# 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, 2011

☐ **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 |
| Series E Common Stock Purchase Warrants | The NASDAQ Stock Market LLC |

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2011 based upon the closing price as of such date was $28,516,172.

As of February 15, 2012, 23,048,488 shares of the registrant's common stock, par value $0.01 per share, were outstanding.

**Table of Contents**

**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: our capital position, our ability to enter into and benefit from a partnering arrangement for our product candidate, Tovaxin, on reasonably satisfactory terms (if at all), and our dependence (if partnered) on the resources and abilities of any partner for the further development of Tovaxin, 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 treatment development program and to undertake and complete any further clinical studies for Tovaxin, the success of our clinical trials, the efficacy of Tovaxin for any particular indication, such as for RR-MS or SP-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 Tovaxin), the risk of litigation regarding our intellectual property rights, 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 candidates is preliminary and investigative. Our product candidates are not approved by the U.S. Food and Drug Administration (FDA).

Our lead product candidate, Tovaxin®, 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 Tovaxin®

Tovaxin® is a novel T-cell immunotherapy positioned to enter Phase IIb clinical development for the treatment of secondary progressive MS (SP-MS) as well as Phase III clinical development for the treatment of relapsing remitting MS (RR-MS). It is a personalized therapy that is specifically tailored to each patient's disease profile. Tovaxin is manufactured using 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.

##### *Summary of TERMS Phase IIb Clinical Trial Data*

*Tovaxin for Early Relapsing Multiple Sclerosis* (TERMS) was a Phase IIb clinical study of Tovaxin in RR-MS patients. 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 RR-MS 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 include:

- In the modified intent to treat patient population (n=142), the annualized relapse rate (ARR) for Tovaxin-treated patients was 0.214 as compared to 0.339 for placebo-treated patients, which represented a 37% decrease in ARR for Tovaxin as compared to placebo in the general population;
- In a prospective group of patients with more active disease (ARR>1, n=50), Tovaxin demonstrated a 55% reduction in ARR as compared to placebo, and a 73% reduction in relapse rate was observed in Tovaxin 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 Tovaxin, had a 64% reduction in ARR versus placebo (p=0.046, n=70).

Tovaxin has demonstrated a favorable side effect profile throughout the clinical development program. In four clinical trials to date, including the Phase IIb TERMS trial, there have been no serious adverse events associated with Tovaxin treatment. The most common side effect is mild to moderate irritation at the site of injection, which is typically resolved in 24 hours. We believe the favorable safety profile of Tovaxin is a key differentiator when compared to marketed or other developmental MS drugs.

##### *T-Cell Therapy Regulatory and Development Status*

In late 2010, we conducted formal End of Phase II meetings with the FDA regarding our planned development program for Tovaxin. These consisted of two separate meetings to review both the complete Tovaxin manufacturing process as well as the prospective clinical trial plan for Tovaxin. The first meeting focused on the improvements and modifications we have incorporated into Tovaxin's manufacturing and CMC (chemistry, manufacturing and control) process in an effort to improve efficiency, reduce overall costs and implement commercial stage requirements. As part of this meeting, we presented data and details supporting an optimized manufacturing process, including a transition to fewer process steps, comparability plans and complete reagent profiles. The FDA agreed that the optimized Tovaxin manufacturing process would meet the requirements for a pivotal Phase III clinical trial, although additional supporting data is expected to be submitted to the FDA prior to initiating such a study.

During the second meeting we presented our rationale and trial design for a Phase III pivotal study of Tovaxin in RR-MS patients. The FDA concurred in general with our proposed clinical trial protocol, including the patient population, end points, patient numbers and overall trial design. The FDA also offered several recommendations to further enhance such a Phase III trial in RR-MS.

In 2011, we submitted our data, rationale and additional background information to support the SP-MS indication. Upon review of the dossier, the FDA granted us Fast Track designation for Tovaxin in SP-MS. 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. SP-MS is characterized by a steady accrual of irreversible disability, despite, in some cases, reversible relapses, remissions or clinical plateau. Only one product is currently approved in the United States specifically for the indication of SP-MS, and we believe that a significant unmet need exists for the safe and effective treatment of SP-MS.

Based on this positive FDA milestone, our encouraging data in SP-MS and supportive discussions with key opinion leaders, clinicians and patients, we have accelerated our plans for SP-MS and are currently planning to initiate a Phase IIb clinical trial of Tovaxin in SP-MS patients, subject to securing the necessary resources to conduct such a trial. We also remain committed to further advancing Tovaxin in RR-MS at a later date. For Opexa, moving forward in progressive MS, an area which we believe represents a higher unmet medical need, could further differentiate the Company and Tovaxin from other MS treatments.

A Phase IIb clinical study in North America of Tovaxin in SP-MS is expected to involve 180 patients and take approximately three years to complete. If we are able to commence such a study in the first half of 2012, the costs of such study as well as the ongoing expenses of our operations through the expected completion date of such study are estimated at approximately $32 million. Our existing resources are not adequate to permit us to proceed materially beyond the initiation of such a study (*i.e.,* the dosing of the first patient) or to complete such study or any significant portion of it. Unless we secure at least a substantial portion of the additional resources that will be necessary to complete the planned Phase IIb study and support our operations during the pendency of such study, or we are reasonably confident that such resources will be secured, we would likely not proceed with the initiation of such study.

Given our need for substantial amounts of capital to undertake a Phase IIb clinical study in North America of Tovaxin in SP-MS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to complete the planned Phase IIb study and to support our operations during the pendency of such study. In addition to one or more additional financings, these opportunities and alternatives may include a partnering arrangement with a large biotech or pharmaceutical company. There can be no assurance that any such financings or partnering arrangement can be consummated on acceptable terms, if at all.

**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.

**Stem Cell Therapy**

In 2009, Novartis Pharmaceuticals acquired our stem cell technology platform and took over all future responsibilities and opportunities for this technology, although we retained an option on certain manufacturing rights. As part of the transaction, we were paid an upfront fee of $3 million and a milestone payment of $500,000 for certain technology transfer activities. Preliminary data for this technology, which had been in early preclinical development at Opexa prior to the 2009 sale, has shown the potential to generate monocyte derived islet cells from peripheral blood mononuclear cells.

In November 2011, we re-acquired the stem cell assets from Novartis in consideration for releasing Novartis from any further payment obligations owed to Opexa by Novartis, including the remaining $0.5 million technology transfer milestone payment. Novartis had advised us that the advancement of the stem cell program was no longer a priority for Novartis, and that Novartis was willing to transfer the assets back to us in exchange for the release. In connection with the re-acquisition of the stem cell assets from Novartis, a related license agreement with the University of Chicago was assigned back to us. Opexa and the University of Chicago entered into a Fourth Amended and Restated License Agreement in connection with such assignment to Opexa.

**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 RR-MS, one-half of whom will develop steadily progressive disease, SP-MS, within 10 years, increasing to 90% within 25 years of MS diagnosis. The MS drug market was approximately $11 billion in 2010 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.

***SP-MS Overview***

SP-MS 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 SP-MS. Males have a shorter time to conversion to SP-MS compared with females. Available immunomodulating and immunosuppressive therapies used for RR-MS have not been effective in SP-MS. In clinical trials, these therapies have demonstrated anti-inflammatory properties as measured by the reduction in number and volume of contrast-enhancing or acutely inflammatory CNS lesions most commonly seen in patients with RR-MS. The typical SP-MS patient, however, has little or no radiographic evidence of acute inflammation. It is a striking observation 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 SP-MS suggests that the relentless cerebral deterioration characterizing progressive disease may be driven by factors other than acute inflammation. For instance, the immunopathology of SP-MS 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 SP-MS include significantly more atrophy of gray matter compared with RR-MS patients. Of note, long-term disability in MS in general is more closely correlated to gray matter atrophy than to white matter inflammation. Such atrophy is highly predictive of progressive clinical disability. Both clinically and radiographically, SP-MS represents a disease process with features strikingly distinct from those of RR-MS, and one with extremely limited treatment options.

***Current Treatment Options for SP-MS***

Only one product, mitoxantrone, is currently approved for the indication of SP-MS. 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.

***Tovaxin Clinical Overview in SP-MS***

A total of 142 MS patients have received Tovaxin to date, with no drug-related serious adverse events reported and an excellent overall safety profile. Clinical benefit of Tovaxin has been suggested by a reduction in relapse rate, slowing of disability progression and relative preservation of whole brain volume. Tovaxin has been administered to a total of 36 subjects with SP-MS across three clinical studies. Safety results as well as preliminary data suggesting stabilized or improved disability among SP-MS subjects receiving Tovaxin suggests that further development of this product in SP-MS is warranted.

***Tovaxin for MS***

We believe that Tovaxin 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. Tovaxin 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.

***Tovaxin Manufacturing***

We manufacture Tovaxin in our own current Good Manufacturing Practice (cGMP) facility. The technology used to produce Tovaxin 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.

***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. Tovaxin 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, Tovaxin 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 Tovaxin product is manufactured against these peptides. Thus Tovaxin 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 Tovaxin 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 Tovaxin doses. Prior to clinical use, a frozen Tovaxin 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.

***Tovaxin Safety and Tolerability***

We believe that Tovaxin 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 Tovaxin 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 Tovaxin 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 Tovaxin development and manufacturing processes that remains a trade secret. Consequently, we consider barriers to entry, relative to Tovaxin 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**

We may choose to partner with large biotech or 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.

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 product outside 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, 2011 were approximately $3.3 million, mainly reflecting the costs of preparation for the next clinical trial for Tovaxin in MS. Research and development expenses for the year ended December 31, 2010 were approximately $2.6 million, mainly reflecting the costs of key laboratory experiments and manufacturing process enhancements in preparation for the next clinical trial for Tovaxin.

**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 January 31, 2012, we had 19 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 and the industry in which we operate. 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**

***Our business is at an early stage of development. We are largely dependent on the success of our lead product candidate, Tovaxin, and we cannot be certain that Tovaxin 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, Tovaxin, which has progressed to the stage of being studied in human clinical trials in the United States. We are still in the very early stages of identifying and conducting research on any other potential products. Tovaxin, 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 Tovaxin, to enter clinical trials (or any development activities) for any other product candidates, or to commercialize any products. Tovaxin, and any other potential products, may prove to have undesirable and unintended side effects or other characteristics adversely affecting their safety, efficacy or cost-effectiveness that could prevent or limit their use. Any product using any of our technology may fail to provide the intended therapeutic benefits or to achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production.

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

***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 clinical trial for Tovaxin), 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, 2011, we had cash and cash equivalents of $7,109,215. During January 2011, we sold an aggregate of 384,759 shares of our common stock for net proceeds of $1,066,266 under an "at the market" continuous offering program pursuant to a prospectus supplement dated May 17, 2010. During February 2011, we raised net proceeds of approximately $7,551,891 through a public offering of common stock and warrants pursuant to a prospectus supplement dated February 8, 2011. In addition to general corporate purposes (including working capital and operational purposes), we used part of the net proceeds from the February 2011 public offering to prepare for and proceed toward the initiation of further clinical studies of Tovaxin in MS. Our burn rate during 2011, in the absence of any clinical trial as well as significant activities in preparation for such a trial, was approximately $470,000 per month. If we do not commence a clinical trial, and if we also do not engage in any significant activities in preparation for such a trial, we believe we have sufficient liquidity to support operations through 2012. However, we will need to raise additional capital to fund our current business plan and support our operations.

We are planning to initiate a Phase IIb clinical trial of Tovaxin in SP-MS patients, subject to securing the necessary resources to conduct such a study. Significant activities in preparation for, and the conduct of, a clinical trial will result in substantial increases in our monthly cash burn. A Phase IIb clinical study in North America of Tovaxin in SP-MS is expected to involve 180 patients and take approximately three years to complete. If we are able to commence such a study in the first half of 2012, the costs of such study as well as the ongoing expenses of our operations through the expected completion date of such study are estimated at approximately $32 million. Our existing resources would not be adequate to permit us to proceed materially beyond the initiation of such a study (*i.e.*, the dosing of the first patient) or to complete such study or any significant portion of it. Unless we secure at least a substantial portion of the additional resources that will be necessary to complete the planned Phase IIb study and support our operations during the pendency of such study, or we are reasonably confident that such resources will be secured, we would likely not proceed with the initiation of such study.

Given our need for substantial amounts of capital to undertake a Phase IIb clinical study for Tovaxin in SP-MS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to complete the planned Phase IIb study and to support the operations of the Company during the pendency of such study. In addition to one or more additional financings, these opportunities and alternatives may include a partnering arrangement with a large biotech or pharmaceutical company. There can be no assurance that any such financings or partnering arrangement can be consummated on acceptable terms, if at all.

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

As we have no sources of debt or equity capital committed for funding, we must rely upon best efforts third-party debt or equity funding and 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 2012 and beyond as well as for any clinical study of Tovaxin;
- 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 through any collaboration, partnering or licensing arrangements with third parties, we may need to relinquish some rights to our product candidate Tovaxin, including commercialization rights, which may harm our ability to generate revenues and achieve or sustain profitability.

If we raise additional funds by issuing equity securities, 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 or secure a development partner, we may not be able to undertake, or complete the planned Phase IIb clinical study of Tovaxin in SP-MS or otherwise continue our operations as proposed, which may require us to modify our business plan or curtail various aspects of our operations. If these measures are not sufficient 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.

***We will depend on strategic collaborations with third parties to develop and commercialize product candidates, such as Tovaxin, and we may not have control over a number of key elements relating to the development and commercialization of any such product candidate.***

A key aspect of our strategy, including with respect to Tovaxin, is to seek collaboration with a partner, such as a large pharmaceutical organization, that is willing to further develop and commercialize a selected product candidate. To date, we have not entered into any such collaborative arrangement with respect to Tovaxin. However, we will need to raise significant additional capital in order to undertake the planned Phase IIb clinical study of Tovaxin in SP-MS as the total costs of conducting this study, if commenced in the near-term, as well as the ongoing expenses of our operations through the expected completion date of such study are estimated at approximately $32 million.

By entering into any such strategic collaboration, we may rely on our partner for financial resources and for development, regulatory and commercialization expertise. Our partner may fail to develop or effectively commercialize our product candidate because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources;
- decide to pursue a competitive potential product developed outside of the collaboration;
- cannot obtain the necessary regulatory approvals;
- determine 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.

We may not be able to enter into a collaboration, including with respect to Tovaxin, 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 we are not successful in attracting a partner and entering into a collaboration on acceptable terms, we may not be able to complete development of or commercialize any product candidate, including Tovaxin. In particular, we may be unable to undertake, or complete, the planned Phase IIb clinical study of Tovaxin in SP-MS. 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.

Third parties to whom we may license or transfer development and commercialization rights for products covered by intellectual property rights may not be successful in their efforts, and as a result, we may not receive future royalty or other milestone payments relating to those products or rights.

***We will need regulatory approvals for any product candidate, including Tovaxin, 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 Tovaxin, 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 a Phase IIb clinical trial in North America of our lead product candidate, Tovaxin, in SP-MS will take approximately three years to complete. In addition, we anticipate that a pivotal Phase III clinical trial would be necessary before we could submit an application for approval of Tovaxin for SP-MS. Failure can occur at any stage of the trials, and we could encounter problems that cause us to be unable to initiate a trial, or to abandon or repeat a clinical trial.

The commencement and completion of clinical trials, including the commencement of the planned Phase IIb clinical trial of Tovaxin in SP-MS, 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 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 our product 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 we obtain regulatory approvals for any product candidate, such as Tovaxin, that 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 will be limited by any failure to obtain or limitation on necessary regulatory approvals.

***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 Tovaxin.***

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 Tovaxin. 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.

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 Tovaxin. 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.***

Given that we have limited internal discovery capabilities, our business over the long term is substantially dependent on our ability to license or acquire product candidates and further develop them for commercialization. The success of this strategy depends upon our ability to 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 Tovaxin, for 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 800 square foot suite of three rooms for the manufacture of T-cell therapies. We believe our current facility should have the capacity to support a Phase IIb trial in North America for the development of Tovaxin for SP-MS. It is not sufficient, however, to support potential European clinical trials, if required, or the commercial launch of Tovaxin. In this case, we would need to expand our manufacturing staff and facility, obtain a new facility or contract with corporate collaborators or other third parties to assist with future drug production and commercialization.

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.***

Our ability to successfully commercialize any product we may eventually have 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 we may eventually have 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 we may eventually have 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 we are unable to obtain adequate coverage of and reimbursement for any product we may eventually have from third-party payors, 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 we may eventually have 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 that we develop, such as Tovaxin, 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 Tovaxin, 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 our or any of our partners' sales and marketing strategies;
- 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 that we develop 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 Tovaxin.***

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 Tovaxin, and such claims are ultimately determined to be valid, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost, if at all, or be able to develop or obtain alternative technology. If we are unable to obtain such licenses at a reasonable cost, we may not be able to develop any affected product candidate, such as Tovaxin, commercially. There can be no assurance that we will not be obliged to defend ourselves in court against allegations of infringement of third party patents. Patent litigation is very expensive and could consume substantial resources and create significant uncertainties. An adverse outcome in such a suit could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties, or require us to cease using such technology.

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

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

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 Tovaxin, 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 Tovaxin;
- 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 Tovaxin. 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 Tovaxin, 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 Tovaxin, 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 Tovaxin. Consequently, no assurance can be given that third-party patents containing claims covering Tovaxin, 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 Tovaxin, which could delay development and commercialization.***

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

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

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

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

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

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

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

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 Tovaxin, 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 Tovaxin, 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 collaborators, and our collaborators 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 and Series E warrants are 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 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. 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. During 2010, the trading price of our common stock was minimally above $1.00 per share for brief periods of time, and during 2011, the trading price of our common stock was minimally above and below $1.00 per share for periods of time. Since the end of December 2011, our stock has continued to trade below the minimum bid price continued listing requirement, and our common stock is in jeopardy of being delisted. 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. The notice further stated that we will be provided a period of 180 calendar days to regain compliance. If our common stock maintains a closing bid price of $1.00 per share or more for a minimum of 10 consecutive business days (or such longer period of time as the NASDAQ staff may require in some circumstances, but generally not more than 20 consecutive business days) before August 8, 2012, we will achieve compliance with the listing standards. If our common stock does not achieve compliance with the minimum bid price by August 8, 2012, we may be eligible for an additional 180 day grace period so long as we continue to meet the other listing standards and provide timely notice of our intention to cure the deficiency. However, if it appears to the NASDAQ staff that we will not be able to cure the deficiency, or if we do not meet the other listing standards, NASDAQ could provide notice that our stock will become subject to delisting. We are exercising diligent efforts to maintain the listing of our common stock and warrants on NASDAQ, but there is no assurance we will be able to do so, and if not, our stock could be delisted. It is also possible that we would otherwise fail to satisfy another NASDAQ requirement for continued listing of our common stock. We may receive additional future notices from NASDAQ that we have failed to meet these requirements. If we are unable to cure any such failures in a timely manner and our common stock is delisted, it could be more difficult to buy or sell our common stock and to 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 Tovaxin, including clinical study results and determinations by regulatory authorities with respect thereto;
- the initiation, termination, or reduction in the scope of any collaboration arrangements or any disputes or developments regarding such collaborations;
- 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; or
- regulatory developments in the United States and in foreign countries.

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.***

During 2011, we sold (i) an aggregate of 384,759 shares of common stock in January pursuant to an "at the market" continuous offering program and (ii) an aggregate of 4,146,500 shares of our common stock, and warrants to acquire another 1,658,600 shares, in a public offering in February. 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 23,048,488 shares of common stock were outstanding as of February 15, 2012, and another 13,621,358 shares were issuable upon exercise of outstanding options or warrants. A substantial majority of the outstanding shares of our common stock are freely tradable without restriction or further registration under the Securities Act of 1933. We may sell additional shares of common stock, as well as securities convertible into or exercisable for common stock, in subsequent public or private offerings. We may also issue additional shares of common stock, as well as securities convertible into or exercisable for common stock, to finance future acquisitions. Among other requirements, we will need to raise significant additional capital, or secure a partnering arrangement, in order to undertake the planned Phase IIb clinical study of Tovaxin in SP-MS, 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.

***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 the event we issue additional shares of our capital stock, dilution to our stockholders could result. In addition, if we issue and designate a class of convertible preferred stock, these securities may provide for rights, preferences or privileges senior to, and thus adverse to, those of holders of our common stock.

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

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

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

In addition to general corporate purposes (including working capital and operational purposes), we used part of the approximately $7.6 million net proceeds from the February 2011 public offering to prepare for and proceed toward the initiation of further clinical studies of Tovaxin in MS. We are currently planning to initiate a Phase IIb clinical trial of Tovaxin in SP-MS patients, subject to securing the necessary resources to conduct such a study. We also remain committed to further advancing Tovaxin in RR-MS (also subject to securing the necessary resources to do so). A Phase IIb clinical study of Tovaxin in SP-MS is expected to involve 180 patients and take approximately three years to complete. If we are able to commence such a study in the first half of 2012, the costs of such study as well as the ongoing expenses of our operations through the expected completion date of such study are estimated at approximately $32 million. Our existing resources are not adequate to permit us to proceed materially beyond the initiation of such a study (*i.e.,* the dosing of the first patient) or to complete such study or any significant portion of it. Unless we secure at least a substantial portion of the additional resources that will be necessary to complete the planned Phase IIb study and support our operations during the pendency of such study, or we are reasonably confident that such resources will be secured, we would likely not proceed with the initiation of such study.

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 Tovaxin, 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. RESERVED.**

## 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, 2010** | | |
| First Quarter | $ 2.86 | $ 1.82 |
| Second Quarter | 3.07 | 1.43 |
| Third Quarter | 2.10 | 1.02 |
| Fourth Quarter | 1.66 | 1.29 |
| **Fiscal Year Ended December 31, 2011** | | |
| First Quarter | $ 2.80 | $ 1.52 |
| Second Quarter | 2.01 | 1.59 |
| Third Quarter | 1.64 | 1.11 |
| Fourth Quarter | 1.40 | 0.90 |

The closing price of our common stock on January 31, 2012 was $0.99 per share, and there were approximately 250 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, 2011, 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 | 1,771,705 | $ 1.93 | 2,781,175 |
| Equity Compensation Plans Not Approved by Stockholders | — | — | — |
| Total | 1,771,705 | $ 1.93 | 2,781,175 |

Refer to Note 9 "Options and Warrants" in the Notes to our financial statements for the fiscal year ended December 31, 2011, 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, 2011 with the Year Ended December 31, 2010**

**Net Sales.** We recorded no commercial revenues for the years ended December 31, 2011 and 2010.

**Research and Development Expenses.** Research and development expenses were $3,340,038 for the year ended December 31, 2011, compared to $2,584,734 for the year ended December 31, 2010. The increase in expenses was primarily due to an increase in personnel to conduct increased development activities as well as prepare for our next clinical trial, an increase in development fees, the initiation of key experiments in preparation for our next clinical trial, and an increase in facilities costs due to increased activity in our laboratory, and was partially offset by a decrease in the engagement of consultants and a decrease in stock compensation expense. The increase in research and development expenses for the year ended December 31, 2011 compared to the year ended December 31, 2010 was also due in part to a one-time $244,479 credit received from the Internal Revenue Service during the year ended December 31, 2010 in payment for our application for the Qualifying Therapeutic Discovery Grant for qualifying 2009 research and development expenses. 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 $2,406,269 for the year ended December 31, 2011, as compared to $2,216,043 for the year ended December 31, 2010. The increase in expense is due to an increase in business development costs, an increase in investor relations outreach, an increase in stock compensation expense and an increase in facilities costs, and was partially offset by a reduction in professional service fees.

**Depreciation and Amortization Expenses**. Depreciation and amortization expenses were $210,252 for the year ended December 31, 2011, as compared to $168,843 for the year ended December 31, 2010. 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 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 $3,135 for the year ended December 31, 2011, compared to $500,648 for the year ended December 31, 2010. The decrease in interest expense was primarily related to the amortized interest incurred during the first half of 2010 and the amortization of the remaining discount and deferred financing fees in connection with the June 23, 2010 conversion of the 10% Convertible Promissory Notes (these notes were converted to common stock in June 2010). Interest expense for the twelve months 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 $932 for the year ended December 31, 2011, compared to $1,660 for the year ended December 31, 2010.

**Net Loss.** We had a net loss for the year ended December 31, 2011 of $5,968,448, or $0.26 per share (basic and diluted), compared with a net loss of $5,469,067, or $0.32 per share (basic and diluted), for the year ended December 31, 2010. The increase in net loss is primarily due to increases in research and development, general and administrative, and depreciation expenses, and was partially offset by a decrease in interest expense.

**Liquidity and Capital Resources**

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of December 31, 2011, we had cash and cash equivalents of $7,109,215. Our financing activities generated $8.6 million for the year ended December 31, 2011, compared to approximately $0.04 million for the year ended December 31, 2010. The cash generated in 2011 was proceeds from the sale of our securities in two separate offerings. During January 2011, we sold an aggregate of 384,759 shares of our common stock for net proceeds of $1,066,266 under an "at the market" continuous offering program pursuant to a prospectus supplement dated May 17, 2010. During February 2011, we raised net proceeds of $7,551,891 through a public offering of common stock and warrants pursuant to a prospectus supplement dated February 8, 2011.

Our burn rate during 2011, in the absence of any clinical trial as well as significant activities in preparation for such a trial, was approximately $470,000 per month. If we do not commence a clinical trial, and if we also do not engage in any significant activities in preparation for such a trial, we believe we have sufficient liquidity to support operations through 2012. However, we will need to raise additional capital to fund our current business plan and support our operations.

We currently intend to continue to use our available cash to fund general corporate purposes (including working capital and operational purposes) and to prepare for and proceed toward the initiation of a Phase IIb clinical study of Tovaxin in SP-MS, subject to securing the necessary resources to conduct such a study. We also remain committed to further advancing Tovaxin in RR-MS at a later date (also subject to securing the necessary resources to do so). Significant activities in preparation for, and the conduct of, a clinical trial will result in substantial increases in our monthly cash burn. A Phase IIb clinical study in North America of Tovaxin is expected to involve 180 patients and take approximately three years to complete. If we are able to commence such a study in the first half of 2012, the costs of such study as well as the ongoing expenses of our operations through the expected completion date of such study are estimated at approximately $32 million. Our existing resources would not be adequate to permit us to proceed materially beyond the initiation of such a study (*i.e.,* the dosing of the first patient) or to complete such study or any significant portion of it. Unless we secure at least a substantial portion of the additional resources that will be necessary to complete the planned Phase IIb study and support our operations during the pendency of such study, or we are reasonably confident that such resources will be secured, we would likely not proceed with the initiation of such study.

Given our need for substantial amounts of capital to undertake a Phase IIb clinical study in North America of Tovaxin in SP-MS, we intend to continue to explore potential opportunities and alternatives to obtain the significant additional resources that will be necessary to complete the planned Phase IIb study and to support the operations of the Company during the pendency of such study. In addition to one or more additional financings, these opportunities and alternatives may include a partnering arrangement with a large biotech or pharmaceutical company. There can be no assurance that any such financings or partnering arrangement can be consummated on acceptable terms, if at all.

Assuming we are able to achieve financing which is sufficient to support the planned Phase IIb study in North America and to support our operations during the pendency of such study, we are also exploring a pivotal Phase III clinical study of Tovaxin in RR-MS. Any such study of Tovaxin in RR-MS would also depend upon the availability of sufficient resources.

We do not maintain any external lines of credit, or have commitments for equity funds, and should we need any additional capital in the future, 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. If we are unable to obtain additional funding for operations in the future, 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.

**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, 2011 and 2010, 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 2011 and 2010, none of which are expected to have a material impact on the Company's 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, 2011 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, 2011 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 | 49 | President, Chief Executive Officer, Acting Chief Financial Officer and Director |
| Jaye L. Thompson | 46 | Senior Vice President of Clinical Development and Regulatory Affairs |
| Donna R. Rill | 58 | 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, as Director since September 2008 and as Acting Chief Financial Officer since March 2009. 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.

**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 | 49 | Director |
| Gail J. Maderis | 54 | Director |
| Michael S. Richman | 51 | Director |
| Scott B. Seaman | 56 | Director |
| Neil K. Warma | 49 | Director, President, Chief Executive Officer and Acting Chief Financial Officer |

**David E. Jorden** has served as a Director since August 2008. Mr. Jorden has 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.

**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. Jorden, Richman and Seaman, 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 Messrs. Jorden and Seaman each qualifies 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 document.

**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, 2011.

**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, 2011. Our Named Executive Officers include persons who (i) served as our principal executive officer or acted in a similar capacity during 2010, (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.

**2011 Summary Compensation Table**

| Name and Principal Position | Year | Salary | Bonus | Options Awards(1) | All Other Compensation | Total |
|---|---|---|---|---|---|---|
| Neil K. Warma | 2011 | $ 385,000 | $ 50,000 | $ 115,051 | — | $ 550,051 |
| *President, Chief Executive Officer, Acting Chief Financial Officer* | 2010 | $ 362,083 | $ 50,000 | — | — | $ 412,083 |
| Donna R. Rill | 2011 | $ 200,000 | $ 15,000 | $ 38,350 | — | $ 253,350 |
| *Senior Vice President of Operations and Quality Systems* | 2010 | $ 208,000 | $ 25,000 | — | — | $ 233,000 |
| Jaye L. Thompson, Ph.D. | 2011 | $ 200,000 | $ 15,000 | $ 38,350 | — | $ 253,350 |
| *Senior Vice President of Clinical Development and Regulatory Affairs* | 2010 | $ 200,000 | $ 25,000 | — | — | $ 225,000 |

(1) Amounts in this column represent the aggregate grant date fair value of awards computed in accordance with FASB ASC Topic 718. See Note 9 to our financial statements included in this annual report on Form 10-K for assumptions underlying the valuation of equity awards.

***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; (ii) a one-time payment of $50,000 cash and 25,000 shares of our common stock to be issued if and when the closing bid price of our common stock equals or exceeds $4.00 for 20 consecutive trading days; and (iii) a 10-year stock option to purchase 250,000 shares of common stock with an exercise price of $1.01 per share that vests 50,000 shares immediately and the balance quarterly in equal amounts over three years. In addition, we provided Mr. Warma with relocation assistance and 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.

***2011 Grants of Plan Based Awards***

The following table presents information regarding stock options granted during the fiscal year ended December 31, 2011 pursuant to our 2010 Stock Incentive Plan to our Named Executive Officers.

| Name | Grant Date | Number of Securities Underlying Options | Exercise Price of Option Awards | Grant Date Fair Value of Options[1] |
|---|---|---|---|---|
| Neil K. Warma | 01/04/11 | 75,000[2] | $ 1.56 | $ 115,051 |
| Donna R. Rill | 01/04/11 | 25,000[2] | $ 1.56 | $ 38,350 |
| Jaye L. Thompson | 01/04/11 | 25,000[2] | $ 1.56 | $ 38,350 |

(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. See Note 9 to our financial statements included in this annual report on Form 10-K for assumptions underlying the valuation of equity awards.

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

***2011 Outstanding Equity Awards at Fiscal Year-End***

The following table presents information regarding outstanding equity awards at December 31, 2011 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 | 250,000 | — | $ 1.01 | 06/16/18 |
| | 150,000 | — | $ 0.22 | 01/16/19 |
| | 75,000 | 25,000(1) | $ 2.05 | 11/30/19 |
| | 31,250 | 43,750(1) | $ 1.56 | 01/04/21 |
| Donna R. Rill | 6,000 | — | $ 7.00 | 12/05/15 |
| | 23,380 | — | $ 5.00 | 04/20/16 |
| | 32,000 | — | $ 5.47 | 06/18/17 |
| | 3,000 | — | $ 1.09 | 05/06/18 |
| | 33,000 | — | $ 1.17 | 06/26/18 |
| | 40,000 | — | $ 0.22 | 01/16/19 |
| | 8,396 | — | $ 0.47 | 02/06/19 |
| | 37,500 | 12,500(1) | $ 2.05 | 11/30/19 |
| | 10,417 | 14,583(1) | $ 1.56 | 01/04/21 |
| Jaye L. Thompson | 37,500 | 12,500(1) | $ 2.05 | 11/30/19 |
| | 10,417 | 14,583(1) | $ 1.56 | 01/04/21 |

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

***2011 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, 2011.

| **Name** | **Fees Earned or Paid in Cash** | **Options Awards** | **Total** |
|---|---|---|---|
| David Hung (former director) (1) | — | $ 35,719(2)(3)(4) | $ 35,719 |
| David E. Jorden | $ 60,000(5) | $ 35,719(2)(3)(4) | $ 95,719 |
| Gail J. Maderis (6) | — | $ 23,816(2)(4)(7) | $ 23,816 |
| Michael S. Richman | — | $ 35,719(2)(3)(4) | $ 35,719 |
| Scott B. Seaman | — | $ 35,719(2)(3)(4) | $ 35,719 |

(1) Dr. Hung did not stand for re-election following expiration of his term of office which expired on October 27, 2011.

(2) 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. See Note 9 to our financial statements included in this annual report on Form 10-K for assumptions underlying the valuation of equity awards.

(3) As compensation for Board services, Dr. Hung and Messrs. Jorden, Richman and Seaman were issued the following two options on April 5, 2011 to purchase shares of our common stock at an exercise price of $1.78 per share, the market value on the date of grant: (i) an option to purchase 10,000 shares, with 50% vesting immediately upon grant and the remaining 50% vesting on April 30, 2012; and (ii) an option to purchase 10,500 shares in lieu of cash compensation for services, with 50% vesting immediately upon grant and the remaining 50% vesting on December 31, 2011.

(4) The aggregate number of shares underlying outstanding option awards as of December 31, 2011 was: Dr. Hung, 89,139 shares; Mr. Jorden, 81,269 shares; Ms. Maderis, 23,423 shares; Mr. Richman, 142,039 shares; and Mr. Seaman, 149,539 shares.

(5) Compensation for services as chair of the Audit Committee.

(6) Ms. Maderis was elected as a director at the October 27, 2011 annual meeting of shareholders.

(7) As compensation for Board services, Ms. Maderis was issued the following three options on October 27, 2011 to purchase shares of our common stock at an exercise price of $1.05 per share, the market value on the date of grant: (i) an option to purchase 20,000 shares, with 33.33% vesting immediately upon grant, 33.33% vesting on October 27, 2012 and 33.33% vesting on October 27, 2013; (ii) an option to purchase 1,667 shares, with 50% vesting immediately upon grant and the remaining 50% vesting on April 5, 2012; and (iii) an option to purchase 1,756 shares in lieu of cash compensation for services, with 50% vesting immediately upon grant and the remaining 50% vesting on December 31, 2011.

***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 2011 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 pay a quarterly retainer of $15,000 in cash to the chair of our Audit Committee.

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

The following table sets forth, as of February 15, 2012, the number and percentage of outstanding shares of our common stock beneficially owned by: (a) each person who is known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock; (b) each of our directors; (c) the Named Executive Officers; and (d) all current directors and executive officers, as a group. As of February 15, 2012 there were 23,048,488 shares of common stock issued and outstanding.

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

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

**Beneficial Ownership Table**

| Name and Address of Beneficial Owner(1) | Number of Shares Owned | Percentage of Class |
|---|---|---|
| **Beneficial Owners of more than 5%:** | | |
| Albert and Margaret Alkek Foundation(2) | 2,091,130(3) | 8.82% |
| Charles E. Sheedy(4) | 1,608,159(5) | 6.80% |
| Visium Balanced Master Fund Ltd.(6) | 1,411,785(7) | 6.07% |
| LBI Group, Inc.(8) | 1,461,754(9) | 6.13% |
| Alkek & Williams Ventures Ltd.(10) | 1,302,323(11) | 5.54% |
| | | |
| **Officers and Directors:** | | |
| David E. Jorden | 1,530,386(12) | 6.46% |
| Scott B. Seaman(10) | 1,523,090(13) | 6.43% |
| Neil K. Warma | 566,540(14) | 2.40% |
| Donna R. Rill | 198,502(15) | * |
| Michael S. Richman | 142,039(16) | * |
| Jaye L. Thompson | 55,429(17) | * |
| Gail J. Maderis | 10,090(18) | * |
| | | |
| All directors and executive officers as a group (7 persons)** | 4,026,075(19) | 15.94% |

* 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 13D/A filed with the SEC on December 16, 2009, 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. 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.

(3) Consisting of: (i) 1,432,965 shares of common stock; (ii) 250,000 shares of common stock underlying Series E warrants; (iii) 158,165 shares of common stock underlying Series F warrants; and (iv) 250,000 shares of common stock underlying Series G 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) 804,593 shares of common stock held by DLD Family; (ii) 100,000 shares of common stock underlying Series E warrants held by DLD Family; (iii) 68,781 shares of common stock underlying Series F warrants held by DLD Family; (iv) 100,000 shares of common stock underlying Series G warrants held by DLD Family; (v) 80,000 shares of common stock underlying Series H warrants held by DLD Family; (vi) 26,667 shares of common stock held by Mr. Arnold; (vii) 50,000 shares of common stock held by Mr. Bailey; (viii) 840,814 shares of common stock held by Ventures; (ix) 200,000 shares of common stock underlying Series E warrants held by Ventures; (x) 61,509 shares of common stock underlying Series F warrants held by Ventures; (xi) 200,000 shares of common stock underlying Series G warrants held by Ventures; (xii) 43,655 shares of common stock held by Mr. Seaman; (xiii) 10,000 shares of common stock underlying Series E warrants held by Mr. Seaman; (xiv) 17,573 shares of common stock underlying Series F warrants held by Mr. Seaman; and (xv) 149,539 shares of common stock underlying currently exercisable stock options held by Mr. Seaman.

(4) 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 11, 2011 by Charles E. Sheedy and other information available to us. The mailing address of the beneficial owner is 909 Fannin Street, Suite 2907, Houston, Texas 77010.

(5) Consisting of: (i) 998,423 shares of common stock; (ii) 150,000 shares of common stock underlying Series E warrants; (iii) 353,736 shares of common stock underlying Series F warrants; (iv) 50,000 shares of common stock underlying Series G warrants; and (v) 56,000 shares of common stock underlying Series H warrants.

(6) This information is based on the Schedule 13G filed with the SEC on February 10, 2012, by Visium Balanced Master Fund, Ltd. ("Visium"), Visium Asset Management, LP ("VAM"), JGAsset, LLC ("JGA"), and Jacob Gottlieb (the "Visium 13G") and other information available to us. Pursuant to the Visium 13G, (i) as investment manager to the pooled investment funds, VAM may be deemed to beneficially own the shares beneficially owned by the funds, (ii) as general partner to VAM, JGA may be deemed to beneficially own the shares beneficially owned by VAM, and (iii) as managing member of JGA, Mr. Gottlieb may be deemed the beneficial owner of the shares beneficially owned by JGA, and he has sole voting and dispositive power over the shares. VAM, JGA and Mr. Gottlieb disclaim beneficial ownership of the securities, except to the extent of his or its pecuniary interest therein. The mailing address of the beneficial owner is 950 Third Avenue, New York, NY 10022.

(7) Consisting of: (i) 1,219,785 shares of common stock and (ii) 192,000 shares of common stock underlying Series H warrants.

(8) Lehman Brothers Holdings Inc. exercises sole voting and dispositive power over all of the shares of common stock beneficially owned by LBI Group Inc. The information in this footnote is primarily based on information reported on the Schedule 13G filed with the SEC on August 19, 2008 by LBI Group Inc. The mailing address of the beneficial owner is 399 Park Avenue, New York, New York 10022.

(9) Consisting of: (i) 675,675 shares of common stock and (ii) 786,079 shares of common stock underlying Series F warrants.

(10) 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.

(11) Consisting of: (i) 840,814 shares of common stock; (ii) 200,000 shares of common stock underlying Series E warrants; (iii) 61,509 shares of common stock underlying Series F warrants; and (iv) 200,000 shares of common stock underlying Series G warrants.

(12) Consisting of: (i) 890,000 shares of common stock; (ii) 145,000 shares of common stock underlying Series E warrants; (iii) 314,117 shares of common stock underlying Series F warrants; (iv) 100,000 shares of common stock underlying Series G warrants; and (v) 81,269 shares of common stock underlying currently exercisable stock options.

(13) Consisting of: (i) 840,814 shares of common stock held by Ventures; (ii) 200,000 shares of common stock underlying Series E warrants held by Ventures; (iii) 61,509 shares of common stock underlying Series F Warrants held by Ventures; (iv) 200,000 shares of common stock underlying Series G warrants held by Ventures; (v) 149,539 shares underlying currently exercisable stock options held by Mr. Seaman; (vi) 10,000 shares of common stock underlying Series E warrants held by Mr. Seaman; (vii) 17,573 shares of common stock underlying Series F warrants held by Mr. Seaman; and (viii) 43,655 shares of common stock held by Mr. Seaman. (See footnotes 10 and 11 for additional discussion of the information set forth in clauses (i) through (iv) 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) 1,432,965 shares of common stock held by the Foundation; (ii) 250,000 shares of common stock underlying Series E warrants held by the Foundation; (iii) 158,165 shares of common stock underlying Series F warrants held by the Foundation; and (iv) 250,000 shares of common stock underlying Series G warrants held by the Foundation. (See footnotes 2 and 3 for additional discussion of the information set forth in clauses (i) through (iv) of the preceding sentence.) The mailing address of the beneficial owner is 1100 Louisiana, Suite 5250, Houston, Texas 77002.

(14) Consisting of: (i) 32,234 shares of common stock; (ii) 3,515 shares of common stock underlying Series F warrants; (iii) 10,000 shares of common stock underlying Series G Warrants; and (iv) 520,791 shares of common stock underlying currently exercisable stock options.

(15) Consisting of: (i) 1,610 shares of common stock and (ii) 196,892 shares of common stock underlying currently exercisable stock options.

(16) Consisting of: 142,039 shares of common stock underlying currently exercisable stock options.

(17) Consisting of: (i) 4,313 shares of common stock and (ii) 51,116 shares of common stock underlying currently exercisable stock options.

(18) Consisting of: 10,090 shares of common stock underlying currently exercisable stock options.

(19) Consisting of: (a) the following held by Mr. Jorden: (i) 890,000 shares of common stock; (ii) 145,000 shares of common stock underlying Series E warrants; (iii) 314,117 shares of common stock underlying Series F warrants; (iv) 100,000 shares underlying Series G warrants; and (v) 81,269 shares of common stock underlying currently exercisable stock options; (b) the following held by Mr. Seaman or for which Mr. Seaman may be deemed to have voting and investment power: (i) 840,814 shares of common stock held by Ventures; (ii) 200,000 shares of common stock underlying Series E warrants held by Ventures; (iii) 61,509 shares of common stock underlying Series F warrants held by Ventures; (iv) 200,000 shares of common stock underlying Series G warrants held by Ventures; (v) 149,539 shares of common stock underlying currently exercisable stock options held by Mr. Seaman; (vi) 10,000 shares of common stock underlying Series E warrants held by Mr. Seaman; (vii) 17,573 shares of common stock underlying Series F warrants held by Mr. Seaman; and (viii) 43,655 shares of common stock held by Mr. Seaman; (c) the following held by Mr. Warma: (i) 32,234 shares of common stock; (ii) 3,515 shares of common stock underlying Series F warrants; (iii) 10,000 shares of common stock underlying Series G warrants; and (iv) 520,791 shares of common stock underlying currently exercisable stock options; (d) 1,610 shares of common stock and 196,892 shares of common stock underlying currently exercisable stock options held by Ms. Rill; (e) 142,039 shares of common stock underlying currently exercisable stock options held by Mr. Richman; (f) 4,313 shares of common stock and 55,429 shares of common stock underlying currently exercisable stock options held by Dr. Thompson; and (g) 10,090 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**

The Audit Committee of our Board is responsible for oversight and review of any related person transactions. We have no related person transactions that require disclosure under this section.

**Director Independence**

The Board determined that Ms. Maderis and Messrs. Jorden, Richman and Seaman (and Dr. Hung, during the time he served on our Board), 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 |
|---|---|---|---|---|
| David E. Jorden | X | X | | X |
| Gail J. Maderis | X | | X | X |
| Michael S. Richman | 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, | |
|---|---|---|
| | 2011 | 2010 |
| Audit fees(1) | $ 75,000 | $ 74,185 |
| Tax fees(2) | 3,750 | 10,410 |
| All other fees(3) | 18,022 | 7,340 |
| | $ 96,772 | $ 91,935 |

(1) Audit fees include professional services rendered for (i) the audit of our annual financial statements for the fiscal years ended December 31, 2010 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, 2011 and 2010 and the period from January 22, 2003 (Inception) through December 31, 2011**



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 | Articles of Amendment and Restatement of the Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 19, 2006, File No. 000-25513). |
| 3.2 | Articles of Amendment to the Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 13, 2009). |
| 3.3 | Amended and Restated By-laws, as amended (incorporated by reference to Exhibit 3.3 to the Company's Annual Report on form 10-K filed on March 8, 2011). |
| 4.1 | Form of Common Stock Certificate (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-3 filed on November 13, 2009, File No. 333-163108). |
| 4.2 | Form of Series E Warrant (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form SB-2 (Amendment No. 1) filed December 20, 2007, File No. 333-147167). |
| 4.3 | Warrant Agent Agreement by and between the Company and Continental Stock Transfer & Trust Company dated February 13, 2008 for the Series E Warrants (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed February 14, 2008). |
| 4.4 | Form of Underwriters' Warrant Agreement by and between the Company and each underwriter party thereto for the Series E Warrants (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed February 14, 2008). |
| 4.5 | Form of Underwriters' Warrant to Acquire Warrants Agreement by and between the Company and each underwriter party thereto for the Series E Warrants (incorporated by reference to Exhibit 4.5 to the Company's Current Report on Form 8-K filed February 14, 2008). |
| 4.6 | Unit Purchase Agreement dated August 8, 2008 by and among the Company 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). |

| Exhibit No. | Description |
|---|---|
| 4.7 | 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). |
| 4.8 | Registration Rights Agreement dated August 8, 2008 between the Company 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). |
| 4.9 | Unit Purchase Agreement dated April 14, 2009 by and among the Company 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). |
| 4.10 | Form of Series G Warrant issued by the Company 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). |
| 4.11 | Placement Agent Agreement dated December 9, 2009 by and between the Company and Rodman & Renshaw, LLC for Unit offering of Common Stock and Series A and Series B Warrants (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed December 10, 2009). |
| 4.12 | Form of Securities Purchase Agreement dated as of December 9, 2009 by and between the Company 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). |
| 4.13 | 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). |
| 4.14 | Form of Series H Warrant issued by the Company 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). |
| 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 the Company 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 the Company 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 the Company 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 the Company 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 the Company 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 the Company 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 Current Report on Form 8-K filed November 4, 2011). |

| Exhibit No. | Description |
|---|---|
| 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 | Continuous Offering Program Agreement dated May 14, 2010 by and between the Company and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on May 17, 2010) (subsequently terminated February 7, 2011 as disclosed in the Company's Current Report on Form 8-K filed on February 7, 2011). |
| 10.13 | Assignment Agreement and General Release, dated November 2, 2011, by and between Opexa Therapeutics, Inc. and Novartis Institutes for BioMedical Research, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 4, 2011). |
| 23.1* | Consent of Independent Registered Public Accounting Firm MaloneBailey, LLP, dated February 27, 2012 to the incorporation by reference of their report dated February 27, 2012, in the Company's Registration Statements on Form S-8 and S-3. |
| 31.1* | Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1* | Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

* Filed herewith

\+ Management contract or compensatory plan or arrangement.

**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, Chief Executive Officer and
Acting Chief Financial Officer

Date: February 27, 2012

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

| Signature | Title | Date |
|---|---|---|
| **/s/ Neil K. Warma**<br>**Neil K. Warma** | President and Chief Executive Officer<br>*(Principal Executive Officer)*<br>Acting Chief Financial Officer<br>*(Principal Financial and Accounting Officer)*<br>Director | February 27, 2012 |
| **/s/ David E. Jorden**<br>**David E. Jorden** | Director | February 27, 2012 |
| **/s/ Gail J. Maderis**<br>**Gail J. Maderis** | Director | February 27, 2012 |
| **/s/ Michael S. Richman**<br>**Michael S. Richman** | Director | February 27, 2012 |
| **/s/ Scott B. Seaman**<br>**Scott B. Seaman** | Director | February 27, 2012 |

**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 balance sheets of Opexa Therapeutics, Inc. (a development stage company), as of December 31, 2011 and 2010 and the related 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, 2011. 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, 2011 and 2010 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, 2011 in conformity with accounting principles generally accepted in the United States of America.

/s/ MALONEBAILEY, LLP
www.malonebailey.com
Houston, Texas
February 27, 2012

**OPEXA THERAPEUTICS, INC.**
**(a development stage company)**

**BALANCE SHEETS**

| | December 31, 2011 | December 31, 2010 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 7,109,215 | $ 3,812,535 |
| Other current assets | 124,773 | 85,525 |
| Total current assets | 7,233,988 | 3,898,060 |
| Property & equipment, net of accumulated depreciation of $1,193,601 and $1,109,558, respectively | 1,029,236 | 815,958 |
| Total assets | $ 8,263,224 | $ 4,714,018 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 476,315 | $ 358,837 |
| Accounts payable—related parties | 15,000 | 15,000 |
| Accrued expenses | 576,545 | 335,861 |
| Current maturity of loan payable | — | 35,607 |
| Total current liabilities | 1,067,860 | 745,305 |
| Total liabilities | 1,067,860 | 745,305 |
| | | |
| 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, 23,048,488 and 18,466,924 shares issued and outstanding | 230,485 | 184,670 |
| Additional paid in capital | 107,645,666 | 98,496,382 |
| Deficit accumulated during the development stage | (100,680,787) | (94,712,339) |
| Total stockholders' equity | 7,195,364 | 3,968,713 |
| Total liabilities and stockholders' equity | $ 8,263,224 | $ 4,714,018 |

See accompanying summary of accounting policies and notes to financial statements

**OPEXA THERAPEUTICS, INC.**
**(a development stage company)**

**STATEMENTS OF EXPENSES**
**Years ended December 31, 2011 and 2010 and the**
**Period from January 22, 2003 (Inception) to December 31, 2011**

| | 2011 | 2010 | Inception through 2011 |
|---|---|---|---|
| Research and development | $ 3,340,038 | $ 2,584,734 | $ 70,178,875 |
| General and administrative | 2,406,269 | 2,216,043 | 27,609,075 |
| Depreciation | 210,252 | 168,843 | 1,346,481 |
| Loss on disposal of fixed assets | 9,686 | 459 | 510,248 |
| Operating loss | (5,966,245) | (4,970,079) | (99,644,679) |
| Interest income | 932 | 1,660 | 1,358,417 |
| Other income and expense, net | — | — | 661,146 |
| Gain on extinguishment of debt | — | — | 1,612,440 |
| Gain (loss) on derivative instruments | — | — | 1,388,848 |
| Gain on sale of technology | — | — | 3,000,000 |
| Interest expense | (3,135) | (500,648) | (9,056,959) |
| Net loss | $ (5,968,448) | $ (5,469,067) | $ (100,680,787) |
| Basic and diluted loss per share | $ (0.26) | $ (0.32) | |
| Weighted average shares outstanding | 22,532,498 | 17,071,691 | |

See accompanying summary of accounting policies and notes to financial statements

**OPEXA THERAPEUTICS, INC.**
**(a development stage company)**

**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**
**Period from January 22, 2003 (Inception) through December 31, 2011**

| | Common Stock | | Additional Paid in Capital | Accumulated Deficit | Total |
|---|---|---|---|---|---|
| | Shares | Par | | | |
| Shares issued for cash | 525,000 | $ 262,500 | $ (261,500) | $ — | $ 1,000 |
| Shares repurchased and cancelled | (170,625) | (85,313) | 84,988 | — | (325) |
| Discount related to: | | | | | |
| beneficial conversion feature | — | — | 28,180 | — | 28,180 |
| warrants attached to debt | — | — | 28,180 | — | 28,180 |
| Net loss | — | — | — | (126,003) | (126,003) |
| Balances at December 31, 2003 | 354,375 | 177,187 | (120,152) | (126,003) | (68,968) |
| Shares issued for: | | | | | |
| cash | 2,250 | 1,125 | 7,875 | — | 9,000 |
| services | 206,500 | 103,250 | 745,750 | — | 849,000 |
| license | 24,269 | 12,135 | 414,940 | — | 427,075 |
| reverse merger with Sportan | 99,740 | 49,870 | (197,603) | — | (147,733) |
| acquisition of Opexa | 250,000 | 125,000 | 23,625,000 | — | 23,750,000 |
| additional shares attached to convertible debt | 16,100 | 8,050 | 280,316 | — | 288,366 |
| conversion of convertible notes | 60,750 | 30,375 | 217,995 | — | 248,370 |
| Shares cancelled | (8,000) | (4,000) | 4,000 | — | — |
| Discount related to: | | | | | |
| beneficial conversion feature | — | — | 855,849 | — | 855,849 |
| 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 | 1,005,984 | 502,992 | 27,805,805 | (31,537,739) | (3,228,942) |
| Shares issued for: | | | | | |
| cash, net of offering costs | 389,451 | 194,725 | 5,151,492 | — | 5,346,217 |
| convertible debt | 611,026 | 305,513 | 7,343,933 | — | 7,649,446 |
| debt | 2,300 | 1,150 | 159,850 | — | 161,000 |
| license | 29,194 | 14,597 | 1,853,787 | — | 1,868,384 |
| services | 24,000 | 12,000 | 1,000,400 | — | 1,012,400 |
| Discount related to: | | | | | |
| beneficial conversion feature | — | — | 831,944 | — | 831,944 |
| 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 | 2,061,955 | 1,030,977 | 39,783,452 | (46,394,463) | (5,580,034) |
| Shares issued for: | | | | | |
| cash, net of offering costs | 4,600,000 | 2,300,000 | 18,853,519 | — | 21,153,519 |
| debt | 34,829 | 17,374 | 162,626 | — | 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 | 6,696,784 | 3,348,351 | 63,118,180 | (59,043,633) | 7,422,898 |

**OPEXA THERAPEUTICS, INC.**
**(a development stage company)**

**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY—(Continued)**
**Period from January 22, 2003 (Inception) through December 31, 2011**

| | 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 | 6,696,784 | 3,348,351 | 76,498,054 | (77,712,820) | 2,133,585 |
| Shares issued for: | | | | | |
| cash, net of offering costs | 5,503,874 | 2,751,937 | 5,899,642 | — | 8,651,579 |
| services | 45,200 | 22,600 | 26,365 | — | 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 | 12,245,858 | 6,122,888 | 84,929,481 | (89,564,972) | 1,487,397 |
| Cumulative effect of change in accounting principle | | | (1,976,457) | 1,755,622 | (220,835) |
| Par value adjustment | — | (6,329,888) | 6,329,888 | — | — |
| 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 | 2,550,000 | 25,500 | 4,663,665 | — | 4,689,165 |
| exercise of options | 60,400 | 26,280 | 37,324 | — | 63,604 |
| exercise of warrants | 619,964 | 309,982 | 764,953 | — | 1,074,935 |
| Option expense | — | — | 650,249 | — | 650,249 |
| Net loss | — | — | — | (1,433,922) | (1,433,922) |
| Balances at December 31, 2009 | 15,476,222 | 154,762 | 96,463,658 | (89,243,272) | 7,375,148 |
| Shares issued for: | | | | | |
| conversion of convertible notes | 2,760,181 | 27,602 | 1,352,489 | — | 1,380,091 |
| exercise of options | 141,520 | 1,416 | 108,225 | — | 109,641 |
| exercise of warrants | 34,001 | 340 | (340) | — | — |
| services | 55,000 | 550 | 63,800 | — | 64,350 |
| Option expense | — | — | 508,550 | — | 508,550 |
| Net loss | — | — | — | (5,469,067) | (5,469,067) |
| Balances at December 31, 2010 | 18,466,924 | 184,670 | 98,496,382 | (94,712,339) | 3,968,713 |
| Shares issued for: | | | | | |
| cash, net of offering costs | 4,531,259 | 45,312 | 8,572,845 | — | 8,618,157 |
| services | 50,305 | 503 | 86,525 | — | 87,028 |
| Option expense | — | — | 489,914 | — | 489,914 |
| Net loss | — | — | — | (5,968,448) | (5,968,448) |
| Balances at December 31, 2011 | 23,048,488 | $ 230,485 | $ 107,645,666 | $ (100,680,787) | $ 7,195,364 |

See accompanying summary of accounting policies and notes to financial statements

**OPEXA THERAPEUTICS, INC.**
**(a development stage company)**

**STATEMENTS OF CASH FLOWS**
**Years ended December 31, 2011 and 2010 and the**
**Period from January 22, 2003 (Inception) to December 31, 2011**

| | 2011 | 2010 | Inception through 2011 |
|---|---|---|---|
| Cash flows from operating activities | | | |
| Net loss | $ (5,968,448) | $ (5,469,067) | $ (100,680,787) |
| 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 | 64,350 | 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 | — | 314,749 | 6,752,698 |
| Gain on extinguishment of debt | — | — | (1,612,440) |
| Depreciation | 210,252 | 168,843 | 1,346,481 |
| Amortization of debt financing costs | — | 108,117 | 524,378 |
| Option and warrant expense | 489,914 | 508,550 | 15,575,207 |
| Loss (gain) on derivative instruments | — | — | (1,388,848) |
| Loss on disposal of fixed assets | 9,686 | 459 | 510,248 |
| Changes in: | | | |
| Accounts receivable | 26,245 | (26,245) | — |
| Prepaid and other expenses | (65,493) | 19,909 | (541,446) |
| Accounts payable – third parties and related parties | (13,028) | (251,765) | (89,241) |
| Accrued expenses | 234,923 | 186,087 | 522,220 |
| Net cash used in operating activities | (4,988,921) | (4,376,013) | (50,511,688) |
| Cash flows from investing activities | | | |
| Purchase of property & equipment | (296,949) | (35,350) | (1,671,810) |
| Net cash used in investing activities | (296,949) | (35,350) | (1,671,810) |
| Cash flows from financing activities | | | |
| Common stock and warrants sold for cash, net of offering costs | 8,618,157 | — | 49,072,488 |
| Common stock repurchased and canceled | — | — | (325) |
| Proceeds from exercise of warrants and options | — | 109,641 | 1,248,588 |
| Proceeds from debt | — | — | 9,283,184 |
| Repayments on loan payable | (35,607) | (67,325) | (311,222) |
| Net cash provided by financing activities | 8,582,550 | 42,316 | 59,292,713 |
| Net change in cash and cash equivalents | 3,296,680 | (4,369,047) | 7,109,215 |
| Cash and cash equivalents at beginning of period | 3,812,535 | 8,181,582 | — |
| Cash and cash equivalents at end of period | $ 7,109,215 | $ 3,812,535 | $ 7,109,215 |
| Cash paid for: | | | |
| Income tax | $ — | $ — | $ — |
| Interest | 3,135 | $ 86,491 | 153,163 |
| | | | |
| NON-CASH TRANSACTIONS | | | |
| Issuance of common stock to Sportan shareholders | — | — | 147,733 |
| Issuance of common stock for accrued interest | — | 78,091 | 603,604 |
| Issuance of warrants to placement agent | — | — | 37,453 |
| Conversion of notes payable to common stock | — | 1,302,000 | 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 | — | — | 3,659,737 |
| Beneficial conversion feature | — | — | 1,805,519 |
| Stock attached to notes | — | — | 1,287,440 |
| Fair value of derivative instrument | — | — | 4,680,220 |
| Derivative reclassified to equity | — | — | 587,609 |
| Unpaid additions to property and equipment | 136,266 | — | 136,266 |

See accompanying summary of accounting policies and notes to financial statements

**NOTE 1—BUSINESS OVERVIEW AND SUMMARY OF ACCOUNTING POLICIES**

Opexa Therapeutics, Inc. ("Opexa" or "the Company") was incorporated in Texas in March 1991 as a bio-pharmaceutical company engaged in developing autologous personalized cellular therapies. During the development stage, Opexa acquired the worldwide license to technology developed at Argonne National Laboratory, a U.S. Department of Energy Laboratory operated by the University of Chicago ("Argonne"). This is an exclusive license to a stem cell technology in which adult multi-potent stem cells are derived from monocytes obtained from the patient's own blood (the "License"). A patent application was filed in November 2003 with the United States Patent and Trade Office regarding the technology involved in the License.

In June 2004, PharmaFrontiers Corp. ("Pharma") was acquired by Sportan United Industries, Inc. ("Sportan") in a transaction accounted for as a reverse acquisition. Pharma's stockholders were issued 6,386,439 Sportan shares in exchange for 100 percent of the outstanding common shares of Pharma. Immediately following the transaction, Sportan changed its name to Pharma and 7,383,838 shares were outstanding.

On October 7, 2004, Opexa acquired all of the outstanding stock of Opexa Pharmaceuticals, Inc., an entity that has the exclusive worldwide license from Baylor College of Medicine to an individualized T-cell therapeutic vaccine, Tovaxin®, for the treatment of multiple sclerosis (MS).

In June 2006, Opexa (i) changed its name to Opexa Therapeutics, Inc. from Pharma and (ii) effected a one-for-ten reverse common stock split (the "Split"). In January 2007, Opexa Therapeutics, Inc., the parent, merged with its wholly owned subsidiary, Opexa Pharmaceuticals, Inc. with Opexa Therapeutics, Inc. being the surviving company.

In August 2009, Opexa entered into an exclusive agreement with Novartis whereby Novartis acquired Opexa's rights to the stem cell 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. On November 2, 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, including the remaining $0.5 million technology transfer milestone payment. In connection with the re-acquisition of the stem cell assets, a related license agreement with the University of Chicago was assigned back to Opexa. Opexa and the University of Chicago entered into a Fourth Amended and Restated License Agreement in connection with such assignment to Opexa.

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

**Basis of Presentation.** All references to number of shares and per share amounts reflect the Split as if it occurred on the first day of the first period presented. The financial statements include the accounts of Opexa and its former wholly-owned subsidiary, Opexa Pharmaceuticals, Inc. through December 31, 2006. All inter-company accounts and transactions have been eliminated.

**Reclassifications.** Certain prior year amounts have been reclassified to conform with the current year presentation.

**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.

**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.

**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.

**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 include salaries, related employee expenses, clinical trial expenses, research expenses, consulting fees, and laboratory costs. All costs for research and development activities are expensed as incurred. 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, 2011 and 2010 was $3,340,038 and $2,584,734, respectively.

**NOTE 2—CASH AND CASH EQUIVALENTS**

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

At December 31, 2010, Opexa invested approximately $3.7 million in a money market account with an average market yield of 0.03%. Interest income of $1,660 was recognized for the year ended December 31, 2010 in the statements of expenses.

**NOTE 3—PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following at December 31, 2011 and 2010:

| Description | Life | 2011 | 2010 |
|---|---|---|---|
| Computer equipment | 3 years | $ 99,603 | $ 117,789 |
| Office furniture and equipment | 5-7 years | 251,170 | 246,117 |
| Software | 3 years | 96,097 | 80,480 |
| Laboratory equipment | 7 years | 994,994 | 990,961 |
| Leasehold improvements | 10 years | 603,445 | 465,601 |
| Manufacturing equipment | 7 years | 177,528 | 24,568 |
| Subtotal | | 2,222,837 | 1,925,516 |
| Less: accumulated depreciation | | (1,193,601) | (1,109,558) |
| Property and equipment, net | | $ 1,029,236 | $ 815,958 |

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 $210,252 and $168,843 for the years ended December 31, 2011 and 2010, respectively.

**NOTE 4—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, 2011, Opexa had approximately $61 million of unused net operating losses available for carryforward to future years. The unused net operating losses begin to expire at December 31, 2024. At December 31, 2011, Opexa's deferred tax asset resulting from its cumulative NOLs amounted to $20,876,592 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.

During 2010, Opexa received a direct payment of $244,479 from the Internal Revenue Service in payment of their application for the Qualifying Therapeutic Discovery Grant. Opexa accounted for this payment as a reduction of research and development expenses for the year ended December 31, 2010.

**NOTE 5—LOAN PAYABLE**

Loan payable consisted of an equipment line of up to $250,000 with Wells Fargo of which $0 and $35,607 were outstanding as of December 31, 2011 and 2010, respectively. This loan had an interest rate of 7.61% per annum, matured in June 2011 and was secured by Opexa's furniture and equipment purchased with the loan proceeds. For the years ended December 31, 2011 and 2010, Opexa recognized interest expense of $775 and $5,522, respectively, associated with its equipment line.

**NOTE 6—CONVERTIBLE PROMISSORY NOTES**

On April 14, 2009 and May 14, 2009, Opexa closed a private offering consisting of secured convertible notes (the "Notes") for gross proceeds of approximately $1.3 million. The Notes matured in two years from the date of issue and accrued interest at a 10% rate, compounded annually. The interest was payable at maturity in either cash or common stock at Opexa's option. The Notes were secured by substantially all of Opexa's assets and were convertible into common stock, at the option of the holders, at a price of $0.50 per share. Additionally, subject to the satisfaction of certain conditions, the Notes were mandatorily convertible into common stock, at Opexa's option, during their term also at $0.50 per share. The required conditions were: (1) Opexa enters into an agreement that will fund a Phase IIb or Phase III clinical trial for the further development of Opexa's product known as Tovaxin®, (2) Opexa's common stock trades at a price greater than or equal to $1.00 per share for 20 consecutive trading days, and (3) Opexa has an effective registration statement on file with the Securities and Exchange Commission for the resale of the shares of common stock issuable upon conversion of the Notes.

In connection with the issuance of the Notes, warrants to purchase a total of 1,302,000 shares of common stock were issued to the investors. See Note 9 "Broker and Investor Warrants" for details on the warrants. The Notes were evaluated for a beneficial conversion feature under FASB ASC 470 and determined to have a beneficial conversion feature totaling $89,546. Opexa recorded a debt discount of $439,493 related to the warrants granted to the investors. Pursuant to FASB ASC 470, the discount on the Notes is amortized over the period between the issuance date and the maturity of the Notes under the effective interest method.

Opexa analyzed the Notes and the warrants for derivative accounting consideration under FASB ASC 470. Opexa determined the embedded conversion option in the Notes and the warrants met the criteria for classification in stockholders equity under FASB ASC 470. Therefore, derivative accounting was not applicable for these Notes payable or their associated warrants.

The total of the fees associated with the financing (broker commissions and legal fees) were $158,468. These fees were to be amortized over the life of the Notes using the effective interest method.

Upon notice of Opexa's intent to prepay the then outstanding $1.25 million aggregate principal balance of the Notes in full on June 23, 2010, the noteholders elected to convert the outstanding principal balance of the Notes into shares of Opexa common stock at the conversion price of $0.50 pursuant to the terms of the Notes. The conversion of all outstanding Notes was effected June 23, 2010, with one Note for $50,000 in principal amount having been previously converted in May 2010 by the holder thereof into 100,000 shares of Opexa common stock pursuant to the terms thereof.

In settlement of accrued and unpaid interest on the Notes in the approximate amount of $156,000, the noteholders accepted Opexa's offer to pay 50% of the accrued interest to June 23, 2010 in cash and 50% of the accrued interest to June 23, 2010 in shares of common stock calculated at the same $0.50 conversion price. As a condition to accepting Opexa's offer, each noteholder agreed to immediately terminate and release the security interest associated with the Notes as well as Opexa's obligations under the Unit Purchase Agreement, Registration Rights Agreement and Security Agreement that were executed in connection with the original issuance of the Notes.

The conversion of the Notes and payment of accrued interest resulted in the issuance of an aggregate of 2,760,181 shares of common stock and an aggregate cash payment in the amount of $78,115. As debt was extinguished in exchange for equity pursuant to a preexisting contractual obligation recognized in the financial statements, management has concluded that no gain or loss should be recognized upon the conversion. As of the date of the conversion, the unamortized discount related to the beneficial conversion feature and the warrants issued with the Notes amounting to $211,590 as well as the unamortized deferred financing costs of $70,191 were charged to interest expense for the year ended December 31, 2010.

**NOTE 7—COMMITMENTS AND CONTINGENCIES**

In October 2005, Opexa entered into a ten-year lease for its office and research facilities. The facility including the property is leased for a term of ten years with two options for an additional five years each at the then prevailing market rate. Future minimum lease payments under the non-cancellable operating lease are $150,133 for 2012, $157,896 for 2013, $157,896 for 2014 and $118,422 for 2015. Rent expense was approximately $136,000 for each of the years ended December 31, 2011 and 2010.

**NOTE 8—EQUITY**

During 2003, equity related transactions were as follows:

- 525,000 shares of common stock were sold for $1,000.
- 170,625 shares were reacquired for $325 and canceled.
- Additional contributions to capital of $56,360 resulted from the discounted value to notes payable due to warrants and beneficial conversion features attached to convertible notes was issued in 2003.

During 2004, equity related transactions were as follows:

- 2,250 shares of common stock were sold for $9,000.
- 206,500 shares of common stock valued at their then fair value of $849,000 were issued to employees and consultants for their services.
- 24,269 shares of common stock valued at their then fair value of $427,075 were issued to the University of Chicago per the terms of a license agreement. See Note 11 for details.
- 99,740 shares of common stock were issued for net liabilities of $147,733 pursuant to the 2004 reorganization.
- 250,000 shares of common stock valued at their then fair value of $23,750,000 were issued to Opexa Pharmaceuticals, Inc. stockholders.
- 16,100 shares of common stock with a relative fair value of $288,366 were issued to noteholders as their additional shares for their subscription investment.
- 60,750 shares of common stock were issued to noteholders for the conversion of $248,370 of principal and interest from convertible notes.
- 8,000 shares of common stock were cancelled pursuant to the terms of an employment separation agreement.
- Additional contributions to capital of $2,704,351 resulted from the discounted value to notes payable from warrants and beneficial conversion features attached to convertible notes.
- Employee stock option compensation expense was $123,333 for 2004.

During 2005, equity related transactions were as follows:

- 389,451 shares of common stock with warrants to purchase 1,070,993 shares were sold for $5,841,769. The relative fair value of the common stock was $1,103,714 and the relative fair value of the warrants was $4,738,055. Offering costs of $495,552 related to shares issued were charged to additional paid in capital.
- 45,168 shares of common stock with a relative fair value of $999,074 were issued to noteholders as their additional shares for their subscription investment.
- 565,858 shares of common stock were issued to noteholders for the conversion of $6,124,859 of principal and $525,513 interest from convertible notes.
- 2,300 shares of common stock valued at their fair value of $161,000 were issued to noteholders for the conversion of $51,930 of principal and interest from the notes.
- 29,194 shares of common stock were issued to the University of Chicago per the terms of a license agreement. These shares were recorded at $1,868,384. See Note 11 for details.
- 24,000 shares of common stock valued at their fair value of $1,012,400 were issued to consultants for their services.
- Additional contributions to capital of $2,265,052 relating to the discounted value to notes payable from warrants, beneficial conversion features attached to convertible notes.
- Employee stock option compensation expense was $2,487,741 for 2005.
- Non-employee stock option compensation expense was $2,373,888 for 2005.
- Transition of warrants from equity instruments to liability instruments in the amount of $10,658,496 was recorded.

During 2006, equity related transactions were as follows:

- In March 2006, 34,829 shares of common stock were issued to settle an outstanding accounts payable in the amount of $180,000.
- In April 2006, Opexa sold 4,600,000 shares of its common stock and warrants to purchase 2,300,000 shares of Opexa's common stock for $23 million. Opexa paid $1,846,481 for the commissions and fees related to this offering and granted to its brokers warrants to purchase 213,720 shares of common stock at an exercise price of $5.00 per share. These warrants are not callable and have a cashless exercise option.
- Employee stock option compensation expense was $2,749,617 for 2006.
- Non-employee stock option compensation expense was $1,568,966 for 2006.

During 2007, equity related transactions were as follows:

- Employee stock option compensation expense was $1,876,103 for 2007.
- Non-employee stock option compensation expense was $845,275 for 2007.

During 2008, equity related transactions were as follows:

- In February 2008, Opexa sold 3,500,000 shares of common stock and 4,025,000 Series E warrants in a public offering for approximately $7.6 million. Opexa paid approximately $1.2 million for the underwriter discounts, commissions and other expenses related to this offering and granted to the underwriter warrants to purchase 350,000 shares of common stock at a price of $2.40 per share and an option to acquire 350,000 Series E warrants at a price of $0.18 per Series E warrant.

- In August, Opexa sold 2,003,874 shares of common stock and Series F warrants to purchase 2,003,874 shares of common stock in a private offering to certain institutional and accredited investors for approximately $3.0 million. Opexa paid approximately $100,000 in expenses related to this offering.

- 45,200 shares of restricted common stock valued at $48,965 were issued to Board members as compensation for their Board services.

- Employee stock option compensation expense was $1,467,364 for 2008.

- Non-employee stock option compensation expense was $434,207 for 2008.

During 2009, equity related transactions were as follows:

- In December 2009, Opexa sold 2,550,000 shares of its common stock and warrants to purchase 1,275,000 shares of Opexa's common stock for $5.1 million. Opexa paid $310,500 for the commissions related to this offering and granted broker warrants to purchase 89,250 shares of common stock at an exercise price of $2.50 per share. These warrants are not callable and have a cashless exercise option.

- 60,400 shares of common stock were issued in connection with the exercise of stock options.

- 48,200 shares of common stock were issued in connection with the exercise of Series E warrants.

- 472,968 shares of common stock were issued in connection with the exercise of Series F warrants

- 98,796 shares of common stock were issued in connection with the exercise of broker warrants.

- On November 11, 2009, the Company's stockholders approved an amendment to the Articles of Incorporation reducing the par value of the common stock from $.50 to $.01 per share. As a result of the reduction in par value, the "Common stock" account was reduced by $6,329,888 and the "Additional paid-in capital" account was increased by the same amount in the accompanying Statements of Changes in Stockholders' Equity.

During 2010, equity related transactions were as follows:

- In June 2010, 2,760,181 shares of common stock were issued to noteholders for the conversion of $1,302,000 of principal and $78,091 of accrued interest from the 10% Convertible Promissory Notes.

- 141,520 shares of common stock were issued in connection with the exercise of stock options.

- 34,001 shares of common stock were issued in connection with the cashless exercise of broker warrants.

- 55,000 shares of common stock valued at their fair value of $64,350 were issued to a consultant in exchange for services.

During 2011, equity related transactions were as follows:

- In January 2011, 384,759 shares of common stock were sold under the Continuous Offering Program Agreement dated May 14, 2010 (the "ATM Agreement") for net proceeds of $1,066,266. Compensation and fees totaling $10,826 was paid to the placement agent with respect to the shares sold. The ATM Agreement was subsequently terminated by Opexa on February 7, 2011.

- In February 2011, an aggregate of 4,146,500 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, having a five-year term and an exercise price of $2.61 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.

- 50,305 shares of common stock valued at their fair value of $87,028 were issued to a consultant in exchange for services.

**NOTE 9—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 2,300,000 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 2,500,000 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 2,066,800 shares. The 2010 Plan provides for the grant of either 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 2004, options to purchase 96,500 shares were granted to employees at exercise prices ranging from $30.00 to $50.00. These options have terms of five years and vest from one to three years. Fair value of $5,623,186 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, 2004 include (1) discount rate of 2%, (2) option life of five years, (3) expected volatility of 75.1% and (4) zero expected dividends.

During 2005, options to purchase 63,050 shares were granted to employees at an exercise price of $7.00. These options have terms of ten years and vest in four years. Fair value of $261,879 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, 2005 include (1) discount rate of 2%, (2) option life of ten years, (3) expected volatility of 175.4% and (4) zero expected dividends.

During 2005, options to purchase 4,167 shares were forfeited and cancelled.

During 2006, options to purchase 389,160 shares of common stock were granted by Opexa to its employees at exercise prices ranging from $5.00 to $9.40. These options have terms from five to ten years and vest from one to three years. Fair value of $3,126,168 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, 2006 include (1) discount rate range of 4.72% to 5.22%, (2) option life of five to ten years, (3) expected volatility range of 401.3% to 429.9% and (4) zero expected dividends.

During 2006, options to purchase 14,133 shares were forfeited.

Opexa recorded $2,749,617 stock-based compensation expense to management and employees during 2006.

During 2007, options to purchase 224,400 shares of common stock were granted by Opexa to its employees at exercise prices ranging from $3.96 to $5.47. These options have terms of ten years and vest annually over a three year period. Fair value of $958,011 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, 2007 include (1) discount rate range of 4.22% to 5.07%, (2) option life is a term with the expected term of five to six years, (3) expected volatility range of 95.4% to 103.9% and (4) zero expected dividends.

During 2007, options to purchase 17,345 shares were forfeited.

Opexa recorded $1,876,103 stock-based compensation expense to management and employees during 2007.

During 2008, options to purchase 469,100 shares of common stock were granted by Opexa to its employees at exercise prices ranging from $1.09 to $1.17. These options have terms of ten years and have vesting ranges from 8 months to three years. Fair value of $433,164 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, 2008 include (1) discount rate range of 3.15% to 3.73%, (2) option life is a term with the expected term of five to six years, (3) expected volatility of 115.3% and (4) zero expected dividends.

During 2008, options to purchase 104,578 shares were forfeited.

Opexa recorded $1,467,364 stock-based compensation expense to management and employees during 2008.

During 2009, options to purchase 535,959 shares of common stock were granted by Opexa to its employees at exercise prices ranging from $0.22 to $2.05. These options have terms of ten years and have vesting ranges from 6 months to three years. Fair value of $512,919 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, 2009 include (1) discount rate range of 1.47% to 2.01%, (2) option life is a term with the expected term of five to six years, (3) expected volatility of 192.4%—207.7% and (4) zero expected dividends.

During 2009, options to purchase 228,786 shares were forfeited.

Opexa recorded $402,803 stock-based compensation expense to management and employees during 2009. Unamortized stock-based compensation expense as of December 31, 2009 amounted to $586,467.

During 2010, options to purchase 60,000 shares of common stock were granted by Opexa to its employees at exercise prices ranging from $1.53 to $2.25. These options have a term of ten years and vest over three years. Fair value of $112,313 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, 2010 include (1) discount rate range of 1.93% to 2.78%, (2) option life is an expected term of six to eight years, (3) expected volatility of 206.0%—212.1% and (4) zero expected dividends.

During 2010, options to purchase 352,578 shares were forfeited and cancelled.

Opexa recorded $289,413 stock-based compensation expense to management and employees during 2010. Unamortized stock-based compensation expense as of December 31, 2010 amounted to $399,638.

During 2011, options to purchase 175,000 shares of common stock were granted by Opexa to its employees at an exercise price of $1.56. 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) option life is an expected term of six years, (3) expected volatility of 192.4% and (4) zero expected dividends.

During 2011, options to purchase 75,000 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.

***Non-Employee Options:***

During 2004, options to purchase 20,000 shares were granted to consultants at exercise prices ranging from $30.00 to $50.00. These options have terms of five years and vest from one to three years. Fair value of $1,011,770 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, 2004 include (1) discount rate of 2% (2) option life of five years, (3) expected volatility of 75.1% and (4) zero expected dividends.

During 2005, options to purchase 71,060 shares were granted to consultants. Using the Black-Scholes option-pricing model fair value for 2005 was $1,552,936. Variables used in the Black-Scholes option-pricing model for options issued during the year ended December 31, 2005 include (1) discount rate of 2%, (2) option life of five years, (3) expected volatility of 175.4% and (4) zero expected dividends.

During 2005, options to purchase 10,000 shares were forfeited and cancelled.

During 2006, options to purchase 156,500 shares of common stock were granted by Opexa to its consultants, directors and exiting directors at exercise prices ranging from $5.20 to $9.80. These warrants have a term of ten years and vest from one to three years. Fair value of $1,496,375 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, 2006 include (1) discount rate range of 4.7%—5.2%, (2) option life of ten years, (3) expected volatility range of 401.3% to 429.9% and (4) zero expected dividends.

During 2006, options to purchase 5,000 shares expired.

Opexa recorded $1,568,966 stock-based compensation expense to consultants, directors and exiting directors during 2006.

During 2007, options to purchase 69,500 shares of common stock were granted by Opexa to its consultants and directors at exercise prices ranging from $3.95 to $5.47. These options have a term of ten years, and have vesting dates that vary from either full or partial vesting at date of grant to full vesting at the first and second year anniversary of the date of grant. Fair value of $268,675 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, 2007 include (1) discount rate range of 4.20% to 5.07%, (2) option life is a term with the expected term of five and three-quarters years, (3) expected volatility range of 95.4% to 95.9% and (4) zero expected dividends.

Opexa recorded $845,275 stock-based compensation expense to consultants and directors during 2007.

During 2008, options to purchase 171,300 shares of common stock were granted by Opexa to its consultants and directors at exercise prices ranging from $0.88 to $1.55. These options have a term of ten years, and have vesting dates that vary from either full or partial vesting at date of grant to full vesting at the first year anniversary of the date of grant. Fair value of $179,340 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, 2008 include (1) discount rate range of 3.07% to 3.44%, (2) option life is a term with the expected term of five and one-half years, (3) expected volatility range of 115.3% to 116.5% and (4) zero expected dividends.

During 2008, options to purchase 22,000 shares were forfeited.

Opexa recorded $434,207 stock-based compensation expense to consultants and directors during 2008.

During 2009, options to purchase 238,380 shares of common stock were granted by Opexa to its consultants and directors at exercise prices ranging from $0.47 to $2.10. These options have a term of ten years, and have vesting dates that vary from either full or partial vesting at date of grant to full vesting at the first year anniversary of the date of grant. Fair value of $215,275 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, 2009 include (1) discount rate range of 1.87% to 2.46%, (2) option life is a term with the expected term of 5 to five and one-half years, (3) expected volatility range of 192.9% to 208.9% and (4) zero expected dividends.

During 2009, options to purchase 113,750 shares were forfeited.

Opexa recorded $247,446 stock-based compensation expense to consultants and directors during 2009. Unamortized stock-based compensation expense as of December 31, 2009 amounted to $33,715.

During 2010, options to purchase 92,556 shares of common stock were granted by Opexa to its consultants and directors at exercise prices ranging from $1.53 to $2.25. 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 $200,209 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, 2010 include (1) discount rate range of 0.97% to 2.43%, (2) option life is an expected term of two to five and one-quarter years, (3) expected volatility of 206.0%—271.6% and (4) zero expected dividends.

During 2010, options to purchase 40,136 shares were forfeited.

Opexa recorded $219,138 stock-based compensation expense to consultants and directors during 2010. Unamortized stock-based compensation expense as of December 31, 2010 amounted to $14,788.

During 2011, options to purchase 129,633 shares of common stock were granted by Opexa to its consultants and directors at exercise prices ranging from $0.95 to $1.78. 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) option life is an expected term of two to five and one-quarter years, (3) expected volatility of 84.7%—198.2% 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.

***Broker and Investor Warrants:***

During 2003, warrants to purchase 15,000 shares were granted to investors related to the convertible notes.

During 2004, warrants to purchase 142,800 shares were granted to investors related to the convertible notes.

During 2005, warrants to purchase 46,084 shares of common stock were issued to several brokerage firms as the offering costs and commissions for Opexa's financing activities at an exercise price of $1.50. These warrants have a fair value of $2,197,162 and vest immediately.

During 2005, warrants to purchase 2,386,984 shares were granted to investors related to the convertible notes.

During 2005 warrants to purchase 254,362 shares were forfeited.

In April 2006, warrants to purchase 213,720 shares of common stock were granted by Opexa to the brokers in connection with the $23 million equity financing, at an exercise price of $5.00. These warrants have a term of three years and vest immediately. Fair value of $1,077,778 was recorded using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for warrants issued during the year ended December 31, 2006 include (1) discount rate of 5.22%, (2) warrant life of three years, (3) expected volatility of 429.9% and (4) zero expected dividends.

During 2006, warrants to purchase 2,765,043 shares were granted to investors related to the April 2006 financing. These warrants have a term of five years and vest immediately. Fair value of $11,729,982 was recorded using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for warrants issued during the year ended December 31, 2006 include (1) discount rate of 4.86%, (2) warrant life of five years, (3) expected volatility of 429.9% and (4) zero expected dividends.

During 2006, warrants to purchase 1,644,908 shares were forfeited.

During 2007, there were no warrants granted to investors.

During 2008, Series E warrants to purchase 4,025,000 shares of common stock were issued by Opexa to the investors and underwriters in connection with the February 2008 public offering, at an exercise price of $2.00. These warrants vest immediately and have a fair value of $603,750. During 2008, Opexa issued warrants to the underwriter of the February 2008 public offering to purchase 350,000 shares of common stock at a price of $2.40 per share and an option to acquire 350,000 Series E warrants at a price of $0.18 per Series E warrant. These warrants are classified as equity and are immediately exercisable. Fair value of $350,061 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, 2008 include (1) discount rate of 2.93%, (2) warrant life is a term with the expected term of five years, (3) expected volatility of 97. 7% and (4) zero expected dividends.

During August 2008, in connection with a private financing, Opexa issued warrants to purchase 2,003,874 shares of its common stock to certain institutional and accredited investors. The warrants expire four years from issuance, are first exercisable after six months of the closing of the financing and are exercisable at $1.78 per share. These warrants are classified as equity. Fair value of $1,976,457 was recorded using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model for warrants issued during the year ended December 31, 2008 include (1) discount rate of 3.27%, (2) warrant life is a term with the expected term of four years, (3) expected volatility of 116.5% and (4) zero expected dividends.

In connection with the April and May 2009 private offering of convertible notes, investors were issued four-year warrants to purchase up to an aggregate of 1,302,000 shares of common stock, at an exercise price of $0.75 per share. The estimated fair value of the investor warrants was $478,577 and was calculated using the Black-Scholes valuation model. The following assumptions were used: (1) no expected dividends, (2) risk free interest rate of 0.86%—0.87%, (3) expected volatility range of 195%,—197% and (4) expected life of four years.

As additional compensation, Opexa issued warrants to the broker to purchase 112,140 shares of common stock also at a price of $0.75 per share. The estimated fair value of the broker warrants was $37,453 and was calculated using the Black-Scholes valuation model. The following assumptions were used: (1) no expected dividends, (2) risk free interest rate of 0.87%, (3) expected volatility of 195% and (4) expected life of four years.

In connection with the December 2009 registered direct offering, institutional investors were issued Series A warrants to purchase 892,500 shares of common stock and Series B warrants to purchase 382,500 shares of common stock. The Series A and Series B warrants are exercisable at $2.55 per share and were first exercisable on June 15, 2010. The Series A Warrants expire on June 15, 2015 and the Series B warrants expire on June 15, 2011.

As additional compensation, Opexa issued warrants to the placement agent to purchase 89,250 shares of common stock at $2.50 per share that were first exercisable on June 15, 2010 and expire on November 23, 2014.

During 2010, warrants to purchase 1,156,633 shares were forfeited.

During 2010, options to acquire Series E warrants of 7,867 shares at a price of $0.18 per Series E warrant were exercised.

At December 31, 2010, the aggregate intrinsic value of the outstanding options and warrants was $588,504 and $1,330,134, respectively.

During 2011, warrants to purchase 2,687,890 shares were forfeited.

In connection with Opexa's February 2011 public offering, as disclosed in Note 8, Opexa issued warrants to purchase an aggregate of 1,658,600 shares of common stock to the investors at an exercise price of $2.61 per share. These warrants have a term of five years and are immediately exercisable.

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

Summary information regarding options and warrants is as follows:

| | Options | Weighted Average Exercise Price | Warrants | Weighted Average Exercise Price |
|---|---|---|---|---|
| Outstanding at December 31, 2006 | 762,970 | $ 11.48 | 3,670,361 | $ 19.51 |
| Year ended December 31, 2007: | | | | |
| Granted | 293,900 | 5.28 | — | — |
| Forfeited and canceled | (17,345) | 7.74 | — | — |
| Outstanding at December 31, 2007 | 1,039,525 | $ 9.79 | 3,670,361 | $ 19.51 |
| Year ended December 31, 2008: | | | | |
| Granted | 640,400 | 1.10 | 6,728,874 | 1.96 |
| Forfeited and canceled | (126,578) | 6.53 | — | — |
| Outstanding at December 31, 2008 | 1,553,347 | $ 6.47 | 10,399,235 | $ 8.15 |
| Year ended December 31, 2009: | | | | |
| Granted | 773,339 | 0.96 | 3,204,620 | 1.67 |
| Exercised | (60,774) | 1.05 | (718,764) | 1.66 |
| Forfeited and canceled | (342,536) | 10.56 | (208,330) | 5.00 |
| Outstanding at December 31, 2009 | 1,923,376 | $ 3.70 | 12,676,761 | $ 6.93 |
| Year ended December 31, 2010: | | | | |
| Granted | 152,556 | 2.08 | 7,867 | 2.00 |
| Exercised | (141,146) | 0.77 | (68,411) | 2.10 |
| Forfeited and canceled | (392,714) | 9.11 | (1,156,641) | 29.40 |
| Outstanding at December 31, 2010 | 1,542,072 | $ 2.15 | 11,459,576 | $ 2.75 |
| Year ended December 31, 2011: | | | | |
| Granted | 304,633 | 1.57 | 1,658,600 | 2.61 |
| Exercised | — | — | — | — |
| Forfeited and canceled | (75,000) | 5.00 | (2,687,890) | 5.93 |
| Outstanding at December 31, 2011 | 1,771,705 | $ 1.93 | 10,430,286 | $ 1.90 |

Summary of options outstanding and exercisable as of December 31, 2011 is as follows:

| | Range of Exercise Prices | Weighted Average Remaining Contractual Life (years) | Number of Options Outstanding | Number of Options Exercisable |
|---|---|---|---|---|
| $ | 0.22 to 4.99 | 6.50 | 1,540,765 | 1,258,388 |
| | 5.00 to 9.80 | 0.61 | 230,940 | 230,940 |
| $ | 0.22 to 9.80 | 7.11 | 1,771,705 | 1,489,328 |

Summary of warrants outstanding and exercisable as of December 31, 2011 is as follows:

| | Range of Exercise Prices | Weighted Average Remaining Contractual Life (years) | Number of Warrants Outstanding | Number of Warrants Exercisable |
|---|---|---|---|---|
| $ | 0.18 to 2.61 | 1.76 | 10,430,286 | 10,430,286 |
| $ | 0.18 to 2.61 | 1.76 | 10,430,286 | 10,430,286 |

**NOTE 10—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 assigned back 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.

On November 2, 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, including the remaining $0.5 million technology transfer milestone payment. In connection with the re-acquisition of the stem cell assets, a related license agreement with the University of Chicago was assigned back 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 11—SUBSEQUENT EVENTS**

Subsequent to December 31, 2011, Opexa granted its management and employees options to purchase an aggregate of 1,409,367 shares of common stock with a fair value of $1,323,063 at an exercise price of $0.95 and an aggregate of 10,000 shares of common stock with a fair value of $9,064 at an exercise price of $0.92. Of those options, 1,019,036 are performance-based and will commence three-year quarterly vesting, if at all, in two tranches upon Opexa achieving certain key milestone events. The remaining options to purchase 400,331 shares are time-based and vest quarterly over a three-year period.

On February 15, 2012, Opexa entered into an agreement with Pharmaceutical Research Associates, Inc. ("PRA"), a contract research organization (CRO), in which PRA will provide Opexa with services related to the design, implementation and management of Opexa's planned Phase II clinical trial program in SP-MS. Under the terms of the agreement, Opexa will pay an upfront cash payment to PRA of $236,830 within ten days of contract execution, an upfront cash payment to PRA of $45,365 as an advance payment of 10% of the estimated pass through costs to be incurred by PRA during the term of the agreement and an upfront cash payment of approximately $24,750 to PRA for certain proprietary system support and administration licensure necessary for data reporting and management. Future payments by Opexa to PRA under the agreement are based on the achievement of certain time and performance milestones as presented in the agreement. Unless terminated by either party without cause on 60 days prior notice or on shorter notice with cause, the initial term of the agreement is for four years and automatically renews for successive one year terms.

**EXHIBIT INDEX**

| 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 | Articles of Amendment and Restatement of the Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 19, 2006, File No. 000-25513). |
| 3.2 | Articles of Amendment to the Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 13, 2009). |
| 3.3 | Amended and Restated By-laws, as amended (incorporated by reference to Exhibit 3.3 to the Company's Annual Report on form 10-K filed on March 8, 2011). |
| 4.1 | Form of Common Stock Certificate (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-3 filed on November 13, 2009, File No. 333-163108). |
| 4.2 | Form of Series E Warrant (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form SB-2 (Amendment No. 1) filed December 20, 2007, File No. 333-147167). |
| 4.3 | Warrant Agent Agreement by and between the Company and Continental Stock Transfer & Trust Company dated February 13, 2008 for the Series E Warrants (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed February 14, 2008). |
| 4.4 | Form of Underwriters' Warrant Agreement by and between the Company and each underwriter party thereto for the Series E Warrants (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed February 14, 2008). |
| 4.5 | Form of Underwriters' Warrant to Acquire Warrants Agreement by and between the Company and each underwriter party thereto for the Series E Warrants (incorporated by reference to Exhibit 4.5 to the Company's Current Report on Form 8-K filed February 14, 2008). |
| 4.6 | Unit Purchase Agreement dated August 8, 2008 by and among the Company 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). |
| 4.7 | 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). |
| 4.8 | Registration Rights Agreement dated August 8, 2008 between the Company 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). |
| 4.9 | Unit Purchase Agreement dated April 14, 2009 by and among the Company 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). |
| 4.10 | Form of Series G Warrant issued by the Company 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). |
| 4.11 | Placement Agent Agreement dated December 9, 2009 by and between the Company and Rodman & Renshaw, LLC for Unit offering of Common Stock and Series A and Series B Warrants (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed December 10, 2009). |
| 4.12 | Form of Securities Purchase Agreement dated as of December 9, 2009 by and between the Company 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). |
| 4.13 | 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). |
| 4.14 | Form of Series H Warrant issued by the Company 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). |

| Exhibit No. | Description |
|---|---|
| 10.1+ | Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan (incorporated by reference to Exhibit B to the Company's Definitive Information Statement on Schedule 14C filed on June 29, 2004, File No. 000-25513). |
| 10.2+ | Certificate of Amendments to the Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan (incorporated by reference to Exhibit 10.15 of the Company's Annual Report on Form 10-K filed March 5, 2010). |
| 10.3+ | Employment Agreement dated June 16, 2008 by and between the Company 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 the Company 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 the Company 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 the Company 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 the Company 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 the Company 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 Current Report on Form 8-K 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 | Continuous Offering Program Agreement dated May 14, 2010 by and between the Company and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on May 17, 2010) (subsequently terminated February 7, 2011 as disclosed in the Company's Current Report on Form 8-K filed on February 7, 2011). |
| 10.13 | Assignment Agreement and General Release, dated November 2, 2011, by and between Opexa Therapeutics, Inc. and Novartis Institutes for BioMedical Research, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 4, 2011). |
| 23.1* | Consent of Independent Registered Public Accounting Firm MaloneBailey, LLP, dated February 27, 2012 to the incorporation by reference of their report dated February 27, 2012, in the Company's Registration Statements on Form S-8 and S-3. |
| 31.1* | Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1* | Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

* Filed herewith

\+ Management contract or compensatory plan or arrangement.

**Exhibit 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statement on Forms S-3 (No. 333-147167, 333-153501 and 333-163108), and Forms S-8 (Nos. 333-139196 and 333-176934) pertaining to the Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan and 2010 Stock Incentive Plan, respectively, of our report dated February 27, 2012 with respect to the audited financial statements of Opexa Therapeutics, Inc. for the years ended December 31, 2011 and 2010.

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

February 27, 2012

**EXHIBIT 31.1**

**CERTIFICATION PURSUANT TO**
**SECTION 302 OF THE SARBANES-OXLEY ACT**

I, Neil K. Warma, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 27, 2012

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

**EXHIBIT 32.1**

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

In connection with the Annual Report of Opexa Therapeutics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2011, (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Neil K. Warma, President, Chief Executive Officer and Acting Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

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

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

Date: February 27, 2012

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