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# 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, 2009

☐ **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 N. Crescent Ridge Drive, 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, 2009 based upon the closing price as of such date was $5,030,578.

As of March 1, 2010, 15,527,322 shares of the registrant's common stock, par value $0.01 per share, were outstanding.

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**Forward Looking Statements**

*Statements contained in this report, other than statements of historical fact, constitute "forward-looking statements." The words "expects," "believes," "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: the success of third party development and commercialization efforts with respect to products covered by intellectual property rights transferred by the Company, the success of third party patent prosecution efforts with respect to such products, the ability of the Company to enter into and benefit from a partnering arrangement for the Company's product candidate, Tovaxin®, on reasonably satisfactory terms (if at all), and the Company's dependence (if partnered) on the resources and abilities of any partner for the further development of Tovaxin, the Company's ability to compete with larger, better financed pharmaceutical and biotechnology companies, new approaches to the treatment of its targeted diseases, the Company's expectation of incurring continued losses, the Company's uncertainty of developing a marketable product, the Company's ability to raise additional capital to continue its treatment development programs, the success of the Company's clinical trials, the Company's ability to develop and commercialize products, the Company's ability to obtain required regulatory approvals, the Company's compliance with all Food and Drug Administration regulations, the Company's ability to obtain, maintain and protect intellectual property rights for its products, the risk of litigation regarding the Company's intellectual property rights, the Company's limited manufacturing capabilities, the Company's dependence on third-party manufacturers and value added resellers, the Company's ability to hire and retain skilled personnel, the Company's volatile stock price, and other risks detailed in its filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this report. The Company assumes 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 the Company makes in the reports it files 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. The information discussed related to our product candidates is preliminary and investigative. Our product candidates are not approved by the 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 N. Crescent Ridge Drive, The Woodlands, Texas 77381, and our telephone number is (281) 272-9331.

### T-Cell Therapy

MS is the result of a person's own T-cells attacking the myelin sheath that coats the nerve cells of the central nervous system (CNS). Tovaxin consists of attenuated patient-specific myelin reactive T-cells (MRTCs) against peptides from one or more of the primary proteins on the surface of the myelin sheath (myelin basic protein (MBP), proteolipid protein (PLP) and myelin oligodendrocyte glycoprotein (MOG)). Patient-specific MRTCs are expanded in culture with specific peptides identified by our proprietary assay of the patient's peripheral blood. The cells are then attenuated, or weakened, by gamma irradiation, and returned to the patient as a subcutaneous injection. Although further testing is necessary, results from our initial human trials appear to indicate that these attenuated T-cells cause an immune response directed at the autoreactive T-cells in the patient's body, resulting in a reduction in the level of harmful T-cells. In 2008, we completed an FDA cleared Phase IIb clinical trial of Tovaxin which enrolled 150-patients. The trial was entitled, A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Subcutaneous Tovaxin in Subjects with Clinically Isolated Syndrome or Relapsing Remitting Multiple Sclerosis (Tovaxin for Early Relapsing-Remitting MS, "TERMS").

The TERMS study was a Phase IIb multi-center, randomized, double blind, placebo-controlled trial in 150 patients with Relapsing-Remitting Multiple Sclerosis (RRMS) or high risk Clinically Isolated Syndrome (CIS). The study involved 2:1 randomization with 100 patients receiving Tovaxin and 50 receiving placebo. According to the study protocol, patients received a total of five subcutaneous injections at weeks 0, 4, 8, 12 and 24. Top-line data from the TERMS trial is as follows:

- 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.

- For patients who had more active disease as indicated by a prospective subgroup of patients with an ARR>1 in the year prior to the study, Tovaxin demonstrated a 55% reduction in ARR as compared to placebo; and an 87% 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 (p=0.039).

- Patients who had an ARR>1 at study entry demonstrated a statistically significant improvement in disability score as measured by the Expanded Disability Status Scale (EDSS) (p =0.045) for patients

treated with Tovaxin as compared to those receiving placebo. The EDSS score is a measure of disability ranging from 0-10. In addition, 28.1% of the Tovaxin patients showed an improvement in EDSS of at least one point as compared to 5.6% in the placebo group.

- Patients who had an ARR>1 at study entry and were treated with Tovaxin experienced an 88% reduction in brain atrophy and a 59% reduction in absolute T-2 lesion volume as compared to placebo.

- Tovaxin was safe and well tolerated with no serious adverse events related to Tovaxin treatment. The most common adverse event was injection site irritation which was generally mild and transient.

Further analysis of the TERMS clinical study of 150 patients with RRMS evaluated those patients with an annualized relapse rate of greater than or equal to one at study entry (ARR≥1). More than 83% of the Tovaxin-treated group (n=85) remained relapse free at one year and the annualized relapse rate after treatment decreased to 0.20, a 42% reduction compared to placebo. The results of this expanded analysis confirm those found in the previously-reported per-protocol analysis of patients in the TERMS study with ARR>1. This *post-hoc* analysis, which represents 86% of the total patient population in the TERMS study, was conducted to evaluate Tovaxin treatment among study patients with the same baseline disease activity that is being targeted for inclusion in future clinical studies. Along with a marked reduction in relapses, 73% of the Tovaxin-treated patients with ARR≥1 showed stabilization or improvement in MS disability, including 16.5% with a sustained improvement in their EDSS score of at least one full point. On MRI, the Tovaxin-treated group also demonstrated a reduction in brain atrophy and fewer inflammatory brain lesions that progressed to "black holes," as compared to the placebo-treated group. Treatment with Tovaxin was well tolerated, with no serious adverse events reported in any Tovaxin-treated patient.

Tovaxin is a personalized T-cell vaccine based on a patient's individual immunologic profile. Detailed immunology data analysis from the TERMS trial indicate that Tovaxin can successfully induce changes in T-cell reactivity to all three targeted myelin antigens implicated in the autoimmune attacks causing neurologic damage in MS. These changes appear epitope-specific, are sustained for six months or more, and match each patient's Tovaxin formulation. Tovaxin is not broadly immunosuppressive, an important feature of its favorable safety profile.

**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 August 2009, we entered into an exclusive agreement with Novartis for the further development of our novel stem cell technology. This technology, which has generated preliminary data showing the potential to generate monocyte derived islet cells from peripheral blood mononuclear cells, was in early preclinical development at Opexa. Under the terms of the agreement, Novartis acquired the stem cell technology from us and Novartis will have full responsibility for funding and carrying out all research, development and commercialization activities. To date we have received $3.5 million from Novartis of which $3 million was attributable to an upfront cash payment and $0.5 million resulted from the completion of the first of two technology transfer milestones. We are eligible to receive an additional $0.5 million technology transfer fee upon the completion of the second technology transfer milestone. We are also eligible to receive certain clinical and commercial milestone payments as well as royalty payments from the sale of any products resulting from the use of the technology and we retain an option on certain manufacturing rights.

**Our T-Cell Platform**

***Multiple Sclerosis—Background***

In the U.S., approximately 400,000 people suffer from MS, a chronic progressive autoimmune disease of the CNS that is caused by myelin autoreactive T-cells progressively eroding the myelin that surrounds and insulates nerve fibers of the brain and spinal cord resulting in varying amounts of disability. Globally, there are approximately 2.5 million MS patients representing a drug market of approximately $9 billion in 2008. The U.S. market accounted for slightly more than 65 percent of global MS drug sales in 2008. The MS drug market is forecasted to reach as much as $16 billion by 2016.

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 axons, which causes nerve impulse transmissions to diffuse into the tissue resulting in disability to the subject.

***Current Therapy for Multiple Sclerosis***

Current MS disease modifying drugs on the market are mostly palliative and generally work by modulation or suppression of the immune system. These therapies for MS are dominated by three forms of interferon that when used as therapies, require frequent subcutaneous or intramuscular injections (Avonex®, Betaseron® and Rebif®). Copaxone® is an immunomodulator that is administered daily. Novantrone® (mitoxanthrone) is an immunosuppressive drug that can only be given four times per year with a lifetime limit of 8 to 12 doses. All of the current therapies only claim to slow the progression of MS and present significant patient compliance challenges because of the dosing schedule, limited decrease in relapse rate and side effects profile. The interferon formulations produce severe flu-like symptoms, injection site reactions, infection and neutralizing antibodies (ranging from 5% to 45%) that limit the efficacy of treatment. Copaxone® causes significant injection site reactions; while Novantrone® causes infections, bone marrow suppression, nausea, hair thinning, bladder infections, and mouth sores. These drugs must be administered daily to weekly. Tysabri®, a selective adhesion molecule inhibitor (an alpha 4 integrin antagonist), represents another class of MS drugs that works by preventing immune system cells from crossing the BBB and from moving into the CNS. Tysabri® requires a once per month infusion and has been reintroduced to the market after being originally withdrawn in 2005 based on safety concerns over several patient deaths due to a virally mediated brain inflammation.

***Tovaxin for Multiple Sclerosis***

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 taking 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 mounts 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***

Tovaxin is a personalized autologous immunotherapy that is not only manufactured for every individual patient but also is tailored to match each patient's evolving disease profile. In preparing Tovaxin for a patient, the patient-specific MRTCs causing the disease are isolated from the blood and expanded in culture with specific peptides identified by assaying peripheral blood mononuclear cell (PBMC) reactivity against 109 peptides derived from MBP, MOG and PLP in the presence of antigen-presenting cells and growth factors. MRTCs are expanded in culture to therapeutic levels and cryopreserved. Prior to use, the MRTCs are expanded, formulated, and attenuated (by irradiation) to render them unable to replicate but viable for therapy. These attenuated T-cells are administered in a defined schedule of five subcutaneous injections. Patients will be treated with a new vaccine series (five subcutaneous injections) each year based on their altered disease profile or epitope shift.

***Tovaxin Safety and Tolerability***

It is believed that Tovaxin treatment selectively targets and depletes the pathogenic T-cell population. It is not a general immune suppressant and, accordingly, 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.

***Clinical Development of Tovaxin***

During 2009, we continued to analyze the data from the TERMS Phase IIb study, which was completed in 2008, and we evaluated options for the further clinical development of Tovaxin. We have been engaged in certain activities with respect to such further clinical development, with a key aspect of our strategy with respect to Tovaxin being to possibly seek a collaboration with a partner. The nature and extent of the further clinical development of Tovaxin may thus be substantially influenced by a potential strategic partner, if applicable, and will in any event depend upon access to resources such as necessary capital.

**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 use, develop, make, have made, market, sell, offer to sell and otherwise commercially exploit the technology, licensed patent pending products and licensed patent products. Opexa has since expanded the patent portfolio related to Tovaxin and T-cell technology with additional applications, from which several patents have issued. 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 in this field, relative to Tovaxin, 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 encompass these additional indications. As the MS clinical trials for Tovaxin have progressed, new patent applications have been filed to reflect the specificity and variety of antigens that have been discovered.

**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 the MS products 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 our MS T-cell therapy products 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**

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 potential 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 and our formulation 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 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. Each protocol is submitted to the FDA as part of the IND.

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 effectiveness 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 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.

*Interaction with the FDA During the Application and Review Process.* Generally, early interaction and ongoing communication with the FDA can facilitate the testing and approval process by helping to clarify FDA expectations, obtain FDA guidance and directions, and resolve disputed issues. In addition, expectations can be formalized in a "Special Protocol Assessment," in which the FDA provides official evaluation and guidance on proposed protocols for pivotal Phase III clinical trials. An SPA documents the FDA's agreement that the design and plan analysis of the Phase III study adequately addresses objectives in support of a regulatory submission such as a BLA.

**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;
- Compliance with GMP and biological product standards (subject to FDA inspection of facilities to determine compliance); and
- Compliance with "Good Tissue Practice" regulations, as applicable. (As defined by regulation, "human cell, tissue and cellular and tissue-based products" (HCT/P), which are subject to additional regulatory requirement, include stem cells that are progenitors of blood cells; however, the FDA makes no explicit statement in the regulations regarding the inclusion of other types of stem cells.)

**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 our products. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursements vary widely from country to country. In particular, the European Union is revising its regulatory approach to high tech products, and representatives from the U.S., Japan and the European Union are in the process of harmonizing and making more uniform the regulations for the registration of pharmaceutical products in these three markets.

**Research and Development**

Research and development expenses for the years ended December 31, 2009 and 2008 were approximately $2.1 million and $8.4 million, respectively, mainly reflecting the costs of Phase IIb clinical trials 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. In 2009, Novartis Pharmaceuticals acquired our stem cell technology. Currently, we remain focused on developing our T-cell technology for MS. To date, we have not generated any commercial revenues from our operations. As we continue to execute our business plan, we expect our development and operating expenses to increase.

**Employees**

As of March 1, 2010, we had 10 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 N. Crescent Ridge Drive, 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 or warrants could decline and you could lose all or part of your investment.*

**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 in late-stage clinical trials nor do we have any products on the market. We are still in the early stages of identifying and conducting research on potential products. We have only one product candidate, Tovaxin, which has progressed to the stage of being studied in human clinical trials in the United States. This product candidate, 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 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 have any sources of revenues and may not have any in the foreseeable future.

***Our ability to obtain necessary funding is uncertain.***

We anticipate that we will need to raise substantial additional working capital to continue our operations beyond 2010. As we have no external 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 2010 and beyond;
- 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 collaborations 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.

If sufficient capital is not available 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.

***Our independent auditor's report in respect of our 2008 fiscal year expressed substantial doubt about our ability to continue as a going concern, which may make raising capital more difficult.***

The report of our independent auditors in respect of the 2008 fiscal year expressed substantial doubt about our ability to continue as a going concern. Specifically, it indicated an absence of obvious or reasonably assured sources of future funding that will be required by us to maintain ongoing operations. Subsequent to our 2008 fiscal year end, the going concern qualification to our financial statements was removed from our quarterly report on Form 10-Q for the quarter ended June 30, 2009, as proceeds from a private offering in May 2009 and a corporate transaction in August 2009 were projected to provide sufficient cash resources through December 2009. Based upon a registered direct offering of shares of our common stock and warrants to acquire our common stock in December 2009, we are currently projected to have sufficient cash reserves beyond December 2010. Although we have been successfully funded to date by attracting investors in our equity and convertible debt securities, there is no assurance that our capital raising efforts will be able to attract the capital needed to sustain our operations beyond that date. The conditions leading to the delivery of a report from our auditors expressing substantial doubt about our ability to continue as a going concern in respect of our 2008 financial year could return, and thus the existence of this prior report as well as the prospect of a similar future report may make it more difficult for us to raise funds. If we are unable to obtain additional funding for operations, we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations. In such event, investors may lose a portion or 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 conduct later-stage clinical trials and further develop and commercialize a selected product candidate. To date, we have not entered into any such collaborative arrangement with respect to Tovaxin.

By entering into such as 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 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 such event, our ability to generate revenues and achieve or sustain profitability would be significantly hindered and we may not be able to continue operations as proposed, requiring us to modify our business plan, curtail various aspects of our operations or cease operations.

***We will need regulatory approvals for any product candidate, including 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 further clinical trials of our lead product candidate, Tovaxin, will take at least several additional years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed 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, which 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 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 effectively operate our business. 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 a number of 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. Our current facility should have the capacity to support a U.S. pivotal Phase III trial for the development of Tovaxin for MS. It is not sufficient, however, to support potential European clinical studies, 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. 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 issue 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 be mature 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 improved 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. 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 were 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.***

We sold 2,550,000 shares of our common stock, and warrants to acquire another 1,275,000 shares, in a registered direct transaction in December 2009. We may sell additional shares of common stock in subsequent

public or private offerings. We may also issue additional shares of common stock to finance future acquisitions. We cannot predict the size of future issuances of our common stock or the effect, if any, that future issuances and sales of shares of our common stock will have on the market price of our common stock. Sales of substantial amounts of our common stock (including shares issued in connection with an acquisition), 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.

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

None.

**Item 2. Properties.**

Our 10,200 square foot facility is located on three acres at 2635 North Crescent Ridge Drive 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. 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, 2008** | | |
| First Quarter | $ 3.93 | $ 0.91 |
| Second Quarter | 1.58 | 0.59 |
| Third Quarter | 2.74 | 0.15 |
| Fourth Quarter | 0.50 | 0.09 |
| **Fiscal Year Ended December 31, 2009** | | |
| First Quarter | $ 0.70 | $ 0.15 |
| Second Quarter | 0.75 | 0.31 |
| Third Quarter | 6.93 | 0.36 |
| Fourth Quarter | 3.77 | 1.61 |

The closing price of our common stock on March 1, 2010 was $2.02 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, 2009, with respect to our compensation plans under which common stock is authorized for issuance. We issue options to officers, directors, employees and consultants under our stockholder-approved 2004 Compensatory Stock Option Plan. We believe that the exercise price for all of the options set forth below reflects 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 | 1,923,376 | $ 3.70 | 315,850 |
| Equity Compensation Plans Not Approved by Stockholders | — | — | — |
| Total | 1,923,376 | $ 3.70 | 315,850 |

Refer to Note 10 "Options and Warrants" in the Notes to our financial statements for the fiscal year ended December 31, 2009, included elsewhere in the annual report for a description of our 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. In 2009, Novartis Pharmaceuticals acquired our stem cell technology. Currently we remain focused on initially developing our T-cell technology for MS. To date, we have not generated any commercial revenues from our 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 FASB ASC 718 which establishes accounting for equity instruments exchanged for employee service. We utilize the Black-Scholes option pricing model to estimate the fair value of employee stock based compensation at the date of grant, which requires the input of highly subjective assumptions, including expected volatility and expected life. Changes in these inputs and assumptions can materially affect the measure of estimated fair value of our share-based compensation. These assumptions are subjective and generally require significant analysis and judgment to develop. When estimating fair value, some of the assumptions will be based on, or determined from, external data and other assumptions may be derived from our historical experience with stock-based payment arrangements. The appropriate weight to place on historical experience is a matter of judgment, based on relevant facts and circumstances.

We estimated volatility by considering historical stock volatility. We have opted to use the simplified method for estimating expected term 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.

**Accounting for Derivative Instruments.** FASB ASC 815 requires all derivatives to be recorded on the balance sheet at fair value. These derivatives are separately valued and accounted for on our balance sheet. Fair values for securities traded in the open market and derivatives are based on quoted market prices. Where market prices are not readily available, fair values are determined using market based pricing models incorporating readily observable market data and requiring judgment and estimates.

The pricing model we use for determining fair values of our derivatives is the Black-Scholes option-pricing model. Valuations derived from this model are subject to ongoing internal and external verification and review. The model uses market-sourced inputs such as interest rates, exchange rates and stock price volatilities. Selection of these inputs involves management's judgment and may impact net income.

In January 2009, we adopted new accounting guidance for determining whether an instrument (or embedded feature) is indexed to an entity's own stock. We evaluated all of our financial instruments and determined that the warrants associated with the August 2008 financing qualified for treatment under this new accounting guidance. As of January 1, 2009, we adjusted our financial statements to reclassify the fair value on these warrants as of January 1, 2009 in the amount of $220,835 from additional paid in capital to derivative liabilities and the cumulative effect of the change in accounting principle in the amount of $1,755,622 is recognized as an adjustment to the opening balance of retained earnings.

**Results of Operations**

**Comparison of Year Ended December 31, 2009 with the Year Ended December 31, 2008**

**Net Sales.** We recorded no commercial revenues for the years ended December 31, 2009 and 2008.

**Research and Development Expenses.** Research and development expenses were $2,107,833 for the year ended December 31, 2009, compared to $8,388,734 for the year ended December 31, 2008. The decrease in expenses was primarily due to a decrease in activities related to the Phase IIb clinical trial for Tovaxin which was completed in 2008, closing the extension trial, a reduction in staff, and a decrease in stock compensation expense. 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 $2,020,572 for the year ended December 31, 2009, as compared to $3,341,415 for the year ended December 31, 2008. The decrease in expense is due to a reduction in staff and a decrease in stock compensation expense, overhead expenses, professional service fees and board compensation fees.

**Gain on Sale of Technology.** Gain on sale of assets was $3 million for the year ended December 31, 2009, compared to $-0- for the year ended December 31, 2008. The gain is attributable to the sale of our stem cell technology program to Novartis for an upfront payment of $3 million. As there was no cost basis associated with the stem cell assets on the financial statements, the entire upfront payment was recognized as a gain on sale of technology.

**Other Income and Expense, Net.** Other income for the year ended December 31, 2009 was $554,242, compared to $34,901 for the year ended December 31, 2008. The increase in other income is primarily attributable to the receipt of an initial $500,000 technology transfer fee pursuant to the terms of the stem cell technology acquisition agreement with Novartis.

**Loss on Derivative Instruments.** We recognized a loss on derivative instruments of $366,774 for the year ended December 31, 2009. The loss is a result of the net unrealized (non-cash) change in the fair value of our derivative instrument liabilities related to warrants associated with the August 2008 financing which had been accounted for under FASB ASC 815 and which accounting treatment was discontinued on June 1, 2009.

**Interest Expense.** Interest expense was $278,127 for the year ended December 31, 2009, compared to $19,983 for the year ended December 31, 2008. Interest expense for 2009 was primarily related to accrued interest on the convertible notes, amortized interest on the convertible notes and the (non-cash) amortization of the financing fees over the life of the notes with the balance related to interest on the equipment line loan payable. Interest expense for 2008 was solely related to the equipment line loan payable of up to $250,000 with Wells Fargo, of which $102,932 was outstanding as of December 31, 2009.

**Interest Income.** Interest income was $1,764 for the year ended December 31, 2009, compared to $100,235 for the year ended December 31, 2008. The decrease was due to the reduction in cash balances that were available for investment in cash equivalent instruments and a reduction in interest rates.

**Net Loss.** We had a net loss for the year ended December 31, 2009 of $1,433,922, or $.11 per share (basic and diluted), compared with a net loss of $11,852,152, or $1.12 per share (basic and diluted), for the year ended December 31, 2008. The decrease in net loss is primarily due to the reduction of costs associated with the Phase IIb clinical trial of Tovaxin that was completed in 2008, a reduction in staff and a decrease in stock compensation expense.

**Liquidity and Capital Resources**

Historically, we have financed our operations primarily from the sale of debt and equity securities. As of December 31, 2009, we had cash and cash equivalents of approximately $8.2 million.

Our financing activities generated $6.9 million for the year ended December 31, 2009, compared to approximately $9.2 million for the year ended December 31, 2008. The cash generated in 2009 was the result of $1.13 million in net proceeds from a convertible note offering closed on April 14 and May 14, 2009, $4.7 million in net proceeds from a registered direct offering on December 14, 2009 and $1.1 million in net proceeds from the exercise of options and warrants.

Our current burn rate is approximately $300,000. We believe that while we have sufficient liquidity to support our operations, at current levels, beyond December 2010, we will need to raise additional capital in the

future to fund our current business plan and support our operations. 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, 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, 2009 and 2008, 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 2009 and 2008, 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(T). 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, 2009 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, 2009 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 temporary 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.**

**Submission of Matters to a Vote of Security Holders**

We held our annual meeting of stockholders on November 11, 2009. At the annual meeting, the following five nominees were elected to serve as directors: David Hung, David E. Jorden, Michael S. Richman, Scott B. Seaman and Neil K. Warma. The votes cast for the election of directors are set forth below:

| Name of Nominee | For | Withheld |
|---|---|---|
| David Hung | 9,676,922 | 91,954 |
| David E. Jorden | 9,678,047 | 90,829 |
| Michael S. Richman | 9,676,847 | 92,029 |
| Scott B. Seaman | 9,677,047 | 91,829 |
| Neil K. Warma | 9,673,914 | 94,962 |

Our stockholders also approved the following additional proposals:

2. Amendment to the Company's Articles of Incorporation to reduce the par value of the Company's common stock from $0.50 per share to $0.01 per share; and
3. Ratification of the appointment of MaloneBailey, LLP, as independent auditors of the Company for the fiscal year ending December 31, 2009.

The votes for these proposals were as follows:

| Proposal | For | Against | Absentions | Broker Non-Votes |
|---|---|---|---|---|
| Proposal 2 | 9,396,727 | 281,281 | 90,868 | 0 |
| Proposal 3 | 9,680,442 | 68,588 | 19,846 | 0 |

## 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 | 47 | President, Chief Executive Officer, Acting Chief Financial Officer and Director |
| Jaye L. Thompson | 44 | Senior Vice President of Clinical Development and Regulatory Affairs |
| Donna R. Rill | 56 | Senior Vice President of Operations |

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 the company founded in 1991 by Dr. Thompson, SYNERGOS, Inc. SYNERGOS was a contract research organization helping companies move through the clinical and regulatory hurdles of product development. Dr. Thompson received a doctorate and master 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 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 will 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 Hung | 52 | Director |
| David E. Jorden | 47 | Director |
| Michael S. Richman | 48 | Director |
| Scott B. Seaman | 54 | Director |
| Neil K. Warma | 47 | Director, President, Chief Executive Officer and Acting Chief Financial Officer |

**David Hung, M.D.,** has served as a Director since May 2006. Dr. Hung has served as the president, chief executive officer and as a director of Medivation, Inc. since December 2004. Dr. Hung also has served as the president and chief executive officer, and member of the board of directors, of Medivation, Inc.'s subsidiary, Medivation Neurology, Inc., since its inception in September 2003. From 1998 until 2001, Dr. Hung was employed by ProDuct Health, Inc., a privately held medical device company, as Chief Scientific Officer (1998-1999), and as president and chief executive officer (1999-2001). From December 2001 to January 2003, Dr. Hung served as a consultant to Cytyc Health Corporation. Dr. Hung received his M.D. from the University of California at San Francisco, and his A.B. in biology and organic chemistry from Harvard College. As the chief executive officer of a public biopharmaceutical company actively engaged in clinical drug development, Dr. Hung offers extensive experience in numerous aspects of managing a pre-commercialization drug development company, including strategic planning, clinical development, and strategic partnering.

**David E. Jorden** has served as a Director since August 2008. Mr. Jorden has served as executive board member for Cytomedix, Inc. 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.

**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 his 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. Since October 2007, Mr. Seaman has served on the board of GeneExcel, Inc., a privately held biotechnology company. Since May 2004, Mr. Seaman has 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, and recommends to our Board whether the audited financials should be included in our Annual Reports to be filed with the SEC. 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 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 these reporting persons complied with all applicable Section 16(a) filing requirements.

## 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, 2009. Our Named Executive Officers include persons who (i) served as our principal executive officer or acted in a similar capacity during 2009; (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) 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.

***2009 Summary Compensation Table***

| Name and Principal Position | Year | Salary | Bonus | Other Compensation | Options Awards(1) | Total |
|---|---|---|---|---|---|---|
| Neil K. Warma | 2009 | $ 312,083 | $ 142,500 | — | $ 235,117 | $ 689,700 |
| *President, Chief Executive Officer, Acting Chief Financial Officer and Director* | 2008 | $ 195,100 | — | $ 62,847(2) | $ 72,869 | $ 330,456 |
| Donna R. Rill | 2009 | $ 197,963 | — | — | $ 113,870(3) | $ 311,833 |
| *Senior Vice President of Operations* | 2008 | $ 141,886 | — | — | $ 110,402 | $ 252,288 |
| Jaye L. Thompson(4) | 2009 | $ 23,590 | — | — | $ 101,440 | $ 125,030 |
| *Senior Vice President of Clinical Development and Regulatory Affairs* | 2008 | — | — | — | — | — |

(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 10 to our financial statements included in this annual report on Form 10-K for assumptions underlying the valuation of equity awards.
(2) Other compensation includes costs of moving and temporary housing in connection with Mr. Warma's relocation to accept employment with Opexa.
(3) Represents Ms. Rill's accrued salary increase from 2008 totaling $8,396 that was exchanged in February 2009 for a fully vested stock option to purchase 8,396 shares of Opexa common stock at an exercise price of $.47 per share, the market value on the date of grant.
(4) Dr. Thompson joined Opexa as executive officer in November 2009.

***Executive Employment Agreements***

We entered into a three-year employment agreement on June 16, 2008 with Neil K. Warma pursuant to which he will serve as President and Chief Executive Officer. Pursuant to the agreement, Mr. Warma is paid $285,000 for the first 12-month period, $335,000 for the second 12-month period and $385,000 for the third 12-month period. 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. If employment is terminated by the Board without cause, Mr. Warma will receive 12 months base salary plus a payment equal to 30% of base salary and including any earned but unpaid bonus. In addition, vesting of stock options will accelerate in full if the effective date of the termination is at least two years after commencement of employment or vesting will be accelerated for a 12-month period if termination is prior to two years of employment. Upon the effectiveness of a change in control, Mr. Warma will receive 18 months of salary and a payment equal to 45% of base salary. In addition, all vesting of options will accelerate in full.

We entered into a one-year employment agreement with Donna R. Rill on May 9, 2008, effective for the period April 1, 2008 through March 31, 2009, at an annual salary of $151,114 pursuant to which Ms. Rill served as Vice President of Operations. On January 16, 2009, Ms. Rill was promoted to Senior Vice President at an annual salary of $200,000. Following termination of the March 31, 2009 employment agreement, we entered into a new one-year employment agreement with Ms. Rill on April 14, 2009, effective for the period April 1, 2009 through March 31, 2010 at an annual salary of $200,000. The employment agreement may be terminated at any time voluntarily by her or without cause by the Board. If employment is terminated by the Board without cause, Ms. Rill will receive six months base salary and any stock options granted to Ms. Rill prior to termination will be accelerated for a 12-month period. Ms. Rill has one year to exercise any vested stock options. In the event of a change of control, any stock options granted to Ms. Rill prior to such change of control will be accelerated to become vested and Ms. Rill has a one-year period from the effective change of control date to exercise any such stock options.

We entered into a one-year employment agreement with Jaye L. Thompson on November 16, 2009, effective for the period of November 16, 2009 through December 31, 2010, at an annual salary of $200,000 pursuant to which Ms. Thompson will serve as Senior Vice President of Clinical Development and Regulatory Affairs. Ms. Thompson is eligible to receive an annual discretionary bonus of up to 20% of her base salary per 12-month period based upon milestones to be agreed upon, with the first measurement period ending on or about December 31, 2010. Pursuant to her employment agreement, Ms. Thompson received a 10-year stock option to purchase 50,000 shares of common stock at an exercise price of $2.05 per share vesting quarterly in equal amounts over three years. Six months after the start of employment, we agreed to meet with Ms. Thompson to consider the addition of severance arrangements to the term of her employment.

***2009 Grants of Plan Based Awards***

The following table presents information regarding stock options granted in 2009 pursuant to our 2004 Compensatory Stock Option Plan to the 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 | | | | |
| | 01/16/09 | 150,000(2) | $ 0.22 | $ 32,237 |
| | 11/30/09 | 100,000(3) | $ 2.05 | $ 202,880 |
| Donna R. Rill | | | | |
| | 01/16/09 | 40,000(2) | $ 0.22 | $ 8,597 |
| | 02/06/09 | 8,396(4) | $ 0.47 | $ 3,833 |
| | 11/30/09 | 50,000(3) | $ 2.05 | $ 101,440 |
| Jaye L. Thompson | | | | |
| | 11/30/09 | 50,000(3) | $ 2.05 | $ 101,440 |

(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 10 to our financial statements included in this annual report on Form 10-K for assumptions underlying the valuation of equity awards.
(2) One-half of the shares vested on the date of grant and the remaining one-half vested on December 31, 2009.
(3) The shares vest quarterly over a three-year period from the grant date.
(4) Fully vested at grant.

### *2009 Outstanding Equity Awards at Fiscal Year-End*

The following table presents information regarding outstanding equity awards at December 31, 2009 for each of the Named Executive Officers.

| Name | Option Awards | | | |
|---|---|---|---|---|
| | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price ($) | Option Expiration Date |
| Neil K. Warma | | | | |
| | 166,669 | 83,331(1) | $ 1.01 | 06/16/18 |
| | 150,000 | — | $ 0.22 | 01/16/19 |
| | — | 100,000(1) | $ 2.05 | 11/30/19 |
| Donna R. Rill | | | | |
| | 6,000 | — | $ 7.00 | 12/05/10 |
| | 23,380 | — | $ 5.00 | 04/20/16 |
| | 21,333 | 10,667(2) | $ 5.47 | 06/18/17 |
| | 3,000 | — | $ 1.09 | 05/06/18 |
| | 19,250 | 13,750(1) | $ 1.17 | 06/26/18 |
| | 40,000 | — | $ 0.22 | 01/16/19 |
| | 8,396 | — | $ 0.47 | 02/06/19 |
| | — | 50,000(1) | $ 2.05 | 11/30/19 |
| Jaye L. Thompson | | | | |
| | — | 50,000(1) | $ 2.05 | 11/30/19 |

(1) The shares vest quarterly over a three-year period from the grant date.
(2) The shares vest on 6/18/10.

### *2009 Director Compensation*

The following table presents summary information for the year ended December 31, 2009 regarding the compensation of the non-employee members of our Board of Directors. Mr. Randall resigned from the Board effective February 19, 2009, and Mr. McWilliams did not stand for re-election at the expiration of his term of office effective November 11, 2009.

| Name | Fees Earned or Paid in Cash | Options Awards(1) | Total |
|---|---|---|---|
| David Hung(2) | — | $ 15,199(11)(12) | $15,199 |
| David E. Jorden(3) | $ 15,000(7)(8) | $ 18,340(11)(12) | $33,340 |
| David B. McWilliams(4) | $ 9,000(9) | $ 15,199(11)(12) | $24,199 |
| Lorin J. Randall | $ 4,600(10) | — | $ 4,600 |
| Michael S. Richman(5) | — (7) | $ 24,887(12) | $24,887 |
| Scott B. Seaman(6) | — (7) | $ 28,097(11)(12) | $28,097 |

(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 10 to our financial statements included in this annual report on Form 10-K for assumptions underlying the valuation of equity awards.
(2) Holds options to purchase 61,000 shares of common stock at fiscal year end.
(3) Holds options to purchase 42,880 shares of common stock at fiscal year end.
(4) Holds options to purchase 268,326 shares of common stock at fiscal year end.
(5) Holds options to purchase 103,650 shares of common stock at fiscal year end.

(6) Holds options to purchase 111,150 shares of common stock at fiscal year end.
(7) Messrs. Jorden, Richman and Seaman elected to exchange Board compensation fees due as of December 31, 2008 for stock options. On February 6, 2009, each named director was issued an option to purchase one share of common stock for each dollar due, fully vested and exercisable for a term of ten years, at an exercise price of $0.47 per share, the market value on the date of grant.
(8) Compensation for services as chair of the Audit Committee for the fourth quarter 2009 and paid in January 2010.
(9) Payment of deferred 2008 board compensation fees in 2009.
(10) Payment of fourth quarter 2008 and first quarter 2009 board compensation fees paid in 2009.
(11) Dr. Hung and Messrs. Jorden, McWilliams and Seaman elected to exchange Board compensation fees due for the period January 1, 2009 to June 30, 2009 for stock options. On February 6, 2 009, each named director was issued an option to purchase 8,000 shares of common stock, fully vested on June 30, 2009 and exercisable for a term of ten years, at an exercise price of $0.47 per share, the market value on the date of grant.
(12) Dr. Hung and Messrs. Jorden, McWilliams, Richman and Seaman elected to exchange Board compensation fees due for the period July 1, 2009 to December 31, 2009 for stock options. On August 26, 2009, each named director was issued an option to purchase 8,000 shares of common stock, fully vested on December 31, 2009 and exercisable for a term of ten years, at an exercise price of $1.47 per share, the market value on the date of grant.

The following table presents information regarding stock option granted in 2009 pursuant to our 2004 Compensatory Stock Option Plan to the non-employee members of our Board of Directors.

| Name | Grant Date | Number of Securities Underlying Options | Exercise Price of Option Awards | Grant Date Fair Value of Options(1) |
|---|---|---|---|---|
| David Hung | | | | |
| | 02/06/09 | 8,000 | $ 0.47 | $ 3,667 |
| | 08/26/09 | 8,000 | $ 1.47 | $ 11,532 |
| David E. Jorden | | | | |
| | 02/06/09 | 6,880 | $ 0.47 | $ 3,141 |
| | 02/06/09 | 8,000 | $ 0.47 | $ 3,667 |
| | 08/26/09 | 8,000 | $ 1.47 | $ 11,532 |
| David B. McWilliams | | | | |
| | 02/06/09 | 8,000 | $ 0.47 | $ 3,667 |
| | 08/26/09 | 8,000 | $ 1.47 | $ 11,532 |
| Michael S. Richman | | | | |
| | 02/06/09 | 29,250 | $ 0.47 | $ 13,355 |
| | 08/26/09 | 8,000 | $ 1.47 | $ 11,532 |
| Scott B. Seaman | | | | |
| | 02/06/09 | 28,250 | $ 0.47 | $ 12,898 |
| | 02/06/09 | 8,000 | $ 0.47 | $ 3,667 |
| | 08/26/09 | 8,000 | $ 1.47 | $ 11,532 |

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

***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. In summary, non-employee Board members receive the following fees:

| | |
|---|---|
| Annual retainer | $ 12,000 |
| For each Board meeting attended in person | $ 1,500 |
| For each Board meeting attended that is held telephonically | $ 750 |
| For each committee meeting attended by a non-chair committee member | $ 750 |
| For each committee meeting attended by the chair of that committee | $ 1,000 |
| Quarterly retainer for Audit Committee chair | $ 15,000 |

In lieu of cash compensation for services as a member of the Board for 2009, the Board elected to temporarily suspend cash payments, and non-employee directors were issued stock options instead, except with respect to the Audit Committee chair quarterly retainer.

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

The following table sets forth, as of February 25, 2010, 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 25, 2010 there were 15,527,322 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 sixty (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%:** | | |
| Charles E. Sheedy(2) | 1,456,090(3) | 8.97% |
| Albert and Margaret Alkek Foundation(4) | 1,624,755(5) | 9.99% |
| LBI Group Inc.(6) | 1,461,755(7) | 8.96% |
| Alkek & Williams Ventures Ltd.(8) | 1,421,269(9) | 8.60% |
| DLD Family Investments, LLC(10) | 989,014(11) | 6.13% |
| Austin W. Marxe(12) | 1,235,800(13) | 7.72% |
| David M. Greenhouse(12) | 1,235,800(13) | 7.72% |
| **Officers and Directors:** | | |
| David E. Jorden | 1,492,332(14) | 9.12% |
| Scott B. Seaman(8) | 1,454,916(15) | 8.81% |
| Neil K. Warma | 353,205(16) | 2.23% |
| Donna R. Rill | 128,136(17) | * |
| Michael S. Richman | 103,650(18) | * |
| David Hung | 78,573(19) | * |
| Jaye L. Thompson | 8,480(20) | * |
| All directors and executive officers as a group (7 persons)** | 3,619,292(21) | 22.19% |

* Less than 1%

** Includes only current directors and officers serving in such capacity as of February 25, 2010.

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

(2) 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 July 23, 2009 by Charles E. Sheedy. The mailing address of the beneficial owner is 909 Fannin Street, Suite 2907, Houston, Texas 77010.

(3) Consisting of: (i) 752,354 shares of common stock; (ii) 50,000 shares of common stock underlying the April 2006 warrants; (iii) 150,000 shares of common stock underlying Series E warrants; (iv) 353,736 shares of common stock underlying Series F warrants; (v) 100,000 shares of common stock resulting from the potential conversion of the April 2009 convertible notes; and (vi) 50,000 shares of common stock underlying the Series G warrants.

(4) 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, and the other reporting persons named therein (the "Foundation 13D") and other information available to the Company. 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.

(5) Consisting of: (i) 902,618 shares of common stock; (ii) 22,222 shares of common stock underlying Series C warrants; (iii) 158,165 shares of common stock underlying the Series F warrants; (iv) 41,750 shares of common stock underlying the Series G warrants; and (v) 500,000 shares of common stock resulting from the potential conversion of the April 2009 convertible notes. Excludes: (i) 250,000 shares of common stock underlying the April 2006 warrants; (ii) 250,000 shares of common stock underlying the Series E warrants; and (iii) 208,250 shares of common stock underlying the Series G warrants because the Foundation is contractually prohibited from exercising any of these warrants to the extent that it would beneficially own in excess of 9.999% of the total number of issued and outstanding shares of common stock after such exercise. 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 the Company held by DLD Family Investments, LLC, Mr. Arnold, Mr. Bailey or Ms. Williams and (ii) that they have agreed to act together with DLD Family Investments, LLC, 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) 392,454 shares of common stock held by DLD Family Investments, LLC; (ii) 17,778 shares of common stock underlying Series C warrants held by DLD Family Investments, LLC; (iii) 110,000 shares of common stock underlying the April 2006 warrants held by DLD Family Investments, LLC; (iv) 100,000 shares of common stock underlying Series E warrants held by DLD Family Investments, LLC; (v) 68,781 shares of common stock underlying Series F warrants; (vi) 200,000 shares of common stock resulting from the potential conversion of the April 2009 convertible notes; (vii) 100,000 shares of common stock underlying the Series G warrants; (viii) 26,667 shares of common stock held by Mr. Arnold; (ix) 8,889 shares of common stock underlying Series C warrants held by Mr. Arnold; (x) 10,000 shares of common stock underlying the April 2006 warrants held by Mr. Arnold; (xi) 50,000 shares of common stock held by Mr. Bailey; (xii) 5,000 shares of common stock underlying a Warrant held by Mr. Bailey; (xiii) 416,537 shares of common stock held by Ventures; (xiv) 18,223 shares of common stock underlying Series C warrants held by Ventures; (xv) 125,000 shares of common stock underlying the April 2006 warrants held by Ventures; (xvi) 200,000 shares of common stock underlying Series E warrants held by Ventures; (xvii) 61,509 shares of common stock underlying Series F warrants held by Ventures; (xviii) 400,000 shares of common stock resulting from the potential conversion of the April 2009 convertible notes; (xix) 200,000 shares of common stock underlying the Series G warrants; (xx) 43,655 shares of common stock held by Mr. Seaman; (xxi) 5,334 shares of common stock underlying Series C warrants held by Mr. Seaman; (xxii) 7,500 shares of common stock underlying the April 2006 warrants held by Mr. Seaman; (xxiii) 10,000 shares of common stock underlying Series E warrants held by Mr. Seaman and (xxiv) 17,573 shares of common stock underlying Series F warrants held by Mr. Seaman. The information in this footnote is primarily based on the Foundation 13D and other information provided to us.

(6) 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 1271 Sixth Avenue, 38th Floor, New York, New York 10020.

(7) Consisting of: (i) 675,675 shares of common stock and (ii) 786,080 shares of common stock underlying Series F warrants.

(8) 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.

(9) Consisting of: (i) 416,537 shares of common stock; (ii) 18,223 shares of common stock underlying Series C warrants; (iii) 125,000 shares of common stock underlying the April 2006 warrants; (iv) 200,000 shares of common stock underlying Series E warrants; (v) 61,509 shares of common stock underlying Series F warrants; and (vi) 400,000 shares of common stock resulting from the potential conversion of the April 2009 convertible notes; and (vii) 200,000 shares underlying the Series G warrants.

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

(11) Consisting of: (i) 392,454 shares of common stock; (ii) 17,779 shares of common stock underlying Series C warrants; (iii) 110,000 shares of common stock underlying the April 2006 warrants; (iv) 100,000 shares of common stock underlying Series E warrants; (v) 68,781 shares of common stock underlying Series F warrants; (vi) 200,000 shares of common stock resulting from the potential conversion of the April 2009 convertible notes; and (vii) 100,000 shares of common stock underlying the Series G warrants.

(12) Austin W. Marxe and David M. Greenhouse are the controlling principals of AWM Investment Company, Inc. ("AWM"), the general partner of and investment advisor to Special Situations Cayman Fund, L.P. ("Cayman"). AWM serves as the investment advisor to Special Situations Fund III QP, L.P. ("SSFQP"), Special Situations Private Equity Fund, L.P. ("SSPE"), and Special Situations Life Sciences Fund, L.P. ("Life Sciences"). Cayman, SSFQP, SSPE, and Life Sciences are collectively referred to as the "Funds." AWM and Messrs. Marxe and Greenhouse are either the general partner or members of entities which are the general partner of the Funds. Messrs. Marxe and Greenhouse exercise joint voting and dispositive power over all of the shares of common stock and warrants owned by the Funds. The information in this footnote is primarily based on a Schedule 13G filed with the SEC on February 12, 2010. The mailing address of Messrs. Marxe and Greenhouse is 527 Madison Ave., Suite 2600, New York, New York 10022.

(13) Consisting of: (i) 750,000 shares of common stock and (ii) 485,800 shares of common stock underlying the April 2006 warrants held by the Funds.

(14) Consisting of: (i) 650,000 shares of common stock (ii) 60,000 shares of common stock underlying the April 2006 warrants; (iii) 132,000 shares of common stock underlying Series E warrants; (iv) 314,118 shares of common stock underlying Series F warrants; (v) 200,000 shares of common stock resulting from the potential conversion of the April 2009 convertible notes; and (vi) 100,000 shares of common stock underlying the Series G Warrants; and (vii) 36,214 shares of common stock underlying currently exercisable stock options.

(15) Consisting of: (i) 111,150 shares underlying stock options; (ii) 416,537 shares of common stock held by Ventures; (iii) 18,223 shares of common stock underlying Series C warrants held by Ventures; (iv) 125,000 shares of common stock underlying the April 2006 warrants held by Ventures; (v) 200,000 shares of common stock underlying Series E warrants held by Ventures; (vi) 61,509 shares of common stock underlying Series F Warrants held by Ventures; (vii) 400,000 shares of common stock resulting from the potential conversion of the April 2009 convertible notes held by Ventures; (viii) 200,000 shares underlying the Series G Warrants held by Ventures; (ix) 5,334 shares of common stock underlying Series C warrants; (x) 7,500 shares of common stock underlying the April 2006 warrants; (xi) 10,000 shares of common stock underlying Series E warrants; (xii) 17,573 shares of common stock underlying Series F warrants; and (xiii) 43,655 shares of common stock. (See footnote 9 for additional discussion of the information set forth in clauses (ii) through (viii) 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) 902,618 shares of common stock held by the Foundation; (ii) 22,222 shares of common stock underlying Series C warrants held by the Foundation; (iii) 250,000 shares of common stock underlying the April 2006 warrants held by the Foundation; (iv) 250,000 shares of common stock underlying Series E warrants held by the Foundation; (v) 158,165 shares of common stock underlying Series F warrants held by the Foundation; (vi) 250,000 shares of common stock underlying Series G warrants held by the Foundation; and (vii) 500,000 shares of common stock resulting from the potential conversion of the April 2009 convertible notes held by the Foundation. (See footnote 5 for additional discussion of the information set forth in clauses (i) through (vii) of the preceding sentence.) The mailing address of the beneficial owner is 1100 Louisiana, Suite 5250, Houston, Texas 77002.

(16) Consisting of: (i) 3,021 shares of common stock; (ii) 3,515 shares of common stock underlying Series F warrants; (iii) 20,000 shares of common stock resulting from the potential conversion of the April 2009 convertible notes; (iv) 10,000 shares of common stock underlying the Series G Warrants; and (v) 316,669 shares of common stock underlying currently exercisable stock options.

(17) Consisting of: (i) 2,610 shares of common stock and (ii) 125,526 shares of common stock underlying currently exercisable stock options.

(18) Consisting of 103,650 shares of common stock underlying currently exercisable stock options.

(19) Consisting of: (i) 17,573 shares of common stock underlying Series F warrants and (ii) 61,000 shares of common stock underlying currently exercisable stock options.

(20) Consisting of: (i) 4,313 shares of common stock and (ii) 4,167 shares of common stock underlying currently exercisable stock options.

(21) Consisting of: (a) the following held by Mr. Jorden (i) 60,000 shares of common stock underlying the April 2006 warrants; (ii) 132,000 shares of common stock underlying Series E warrants; (iii) 314,118 shares of common stock underlying Series F warrants; (iv) 36,214 shares of common stock underlying currently exercisable stock options; (v) 200,000 shares of common stock underlying convertible promissory notes; (vi) 100,000 shares underlying Series G warrants; and (vii) 650,000 shares of common stock; (b) the following held by Mr. Seaman or for which Mr. Seaman may be deemed to have voting and investment power: (i) 111,150 shares of common stock underlying currently exercisable stock options; (ii) 416,537 shares of common stock held by Ventures; (iii) 18,223 shares of common stock underlying Series C warrants held by Ventures; (iv) 125,000 shares of common stock underlying April 2006 warrants held by Ventures; (v) 200,000 shares of common stock underlying Series E warrants held by Ventures; (vi) 61,509 shares of common stock underlying Series F warrants held by Ventures; (vii) 400,000 shares of common stock underlying convertible promissory notes; (viii) 5,334 shares of common stock underlying Series C warrants; (ix) 7,500 shares of common stock underlying the April 2006 warrants; (x) 10,000 shares of common stock underlying Series E warrants; (xi) 17,573 shares of common stock underlying Series F warrants; and (xii) 43,655 shares of common stock; (c) the following held by Dr. Hung (i) 17,573 shares of common stock underlying warrants and (ii) 61,000 shares of common stock underlying currently exercisable stock options; (d) the following held by Mr. Warma (i) 3,021 shares of common stock; (ii) 3,515 shares underlying Series F warrants; (iii) 20,000 shares underlying convertible promissory notes; (iv) 10,000 shares underlying Series G warrants; and (v) 316,669 shares of common stock underlying currently exercisable stock options; (e) 103,650 shares underlying currently exercisable stock options held by Mr. Richman and (f) 2,610 shares of common stock and 125,526 shares of common stock underlying currently exercisable stock options held by Ms. Rill and (g) 4,313 shares of common stock and 4,167 shares of common stock underlying currently exercisable stock options held by Ms. Thompson.

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

| Director | Independent | Audit Committee | Compensation Committee | Nominating and Corporate Governance Committee |
|---|---|---|---|---|
| David Hung | X | | X | X |
| David E. Jorden | 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, 2009 | 2008 |
|---|---|---|
| Audit fees(1) | $ 75,375 | $ 67,415 |
| Tax fees(2) | — | 5,600 |
| All other fees(3) | 7,125 | 11,875 |
| | $ 82,500 | $ 84,800 |

(1) Audit fees include professional services rendered for (i) the audit of our annual financial statements for the fiscal years ended December 31, 2008 and 2009, (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, 2009 and 2008 and the period from January 22, 2003 (Inception) through December 31, 2009**



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). |
| 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). |
| 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). |
| 3.2 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company (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 (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on November 13, 2009). |
| 4.1 | Form of Common Stock Certificate (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-3 (File No. 333-163108), filed on November 13, 2009). |
| 4.2 | Registration Rights Agreement dated June 17, 2005 by and among the purchasers named therein for Series C Warrants (incorporated by reference to Exhibit 10.19 to Form SB-2 filed July 19, 2005). |
| 4.3 | Securities Purchase Agreement dated June 17, 2005 by and among the Company and the Investors named therein for Series C Warrants (incorporated by reference to Exhibit 10.18 to Form SB-2 filed July 19, 2005). |

| | |
|---|---|
| 4.4 | Securities Purchase Agreement dated June 30, 2005 by and among the Company and the purchasers named therein for Series C Warrants (incorporated by reference to Exhibit 10.20 to Form SB-2 filed July 19, 2005). |
| 4.5 | Securities Purchase Agreement dated July 15, 2005 by and among the Company and the Investors named therein for Series C Warrants (incorporated by reference to Exhibit 10.21 to Form SB-2 filed July 19, 2005). |
| 4.6 | Registration Rights Agreement dated July 15, 2005 by and among the Company and the Investors named therein for Series C and Series D Warrants (incorporated by reference to Exhibit 10.22 to Form SB-2 filed July 19, 2005). |
| 4.7 | Form of Series C Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.17 to Form SB-2 filed July 19, 2005). |
| 4.8 | Form of Series D Warrant Agreement issued to brokers in connection with 2005 Series A, Series B and Series C Warrant offerings (incorporated by reference to Exhibit 10.25 to Amendment No. 2 to Form SB-2 filed April 11, 2006). |
| 4.9 | Purchase Agreement dated April 11, 2006 by and among the Company and the Investors named therein for April 2006 common stock and warrant offering (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 18, 2006). |
| 4.10 | Form of Warrant issued in connection with April 2006 offering (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed April 18, 2006). |
| 4.11 | Registration Rights Agreement dated April 11, 2006 by and among the Company and the Investors named therein for April 2006 offering common stock and warrants (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed April 18, 2006). |
| 4.12 | 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) (File No. 333-147167) filed December 20, 2007). |
| 4.13 | 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). |
| 4.14 | 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). |
| 4.15 | 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). |
| 4.16 | 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). |
| 4.17 | 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). |
| 4.18 | 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). |
| 4.19 | 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). |

| | |
|---|---|
| 4.20 | Form of 10% Convertible Promissory Note due April 14, 2011 issued by the Company on April 14, 2009 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed April 16, 2009). |
| 4.21 | Registration Rights Agreement dated April 14, 2009 by and among the Company and the investors party thereto (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed April 16, 2009). |
| 4.22 | 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). |
| 4.23 | Security Agreement dated April 14, 2009 by and among the Company and the investors party thereto (incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K filed April 16, 2009). |
| 4.24 | 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). |
| 4.25 | 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). |
| 4.26 | 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). |
| 10.1+ | 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). |
| 10.2+ | Amended and Restated Employment Agreement dated June 15, 2006 by and between the Company and David B. McWilliams (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-QSB filed August 14, 2006). |
| 10.3+ | Amendment to Employment Agreement dated May 9, 2008 by and between the Company and David B. McWilliams (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed May 13, 2008). |
| 10.4+ | Employment Agreement dated May 9, 2008 by and between the Company and Lynne Hohlfeld (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed May 13, 2008). |
| 10.5+ | Employment Agreement dated May 9, 2008 by and between the Company and Jim C. Williams, Ph.D (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed May 13, 2008). |
| 10.6+ | Employment Agreement dated May 9, 2008, between the Company and Donna R. Rill (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed May 13, 2008). |
| 10.7+ | 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). |
| 10.8+ | Employment Agreement dated April 14, 2009 between the Company and Donna R. Rill (incorporated by reference to Exhibit 10.6 of the Company's Current Report on Form 8-K filed April 16, 2009). |

| | |
|---|---|
| 10.9*+ | Employment Agreement dated November 16, 2009 by and between the Company and Jaye L. Thompson. |
| 10.10 | 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). |
| 10.11 | 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). |
| 10.12 | 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 Amendment No. 1 to Form SB-2 filed February 9, 2006). |
| 10.13 | Second Amended and Restated License Agreement dated July 31, 2007 by and between the Company and the University of Chicago (incorporated by reference to Exhibit 10.1 of the Company's Report on Form 8-K filed August 3, 2007). |
| 10.14++ | Asset Purchase Agreement by and between the Company and Novartis Institutes for Biomedical Research, Inc. dated August 6, 2009 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed August 7, 2009). |
| 10.15*+ | Certificate of Amendments to the Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan. |
| 23* | Consent of Independent Registered Public Accounting Firm MaloneBailey, LLP, dated March 4, 2010 to the incorporation by reference of their report dated March 4, 2010, 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.
++ Confidential treatment has been requested as to certain portions of this Exhibit pursuant to Rule 406 promulgated under the Securities Act. Such portions have been omitted and filed separately with the SEC.

**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: March 4, 2010

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 | March 4, 2010 |
| /S/ DAVID HUNG<br>**David Hung** | Director | March 4, 2010 |
| /S/ DAVID E. JORDEN<br>**David E. Jorden** | Director | March 4, 2010 |
| /S/ MICHAEL S. RICHMAN<br>**Michael S. Richman** | Director | March 4, 2010 |
| /S/ SCOTT B. SEAMAN<br>**Scott B. Seaman** | Director | March 4, 2010 |

## 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, 2009 and 2008 and the related statements of expenses, changes in stockholders' equity and cash flows for the years then ended and for the period from January 22, 2003 (Inception) through December 31, 2009. 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, 2009 and 2008 and the results of its operations and its cash flows for the years then ended and for the period from January 22, 2003 (Inception) through December 31, 2009 in conformity with accounting principles generally accepted in the United States of America.

/s/ MALONEBAILEY, LLP
www.malone-bailey.com
Houston, Texas

March 4, 2010

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

| | December 31, 2009 | December 31, 2008 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 8,181,582 | $ 1,243,187 |
| Other current assets | 187,306 | 86,705 |
| Total current assets | 8,368,888 | 1,329,892 |
| Property & equipment, net of accumulated depreciation of $1,029,241 and $847,244, respectively | 949,910 | 1,166,530 |
| Total assets | $ 9,318,798 | $ 2,496,422 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 593,011 | $ 482,838 |
| Accounts payable—related parties | 32,591 | 161,714 |
| Accrued expenses | 141,065 | 199,272 |
| Current maturity of loan payable | 67,307 | 62,423 |
| Total current liabilities | 833,974 | 906,247 |
| Long term liabilities: | | |
| Convertible promissory notes, net of discount of $314,749 | 987,251 | — |
| Loan payable | 35,625 | 102,778 |
| Accrued interest | 86,800 | — |
| Total liabilities | 1,943,650 | 1,009,025 |
| 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, 15,476,222 and 12,245,858 shares issued and outstanding | 154,762 | 6,122,888 |
| Additional paid in capital | 96,463,658 | 84,929,481 |
| Deficit accumulated during the development stage | (89,243,272) | (89,564,972) |

| | | |
|---|---|---|
| Total stockholders' equity | 7,375,148 | 1,487,397 |
| Total liabilities and stockholders' equity | $ 9,318,798 | $ 2,496,422 |

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, 2009 and 2008 and the**
**Period from January 22, 2003 (Inception) to December 31, 2009**

| | 2009 | 2008 | Inception through 2009 |
|---|---|---|---|
| Research and development | $ 2,107,833 | $ 8,388,734 | $ 64,254,104 |
| General and administrative | 2,020,572 | 3,341,415 | 22,986,762 |
| Depreciation and amortization | 214,851 | 234,325 | 967,386 |
| Loss on disposal of assets | 1,771 | 2,831 | 500,103 |
| Operating loss | (4,345,027) | (11,967,305) | (88,708,355) |
| Interest income | 1,764 | 100,235 | 1,355,825 |
| Other income and expense, net | 554,242 | 34,901 | 661,146 |
| Gain on extinguishment of debt | — | — | 1,612,440 |
| Gain (loss) on derivative instruments | (366,774) | — | 1,388,848 |
| Gain on sale of technology | 3,000,000 | — | 3,000,000 |
| Interest expense | (278,127) | (19,983) | (8,553,176) |
| Net loss | $ (1,433,922) | $ (11,852,152) | $ (89,243,272) |
| Basic and diluted loss per share | $ (0.11) | $ (1.12) | |
| Weighted average shares outstanding | 12,556,056 | 10,551,321 | |

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, 2009**

| | 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) |

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

**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY—(Continued)**
**Period from January 22, 2003 (Inception) through December 31, 2009**

| | Common Stock | | Additional Paid in Capital | Accumulated Deficit | Total |
|---|---|---|---|---|---|
| | Shares | Par | | | |
| 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 |
| 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 |

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, 2009 and 2008 and the**
**Period from January 22, 2003 (Inception) to December 31, 2009**

| | 2009 | 2008 | Inception through 2009 |
|---|---|---|---|
| Cash flows from operating activities | | | |
| Net loss | $ (1,433,922) | $ (11,852,152) | $ (89,243,272) |
| 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 | — | 48,964 | 1,910,365 |
| Stock issued for debt in excess of principal | — | — | 109,070 |
| Amortization of discount on notes payable due to warrants and beneficial conversion feature | 124,744 | — | 6,437,949 |
| Unrealized gain on marketable securities | — | | — |
| Gain on extinguishment of debt | — | — | (1,612,440) |
| Depreciation | 214,851 | 234,325 | 967,386 |
| Amortization of debt financing costs | 50,351 | — | 416,261 |
| Option and warrant expense | 650,249 | 1,901,571 | 14,576,743 |
| Loss on derivative instruments | 366,774 | — | (1,388,848) |
| Loss on disposition of fixed assets | 1,771 | 2,831 | 500,103 |
| Changes in: | | | |
| Accounts receivable | — | — | — |
| Prepaid and other expenses | 7,516 | 268,561 | (495,862) |
| Accounts payable | (19,360) | (347,980) | 175,552 |
| Accrued expenses | 28,593 | (823,189) | 101,210 |
| Net cash provided by (used in) operating activities | (8,433) | (10,567,069) | (41,146,754) |
| Cash flows from investing activities | | | |
| Purchase of property & equipment | — | (33,040) | (1,339,511) |
| Net cash provided by (used in) investing activities | — | (33,040) | (1,339,511) |
| Cash flows from financing activities | | | |

| | | | |
|---|---|---|---|
| Common stock and warrants sold for cash, net of offering costs | 4,689,165 | 9,255,429 | 40,454,331 |
| Common stock repurchased and canceled | — | — | (325) |
| Proceeds from exercise of warrants and options | 1,138,947 | — | 1,138,947 |
| Proceeds from debt | 1,180,985 | | 9,283,184 |
| Repayments on notes payable | (62,269) | (57,615) | (208,290) |
| Net cash provided by financing activities | 6,946,828 | 9,197,814 | 50,667,847 |
| Net change in cash and cash equivalents | 6,938,395 | (1,402,295) | 8,181,582 |
| Cash and cash equivalents at beginning of period | 1,243,187 | 2,645,482 | — |
| Cash and cash equivalents at end of period | $ 8,181,582 | $ 1,243,187 | $ 8,181,582 |
| Cash paid for: | | | |
| Income tax | $ — | $ — | $ — |
| Interest | 16,232 | $ 19,984 | 63,357 |
| NON-CASH TRANSACTIONS | | | |
| Issuance of common stock to Sportan shareholders | — | — | 147,733 |
| Issuance of common stock for accrued interest | — | — | 525,513 |
| Issuance of warrants to placement agent | 37,453 | — | 37,453 |
| Conversion of notes payable to common stock | — | — | 6,407,980 |
| 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 | 349,947 | — | 3,659,737 |
| Beneficial conversion feature | 89,546 | — | 1,805,519 |
| Stock attached to notes | — | — | 1,287,440 |
| Fair value of derivative instrument | (1,976,457) | — | 4,680,220 |
| Derivative reclassified to equity | 587,609 | — | 587,609 |

See accompanying summary of accounting policies and notes to financial statements

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

**NOTES TO FINANCIAL STATEMENTS**

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

Opexa Therapeutics, Inc. ("Opexa") 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. Effective August 6, 2009, the Company entered into an exclusive agreement with Novartis whereby Novartis acquired the Company's rights to the technology and has full responsibility for funding and carrying out all research, development and commercialization activities. The Company 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. The Company will receive an additional $0.5 million technology transfer fee in 2010. The Company is eligible to receive certain clinical and commercial milestone payments as well as royalty payments from the sale of any products resulting from the use of the technology and the Company retains an option on certain manufacturing rights.

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).

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

**Basis of Presentation.** In June 2006, Opexa (i) changed its name to Opexa Therapeutics, Inc. from Pharma and (ii) affected a one-for-ten reverse common stock split. All references to number of shares and per share amounts reflect such split as if it occurred on the first day of the first period presented. The financial statements include the accounts of Opexa and its wholly-owned subsidiary, Opexa Pharmaceuticals, Inc. through December 31, 2006. All inter-company accounts and transactions have been eliminated. 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.

**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.

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

**NOTES TO FINANCIAL STATEMENTS**

**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. Marketable securities include investments with maturities greater than three months but less than one year. 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.

**Stock-Based Compensation.** On January 1, 2006, Opexa began recording compensation expense associated with stock options and other forms of equity compensation in accordance with FASB ASC 718. Prior to January 1, 2006, Opexa had accounted for stock options according to the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations, and therefore no related compensation expense was recorded for awards granted with no intrinsic value. Opexa adopted the modified prospective transition method provided for under FASB ASC 718, and, consequently, has not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options recognized in the first quarter of fiscal 2006 includes the quarterly amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006, based on the estimated grant date 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, 2009 and 2008 was $2,107,833 and $8,388,734, respectively.

**Accounting for Derivative Instruments.** In accordance with FASB ASC 815, all derivatives are to be recorded on the balance sheets at fair value. Opexa's derivatives are separately valued and accounted for on the balance sheets. Fair values for securities traded in the open market and derivatives are based on quoted market prices. Where market prices are not readily available, fair values are determined using market based pricing models incorporating readily observable market data and requiring judgment and estimates.

The pricing model Opexa used for determining fair values of its derivatives is the Black-Scholes option-pricing model. Valuations derived from this model are subject to ongoing internal and external verification and review. The model uses market-sourced inputs such as interest rates, exchange rates and option volatilities. Selection of these inputs involves management's judgment and may impact net income.

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

**NOTES TO FINANCIAL STATEMENTS**

**Subsequent Events.** In accordance with applicable accounting standards for the disclosure of events that occur after the balance sheet date but before the financial statements are issued, we have evaluated all events or transactions that occurred after December 31, 2009. Please see Note 13 for details.

**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." The Company has incorporated the current codification in its Form 10-K.

In January 2009, Opexa adopted new accounting guidance for determining whether an instrument or an embedded feature is indexed to an entity's stock. The new guidance provides a new two-step model to be applied in determining whether a financial instrument or an embedded feature is indexed to an issuer's own stock, including evaluating the instrument's contingent exercise and settlement provisions. It also clarifies the impact of foreign-currency-denominated strike prices and market-based employee stock option valuation instruments on the evaluation. See also Note 11. There were various other accounting standards and interpretations issued during 2009 and 2008, none of which are expected to have a material impact on the Opexa's financial position, operations or cash flows.

**NOTE 2—RESTRUCTURING**

In November 2008, Opexa implemented a restructuring plan to terminate the one-year open label extension of the TERMS Phase IIb Clinical Trial of Tovaxin® therapy for multiple sclerosis (OLTERMS). The trial was enrolled with patients that had previously completed one year in the TERMS, Tovaxin Phase IIb multi-center, randomized, double blind, placebo-controlled trial. The Company terminated OLTERMS to conserve financial resources for clinical data analysis, future clinical trial planning and seeking a development partner for Tovaxin. As a result of this restructuring, the Company reduced its staff of 29 to 12 people. Personnel-related severance and benefits payments of $77,075 were paid in 2008.

**NOTE 3—CASH AND CASH EQUIVALENTS**

Opexa considers all highly liquid investments with an original maturity of three months or less, when purchased, to be cash equivalents.

At December 31, 2009, Opexa invested approximately $8 million in a money market account with an average market yield of 0.01%. Interest income of $1,764 was recognized for the year ended December 31, 2009 in the statements of expenses.

At December 31, 2008, Opexa invested approximately $1.2 million in a money market account with an average market yield of 0.8%. Interest income of $100,235 was recognized for the twelve months ended December 31, 2008 in the statements of expense.

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

**NOTE 4—PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following at December 31, 2009 and 2008:

| Description | Life | 2008 | 2009 |
|---|---|---|---|
| Computer equipment | 3 years | $ 123,155 | $ 155,018 |
| Office furniture and equipment | 3-10 years | 317,657 | 328,368 |
| Software | 3-5 years | 87,929 | 90,689 |
| Laboratory equipment | 3-10 years | 984,809 | 984,809 |
| Leasehold improvements | 10 years | 465,601 | 454,890 |
| Subtotal | | 1,979,151 | 2,013,774 |
| Less: accumulated depreciation | | (1,029,241) | (847,244) |
| Property and equipment, net | | $ 949,910 | $ 1,166,530 |

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 $214,851 and $234,325 for the years ended December 31, 2009 and 2008 respectively.

**NOTE 5—INCOME TAXES**

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

At December 31, 2009, for federal income tax and alternative minimum tax reporting purposes, Opexa had approximately $79 million of unused net operating losses available for carryforward to future years. The benefit from carryforward of such net operating losses will start to expire beginning on 2024. Under the provisions of Section 382 of the Internal Revenue Code, the benefit from utilization of approximately $5,650,429 of net operating losses incurred prior to October 7, 2004 was significantly limited as a result of the change of control that occurred in connection with Opexa's acquisition of Opexa Pharmaceuticals, Inc. The benefit could be subject to further limitations if significant future ownership changes occur in Opexa.

At December 31, 2009, deferred tax assets consisted of the following:

| | |
|---|---|
| NOL @ 12/31/09 | $ (78,786,494) |
| Estimated tax rate | X 34% |
| Deferred tax asset | (26,787,408) |
| Valuation allowance | 26,787,408 |
| Net deferred tax asset | $ — |

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

**NOTES TO FINANCIAL STATEMENTS**

**NOTE 6—LOAN PAYABLE**

Loan payable consists of an equipment line of up to $250,000 with Wells Fargo of which $102,932 and $165,201 were outstanding as of December 31, 2009 and 2008, respectively. This loan has an interest rate of 7.61% per annum, matures in May 2011 and is secured by Opexa's furniture and equipment purchased with the loan proceeds. For the years ended December 31, 2009 and 2008, Opexa recognized interest expense of $10,578 and $15,233, respectively associated with its equipment line.

**NOTE 7—CONVERTIBLE PROMISSORY NOTES**

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

In connection with the issuance of convertible promissory notes, warrants to purchase a total of 1,302,000 shares of common stock were issued to the investors. See Note 10 "Broker and Investor Warrants" section for details on the warrants. The convertible promissory notes were evaluated for a beneficial conversion feature under FASB ASC 470 and determined to have a beneficial conversion feature totaling $89,546. The Company recorded a debt discount of $439,493 related to the warrants granted to the investors. Pursuant to FASB ASC 470, the discount on the convertible promissory notes is amortized over the period between the issuance date and the maturity of the note under the effective interest method. The amortized discount for the year ended December 31, 2009 was $124,744.

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

The total of the fees associated with the financing (broker commissions and legal fees) was $158,468. These fees will be amortized over the life of the notes using the effective interest method. The amortized offering costs for the year ended December 31, 2009 was $50,351. Interest on the 10% promissory notes in the amount of $86,800 has been accrued as of December 31, 2009.

**NOTE 8—COMMITMENTS AND CONTINGENCIES**

In October 2005, Opexa entered into a ten-year lease for its office and research facilities. The facility including the property 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 $147,540 for 2010 and 2011, $150,129 for 2012 and a total of $434,221 for years 2013 to 2015. Rent expense was approximately $136,000 for each of the years ended December 31, 2009 and 2008.

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

**NOTE 9—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 12 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 note holders as their additional shares for their subscription investment.
- 60,750 shares of common stock were issued to note holders 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 is $1,103,714 and the relative fair value of the warrants is $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 note holders as their additional shares for their subscription investment.
- 565,858 shares of common stock were issued to note holders 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 note holders for the conversion of $51,930 of principal and interest from the notes.

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- 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.
- 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 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.

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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.

**NOTE 10—OPTIONS AND WARRANTS**

In 2004, Opexa adopted the June 2004 Compensatory Stock Option Plan ("the Plan") for the granting of stock options to employees and consultants of Opexa. Options granted under the Plan may be either incentive stock options or nonqualified stock options. The Board of Directors has discretion to determine the number, term, exercise price and vesting of all grants.

***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 5 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 10 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 5 to 10 years, (3) expected volatility range of 401.3% to 429.9% and (4) zero expected dividends.

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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 5 to 6 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 5to 6 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 5 to 6 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.

***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 5 years, (3) expected volatility of 75.1% and (4) zero expected dividends.

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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 5 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 10 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 5.75 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 5.5 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 5.5 years, (3) expected volatility range of 192.9% to 208.9% and (4) zero expected dividends.

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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.

***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 $23,000,000 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 3 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 5 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 5 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

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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 4 years, (3) expected volatility of 116.5% and (4) zero expected dividends.

In connection with the closing of 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 our 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 4 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 4 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 are 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 are first exercisable on June 15, 2010 and expire on November 23, 2014.

At December 31, 2009, the aggregate intrinsic value of the outstanding options and warrants were $1,106,364 and $2,740,166, 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 |

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Summary of options outstanding and exercisable as of December 31, 2009 is as follows:

| Range of Exercise Prices | Weighted Average Remaining Contractual Life (years) | Number of Options Outstanding | Number of Options Exercisable |
|---|---|---|---|
| $ 0.88 to 4.99 | 8.97 | 1,246,748 | 874,748 |
| 5.00 to 9.99 | 5.06 | 611,568 | 592,735 |
| 10.00 to 15.00 | 3.71 | 8,500 | 8,500 |
| 30.00 to 40.00 | 0.26 | 56,560 | 56,560 |
| $ 0.88 to 40.00 | 7.45 | 1,923,376 | 1,532,543 |

Summary of warrants outstanding and exercisable as of December 31, 2009 is as follows:

| Range of Exercise Prices | Weighted Average Remaining Contractual Life (years) | Number of Warrants Outstanding | Number of Warrants Exercisable |
|---|---|---|---|
| $ 0.75 to 4.99 | 3.23 | 9,214,737 | 7,850,487 |
| 5.00 to 9.99 | 1.28 | 2,305,390 | 2,305,390 |
| 15.00 to 30.00 | 0.46 | 1,156,634 | 1,156,634 |
| $ 0.75 to 30.00 | 2.62 | 12,676,761 | 11,312,511 |

**NOTE 11—DERIVATIVE INSTRUMENTS**

FASB ASC 815, "Accounting for Derivatives and Hedging Activities" ("FASB ASC 815") specifies that a contract that would otherwise meet the definition of a derivative, but is both (a) indexed to its own stock and (b) classified in stockholders' equity in the statement of financial position would not be considered a derivative financial instrument. FASB ASC 815 provides a new two-step model to be applied in determining whether a financial instrument or an embedded feature is indexed to an issuer's own stock, including evaluating the instrument's contingent exercise and settlement provisions, and thus able to qualify for the FASB ASC 815-10 scope exception. It also clarifies the impact of foreign-currency-denominated strike prices and market-based employee stock option valuation instruments on the evaluation. Initially, Opexa evaluated all of its financial instruments and determined that the Series F warrants associated with the August 2008 financing qualified for treatment under FASB ASC 815 and adjusted its financial statements to reflect the adoption of the FASB ASC 815 as of January 1, 2009. The fair value of these warrants were reclassified as of January 1, 2009 in the amount of $220,835 from additional paid in capital to derivative liability and the cumulative effect of the change in accounting principle in the amount of $1,755,622 was recognized as an adjustment to the opening balance of retained earnings. The impact of FASB ASC 815 for the year to date period ended June 1, 2009 resulted in an increase in the derivative liability of $366,774 with a corresponding loss on derivative instruments. On June 1, 2009, it was determined that the floor for resetting the exercise price was met and that any further adjustments to the exercise price of the Series F warrants would require a vote by the shareholders of the company. Therefore, the Series F warrants were considered indexed to the company's stock and qualified for the scope exception under FASB ASC 815-10 allowing for a transfer from liability classification to equity classification. Consequently, the remaining derivative liability of $587,609 at June 1, 2009 was reclassified to additional paid in capital.

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**NOTE 12—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 of Chicago 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 of Chicago $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. Effective August 6, 2009, the University of Chicago license agreement was assigned to Novartis as part of an agreement as further described below.

***Stem Cell Technology Agreement***

Effective August 6, 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 will have 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. Opexa will receive an additional $0.5 million technology transfer fee in 2010. The $3 million was recorded as a gain on sale of technology and the $0.5 million technology transfer fee was recorded as other income for the year end December 31, 2009.

Opexa is eligible to receive certain clinical and commercial milestone payments as well as royalty payments from the sale of any products resulting from the use of the technology and retains an option on certain manufacturing rights.

**NOTE 13—SUBSEQUENT EVENTS**

Subsequent to December 31, 2009, former employees exercised their options to purchase 65,726 shares for a total of $51,433 at exercise prices ranging from $0.47 per share to $1.17 per share.

## 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). |
| 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). |
| 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). |
| 3.2 | Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company (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 (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on November 13, 2009). |
| 4.1 | Form of Common Stock Certificate (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-3 (File No. 333-163108), filed on November 13, 2009). |
| 4.2 | Registration Rights Agreement dated June 17, 2005 by and among the purchasers named therein for Series C Warrants (incorporated by reference to Exhibit 10.19 to Form SB-2 filed July 19, 2005). |
| 4.3 | Securities Purchase Agreement dated June 17, 2005 by and among the Company and the Investors named therein for Series C Warrants (incorporated by reference to Exhibit 10.18 to Form SB-2 filed July 19, 2005). |
| 4.4 | Securities Purchase Agreement dated June 30, 2005 by and among the Company and the purchasers named therein for Series C Warrants (incorporated by reference to Exhibit 10.20 to Form SB-2 filed July 19, 2005). |
| 4.5 | Securities Purchase Agreement dated July 15, 2005 by and among the Company and the Investors named therein for Series C Warrants (incorporated by reference to Exhibit 10.21 to Form SB-2 filed July 19, 2005). |
| 4.6 | Registration Rights Agreement dated July 15, 2005 by and among the Company and the Investors named therein for Series C and Series D Warrants (incorporated by reference to Exhibit 10.22 to Form SB-2 filed July 19, 2005). |
| 4.7 | Form of Series C Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.17 to Form SB-2 filed July 19, 2005). |
| 4.8 | Form of Series D Warrant Agreement issued to brokers in connection with 2005 Series A, Series B and Series C Warrant offerings (incorporated by reference to Exhibit 10.25 to Amendment No. 2 to Form SB-2 filed April 11, 2006). |
| 4.9 | Purchase Agreement dated April 11, 2006 by and among the Company and the Investors named therein for April 2006 common stock and warrant offering (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 18, 2006). |
| 4.10 | Form of Warrant issued in connection with April 2006 offering (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed April 18, 2006). |
| 4.11 | Registration Rights Agreement dated April 11, 2006 by and among the Company and the Investors named therein for April 2006 offering common stock and warrants (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed April 18, 2006). |

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| 4.12 | 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) (File No. 333-147167) filed December 20, 2007). |
| 4.13 | 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). |
| 4.14 | 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). |
| 4.15 | 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). |
| 4.16 | 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). |
| 4.17 | 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). |
| 4.18 | 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). |
| 4.19 | 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). |
| 4.20 | Form of 10% Convertible Promissory Note due April 14, 2011 issued by the Company on April 14, 2009 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed April 16, 2009). |
| 4.21 | Registration Rights Agreement dated April 14, 2009 by and among the Company and the investors party thereto (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed April 16, 2009). |
| 4.22 | 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). |
| 4.23 | Security Agreement dated April 14, 2009 by and among the Company and the investors party thereto (incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K filed April 16, 2009). |
| 4.24 | 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). |
| 4.25 | 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). |
| 4.26 | 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). |
| 10.1+ | 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). |

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| 10.2+ | Amended and Restated Employment Agreement dated June 15, 2006 by and between the Company and David B. McWilliams (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-QSB filed August 14, 2006). |
| 10.3+ | Amendment to Employment Agreement dated May 9, 2008 by and between the Company and David B. McWilliams (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed May 13, 2008). |
| 10.4+ | Employment Agreement dated May 9, 2008 by and between the Company and Lynne Hohlfeld (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed May 13, 2008). |
| 10.5+ | Employment Agreement dated May 9, 2008 by and between the Company and Jim C. Williams, Ph.D (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed May 13, 2008). |
| 10.6+ | Employment Agreement dated May 9, 2008, between the Company and Donna R. Rill (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed May 13, 2008). |
| 10.7+ | 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). |
| 10.8+ | Employment Agreement dated April 14, 2009 between the Company and Donna R. Rill (incorporated by reference to Exhibit 10.6 of the Company's Current Report on Form 8-K filed April 16, 2009). |
| 10.9*+ | Employment Agreement dated November 16, 2009 by and between the Company and Jaye L. Thompson. |
| 10.10 | 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). |
| 10.11 | 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). |
| 10.12 | 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 Amendment No. 1 to Form SB-2 filed February 9, 2006). |
| 10.13 | Second Amended and Restated License Agreement dated July 31, 2007 by and between the Company and the University of Chicago (incorporated by reference to Exhibit 10.1 of the Company's Report on Form 8-K filed August 3, 2007). |
| 10.14++ | Asset Purchase Agreement by and between the Company and Novartis Institutes for Biomedical Research, Inc. dated August 6, 2009 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed August 7, 2009). |
| 10.15*+ | Certificate of Amendments to the Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan. |
| 23* | Consent of Independent Registered Public Accounting Firm MaloneBailey, LLP, dated March 4, 2010 to the incorporation by reference of their report dated March 4, 2010, 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.
++ Confidential treatment has been requested as to certain portions of this Exhibit pursuant to Rule 406 promulgated under the Securities Act. Such portions have been omitted and filed separately with the SEC.

**Exhibit 10.9**

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

November 16, 2009

Jaye Thompson, Ph.D.
58 N. Brokenfern Drive
The Woodlands, TX 77380

Dear Jaye:

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

1. Compensation.

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

b. Stock Plan. Subject to approval by the Board in its discretion, you will be granted the option (the "*Option*") to purchase 50,000 shares of the Company's common stock pursuant to the Company's stock option plan (the "*Plan*"). The Option will be subject to the terms and conditions set forth in a notice of stock option grant and an accompanying stock option agreement as well as the Plan. The exercise price for the shares at issue under the Option will be no less than their fair market value on the date of grant.

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

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

e. Six-Month Review. Following the date that is six months after the start of your employment with the Company, you and the CEO will meet to consider the addition of severance arrangements to the terms of your employment.

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

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

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

5. Non-Compete and Outside Activities. As more fully set forth in the Company's Proprietary Information and Inventions Agreement (attached hereto as Exhibit B), you agree that, while serving as a full-time employee of the Company, you will not engage in any activity which is competitive with the Company. In addition, during your employment with the Company, you shall devote your best efforts and your full business time, skill and attention to the performance of your duties on behalf of the Company.

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

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

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

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

If you wish to accept employment at the Company under the terms set out above and in the enclosed Acknowledgement of At-Will Employment, Proprietary Information and Inventions Agreement and Agreement to Arbitrate, please sign and date this letter and the enclosed documents, and return them to me. If you accept our offer, your first day of employment will be November 30, 2009.

This offer, if not accepted, will expire on November 18, 2009.

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

Sincerely,

/s/ Neil K Warma

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

Approved and Accepted:

/s/ Jaye Thompson, PhD. Date: November 16, 2009

Name: Jaye Thompson, Ph.D.

**EXHIBIT A**

**ACKNOWLEDGEMENT OF AT-WILL EMPLOYMENT**

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

Date: November 16, 2009

Name:
Jaye Thompson, Ph.D.

Signature: /s/ Jaye Thompson, PhD.

**EXHIBIT B**

**OPEXA THERAPEUTICS, INC.**

**PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT**

(Jaye Thompson, Ph.D.)

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

Ladies and Gentlemen:

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

I understand that:

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

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

(1) applicable to the business of Opexa; or

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

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

C. Opexa possesses and will continue to possess information that has been or will be created, discovered or developed, or has or will otherwise become known to Opexa (including, without limitation, information created, discovered, developed or made known by or to me during the period of or arising out of my employment by Opexa), and/or in which property rights have been or will be assigned or otherwise conveyed to Opexa, which information has commercial value in the business in which Opexa is engaged. All of the aforementioned information is hereinafter called "*Confidential Information*." By way of illustration, but not limitation, Confidential Information includes all data, compilations, blueprints, plans, audio and/or video recordings and/or devices, information on computer disks, software, tapes, printouts and other printed, typewritten or handwritten documents, specifications, strategies, systems,

schemas, methods, business and marketing development plans, customer, employee and supplier lists, budgets and unpublished financial statements, licenses and license agreements, research projections, processes, techniques, designs, sequences, components, programs, technology, ideas, know-how, improvements, inventions (whether or not patentable or copyrightable), information about operations and maintenance, trade secrets, formulae, models, patent disclosures, information regarding the skills and compensation of other employees of Opexa and other information concerning the actual or anticipated business, research or development of Opexa or its actual or potential customers, suppliers or partners or which is or has been generated or received in confidence by or for Opexa by or from any person; and all tangible and intangible embodiments thereof of any kind whatsoever including, where appropriate and without limitation, all compositions, machinery, apparatus, records, reports, drawings, copyright applications, patent applications, documents, samples, prototypes, models, products and the like.

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

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

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

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

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

product or product line of Opexa, (iii) a manufacturing, development or research methodology or process of Opexa or (iv) any activity that I may be involved with on behalf of Opexa.

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

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

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

8. As a matter of record I have identified on Annex 1 hereto a complete list of all inventions or improvements relevant to the subject matter of my employment by Opexa which have been made or conceived or first reduced to practice by me alone or jointly with others prior to my employment by Opexa (**"***Prior Inventions"*) which I desire to remove from the operation of this Agreement. If disclosure of any such Prior Invention would cause me to violate any prior

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Dated as of: November 16, 2009

Signature: /s/ Jaye Thompson, PhD.
Jaye Thompson, Ph.D.

Accepted and Agreed to
as of November 16, 2009

**OPEXA THERAPEUTICS, INC.**

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

**Annex 1**

(Jaye Thompson, Ph.D.)

**Prior Inventions**

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

☒ None.

☐ See below.

☐ Additional sheets attached.

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

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

☐ Additional Sheets Attached.

**EXHIBIT C**

**AGREEMENT TO ARBITRATE**

I, Jaye Thompson, Ph.D. (the "*Employee*"), and Opexa Therapeutics, Inc. (the "*Company*"), hereby enter into this agreement to arbitrate (the "*Agreement*").

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

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

Notwithstanding the above: (a) nothing in this Agreement shall be construed as limiting the Employee's right to file a claim with or seek the assistance of the Equal Employment Opportunity Commission, or any similar state agency, however, any claim that cannot be

resolved administratively shall be subject to this Agreement; (b) the following disputes and claims are not covered by this Agreement and shall therefore be resolved by both parties in any appropriate forum, including courts of law, as required by the laws then in effect: (i) claims for workers' compensation benefits; (ii) claims for unemployment insurance benefits; and (iii) claims for state or federal disability insurance benefits; and (c) neither party waives the right to seek through judicial process, preliminary injunctive relief to preserve the status quo or prevent irreparable injury before the matter can be heard in arbitration.

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

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

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

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

The parties understand and agree that neither the terms nor the conditions described in this Agreement are intended to create a contract of employment for a specific duration of time or to limit the circumstances under which the Employee's employment may be terminated.

This is the complete agreement between the Employee and the Company on the subject of the arbitration of disputes. This Agreement supersedes any prior or contemporaneous oral or written understanding on the subject. This Agreement shall be governed by and shall be interpreted in accordance with the laws of the State of Texas. The terms of this Agreement may not be orally modified. This Agreement can be modified only by a written document signed by the CEO of the Company and the Employee. The parties hereto further agree that this Agreement shall survive the termination of the Employee's employment.

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

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

EMPLOYEE

/s/ Jaye Thompson, PhD.
Signature

November 16, 2009
Date

Jaye Thompson, Ph.D.
Print Name

OPEXA THERAPEUTICS, INC.

/s/ Neil K Warma
Signature

November 16, 2009
Date

Neil K. Warma
Print Name

President and CEO
Title

**CERTIFICATE OF AMENDMENTS**
**TO THE**
**OPEXA THERAPEUTICS, INC.**
**JUNE 2004 COMPENSATORY STOCK OPTION PLAN**
(f/k/a PharmaFrontiers Corp. June 2004 Compensatory Stock Option Plan)

This Certificate of Amendments sets forth certain prior amendments to the June 2004 Compensatory Stock Option Plan (the "**Plan**") of Opexa Therapeutics, Inc., a Texas corporation (the "**Company**"). Unless otherwise specifically defined herein, each capitalized term used herein shall have the meaning afforded such term under the Plan.

**W I T N E S S E T H:**

**WHEREAS,** the Plan originally reserved an aggregate of 200,000 Shares (post-split) for issuance of Awards thereunder;

**WHEREAS,** the Company's Board of Directors (the "**Board**") previously approved certain amendments to the Plan, subject to stockholder approval, on three prior occasions, and such stockholder approval was subsequently obtained;

**WHEREAS,** the Company effected a 1-for-10 reverse split of the Shares on June 16, 2006, and all Share numbers set forth herein have been adjusted to reflect such reverse split; and

**WHEREAS,** the purpose of this Certificate of Amendments is to set forth those prior amendments to the Plan duly adopted by the Board and stockholders.

**NOW, THEREFORE,** the following recites the amendments to the Plan to date:

**1. First Amendment.** Section 5(a) of the Plan was amended by replacing the first sentence of such section with the following:

"Subject to adjustment as provided in Section 5(c) of the Plan, the aggregate number of Shares that may be issued under the Plan shall be 300,000."[1]

The foregoing amendment was (i) approved by the Board as of April 19, 2005 and (ii) approved by the stockholders of the Company and became effective on June 21, 2005.

[1] Prior to the effectiveness of the First Amendment, 200,000 Shares were subject to the Plan.

**2. Second Amendment.**

(a) Section 5(a) of the Plan was amended by replacing the first sentence of such section with the following:

"Subject to adjustment as provided in Section 5(c) of the Plan, the aggregate number of Shares that may be issued under the Plan shall be 1,200,000." [2]

(b) Section 5(d) of the Plan was amended by replacing the first sentence of such section with the following:

"No more than 50,000 shares of Common Stock may be subject to Qualified Performance-Based Awards granted to any Eligible Individual, including a Covered Employee, in any Fiscal Year."

The foregoing amendments were (i) approved by the Board as of April 20 and 26, 2006 and (ii) approved by the stockholders of the Company and became effective on June 15, 2006.

**3. Third Amendment.** Section 5(a) of the Plan was amended by replacing the first sentence of such section with the following:

"Subject to adjustment as provided in Section 5(c) of the Plan, the aggregate number of Shares that may be issued under the Plan shall be 2,300,000."[3]

The foregoing amendment was (i) approved by the Board as of August 12, 2008 and (ii) approved by the stockholders of the Company and became effective on September 26, 2008.

IN WITNESS WHEREOF, the Company has caused its authorized officer to execute this Certificate of Amendments to the Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan to evidence the foregoing amendments.

**OPEXA THEREAPEUTICS, INC.**

Dated: March 3, 2010

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

[2] Prior to the effectiveness of the Second Amendment, 300,000 Shares were subject to the Plan.

[3] Prior to the effectiveness of the Third Amendment, 1,200,000 Shares were subject to the Plan.

**EXHIBIT 23**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statement on Forms S-3 (No. 333-153501, 333-162397 and 333-163108), and Form S-8 (No. 139196) pertaining to the Opexa Therapeutics, Inc. June 2004 Compensatory Stock Option Plan, of our report dated March 4, 2010 with respect to the audited financial statements of Opexa Therapeutics, Inc. for the years ended December 31, 2009 and 2008.

/s/ MaloneBailey, LLP

MaloneBailey, LLP
www.malone-bailey.com
Houston, Texas

March 4, 2010

**EXHIBIT 31.1**

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

I, Neil K. Warma, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 4, 2010

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, 2009, (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: March 4, 2010

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)*