company issued an aggregate of 288,229 shares of common stock to the holders.

In February 2013, Opexa sold an aggregate of 167,618 shares of common stock under the ATM Agreement dated September 6, 2012 for gross proceeds of $536,417. Under the ATM Agreement, Opexa may sell an aggregate of up to 1,000,000 shares of common stock from time to time through the placement agent with a commission equal to 3% of the gross proceeds. Opexa paid compensation and fees totaling $16,105 to the placement agent with respect to the shares sold.

On February 4, 2013, Opexa entered into an option and license agreement with Merck. Pursuant to the agreement, Merck has an option to acquire an exclusive, worldwide (excluding Japan) license of the Company's Tcelna program for the treatment of multiple sclerosis. Under the terms of the agreement, the Company received an upfront payment of $5 million on February 20, 2013.

On February 11, 2013, Opexa sold an aggregate of 1,083,334 units in a registered offering, with each unit consisting of one share of common stock and a warrant to purchase half (0.5) a share of common stock, at a price of $3.00 per unit, for gross proceeds of $3,250,002. The shares of common stock and warrants were immediately separable and were issued separately such that no units were issued. The warrants are exercisable immediately upon issuance, have a four-year term and an exercise price of $3.00 per share. A fee of 6.0% of the gross proceeds was paid to the placement agent.