

OPEXA THERAPEUTICS, INC.

FORM 10KSB (Annual Report (Small Business Issuers))

Filed 03/16/07 for the Period Ending 12/31/06

Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
Telephone	(281) 272-9331
CIK	0001069308
Symbol	OPXA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

OPEXA THERAPEUTICS, INC.

FORM 10KSB

(Annual Report (Small Business Issuers))

Filed 3/16/2007 For Period Ending 12/31/2006

Address	2635 N. CRESCENT RIDGE DRIVE THE WOODLANDS, Texas 77381
Telephone	(281) 272-9331
CIK	0001069308
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-KSB

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2006

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

Commission file number: 0-25513



Opexa Therapeutics, Inc.

(Exact name of small business issuer 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: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock

Check whether the Issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. ☐

Check whether the Issuer (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 ☐

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. ☒

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

Issuer's revenues for the fiscal year ended December 31, 2006: \$0.

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Issuer as of March 13, 2007 based upon the average bid and asked price as of such date, was \$18,678,512.

The Registrant's common stock outstanding as of March 13, 2007, was 6,696,784 shares.

DOCUMENTS INCORPORATED BY REFERENCE:

The Registrant is incorporating by reference in Part III of this Form 10-KSB certain information contained in the Registrant's proxy statement for its annual meeting of shareholders, which proxy statement will be filed by the Registrant on or before April 30, 2007.

Transitional Small Business Disclosure Format (Check One): Yes ☐ No ☒

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Forward Looking Statement

The statements contained in this report, other than statements of historical fact, constitute forward-looking statements. Such statements include, without limitation, all statements as to expectation, belief, estimation, intent, anticipation, development, trial, contingency and statements as to our future results of operations, the progress of our research and product development programs, the need for, and timing of, additional capital and capital expenditures, partnering prospects, the need for additional intellectual property rights, effects of regulations, and the potential market opportunities. These statements relate to events and/or future financial performance and involve known and unknown risks, uncertainties and other factors that may cause the actual results, levels of activity, performance or achievements of the Company or the industry in which it operates to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. These risks and other factors include those listed under "Risk Factors" and those described elsewhere in this report.

In some cases, you can identify forward-looking statements by the Company's use of terms such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or the negative of these terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially. In evaluating these statements, you should specifically consider various factors, including the risks outlined under "Risk Factors." These factors may cause the Company's actual results to differ materially from any forward-looking statement.

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance, or achievements. Moreover, neither the Company nor any other person assumes responsibility for the accuracy and completeness of these forward-looking statements. The Company does not intend to update any of the forward-looking statements after the date of this report to conform prior statements to actual results.

Stock Split

In June 2006, the Company's shareholders approved a one for ten reverse common stock split. All share, par share and par value amounts (except authorized shares) have been retroactively adjusted to reflect the split.

PART I

ITEM 1. DESCRIPTION OF BUSINESS

Overview

Opexa Therapeutics, Inc. (the "Company", "we", "Opexa" or "Opexa Therapeutics") is a biopharmaceutical company developing autologous cellular therapies to treat several major illnesses, including multiple sclerosis (MS), rheumatoid arthritis (RA), diabetes, and cardiovascular disease. These therapies are based on the Company's proprietary T-cell and adult stem cell technologies.

Opexa Therapeutics' lead product, Tovaxin™, is a T-cell based therapeutic vaccine for MS licensed from the Baylor College of Medicine, which offers a unique and personalized approach to treating the disease by inducing an immune response against the autoimmune myelin peptide-reactive T-cells (MRTCs), which are believed to be responsible for the initiation of the disease process.

Tovaxin™ is currently in a Phase IIb clinical trial. Initial Phase I/II open-label human trials show that T-cell vaccination (TCV) appears to safely induce immune responses that deplete and regulate MRTCs. In two open-label Phase I/II clinical trials, the annualized relapse rates of patients were reduced by an average of approximately 90% compared to their prior history of relapses. Some patients also appear to experience an improvement of their Kurtzke Expanded Disability Status Scale, a scoring method used to measure the disability of MS patients (EDSS). Improvements in EDSS are not frequently observed in patients following treatment with other currently licensed therapies. Although the data from our Phase I/II trials appears to be promising, the Phase IIb trial is being conducted to confirm these results. Opexa Therapeutics believes that Tovaxin™ could be ready for commercialization as early as 2011.

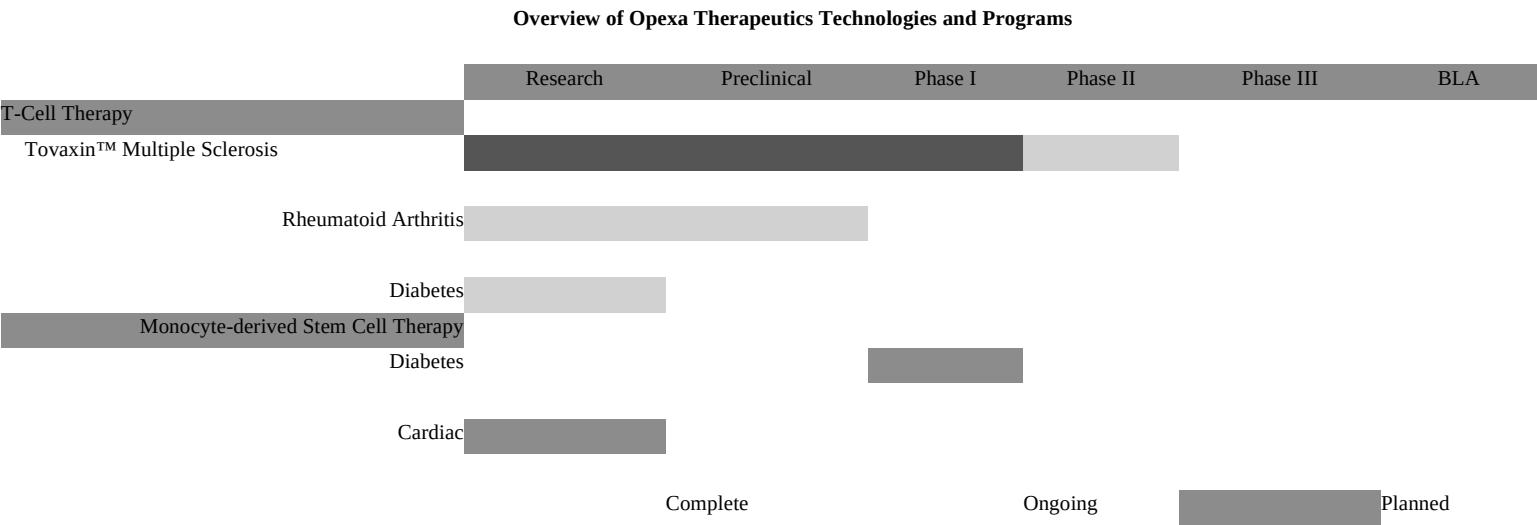
We also hold exclusive worldwide license for the intellectual property rights and research results of an autologous T-cell vaccine for RA from the Shanghai Institutes for Biological Sciences (SIBS), Chinese Academy of Sciences of the People's Republic of China.

Opexa’s RA T-cell vaccination (TCV) technology is conceptually similar to Tovaxin™. RA is an autoimmune T-cell-mediated disease in which pathogenic T-cells trigger an inflammatory autoimmune response of the synovial joints of the wrists, shoulders, knees, ankles and feet which causes pain, stiffness, and swelling around the joints and erosion into cartilage and bone. The RA TCV technology allows the isolation of these pathogenic T-cells from synovial fluid drawn from a patient. These T-cells will be grown to therapeutic levels and attenuated by gamma irradiation in our laboratory. The attenuated T-cells will be injected subcutaneously into patients thereby inducing an immune response directed at the pathogenic T-cells in the patient’s body. This immune response regulates the level of pathogenic T-cells and potentially allows the reduction of joint swelling in RA patients. Human trials that have been conducted in China show minimal side-effects and promising efficacy measured as a reduction of joint swelling following the T-cell vaccination.

We also have an exclusive license from the University of Chicago, through its prime contractor relationship with Argonne National Laboratory, to a stem cell technology in which adult multipotent stem cells are derived from monocytes (white blood cells) obtained from the patient’s own blood. We are initially pursuing indications in diabetes mellitus with our stem cell therapy and are conducting preclinical animal studies.

The Company’s stem cell technology isolates novel multipotent stem cells derived from peripheral blood monocytes. *In vitro* experiments with monocyte-derived stem cells (MDSC) have shown their capacity to differentiate into a wide variety of cell types including pancreatic β cells. We have demonstrated that these pancreatic islets clusters derived from MDSCs are composed of three pancreatic cells types (α , β and δ). These islet clusters are responsive to glucose and mimics the normal pulsatile pattern observed in human islets. The importance of these stem cells is the ability to easily isolate them from an individual’s circulating monocytes, expand them and administer them back into the same patient. This autologous approach provides a method to overcome any rejection issues and the need for immunosuppressant drugs which are often associated with current islet cell transplantations. This technology may lead to the formation of an unlimited source of pancreatic islet cells suitable for an autologous cell therapy for the treatment of diabetes mellitus.

An overview of Opexa’s technologies and pipeline is provided in the following chart:



T-Cell Therapy

Opexa Therapeutics has the exclusive worldwide license from Baylor College of Medicine to an individualized T-cell therapeutic vaccine, Tovaxin™, which is in U.S. FDA Phase IIb human clinical trials to evaluate its safety and effectiveness in treating MS.

Tovaxin™ consists of attenuated patient-specific MRTCs against peptides from either myelin basic protein [MBP], proteolipid protein [PLP], myelin oligodendrocyte glycoprotein [MOG]) peptides or combinations thereof. Patient-specific MRTCs are expanded in culture with specific peptides identified by the Company's proprietary test of the patient's peripheral blood. 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). Opexa Therapeutics' unique T-cell technology takes these autoreactive T-cells from the patient and expands them ex vivo (in a cell-culture environment outside the body), attenuates them by gamma irradiation, and then returns them 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, stimulating a reduction in the level of harmful T-cells.

We believe that our initial human trials show that Tovaxin™ safely induces the depletion and regulation of MRTCs, possibly stabilizing the disease, reducing the annualized relapse rate, and potentially improving the disability scores of patients. In November 2006, the Company enrolled the first patient in a double blind, placebo controlled, 150 patient Phase IIb clinical trial. We expect to complete enrollment in mid 2007.

Our Rheumatoid Arthritis (RA) T-cell vaccination (TCV) technology is conceptually similar to Tovaxin™. RA is an autoimmune T-cell-mediated disease in which pathogenic T-cells trigger an inflammatory autoimmune response of the synovial joints of the wrists, shoulders, knees, ankles and feet which causes pain, stiffness, and swelling around the joints and erosion into cartilage and bone. Our RA TCV technology allows the isolation of these pathogenic T-cells from synovial fluid drawn from a patient. We will expand and attenuate these T-cells in our laboratory. The attenuated T-cells will be injected subcutaneously into patients with the goal of inducing an immune response directed at the Pathogenic T-cells in the patient's body. We believe this immune response could reduce the level of pathogenic T-cells and potentially allow the reduction of joint swelling in RA patients.

Stem Cell Therapy

Opexa has developed a proprietary adult stem cell technology to produce novel monocyte-derived stem cells (MDSC) from blood. These MDSC can be derived from a patient's monocytes, expanded ex vivo, and then administered to the same patient. The Company believes that because this is an autologous therapy, there should be no rejection issues as self-derived MDSC pose no immunological problems. Normally, allogenic cells are deleted by host immune responses and require the use of anti-rejection drugs.

Our novel multi-potent stem cell is derived from peripheral blood monocytes which when cultured under defined conditions are able to further differentiate into several cellular lineages. Molecular biology and immunohistochemical studies have shown that these MDSCs have specific markers that distinguish them from other stem cells. In addition these studies have also shown a time-dependence for the expression of these specific gene products during the growth and differentiation of MDSCs. In vitro experiments with MDSCs have shown their capacity to differentiate towards hematopoietic, epithelial, endothelial, endocrine and neuronal cells. Our main focus is the further development of this monocyte-derived stem cell (MDSC) technology as a novel platform for the in vitro generation of highly specialized cells for potential application in autologous cell therapy for patients with diseases such as diabetes mellitus and cardiovascular disease.

Other Opportunities

The Company intends to conduct basic research to determine the potential use of its stem cells and differentiated cells in other indications, such as macular degeneration, stroke, myocardial infarction, wound healing and Parkinson's disease. Opexa Therapeutics intends to partner or sublicense some of these indications if they are not pursued for internal development. For those indications where the Company feels it can participate commercially, Opexa Therapeutics desires to partner in key commercial markets outside of the United States.

Organizational History

We were incorporated in Texas in 1991 and in May 2004, we entered the biopharmaceutical business by acquiring an entity that held rights to treatments using adult multipotent stem cells derived from adult human peripheral blood. From an accounting standpoint, the subsidiary is deemed the acquirer in a reverse merger whereby the parent is deemed the survivor of the reorganization. As such, our financial statements are those of the subsidiary. In November 2004, we acquired Opexa Pharmaceuticals, Inc. which holds rights to technology to an individualized T-cell therapeutic technology for treating MS.

The Company's Products and Services

Our T-cell Platform

Multiple Sclerosis - Background

In the United States, approximately 400,000 people suffer from multiple sclerosis, a chronic progressive autoimmune disease of the central nervous system (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 believed to be approximately \$5 billion in 2005. The US markets accounted for slightly more than 50 percent of global MS sales in 2005, approximately \$2.5 billion. MS remains a challenging autoimmune disease to study 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 can safely prevent or stop the progression of disease and allow reversal of the neurological damage and disability caused by the 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. Healthy individuals have been found to have autoreactive T-cells, which recognize a variety of self-antigens (e.g., myelin basic protein [MBP], proteolipid protein [PLP], and myelin oligodendrocyte glycoprotein [MOG]) as part of the normal T-cell repertoire and circulate naturally in the periphery without causing an autoimmune disease.

Some subjects unfortunately who have the appropriate genetic background have increased susceptibility for the in vivo activation and clonal expansion of myelin autoreactive T-cells. These myelin autoreactive T-cells may remain dormant, but at some point they are activated in the periphery, possibly by molecular mimicry (i.e., recognition of epitopes that are common to autoantigens and microbial antigens as exogenous triggers), 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.

Current Therapy for Multiple Sclerosis

Current MS disease modifying drugs on the market are mostly palliative and generally work through a mechanism of immunomodulation or immunosuppression. These therapies for MS are dominated by three forms of interferon that require frequent subcutaneous or intramuscular injections (Avonex, Betaseron and Rebif). Copaxone is an immunomodulator composed of a random copolymer of amino acids that is administered daily. Novantrone (mitoxanthrone) is an immunosuppressive drug that can only be given four times per year with a life time limit of 8 to 12 doses. All of the current therapies only slow the progression of MS and they have significant patient compliance challenges because of the dosing schedule, limited decrease in relapse rate, side effects profile (e.g., the interferon formulations produce severe flu-like symptoms, injection site reactions, infection and neutralizing antibodies (ranging from 5% to 45%) are developed that limits 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 which works by preventing immune system cells (all leukocytes carrying the alpha 4 integrin glycoprotein on their surface) from crossing the BBB and move into the CNS. Tysabri® requires a once per month infusion and has recently been reintroduced to the market after being originally withdrawn in 2005 based on safety concerns over several patient deaths due to virally mediated brain inflammation - a condition called progressive multifocal leukoencephalopathy (PML).

Tovaxin™ for Multiple Sclerosis

The Company believes 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 large quantities. 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 is injection site reaction in a small percentage of the patients. These reactions clear within 24 hours.

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

Tovaxin™ Intellectual Property

The technology is based on discoveries made by Dr. Jingwu Zang of Baylor College of Medicine in Houston. The Company has an exclusive, worldwide license from the Baylor College of Medicine to develop and commercialize three technology areas for MS, namely T-cell vaccination, peptides, and diagnostics. Under the License Agreement with the Baylor College of Medicine, the Company has rights to a total of 11 patents (2 U.S. and 9 foreign) and 80 patent applications (6 U.S. and 74 foreign).

Tovaxin™ Manufacturing

Opexa Therapeutics' manufactures its TCV therapy in its own Good Manufacturing Practice ("GMP") facility. The TCV technology 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. In preparing a TCV therapy, the myelin autoreactive T-cells causing the disease are taken from the blood, specifically identified, and expanded ex vivo by incubating these T-cells with selected peptides of MBP, PLP, and MOG in the presence of antigen-presenting cells and growth factors. Myelin-peptide reactive T-cells are grown to therapeutic levels and cryopreserved. Prior to use, the MRTCs are expanded, formulated, and attenuated (by irradiation) to render them incompetent to replicate but viable for therapy. These attenuated T-cells are administered in a defined schedule of subcutaneous injections. We expect that a single draw of a 500 ml bag of blood is sufficient to provide a full year's therapeutic regimen of Tovaxin™.

Clinical Development of Tovaxin™

Tovaxin™ is currently in a Phase IIb clinical trial. Patients treated in Opexa Therapeutics Phase I/II open-label studies with trivalent (MBP, MOG, and PLP) formulations have experienced minimal side effects, an approximate 90% average reduction in annualized relapse rate and improvements in EDSS scores.

Tovaxin™ Phase IIb Clinical Trial

The Phase IIb trial, entitled "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Subcutaneous Tovaxin™ in Subjects with Clinically Isolated Syndrome or Relapsing Remitting Multiple Sclerosis", is a multi-site double-blind, randomized, placebo-controlled 150 (100 treated, 50 placebo) patient trial. The primary endpoint will be lesion evaluation (the total number of gadolinium-enhancing lesions) via MRI with a secondary endpoint being annual relapse rate. This trial is designed to demonstrate the safety and efficacy of Tovaxin™. The Company enrolled its first patient in November 2006 and expects to complete enrollment in mid 2007.

Our Stem Cell Platform

Stem Cells - Background

Stem cells are undifferentiated primary cells that have the potential to become any tissue or organ of the body. They hold therapeutic promise for the development of effective treatments and possibly cure for various diseases. The current stem cell research efforts have been divided between embryonic and tissue specific adult stem cells as potential therapeutic progenitor cells. Recent experiments with Embryonic stem (ES) cells have demonstrated that these highly proliferative, pluripotent cells can differentiate into pancreatic-like β -cells. The major problem with ES cells is their pluripotency and risk that these cells, once transplanted, could form tumors. Given that, adult tissue specific stem cells have become attractive as a potential cell therapeutic. Adult tissue specific stem cells have advantages over ES cells; first, these cells can be isolated from a more manageable source such as bone marrow or other tissues; second, they proliferate in a controlled fashion and without the likelihood of tumorigenicity, and third, they can be used in an autologous setting and avoid the potential for rejection which exists for allogenic use of stem cells.

Hematopoietic stem cells (HSC's), present in the bone marrow and precursors to all blood cells, are currently the only type of stem cells commonly used for therapy. Doctors have been transferring HSC's in bone marrow transplants for more than 40 years. Advanced techniques for collecting or "harvesting" HSC's are now used to treat leukemia, lymphoma and several inherited blood disorders.

The clinical potential of stem cells has also been demonstrated in the treatment of other human diseases, including diabetes and advanced kidney cancer. However, these new therapies have been offered only to a very limited number of patients using adult stem cells.

Unfortunately stem cell therapies have technical, ethical and legal hurdles to overcome before they will be able to be used to possibly effect tissue and organ repair in disease states that heretofore have only treated the symptoms. A significant hurdle to most uses of stem cells is that scientists do not yet fully understand the signals that turn specific genes on and off to influence the differentiation of the stem cell. Therefore, scientists will have to be able to precisely control the differentiation of stem cells into the specific cell type to be used in therapy and drug testing. Current knowledge of the signals controlling differentiation fall well short of being able to mimic these conditions precisely to consistently have identical differentiated cells for each specified use.

To realize the promise of novel cell-based therapies for such pervasive and debilitating diseases, scientists must be able to easily and reproducibly manipulate stem cells so that they possess the necessary characteristics for successful differentiation, transplantation and engraftment. To be useful for transplant purposes, stem cells must be reproducibly made to: proliferate extensively and generate sufficient quantities of tissue, differentiate into the desired cell type(s), survive in the recipient after transplant, integrate into the surrounding tissue after transplant, function appropriately for the duration of the recipient's life, avoid harming the recipient in any way, and avoid the problem of immune rejection. There is no assurance that any commercialized cell-based therapies will ever be developed.

Although there are many ways to access stem cells, the Company believes that its autologous blood monocyte-derived stem cells offer distinct advantages.

Therapies utilizing Our Stem Cell Platform

Opexa has developed a proprietary adult stem cell technology to produce monocyte-derived stem cells (MDSC) from blood. These MDSC can be derived from a patient's monocytes, expanded ex vivo, and then administered to the same patient. The Company believes that because this is an autologous therapy, there should be no allogenic rejection issues as self-derived MDSC pose no immunological problems. Normally, allogenic cells are deleted by host immune responses and require the use of anti-rejection drugs.

Our novel multi-potent stem cell is derived from peripheral blood monocytes which when cultured under defined conditions are able to further differentiate into several cellular lineages. Molecular biology and immunohistochemical studies have shown that these MDSCs have specific markers that distinguish them from other stem cells. In addition these studies have also shown a time-dependence for the expression of these specific gene products during the growth and differentiation of MDSCs. In vitro experiments with MDSCs have shown their capacity to differentiate towards hematopoietic, epithelial, endothelial, endocrine and neuronal cells. Our main focus is the further development of this monocyte-derived stem cell (MDSC) technology as a novel platform for the in vitro generation of highly specialized cells for potential application in autologous cell therapy for patients with diseases such as diabetes mellitus and cardiovascular disease.

Opexa Therapeutics, working either by itself or in conjunction with strategic partners, expects to utilize these MDSC from the same patient to develop a therapy which may cause autologous tissue or organ repair. The initial internal therapeutic target is diabetes mellitus. Other therapeutic targets would be pursued through early-stage licensing or strategic alliances. The diabetes program is currently in pre-clinical development.

Pancreatic Islet Cell Development

Diabetes is a disease characterized by the failure or loss of pancreatic β -cells to generate sufficient levels of the hormone insulin required to meet the body's need to maintain normal nutrient homeostasis. Type 1 diabetes is caused by the complete loss of pancreatic β -cells when the body's own immune system mistakenly attacks and destroys a person's β -cells. While for Type 2 diabetes the causes are far more complicated and poorly understood, the results of the disease are similar in that often the β -cells fail to generate sufficient amounts of insulin to maintain normal homeostasis. The loss of insulin results in an increase in blood glucose levels and will eventually lead to the development of premature cardiovascular disease, stroke, and kidney failure. Currently there is no permanent cure for diabetes; however, recent clinical islet cell transplantations have shown good success in restoring long-term endogenous insulin production and glycemic stability in subjects who have Type 1 diabetes mellitus with unstable baseline control. Persistent islet function without injected insulin dependence provides considerable benefit.

Current cell transplant therapy for the treatment of diabetes is limited by an inadequate supply of insulin-producing cells. Cadaveric sources are limited and up to three pancreas are required to obtain clinically significant quantities of β -cells for one patient. The identification of novel adult human stem cells provides a new prospect for obtaining a sufficient number of insulin-producing β -cells for transplantation. Using our technology a single blood draw may be adequate to produce clinical quantities of β -cells for a patient.

In vitro experiments with MDSC have shown their capacity to differentiate toward a wide variety of cell types including pancreatic β -like cells. These cells aggregate into clusters resembling pancreatic Islets of Langerhans termed Monocyte Derived Islets (MDI). The cluster aggregates show endocrine gene expression. Biochemical assays have demonstrated that MDI can synthesize and secrete significant amounts of insulin during their growth and respond in a glucose-dependent manner. In addition, MDI can be stimulated or repressed by the addition of agonists or antagonists of insulin in vitro.

The importance of these stem cells is the ability to easily and cost effectively derive them from an individual's circulating monocytes, expand them and administer them back into the same patient. This autologous approach provides a method to overcome any rejection issues and the need for immunosuppressant drugs which are often associated with current transplantations. This technology may lead to the formation of an unlimited source of β cells suitable for an autologous cell therapy for the treatment of diabetes mellitus.

Stem Cell Pre-Clinical and Clinical Development

Opexa is conducting pre-clinical studies to demonstrate proof of concept and method of delivery with a planned IND (Investigational New Drug) submission to the FDA during 2007. The Company is targeting a 2008 Phase I study for monocyte-derived islet transplantation of patients with Type 1 diabetes mellitus.

Licenses, Patents and Proprietary Rights

We believe that proprietary protection of our technologies is critical to the development of our business. We intend to continue to protect our proprietary intellectual property through patents and other appropriate means. We rely upon trade-secret protection for some 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 Company's intellectual property strategy includes developing proprietary technology for the sourcing, scale up, manufacturing, and storage of T cells and multipotent adult stem cells and the use of these cells in multiple therapeutic applications. This strategy will include expanding on technologies in-licensed to us as well as in-licensing additional technologies through collaborations with universities and biotech companies.

We have exclusive, worldwide licenses to certain patents that relate to our T-cell technology and our multipotent adult stem cell technology.

T-Cell Therapy IP

We have an exclusive, worldwide license from the Baylor College of Medicine to patent applications claiming rights to the treatment of multiple sclerosis using attenuated modified T-cells and to the use of the T-cell technology as a diagnostic. The license was granted to the Company by Baylor in exchange for common stock in Opexa Pharmaceuticals which was acquired by the Company in November 2004. The key terms of the agreement are: exclusive, worldwide, and a 2% royalty on net sales of licensed products. The royalty decreases to 1% after the aggregate net sales exceed \$500 million. There are no other performance or payment terms in the license. The Company also has a separate consulting agreement with the inventor, Jingwu Zang, M.D., Ph.D. which grants the Company the right of first refusal on all future discoveries made by Dr. Zang.

The Company has filed additional patent applications related to T-Cell vaccination for MS.

Rheumatoid Arthritis Therapy IP

We have an exclusive worldwide license for the intellectual property rights and research results of an autologous T cell vaccine for rheumatoid arthritis from the Shanghai Institutes for Biological Sciences (SIBS), Chinese Academy of Sciences of the People's Republic of China. We made a \$125,000 license payment and agreed to pay a 0.5% royalty on net sales of licensed products.

The Company has filed additional patent applications related to T-Cell vaccination for RA.

Stem Cell Therapy IP

We have an exclusive, worldwide license from the University of Chicago, through its prime contractor relationship with Argonne National Laboratory, to a patent application claiming rights to the development of adult multipotent stem cells from monocytes isolated from adult human peripheral blood. The technology was discovered and developed at the Argonne National Laboratory, a U.S. Department of Energy Laboratory.

Pursuant to the license we have issued a total of 53,463 shares of our common stock to the University of Chicago. We have also agreed to pay the University of Chicago \$1.5 million and issue to them 21,623 shares of Opexa Common Stock by April 30, 2007. We have agreed to pay a percentage of royalties on sales of products subject to the licensed patents, as well as sublicense fees. In addition, the University of Chicago license requires us to expend on research and development at least \$2,000,000 within two (2) years of the execution of the license and at least an additional \$4,000,000 within four (4) years of the execution of the license. Research and development expenditures by sublicensees may account for half of each amount. The license also requires us to sell a product or method based on the licensed technology by February 2011.

The Company has filed patent applications related to the process of obtaining monocyte-derived stem cells and the further differentiation of the cells into pancreatic islet cells.

Our Product Pipeline

Tovaxin™ is a vaccine approach to treating multiple sclerosis in that it induces the body's immune system to attack the MRTCs that we believe are responsible for destroying the myelin sheath coating of the axons in the central nervous system. We believe that the depletion and regulation of the MRTCs may stop progression of multiple sclerosis. Tovaxin™ is currently in a Phase IIb clinical trial. The Company enrolled its first patient in November 2006 and expects to complete enrollment in mid 2007.

Rheumatoid Arthritis Therapy

Our Rheumatoid Arthritis (RA) T-cell vaccination (TCV) technology is conceptually similar to Tovaxin™. RA is an autoimmune T-cell-mediated disease in which Pathogenic T-cells trigger an inflammatory autoimmune response of the synovial joints of the wrists, shoulders, knees, ankles and feet which causes pain, stiffness, and swelling around the joints. We are currently transferring the technology to our laboratory and will present data to the FDA in 2007 with the intention of filing an IND and initiating a Phase I clinical trial in 2008.

Diabetes Stem Cell Therapy

We believe that there are approximately 20.8 million people in the United States who have diabetes. More than 1 million of these people have Type 1 diabetes mellitus. Among adults with diagnosed diabetes, 31% take insulin to control their disease. Research studies have found that improved glycemic control benefits people with either Type 1 or Type 2 diabetes. Islet transplantation using Opexa's proprietary monocyte-derived islet cell may offer the potential to improve glycemic control in a subgroup of patients with Type 1 and Type 2 diabetes mellitus who are disabled by refractory hypoglycemia. The Company is in preclinical development and plans to file an IND in 2007 and initiate a Phase I clinical trial in 2008.

Cardiac Stem Cell Therapy

Stem cell treatment of congestive heart failure could revolutionize treatment of the disease because it may treat the source of the problem by replacing diseased cardiac muscle tissue with stem cells that grow or induce the growth of new healthy cardiac tissue. Elsewhere multiple Phase I clinical studies encompassing more than 70 patients have been run with autologous bone marrow stem cells that report improved cardiac perfusion. A recent (2003-2004) trial reported that injected autologous bone marrow mononuclear cells, using electromechanical mapping into areas of ischemic myocardium in patients with endstage ischemic cardiomyopathy and heart failure, showed a therapeutic effect with improved myocardial perfusion and exercise capacity, at 6 and 12 months, as well as increased global left ventricular function. Using the experience of these Phase I trials we plan to move through pre-clinical development and, if successful, initiate human testing as soon as practicable.

Other Opportunities

The Company intends to conduct basic research to determine the potential use of the Company's stem cells in other indications such as macular degeneration, heart attack, and Parkinson's disease. Liver cells (hepatocytes) derived from our stem cells may be valuable across the biopharmaceutical industry to test for drug toxicity or to help cure liver diseases. The Company intends to partner or sublicense some of these indications if they are not pursued for internal development. For those indications where the Company feels it can participate commercially, the Company will possibly take partners in key commercial markets outside of the United States.

Research Collaborations

We anticipate that from time to time in the future we will enter into collaborative research agreements with other academic and research institutions. We will use such agreements to enhance our research capabilities. Typically, in the industry, such agreements provide the industry partner with rights to license the intellectual property created through the collaboration. We may also enter into collaborative research agreements with other pharmaceutical companies when we believe such collaboration will support the development and commercialization of our technology.

Commercialization Through Third Parties

We anticipate that we will possibly grant sublicenses for certain applications of our technologies. We believe that by sublicensing some of the rights to our technology to pharmaceutical companies and other third parties, we will be able to develop more efficiently some applications of our technologies. We currently do not have any sublicenses.

Competition

The development of therapeutic and diagnostic agents for human disease is intensely competitive. Major pharmaceutical companies currently offer a number of pharmaceutical products to treat heart attack, stroke, Parkinson's disease, diabetes, liver diseases, arthritis 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 multiple sclerosis include Biogen-Idec, Elan, Serono, Aventis, Teva, and Schering AG. Some of our primary competitors in the development of stem cell therapies include Aastrom Biosciences, Geron, Gamida-Cell Ltd, Stem Cells Inc., Cellerant Therapeutics, Viacell, and Osiris Therapeutics. Many of these competitors have significant products in development that could be competitive with our potential products.

Sales and Marketing

We intend to develop a sales force to market our multiple sclerosis cell therapy products in the U.S. Given the concentration of multiple sclerosis among a relatively small number of specialized neurologists, we believe that a modest size sales force would be sufficient to market the multiple sclerosis products.

We plan to partner with large biotech and pharmaceutical companies for the marketing and sales of our MS and RA T-cell products outside the United States and our stem cell therapy products.

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 United States and other countries.

In the United States, 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, 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 steps required before our potential products may be marketed in the United States include:

1. *Preclinical Laboratory and Animal Tests* . Preclinical tests include laboratory evaluation of the product and animal studies in specific disease models to assess the potential safety and efficacy of the product and our formulation as well as the quality and consistency of the manufacturing process.
2. *Submission to the FDA of an Application for an Investigational New Drug Exemption, 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 as part of an IND, 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.
3. *Adequate and Well-Controlled Human Clinical Trials to Establish the Safety and Efficacy of the Product*. Clinical trials involve the evaluation of the product in healthy volunteers or, as may be the case with our potential products, in a small number of patients under the supervision of a qualified physician. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Any product administered in a U.S. clinical trial must be manufactured in accordance with GMP. 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, 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, products are typically introduced into healthy human subjects or into selected patient populations to test for adverse reactions, dosage tolerance, absorption and distribution, metabolism, excretion and clinical pharmacology.
- Phase II involves studies in a limited patient population to (i) determine the efficacy of the product for specific targeted indications and populations, (ii) determine optimal dosage and dosage tolerance and (iii) identify possible adverse effects and safety risks. When a dose is chosen and a candidate product is found to be effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials begin.
- Phase III trials are undertaken to conclusively demonstrate clinical efficacy and to test further for safety within an expanded patient population, generally at multiple study sites.

The FDA continually reviews the clinical trial plans and results and may suggest changes or may require discontinuance of the trials at any time if significant safety issues arise.

1. *Submission to the FDA of Marketing Authorization Applications* . The results of the preclinical studies and clinical studies are submitted to the FDA in the form of marketing approval authorization applications.

2. *FDA Approval of the Application(S) Prior to Any Commercial Sale or Shipment of the Drug Biologic Product Manufacturing Establishments Located in Certain States Also May be Subject to Separate Regulatory and Licensing Requirement* . The testing and approval process will require substantial time, effort and expense. The time for approval is affected by a number of factors, including relative risks and benefits demonstrated 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 to that time.

After FDA approval for the product, the manufacturing and the initial indications, further clinical trials may be required to gain approval for the use of the product for additional indications. The FDA may also require unusual or restrictive post-marketing testing and surveillance to monitor for adverse effects, which could involve significant expense, or may elect to grant only conditional approvals.

FDA Manufacturing Requirements

Among the conditions for product licensure is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the FDA's Good Manufacturing Practice, or GMP requirements. Even after product licensure approval, the manufacturer must comply with GMP on a continuing basis, and what constitutes GMP may change as the state of the art of manufacturing changes. Domestic manufacturing facilities are subject to regular FDA inspections for GMP compliance, which are normally held at least every two years. Foreign manufacturing facilities are subject to periodic FDA inspections or inspections by the foreign regulatory authorities with reciprocal inspection agreements with the FDA. Domestic manufacturing facilities may also be subject to inspection by foreign authorities.

Fast Track, Priority Review and Accelerated Approval

Fast Track refers to a process for interacting with the FDA during drug development. Priority Review applies to the time frame the FDA targets for reviewing a completed application. Accelerated Approval (Subpart H) applies to the design and content of the studies used to support a marketing claim.

Fast Track is a formal mechanism to interact with the FDA using approaches that are available to all applicants for marketing claims. The Fast Track mechanism is described in the Food and Drug Administration Modernization Act of 1997. The benefits of Fast Track include scheduled meetings to seek FDA input into development plans, the option of submitting a New Drug Application (NDA) in sections rather than all components simultaneously, and the option of requesting evaluation of studies using surrogate endpoints as discussed below. The Fast Track designation is intended for the combination of a product and a claim that addresses an unmet medical need, but is independent of Priority Review and Accelerated Approval. An applicant may use any or all of the components of Fast Track without the formal designation. Fast Track designation does not necessarily lead to a Priority Review or Accelerated Approval.

Priority Review is a designation for an application after it has been submitted to the FDA for review for approval of a marketing claim. Under the Food and Drug Administration Modernization Act of 1997, reviews for NDAs are designated as either Standard or Priority. A Standard designation sets the target date for completing all aspects of a review and the FDA taking an action on the application (approve or not approve) at 10 months after the date it was filed. A Priority designation sets the target date for the FDA action at 6 months. A Priority designation is intended for those products that address unmet medical needs.

Accelerated Approval or Subpart H Approval is a program described in the NDA regulations that is intended to make promising products for life threatening diseases available on the market on the basis of preliminary evidence prior to formal demonstration of patient benefit. The studies are designed to measure and the FDA evaluation is performed on the basis of a surrogate marker (a measurement intended to substitute for the clinical measurement of interest, usually prolongation of survival) that is considered likely to predict patient benefit. The approval that is granted may be considered a provisional approval with a written commitment to complete clinical studies that formally demonstrate patient benefit. The Federal Register published a discussion of Accelerated Approval with comments. Absent a formal demonstration of patient benefit, a risk benefit assessment cannot be made. Accelerated Approval designation does not necessarily lead to a Priority Review.

Special Protocol Assessment

The Special Protocol Assessment (SPA) process is a procedure by 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 biologics license application (BLA).

Good Tissue Practices Regulation

The FDA requires human cell, tissue, and cellular and tissue-based product (HCT/P) establishments to follow current good tissue practice, which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps; recordkeeping; and the establishment of a quality program. The agency has issued regulations pertaining to labeling, reporting, inspections, and enforcement that apply to manufacturers of those HCT/Ps regulated under the authority of the Public Health Service Act, or as drugs, devices, and/or biological products.

As part of this approach, the FDA requires registration of establishments that engage in the recovery, screening, testing, processing, storage or distribution of human cells, tissues, and cellular and tissue-based products, and for the listing of such products unless such products are performed under an IND (Investigational New Drug) . These products specifically include stem cells that are progenitors of blood cells; however, the FDA makes no explicit statement regarding the inclusion of other types of stem cells. In addition, the FDA has published rules for making suitability determinations for donors of cells and tissue and for current good tissue practice for manufacturers using them.

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.

Outside the United States, we will be subject to regulations that govern the import of drug products from the United States 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 United States, 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 year ended December 31, 2006 were approximately \$7.6 million, mainly reflecting the costs of the Phase I/II and Phase IIB clinical trials for Tovaxin™ and research and development in support of pre-clinical diabetes stem cell therapies. Research and development expenses for the year ended December 31, 2005, were approximately \$4.2 million.

Risk Factors

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 .

Our business is at an early stage of development.

Our business is at an early stage of development. We do not have any products in late-stage clinical trials or on the market. We are still in the early stages of identifying and conducting research on potential products. Only one of our products has progressed to the stage of being studied in human clinical trials in the U.S. Our potential products will require significant research and development and preclinical and clinical testing prior to regulatory approval in the United States and other countries. We may not be able to develop any products, to obtain regulatory approvals, to enter clinical trials for any of our product candidates, or to commercialize any products. Our product candidates 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 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, have no source of revenues, and have incurred significant operating losses. We expect to incur additional operating losses for the foreseeable future and, as we increase our research and development activities, we expect our operating losses to increase significantly. We do not have any sources of revenues and may not have any in the foreseeable future.

We will need additional capital to conduct our operations and develop our products and our ability to obtain the necessary funding is uncertain.

We need to obtain significant additional capital resources from sources including equity and/or debt financings, license arrangements, grants and/or collaborative research arrangements in order to develop products and continue our business. As of December 31, 2006, we had cash, cash equivalents and marketable securities of approximately \$15 million. Our current burn rate is approximately \$1,000,000 per month excluding capital expenditures. We will need to raise additional capital to fund our working capital needs beyond first quarter 2008. 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 failure to raise such funds will necessitate the curtailment of operations and impact the completion of the clinical trials.

The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for capital needs in 2007 and beyond;
- scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs;
- our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- 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.

We do not have any committed sources of capital, although we have issued and outstanding warrants that, if exercised, would result in an equity capital raising transaction. Additional financing through strategic collaborations, public or private equity financings, capital lease transactions or other financing sources may not be available on acceptable terms, or at all. Additional equity financings could result in significant dilution to our stockholders. Further, if additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize ourselves. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our programs, any of which could have a material adverse effect on our financial condition or business prospects.

Approximately 60% of our total assets are comprised of intangible assets that are subject to review on a periodic basis to determine whether an impairment on these assets is required. An impairment would not only greatly diminish our assets, but would also require us to record a significant non-cash expense charge.

We are required under generally accepted accounting principles to review our intangible assets for impairment when events or changes in circumstances indicate the carrying value may not be recoverable. At December 31, 2006, our net intangible assets, consisting of the University of Chicago license, acquired intangible assets from the Opexa acquisition that is an inseparable group of patents and licenses that can't function independently and the RA license acquired from the Shanghai Institutes for Biological Sciences, Chinese Academy of Sciences of the People's Republic of China were approximately \$24.7 million. If management determines that impairment exists, we will be required to record a significant charge to expense in our financial statements during the period in which any impairment of our intangibles is determined. An impairment analysis, as defined in FAS 142, conducted by an independent consultant determined that there is no impairment of Opexa's intangible assets for 2006.

Our financial statements include substantial non-operating gains or losses resulting from required quarterly revaluation under GAAP of our outstanding derivative instruments.

Generally accepted accounting principles in the United States require that we report the value of certain derivative instruments we have issued as current liabilities on our balance sheet and report changes in the value of these derivatives as non-operating gains or losses on our statement of operations. The value of the derivatives is required to be recalculated (and resulting non-operating gains or losses reflected in our statement of operations and resulting adjustments to the associated liability amounts reflected on our balance sheet) on a quarterly basis, and is based on the market value of our common stock. Due to the nature of the required calculations and the large number of shares of our common stock involved in such calculations, changes in our common stock price may result in significant changes in the value of the derivatives and resulting gains and losses on our statement of operations.

Clinical trials are subject to extensive regulatory requirements, very expensive, time-consuming and difficult to design and implement. Our products may fail to achieve necessary safety and efficacy endpoints during clinical trials.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of our product candidates will take at least several 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:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials.

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. We believe that the special knowledge of these individuals gives us a competitive advantage. 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.

We are dependent on contract research organizations and other contractors for clinical testing and for certain research and development activities, thus the timing and adequacy of our clinical trials and such research activities are, to a certain extent, beyond our control.

The nature of clinical trials and our business strategy requires us to rely on contract research organizations, independent clinical investigators and other third party service providers to assist us with clinical testing and certain research and development activities. As a result, our success is dependent upon the success of these outside parties in performing their responsibilities. Although we believe our contractors are economically motivated to perform on their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise applied to these activities by our contractors. If our contractors do not perform their activities in an adequate or timely manner, the development and commercialization of our drug candidates could be delayed.

Our current research and manufacturing facility is not large enough to manufacture future stem cell and T-cell therapies.

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 stem cell and T-cell therapies through Phase III trials. Our current facility is not large enough to conduct commercial-scale manufacturing operations. We will need to expand further our manufacturing staff and facility, obtain a new facility or contract with corporate collaborators or other third parties to assist with future drug production.

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 the FDA's current Good Manufacturing Practices 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.

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.

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, stem cells, T-cells, and other technologies potentially relevant to or required by our expected products. We cannot predict which, if any, of such applications will issue as patents or the claims that might be allowed. We are aware that a number of companies have filed applications relating to stem cells. We are also aware of a number of patent applications and patents claiming use of stem cells and other modified cells to treat disease, disorder or injury.

If third party patents or patent applications contain claims infringed by either our licensed technology or other technology required to make and use our potential products 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 some products 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 future patents and other proprietary rights our operations will be significantly harmed.

Our ability to compete effectively is dependent in part 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 the patent applications for our technology will result in the issuance of patents, or if any future 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 eighteen 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 licensed patents were the first to make the inventions covered by the patent applications or that the licensed patent applications were the first to be filed for such inventions. There can be no assurance that patents will issue from the 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.

Our competition includes fully integrated biopharmaceutical and pharmaceutical companies that have significant advantages over us.

The markets for therapeutic stem cell products, multiple sclerosis products, and rheumatoid arthritis products are highly competitive. We expect that our most significant competitors are fully integrated pharmaceutical companies and more established biotechnology companies. These companies are developing stem cell-based products and they have significantly greater capital resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals, and marketing than we currently do. Many of these potential 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 product commercialization than we are able to achieve. Competitive products may render any products or product candidates that we develop obsolete.

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 three licenses from third parties. These third party license agreements impose obligations on us, such as payment obligations and obligations to diligently 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 severely adversely affected.

Restrictive and extensive government regulation could slow or hinder our production of a cellular product.

The research and development of stem cell therapies is subject to and restricted by extensive regulation by governmental authorities in the United States and other countries. The process of obtaining U.S. Food and Drug Administration, or FDA, and other necessary regulatory approvals is lengthy, expensive and uncertain. We may fail to obtain the necessary approvals to continue our research and development, which would hinder our ability to manufacture or market any future product.

To be successful, our product candidates must be accepted by the health care community, which can be very slow to adopt or unreceptive to new technologies and products.

Our product candidates, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community in general may decide to not accept and utilize these products. The product candidates that we are attempting to develop represent substantial departures from established treatment methods and will compete with a number of more conventional drugs and therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any of our developed products will depend on a number of factors, including:

- our establishment and demonstration to the medical community of the clinical efficacy and safety of our product candidates;
- our ability to create products that are superior to alternatives currently on the market;
- our ability to establish in the medical community the potential advantage of our treatments over alternative treatment methods; and
- reimbursement policies of government and third-party payers.

If the health care community does not accept our products for any of the foregoing reasons, or for any other reason, our business would be materially harmed.

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

Although our common stock is traded on the Nasdaq Global Market, there is currently a limited market for our common stock 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.

As our share price is volatile, 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 common stock experiences 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 shareholders.

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 shareholder approval. Our preferred stock could be utilized as a method of discouraging, delaying, or preventing a change in our control and as a method of preventing shareholders from receiving a premium for their shares in connection with a change of control.

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

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 the our business.

Employees

As of December 31, 2006, we had 32 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.

ITEM 2. DESCRIPTION OF PROPERTY

Our 10,200 sq. ft. facility is located on 3 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 sq. ft. of GMP (good manufacturing practice) manufacturing suites; Quality Systems management with Quality Control Laboratory, Regulatory Affairs, Quality Assurance; as well as administrative support space. There is 2,500 sq. ft. of space still available for future build-out. 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.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY , RELATED STOCKHOLDERS MATTERS AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES

Shares of our common stock are traded on the Nasdaq Global Market under the symbol "OPXA". Our common stock trades on a limited, sporadic and volatile basis.

The following table sets forth, for the periods indicated, the range of high and low bid information for our common stock. These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

	Price Ranges	
	High	Low
Fiscal Year Ended December 31, 2005		
First Quarter	\$ 87.00	\$ 45.00
Second Quarter	55.00	24.60
Third Quarter	14.10	12.50
Fourth Quarter	6.30	5.90
Fiscal Year Ended December 31, 2006		
First Quarter	\$ 7.00	\$ 4.40
Second Quarter	10.10	5.10
Third Quarter	9.15	4.93
Fourth Quarter	7.03	5.10

No cash dividends have been declared on the Company common stock since the Company's inception and it is not anticipated that dividends will be declared on our common stock in the foreseeable future.

As of December 31, 2006, there were approximately 358 holders of record of our Common Stock.

Equity Compensation Plan Information

The following table sets forth information, as of December 31, 2006, with respect to the Company's 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 Plan. We believe that the exercise price for all of the options set forth below reflects fair market value.

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 for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column A) (C)
Equity Compensation Plans			
Approved by Security Shareholders	762,970	\$ 10.83	437,030
Equity Compensation Plans Not			
Approved by Security Shareholders	-	-	-
Total	762,970	\$ 10.83	437,030

Recent Sales of Unregistered Securities and Equity Purchases by Company

None .

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

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 History

We were incorporated in Texas in 1991 and in May 2004, we entered the biopharmaceutical business by acquiring an entity that held rights to treatments using adult multipotent stem cells derived from adult human peripheral blood. From an accounting standpoint, the subsidiary is deemed the acquirer in a reverse merger whereby the parent is deemed the survivor of the reorganization. As such, our financial statements are those of the subsidiary. In November 2004, we acquired Opexa Pharmaceuticals, Inc. which holds rights to technology to an individualized T-cell therapeutic technology for treating MS.

Critical Accounting Policies

General

The Consolidated Financial Statements and Notes to Consolidated Financial Statements contain information that is pertinent to this management's discussion and analysis. The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of any contingent assets and liabilities. Management believes these accounting policies involve judgment due to the sensitivity of the methods, assumptions and estimates necessary in determining the related asset and liability amounts. Management believes it has exercised proper judgment in determining these estimates based on the facts and circumstances available to it at the time the estimates were made. The significant accounting policies are described in the Company's financial statements.

Principles of Consolidation

The accompanying consolidated financial statements of the Company include the accounts of its wholly owned subsidiary. All significant intercompany accounts and transactions have been eliminated.

Long-Lived Assets

Long-lived assets (i.e., intangible assets) are reviewed for impairment whenever events or changes in circumstances indicate that the net book value of the asset may not be recoverable. An impairment loss is recognized if the sum of the expected future cash flows (undiscounted and before interest) from the use of the asset is less than the net book value of the asset. Generally, the amount of the impairment loss is measured as the difference between the net book value of the asset and the estimated fair value of the related asset. Management does not believe any assets were impaired at December 31, 2006.

Revenue

We did not receive any revenue in 2005 and 2006 and do not expect any revenue in 2007.

Intellectual Property

As of December 31, 2006, we had \$28,256,772 of intellectual property, \$23,991,128 of which resulted from the acquisition of Opexa, \$4,028,204 which pertained to the consideration paid to date to the University of Chicago for the worldwide license to technology developed at Argonne National Laboratory, \$112,440 stock payable to the University of Chicago accrued at September 30, 2006 for 21,623 shares of common stock, and \$125,000 paid to the Shanghai Institute for Biological Science, China Academy of Science of the People's Republic of China whereby it acquired an exclusive worldwide license for the intellectual property rights and research results of an autologous T cell vaccine for rheumatoid arthritis. Of the \$23,991,128 of acquired intangible assets, the full amount is assigned to an inseparable group of patents and licenses that cannot function independently by themselves. The weighted average useful life of the intangible group as of December 31, 2006 is approximately 17 years. The weighted average useful life of the University of Chicago license is approximately 17 years. Accumulated amortization for the Intellectual Property as of December 31, 2006 is \$3,533,569. In April 2005 the Company obtained a fairness opinion from an independent investment banking firm with respect to the Opexa acquisition and there was no impairment at that time. In accordance with FAS 142, the Board authorized an update to this impairment analysis as of December 31, 2006 and it was determined that no impairment existed.

Accounting for Derivative Instruments

Statement of Financial Accounting Standard ("SFAS") No. 133, "Accounting for Derivative Instruments and Hedging Activities," as amended, 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 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 September 2000, the Emerging Issues Task Force ("EITF") issued EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in, a Company's Own Stock," ("EITF 00-19") which requires freestanding contracts that are settled in a company's own stock, including common stock warrants, to be designated as an equity instrument, asset or a liability. Under the provisions of EITF 00-19, a contract designated as an asset or a liability must be carried at fair value on a company's balance sheet, with any changes in fair value recorded in the company's results of operations. A contract designated as an equity instrument must be included within equity, and no fair value adjustments are required. In accordance with EITF 00-19, in June 2006, we determined that certain outstanding warrants to purchase our common stock should be separately accounted for as liabilities. We had not classified these derivative liabilities as such in our historical financial statements. In order to reflect these changes, we restated our financial statements for the year ended December 31, 2005 to record the fair value of these warrants on our balance sheet and record unrealized changes in the values of these derivatives in our consolidated statement of operations as "Gain (loss) on derivative liabilities."

We have evaluated the provisions of the registration rights agreement that require us to pay registration delay payments in combination with the financial instrument and concluded that the combined instrument meets the definition of a derivative under SFAS 133.

In December 2006, the FASB issued FASB Staff Position No. EITF 00-19-2, Accounting for Registration Payment Arrangements (EITF 00-19-2). EITF 00-19-2 addresses an issuer's accounting for registration payment arrangements. It specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5, Accounting for Contingencies. The guidance in EITF 00-19-2 amends FASB Statements No. 133, Accounting for Derivative Instruments and Hedging Activities, and No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity , and FASB Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, to include scope exceptions for registration payment arrangements. EITF 00-19-2 also requires additional disclosure regarding the nature of any registration payment arrangements, alternative settlement methods, the maximum potential amount of consideration and the current carrying amount of the liability, if any. This EITF is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issue of this EITF. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of this EITF, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. The impact of implementing EITF 00-19-2 in the fiscal year 2007 will result in a cumulative effect of a change in accounting principle with a credit to beginning retained earnings of \$6,656,677 and a reversal of the same amount to the derivative liability account.

Results of Operations and Financial Condition

Net Sales.

We recorded no sales for the twelve months ended December 31, 2006 and 2005.

General and Administrative Expenses

Our general and administrative expenses during the twelve months ended December 31, 2006, was \$ 5,461,047 as compared to \$6,259,075 for the twelve months ended December 31, 2005. The decrease in expenses is due to a combination of factors including a decrease in stock compensation expenses, professional service fees and overhead expenses in 2006. General and administrative expenses consist primarily of salaries and benefits, stock compensation expense, office expense, professional services fees, and other corporate overhead costs. We anticipate increases in general and administrative expenses as we continue to develop and prepare for commercialization of our technology.

Research and Development Expense

Research and development expense was \$7,612,932 for the twelve months ended December 31, 2006, as compared to \$4,183,356 the twelve months ended December 31, 2005. The increase in expenses was primarily due to the costs of the Phase I/II and Phase IIb clinical trials for Tovaxin™ and research and development in support of pre-clinical diabetes stem cell therapies. 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. Property, plant and equipment for research and development that has an alternative future use is capitalized and the related depreciation is expensed as research and development costs. We expect our research and development expense to increase as we continue to invest in the development of our technology.

Interest Expense

Interest expense was \$984 for the twelve months ended December 31, 2006 compared to \$7,323,851 for the twelve months ended December 31, 2005. Interest expense during 2005 was due to notes payable that were outstanding during the second quarter of 2005 which were subsequently converted into equity in June 2005, resulting in acceleration of the amortization of the discount related to the notes.

Interest Income

Interest income was \$688,299 for the twelve months ended December 31, 2006 compared to \$81,930 for the twelve months ended December 31, 2005. The increase was due to the investment of the cash proceeds from a 2006 equity financing in short term and cash equivalent investments.

Gain (Loss) on Derivative Instruments Liabilities, net.

The Company recognized a gain on derivative instruments of \$104,978 for the twelve months ended December 31, 2006 compared to \$3,896,841 for the twelve months ended December 31, 2005. The decrease is a result of the net unrealized (non-cash) change in the fair value of our derivative instrument liabilities.

Net Loss

We had net loss for the year ended December 31, 2006, of \$14,056,407 or (\$2.61) per share (basic and diluted), compared with a net loss of \$15,517,356 or (\$9.90) per share (basic and diluted), for the twelve months ended December 31, 2005.

Liquidity and Capital Resources

Historically, the Company has financed its operations primarily from the sale of its debt and equity securities. As of December 31, 2006, the Company had cash, cash equivalents and marketable securities of approximately \$15 million.

We used approximately \$11.0 million of cash for operating activities for the year ended December 31, 2006 compared to approximately \$6.2 million for the same period of 2005. The increase in use of cash is primarily due to an increase in research and development expenditures related to the clinical trials for our Tovaxin therapy for MS and the purchase of marketable securities.

Capital expenditures were approximately \$0.6 million in 2006 and consisted primarily of laboratory equipment and leasehold improvements related to the construction of manufacturing facilities.

Our financing activities generated approximately \$21.3 million for the year ended December 31, 2006 as compared to approximately \$8.2 million for the same period of 2005. In both periods, the cash generated from financing activities resulted from the sale of Common Stock in equity financings.

Our current burn rate is approximately \$1,000,000 per month excluding capital expenditures. We will need to raise additional capital to fund our working capital needs beyond the first quarter of 2008. 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 failure to raise such funds will necessitate the curtailment of operations and impact the completion of the clinical trials.

Contractual Commitments

A tabular disclosure of contractual obligations at December 31, 2006, is as follows:

	Total	Payments Due by Period			
		Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Leases	\$ 1,274,175	\$ 117,774	\$ 276,978	\$ 295,080	\$ 584,343
Consulting and Research Agreements	\$ 142,646.5	\$ 142,147	\$ 500	\$ -	\$ -
Total	<u>\$ 1,416,822</u>	<u>\$ 259,921</u>	<u>\$ 277,478</u>	<u>\$ 295,080</u>	<u>\$ 584,343</u>

Off-Balance Sheet Arrangements

As of December 31, 2006, the Company had no off-balance sheet arrangements.

Recent Accounting Pronouncements

Effective January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards No. 123R, "Share-Based Payment" 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. Further, as required under SFAS 123R, we now estimate forfeitures for options granted, which are not expected to vest. 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.

ITEM 7. FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheet of Opexa Therapeutics, Inc. (a development stage company), as of December 31, 2006 and the related consolidated statements of expenses, changes in stockholders' equity and cash flows for the years ended December 31, 2006 and 2005 and the period from January 22, 2003 (Inception) through December 31, 2006. These consolidated financial statements are the responsibility of Opexa's management. Our responsibility is to express an opinion on these consolidated 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 consolidated financial statements are free of material misstatements. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Pharma as of December 31, 2006 and the consolidated results of its operations and its cash flows for the periods described in conformity with accounting principles generally accepted in the United States of America.

MALONE & BAILEY, PC
www.malone-bailey.com
Houston, Texas

March 14, 2007

OPEXA THERAPEUTICS, INC.
(a development stage company)
(formerly PharmaFrontiers Corp.)
CONSOLIDATED BALANCE SHEET

	December 31,
	<u>2006</u>
Assets	
Current assets:	
Cash and cash equivalents	\$ 12,019,914
Investment in marketable securities	2,952,096
Other current assets	<u>472,881</u>
Total current assets	15,444,891
Intangible assets, net accumulated amortization of \$3,533,569	24,723,203
Property & equipment, net accumulated amortization of \$395,284	<u>1,361,377</u>
Total assets	<u><u>\$ 41,529,471</u></u>
Liabilities and Stockholders' Equity	
Current liabilities:	
Accounts payable	\$ 868,862
Stock payable	112,440
Accrued expenses	135,069
Note payable	1,500,000
Current maturity of long term debt	14,080
Derivative liability	<u>6,656,677</u>
Total current liabilities	9,287,128
Long term liabilities:	
Loan payable	<u>96,242</u>
Total liabilities	<u>9,383,370</u>
Commitments and contingencies	-
Stockholders' equity:	
Convertible preferred stock, no par value, 10,000,000 shares authorized, none issued and outstanding	-
Common stock, \$0.50 par value, 100,000,000 shares authorized, 6,696,784 shares issued and outstanding	3,348,351
Additional paid in capital	63,118,180
Deficit accumulated during the development stage	<u>(34,320,430)</u>
Total stockholders' equity	<u>32,146,101</u>
Total liabilities and stockholders' equity	<u><u>\$ 41,529,471</u></u>

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

OPEXA THERAPEUTICS, INC.
(a development stage company)
(formerly PharmaFrontiers Corp.)
CONSOLIDATED STATEMENTS OF EXPENSES
Years ended December 31, 2006 and 2005 and the
Period from January 22, 2003 (Inception) to December 31, 2006

	2006	2005	Inception through 2006
Research and development	\$ 7,612,932	\$ 4,183,356	\$ 12,428,909
General and administrative	5,461,047	6,259,075	14,206,469
Depreciation and amortization	1,818,795	1,735,209	3,818,823
Loss on disposal of assets	2,376	22,810	482,309
Operating loss	(14,895,150)	(12,200,450)	(30,936,510)
Interest income	688,299	81,930	776,221
Other income	46,450	28,174	77,003
Gain on derivative liability	104,978	3,896,841	4,001,819
Interest expense	(984)	(7,323,851)	(8,238,963)
Net loss	<u>\$ (14,056,407)</u>	<u>\$ (15,517,356)</u>	<u>\$ (34,320,430)</u>
Basic and diluted loss per share	\$ (2.61)	\$ (9.90)	N/A
Weighted average shares outstanding	5,390,910	1,564,837	N/A

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

OPEXA THERAPEUTICS, INC
(a development stage company)
(formerly PharmaFrontiers Corp.)
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
Period from January 22, 2003 (Inception) through December 31, 2006

	Common Stock		Additional Paid in	Accumulated	
	Shares	Par	Capital	Deficit	Total
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	-	-	-	(4,620,664)	(4,620,664)
Balances at December 31, 2004	1,005,984	502,992	27,805,805	(4,746,667)	23,562,130
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	-	-	-	(15,517,356)	(15,517,356)
Balances at December 31, 2005	2,061,955	1,030,977	39,783,452	(20,264,023)	20,550,406
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	-	-	-	(14,056,407)	(14,056,407)
Balances at December 31, 2006	<u>6,696,864</u>	<u>\$ 3,348,351</u>	<u>\$ 63,118,180</u>	<u>\$ (34,320,430)</u>	<u>\$ 32,146,101</u>

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

OPEXA THERAPEUTICS, INC.
(a development stage company)
(formerly PharmaFrontiers Corp.)
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2006 and 2005 and the
Period from January 22, 2003 (Inception) to December 31, 2006

					Inception through 2006
	2006	2005	2006	2005	2006
Cash flows from operating activities					
Net loss	\$ (14,056,407)	\$ (15,517,356)	\$ (34,320,430)		
Adjustments to reconcile net loss to net cash used in operating activities					
Stock issued for services	-	1,012,400	1,861,400		
Stock issued for debt in excess of principal	-	109,070	109,070		
Amortization of discount on notes payable due to warrants and beneficial conversion feature	-	5,516,638	6,313,205		
Unrealized gain on marketable securities	(25,912)	-	(25,912)		
Amortization of intangible assets	1,644,678	1,637,129	3,533,569		
(Gain) on derivative liability	(104,978)	(3,896,841)	(4,001,819)		
Depreciation	174,117	98,080	285,254		
Debt financing costs	-	365,910	365,910		
Option and warrant expense	4,318,583	4,861,629	9,303,545		
Loss on disposition of fixed assets	2,376	22,810	482,309		
Changes in:					
Accounts payable	359,396	26,360	444,562		
Marketable securities	(2,926,184)	-	(2,926,184)		
Prepaid expenses	(340,876)	(88,185)	(468,011)		
Accrued expenses	(105,240)	23,655	(50,259)		
Other assets	-	(388,210)	(388,210)		
Net cash used in operating activities	(11,060,447)	(6,216,911)	(19,482,001)		
Cash flows from investing activities					
Purchase of licenses	(125,000)	-	(357,742)		
Purchase of property & equipment	(619,147)	(258,903)	(1,051,054)		
Net cash used in investing activities	(744,147)	(258,903)	(1,408,796)		
Cash flows from financing activities					
Common stock sold for cash, net of offering costs	21,153,520	5,346,217	26,509,737		
Common stock repurchased and canceled	-	-	(325)		
Proceeds from debt	110,322	2,896,885	6,464,913		
Repayments on notes payable	-	(58,614)	(63,614)		
Net cash provided by financing activities	21,263,842	8,184,488	32,910,711		
Net change in cash and cash equivalents	9,459,248	1,708,674	12,019,914		
Cash and cash equivalents at beginning of period	2,560,666	851,992	-		
Cash and cash equivalents at end of period	\$ 12,019,914	\$ 2,560,666	\$ 12,019,914		
Cash paid for:					
Income tax	\$ -	\$ -	\$ -		

Interest	-	-	429
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NON-CASH TRANSACTIONS

Issuance of common stock for purchase of Opexa	\$	-	\$	-	\$	23,750,000
Issuance of common stock to Sportan shareholders	-	-	-	-	-	147,733
Issuance of common stock for University of Chicago license	-	-	1,868,384	-	-	2,295,459
Issuance of common stock for accrued interest	-	-	525,513	-	-	525,513
Conversion of notes payable to common stock	-	-	6,159,610	-	-	6,407,980
Conversion of accrued liabilities to common stock	180,000	-	17,176	-	-	197,176
Conversion of accounts payable to note payable	-	-	-	-	-	93,364
Discount on convertible notes relating to:						
- warrants	-	-	1,433,108	-	-	3,309,790
- beneficial conversion feature	-	-	831,944	-	-	1,715,973
- stock attached to notes	-	-	999,074	-	-	1,287,440
Fair value of derivative instrument	-	-	6,761,655	-	-	6,761,655
Stock payable	112,440	-	-	-	-	112,440

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

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

NOTE 1 – 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 cell 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.

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™, which is in U.S. FDA Phase IIb human clinical trials to evaluate its safety and effectiveness in treating multiple sclerosis.

Development Stage Company. The Company is considered to be in the Development stage as defined in Statement of Financial Accounting Standards No. 7. The Company has no revenues to date.

Basis of Presentation. In June 2006, the Company (i) changed its name to Opexa Therapeutics, Inc. from PharmaFrontiers Corp. and (ii) effected 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 consolidated financial statements include the accounts of Opexa Therapeutics, Inc. and its wholly-owned subsidiary, Opexa Pharmaceuticals, Inc. Significant inter-company accounts and transactions have been eliminated.

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

Use of Estimates in Financial Statement Preparation. The preparation of consolidated 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 consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash, Cash Equivalents and Marketable Securities. 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 consolidated 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 Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, as interpreted by SEC Staff Accounting Bulletin No. 107. 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 SFAS No. 123R, and, consequently, have 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 grant date fair value estimated in accordance with the original provisions of SFAS No. 123.

The following table illustrates the effect on net loss and net loss per share if Opexa had applied the fair value provisions of FASB Statement No. 123 to stock-based employee compensation prior to January 1, 2006:

	2005	Inception through 2006
Net loss as reported	\$ (15,517,356)	\$ (34,320,430)
Add: stock based compensation determined under intrinsic value based method	2,487,741	2,611,074
Less: stock based compensation determined under fair value based method	(4,264,013)	(4,417,377)
Pro forma net loss	<u>\$ (17,293,628)</u>	<u>\$ (36,126,733)</u>
Basic and diluted		
Net loss per common share	\$ (9.90)	N/A
As reported	\$ (11.10)	N/A

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 year ended December 31, 2006 was \$7,612,932, as compared to \$4,183,356 for the year ended December 31, 2005.

Accounting for Derivative Instruments. Statement of Financial Accounting Standard ("SFAS") No. 133, "Accounting for Derivative Instruments and Hedging Activities," as amended, requires all derivatives to be recorded on the balance sheet at fair value. Opexa's 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 Opexa used for determining fair values of its derivatives is the Black Scholes 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.

In September 2000, the Emerging Issues Task Force ("EITF") issued EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in, a Company's Own Stock," ("EITF 00-19") which requires freestanding contracts that are settled in a company's own stock, including common stock warrants, to be designated as an equity instrument, asset or a liability. Under the provisions of EITF 00-19, a contract designated as an asset or a liability must be carried at fair value on a company's balance sheet, with any changes in fair value recorded in the company's results of operations. A contract designated as an equity instrument must be included within equity, and no fair value adjustments are required.

In December 2006, the FASB issued FASB Staff Position No. EITF 00-19-2, Accounting for Registration Payment Arrangements (EITF 00-19-2). EITF 00-19-2 addresses an issuer's accounting for registration payment arrangements. It specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5, Accounting for Contingencies. The guidance in EITF 00-19-2 amends FASB Statements No. 133, Accounting for Derivative Instruments and Hedging Activities, and No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, and FASB Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, to include scope exceptions for registration payment arrangements. EITF 00-19-2 also requires additional disclosure regarding the nature of any registration payment arrangements, alternative settlement methods, the maximum potential amount of consideration and the current carrying amount of the liability, if any. This EITF is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issue of this EITF. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of this EITF, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. The impact of implementing EITF 00-19-2 in the fiscal year 2007 will result in a cumulative effect of a change in accounting principle with a credit to beginning retained earnings of \$6,656,677 and a reversal of the same amount to the derivative liability account.

Recently Issued Accounting Pronouncements.

In February 2006, the FASB issued SFAS 155, "Accounting for Certain Hybrid Financial Instruments," which amends SFAS 133, "Accounting for Derivative Instruments and Hedging Activities" and SFAS 140, "Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities." SFAS 155 simplifies the accounting for certain derivatives embedded in other financial instruments by allowing them to be accounted for as a whole if the holder elects to account for the whole instrument on a fair value basis. SFA 155 also clarifies and amends certain other provisions of SFAS 133 and SFAS 140. SFAS 155 is effective for all financial instruments acquired, issued or subject to a remeasurement event occurring in fiscal years beginning after September 15, 2006 and is therefore required to be adopted by the Company as of October 1, 2006. Management is still evaluating what effect this will have on the Company's financial statements.

In July 2006, the FASB issued Interpretation No. 48 (FIN No. 48), "Accounting for Uncertainty in Income Taxes." This interpretation requires recognition and measurement of uncertain income tax positions using a "more-likely-than-not" approach. FIN No. 48 is effective for fiscal years beginning after December 15, 2006. Management is still evaluating what effect this will have on the Company's financial statements.

In September 2006, the FASB issued SFAS 157, "Fair Value Measurements." This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosure about fair value measurements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007. Early adoption is encouraged. The adoption of SFAS 157 is not expected to have a material impact on the financial statements.

There were various other accounting standards and interpretations issued during 2006 and 2005, none of which are expected to have a material impact on the Company's consolidated financial position, operations or cash flows.

NOTE 2 – MARKETABLE SECURITIES

At December 31, 2006, Opexa invested \$10.9 million in in A-1/P-1 commercial paper, of which \$2.9 million is invested in marketable securities, and \$3.9 million is invested in a money market account with an average market yield of 5.33% and average time to maturity of 1.32 months. Interest income of \$688,299 was recognized for the twelve months ended December 31, 2006 in the consolidated statements of expenses.

NOTE 3 – LICENSE AGREEMENTS

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. In consideration for the license, Opexa paid the University \$57,742 and issued 237,188 shares valued at \$1,199,706. In December 2004, the License Agreement was amended granting Opexa an exclusive, non-transferable worldwide license to the University’s stem cell technology. In consideration for the amendment, Opexa paid the University an additional \$175,000, issued the University 5,500 shares of common stock valued at \$352,000, agreed to pay the University \$1,500,000 on October 30, 2005 and agreed to issue the University shares of Opexa common stock, including the shares already issued, equal to 2.6% of the total outstanding number of shares after conversion of the 15% exchangeable convertible subordinated promissory notes. In June 2005, 27,484 shares of common stock were issued to the University of Chicago per the terms of a license agreement. These shares were recorded at \$867,064. In August 2005, 1,710 shares of common stock were issued to the University of Chicago per the terms of a license agreement. These shares were recorded at \$109,434. In October 2006, the \$1,500,000 cash payment obligation was extended until April 30, 2007 and (ii) the obligation to issue 21,623 shares of Opexa’s common stock issuable was extended until April 30, 2007, with \$112,440 accrued at December 31, 2006.

Shanghai Institute for Biological Science License Agreement

In January 2006, Opexa acquired an exclusive worldwide license for the intellectual property rights and research results of an autologous T cell vaccine for rheumatoid arthritis from the Shanghai Institute for Biological Science, China Academy of Science of the People’s Republic of China. In exchange for a payment of \$125,000 and an agreed running royalty from the sale of commercialized products, Opexa receives all information and data related to all clinical trials on all patient controls and patients with rheumatoid arthritis with the T cell vaccine. This includes all clinical, cell procurement and manufacturing protocols, complete patient data sheets, all laboratory materials, methods and results and manufacturing records and documents and any other data related to the intellectual property. The first payment under the license occurred in April 2006 upon the delivery of materials pursuant to the terms of the licensing agreement. Opexa amortizes this intangible asset over its life of 19 years and as of December 31, 2006 the intangible asset had an unamortized balance of \$120,311.

NOTE 4 – INTANGIBLE ASSETS

Intangible assets consisted of the following at December 31, 2006:

Description	Life	Amount
University of Chicago license (see Note 2)	17 years	\$ 4,140,644
Opexa intangible group (see Note 11)	15 years	23,991,128
Rheumatoid arthritis license (see Note 2)	19 years	125,000
Subtotal		28,256,772
Less: accumulated amortization		(3,533,569)
Intangible assets, net		\$ 24,723,203

The Company believes that patent rights form one of its most valuable assets. Patents and patent applications are a key currency of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives the Company access to key product development rights from Opexa’s academic partners. The company amortizes its patent and license costs over a period of 15 to 19 years. These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets. The Company expenses payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for our current products in both the domestic and international markets. Amortization expense totaled \$1,644,678 and \$1,637,129 in fiscal 2006 and 2005, respectively.

NOTE 5 – PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31, 2006:

Description	Life	Amount
Computer equipment	3 years	\$ 134,023
Office furniture and equipment	3-10 years	220,113
Software	3-5 years	46,089
Laboratory equipment	3-10 years	912,709
Leasehold improvements	10 years	443,727
Subtotal		1,756,661
Less: accumulated depreciation		(395,284)
Property and equipment, net		<u>\$ 1,361,377</u>

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 \$174,117 and \$98,080 in fiscal 2006 and 2005, respectively.

NOTE 6 – INCOME TAXES

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

At December 31, 2006, for federal income tax and alternative minimum tax reporting purposes, the Company had approximately \$31,383,048 of unused net operating losses available for carryforward to future years. The benefit from carryforward of such net operating losses will expire in various years through 2026. 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 the Company's acquisition of Opexa. The benefit could be subject to further limitations if significant future ownership changes occur in the Company.

At December 31, 2006, deferred tax assets consisted of the following:

NOL @ 12/31/05	\$(21,540,246)
Net loss - 2006	<u>\$(14,056,407)</u>
Subtotal	(35,596,653)
Derivative (gain) loss	(104,978)
Option expense	2,749,617
Warrant expense	<u>1,568,966</u>
NOL @ 12/31/06	(31,383,048)
Estimated tax rate	<u>X 34%</u>
Deferred tax asset	(10,670,236)
Valuation allowance	<u>10,670,236</u>
Net deferred tax asset	<u>\$ -</u>

NOTE 7 – THIRD PARTY CONVERTIBLE NOTES

Between September 2004 and February 2005, Opexa issued convertible notes to investors totaling \$6,124,859. In March 2005, 45,169 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 in Opexa. In June 2005, a total of \$6,650,372 comprised of the principal of the notes of \$6,124,859 and accumulated interest of \$525,513, which accrued at a rate of 15% per annum, was exchanged for 443,360 shares of common stock, Class A and Class B warrants that expired in 2006, and Class C warrants to purchase 1,110,548 shares at an exercise price of \$30 per share.

Opexa analyzed the convertible notes and the warrants for derivative accounting consideration under SFAS 133 and EITF 00-19. Opexa determined the embedded conversion option in the convertible notes met the criteria for classification in stockholders equity under SFAS 133 and EITF 00-19. Therefore, derivative accounting was not applicable for these convertible notes payable. See Note 13 for a discussion of the accounting for the warrants.

NOTE 8 – NOTE PAYABLE

Note payable consists of a note in the amount of \$1,500,000 payable to the University of Chicago, secured by license, no interest and due April 30, 2007. See Note 3 for details.

Loan payable consists of an equipment line of up to \$250,000 with Wells Fargo of which \$110,322 was outstanding as of December 31, 2006. 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.

NOTE 9 – COMMITMENTS AND CONTINGENCIES

Office Lease

In October 2005, Opexa entered into a ten-year lease for its office and research facilities. There is 2,500 sq. ft. of space still available for future build-out. 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 \$117,774 for 2007, \$137,196 for 2008, \$139,782 for 2009, \$147,540 for 2010, \$147,540 for 2011 and \$584,343 for years 2012 to 2015. Rent expense for 2006 was \$136,153 and \$178,963 for 2005.

Contract Research Organization Agreement

In September 2006, Opexa engaged PharmaNet, LLC, a contract research organization focused on managing central nervous system trials to provide it with services in connection with its Phase IIb clinical trial. An initial pre-payment of \$400,000 was made to PharmaNet, LLC in April 2006, of which \$133,334 remains as a prepaid balance as of December 31, 2006. An additional \$235,000 payment was made in October representing an advance for investigator grant expenses, of which \$191,329 remains a prepaid balance as of December 31, 2006.

NOTE 10 – 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 2 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., shareholders. See Note 12 for details.
- 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, beneficial conversion features attached to convertible notes.
- Employee stock option 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 \$4,748,055. 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.
- 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 expense was \$2,487,741 for 2005.
- Warrant 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. See Note 13 for details.

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 \$23,000,000. 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 expense was \$2,749,617 for 2006.
- Warrant expense was \$1,568,966 for 2006.

NOTE 11 – STOCK OPTIONS AND WARRANTS

In 2004, Opexa adopted the 2004 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 Stock 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 method of calculation with a volatility of 75.05% and a discount rate of 2%.

During 2005, options to purchase 63,050 shares were granted to employees. at exercise prices 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 method of calculation with a volatility range of 175.4% and a discount rate of 2%.

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, vest from one to three years and have a fair value of \$3,126,168. Using the Black-Scholes method, stock compensation for 2006 was \$1,066,451 with a volatility range of 401.34% to 429.86% and a discount rate range of 4.72% - 5.22%.

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

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

Consultant Warrants:

During 2004, warrants 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 method with a volatility range of 75.05% and a discount rate of 2%.

During 2005, warrants to purchase 71,060 shares were granted to consultants. Using the Black-Scholes method, fair value for 2005 was \$1,552,936 with a volatility range of 175.4% and a discount rate of 2%.

During 2005, warrants to purchase 46,085 shares of Common Stock ere issued to several brokerage firms as the offering costs and commissions for Opexa’s financing activities at an exercise price of \$1.50 per share. These warrants have a fair value of \$2,197,162 and vest immediately.

During 2005, warrants to purchase 9,914 shares were forfeited and cancelled.

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 \$5.20. These warrants have a term of three years, vest immediately and have a fair value of \$1,077,778.

During 2006, warrants to purchase 156,500 shares of common stock were granted by Opexa to its consultants, directors and exiting directors at the exercise prices ranging from \$5.20 to \$9.80. These warrants have a term of ten years, vest from one to three years and have a fair value of \$1,496,375. Using the Black-Scholes method, stock compensation for 2006 was \$931,597 with a volatility range of 401.34% to 429.86% and a discount rate range of 4.72% - 5.22%.

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

During 2006, warrants to purchase 5,000 shares were expired.

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 2,386,984 shares were granted to investors related to the convertible notes and warrants to purchase 254,363 shares were forfeited and cancelled.

During 2006, warrants to purchase 2,765,043 shares were granted to investors related to the Aril 2006 financing and warrants to purchase 1,645,002 shares were forfeited and cancelled.

Summary information regarding options and warrants is as follows:

	Options	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price
Year ended December 31, 2003:				
Granted	-	\$ -	15,000	\$ 1.00
Outstanding at December 31, 2003	-	-	15,000	1.00
Year ended December 31, 2004:				
Granted	96,500	31.70	162,800	22.30
Outstanding at December 31, 2004	96,500	31.70	177,800	22.40
Year ended December 31, 2005:				
Granted	63,050	15.70	2,504,129	28.60
Forfeited and canceled	(4,167)	42.80	(264,277)	24.50
Outstanding at December 31, 2005	155,383	24.90	2,417,652	23.51
Year ended December 31, 2006:				
Granted	389,160	5.48	3,135,264	9.28
Forfeited and canceled	(14,133)	34.79	(1,649,995)	12.77
Outstanding at December 31, 2006	<u>530,410</u>	<u>\$ 10.38</u>	<u>3,902,921</u>	<u>\$ 13.52</u>

Summary of options and warrants outstanding and exercisable as of December 31, 2006 is as follows:

Exercise Price	Remaining Life	Options Outstanding	Options Exercisable	Warrants Outstanding	Warrants Exercisable
\$ 40.00	3 - 4 years	-	-	17,500	8,375
\$ 30.00	2 - 3 years	84,500	58,667	5,000	3,333
\$ 30.00	3 - 4 years	18,850	8,950	1,125,056	1,116,389
\$ 15.00	3 - 4 years	-	-	46,895	46,895
\$ 11.90	3 - 4 years	-	-	21,500	3,000
\$ 11.50	2 - 3 years	-	-	16,750	-
\$ 11.40	2 - 3 years	2,000	-	-	-
\$ 9.80	9 - 10 years	-	-	37,000	17,500
\$ 9.40	9 - 10 years	30,900	-	4,500	500
\$ 8.25	9 - 10 years	12,500	-	1,500	-
\$ 7.09	9 - 10 years	3,300	-	-	-
\$ 7.00	9 - 10 years	37,000	9,250	-	-
\$ 6.50	4 - 5 years	-	-	2,300,000	2,300,000
\$ 5.20	2 - 3 years	-	-	8,500	-
\$ 5.20	9 - 10 years	-	-	105,000	52,500
\$ 5.00	3 - 4 years	-	-	213,720	213,720
\$ 5.00	4 - 5 years	75,000	32,100	-	-
\$ 5.00	9 - 10 years	266,360	-	-	-
		<u>530,410</u>	<u>108,967</u>	<u>3,902,921</u>	<u>3,762,213</u>

NOTE 12 – PURCHASE OF OPEXA PHARMACEUTICALS

In October 2004, Opexa acquired all of the outstanding stock of Opexa Pharmaceuticals, Inc. The acquisition was accounted for under the purchase method, where all of Opexa Pharmaceuticals, Inc.'s assets are restated to their fair market value on the acquisition date. The 250,000 shares of Opexa were valued at their then fair value of \$23,750,000 or \$95.00 per share. The results of operations for Opexa from November 6, 2004 through December 31, 2005 are included in the Statements of Operations and the Statements of Cash Flows.

The following table summarizes the estimated fair values of the assets acquired and the liabilities assumed at the date of acquisition:

Current assets	\$	55,387
Property, plant and equipment, net		639,160
Intangible assets		<u>23,991,128</u>
Total assets, net		24,685,675
Current liabilities		<u>935,675</u>
Total liabilities assumed		<u>935,675</u>
Net assets acquired	\$	<u><u>23,750,000</u></u>

Of the \$23,991,128 of acquired intangible assets, the full amount is assigned to an inseparable group of patents and licenses that cannot function independently by themselves. The weighted average useful life of the intangible group as of December 31, 2006 is approximately 15 years.

NOTE 13 – DERIVATIVE INSTRUMENTS

For the years ended December 31, 2006 and 2005, Opexa evaluated the application of SFAS 133 and EITF 00-19 for all of its financial instruments and identified the following financial instruments as derivatives:

- (1) Series A Warrants issued in conjunction with the bridge note exchange and private placement offerings in June and July 2005, which expired on February 17, 2006;
- (2) Series B Warrants issued in conjunction with the bridge note exchange and private placement offerings in June and July 2005, which expired on October 17, 2006; and
- (3) Series C Warrants issued in conjunction with the bridge note exchange and private placement offerings in June and July 2005.

These three series of warrants are derivatives because the liquidated damage provision in the registration rights agreement covering each warrant resulted in the conclusion that it was more economic to issue registered shares than to issue unregistered shares and pay the penalty. Because issuing registered shares is outside of Opexa's control, Opexa concluded the warrants should be accounted for as derivative liabilities under SFAS 133 and EITF 00-19.

As a result, Opexa reports the value of these derivatives as current liabilities in its balance sheet and report changes in the value of these derivatives as non-operating gains or losses in its statements of operations. The value of the derivatives is required to be remeasured on a quarterly basis, and is based on the Black Scholes Pricing Model.

Variables used in the Black-Scholes option-pricing model include (1) risk free interest rate, (2) expected warrant life is the actual remaining life of the warrants as of each period end, (3) expected volatility and (4) zero expected dividends as further detailed in the table as follows:

	<u>As of 12/31/2005</u>	<u>As of 12/31/2006</u>
Risk-free rate for term		
A Warrant	4.08%	-
B Warrant	4.37%	-
C Warrant	4.35%	501%
Expected volatility		
A Warrant	30%	-
B Warrant	112%	-
C Warrant	475%	487%

The impact of the application of SFAS 133 and EITF 00-19 on the balance sheets as of December 31, 2006 and 2005 and the statements of operations and for the years ended December 31, 2006 and 2005 and the period from inception through December 31, 2006 is as follows:

	<u>As of 12/31/2005</u>	<u>As of 12/31/2006</u>	<u>Gain(Loss) Year Ended 12/31/2005</u>	<u>Gain(Loss) Year Ended 12/31/2006</u>	<u>Gain(Loss) Inception Through 12/31/2006</u>
Series A Warrants	\$ -	\$ -	\$ 332,440	\$ -	\$ 332,440
Series B Warrants	264,957	-	640,882	264,957	\$ 905,839
Series C Warrants	6,496,698	6,656,677	2,923,519	(159,979)	\$ 2,763,540
Totals	<u>\$ 6,761,655</u>	<u>\$ 6,656,677</u>	<u>\$ 3,896,841</u>	<u>\$ 104,978</u>	<u>\$ 4,001,819</u>

The warrants granted during the April 2006 financing were determined to qualify as for equity treatment under SFAS 133 and EITF 00-19. Nothing in the warrant agreements required cash settlement or allowed for the possibility of cash settlement including the impact of the liquidated damages penalty under the registration rights agreement. It was determined on the date of grant and at December 31, 2006 that it was more economic to issue unregistered shares and pay the penalty than to issue registered shares.

In December 2006, the FASB issued FASB Staff Position No. EITF 00-19-2, Accounting for Registration Payment Arrangements (EITF 00-19-2). EITF 00-19-2 addresses an issuer's accounting for registration payment arrangements. It specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5, Accounting for Contingencies. The guidance in EITF 00-19-2 amends FASB Statements No. 133, Accounting for Derivative Instruments and Hedging Activities, and No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, and FASB Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, to include scope exceptions for registration payment arrangements. EITF 00-19-2 also requires additional disclosure regarding the nature of any registration payment arrangements, alternative settlement methods, the maximum potential amount of consideration and the current carrying amount of the liability, if any. This EITF is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issue of this EITF. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of this EITF, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. The impact of implementing EITF 00-19-2 in the fiscal year 2007 will result in a cumulative effect of a change in accounting principle with a credit to beginning retained earnings of \$6,656,677 and a reversal of the same amount to the derivative liability account.

NOTE 14 – STOCK PURCHASE AGREEMENT

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

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 8A. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit to the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified by the Securities and Exchange Commission's rules and forms, and that information is accumulated and communicated to our management, including our principal executive and principal financial officers (whom we refer to in this periodic report as our Certifying Officers), as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Certifying Officers, the effectiveness of our disclosure controls and procedures as of December 31, 2006, pursuant to Rule 13a-15(b) under the Securities Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of December 31, 2006, our disclosure controls and procedures were effective.

There were no changes in our internal control over financial reporting that occurred during our most recently completed fiscal year that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 8B. OTHER INFORMATION

None

PART III

ITEM 9. DIRECTORS , EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

The information required by this item with respect to the directors, executive officers and compliance with Section 16(a) of the Exchange Act is incorporated by reference from the information provided under the headings "Election of Directors," "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance," respectively, contained in the Company's Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of the proxies for the Company's Annual Meeting of Stockholders.

ITEM 10. EXECUTIVE COMPENSATION.

The information required by this item is incorporated by reference from the information provided under the heading "Executive Compensation" of the Company's Proxy Statement.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this item is incorporated herein by reference from the information provided in the Company's Proxy Statement.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated herein by reference from the information provided in the Company's Proxy Statement.

ITEM 13. EXHIBITS

(a) Exhibits. The following exhibits of the Company are included herein.

<u>Exhibit No.</u>	<u>Description</u>
Exhibit 2.1	Stock Purchase Agreement (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form K filed June 4, 2004)
Exhibit 2.2	Merger Agreement (incorporated by reference to Exhibit 2.1 to the Company's Current Report on 8-K filed October 8, 2004)
Exhibit 3.1	Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit A to the Company's Definitive Information Statement filed June 29, 2004)
Exhibit 3.2	By-laws (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form SB-2 filed July 19, 2005)
Exhibit 3.3	Amended and Restated Articles of Incorporation incorporated by reference to Exhibit 3.1 of the Company's Report on Form 8-K filed June 19, 2006)
Exhibit 4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 2.3 to the Company's Registration Statement on Form 10-SB (File No. 000-25513), initially filed March 8, 1999
Exhibit 10.1	2004 Compensatory Stock Option Plan (incorporated by reference to Exhibit B to the Company's Definitive Information Statement filed June 29, 2004)
Exhibit 10.2	Employment Agreement of David McWilliams (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-QSB filed November 16, 2004)
Exhibit 10.3	Second Amended Employment Agreement of William Rouse (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed February 4, 2005)
Exhibit 10.4	Director's Agreement of David McWilliams (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-QSB filed November 16, 2004)
Exhibit 10.5	Director's Agreement of Paul Frison (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-KSB filed April 15, 2005)
Exhibit 10.6	Termination Settlement and Release Agreement with R. Wayne Fritzsche (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K filed February 4, 2005)
Exhibit 10.7	Form of Warrant Agreement (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-KSB filed April 15, 2005)
Exhibit 10.8	Amended and Restated License Agreement with 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)
Exhibit 10.9	Amended and Restated License Agreement with University of Chicago (incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-KSB filed April 15, 2005)
Exhibit 10.10	Second Amendment to the Amended and Restated License Agreement (incorporated by reference to Exhibit 10.4 of the Company's Report on Form 8-K filed April 18, 2006)
Exhibit 10.11	Form of Series A Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form SB-2 filed July 19, 2005)

Exhibit 10.12	Form of Series B Common Stock Purchase Warrant(incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form SB-2 filed July 19, 2005)
Exhibit 10.13	Form of Series C Common Stock Purchase Warrant(incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form SB-2 filed July 19, 2005)
Exhibit 10.14	Securities Purchase Agreement dated June 17, 2005 by and among the Company and the Investors named therein. (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form SB-2 filed July 19, 2005)
Exhibit 10.15	Registration Rights Agreement dated June 17, 2005 by and among the purchasers of common stock named therein(incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form SB-2 filed July 19, 2005)
Exhibit 10.16	Securities Purchase Agreement dated June 30, 2005 by and among the Company and the purchasers of common stock named therein (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form SB-2 filed July 19, 2005)
Exhibit 10.17	Securities Purchase Agreement dated July 15, 2005 by and among the Company and the Investors named therein. (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form SB-2 filed July 19, 2005)
Exhibit 10.18	Registration Rights Agreement dated July 15, 2005 by and among the Company and the Investors named therein. (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form SB-2 filed July 19, 2005)
Exhibit 10.19	License Agreement dated January 13, 2006 by the Company and Shanghai Institute for Biological Services. (incorporated by reference to Exhibit 10.23 to the Post-Effective Amendment No. 1 of the Company's Registration Statement on Form SB-2 filed February 9,2006)
Exhibit 10.20	Lease Agreement dated August 19, 2005 by 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)
Exhibit 10.21	Purchase Agreement dated April 11, 2006 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 18, 2006)
Exhibit 10.22	Registration Rights Agreement dated April 11, 2006 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed April 18, 2006)
Exhibit 10.23	Form of Warrant issued in connection with April 2006 financing (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed April 18, 2006)
Exhibit 10.24	Form of Broker Stock Purchase Warrant issued to MDB Capital Group LLC (incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K filed April 18, 2006)
Exhibit 10.25	Third Amendment to the Amended and Restated License Agreement (incorporated by reference to Exhibit 10.1 of the Company's Report on Form 8-K filed October 31, 2006)
Exhibit 31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Exhibit 31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Exhibit 32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
Exhibit 32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by this item is incorporated by reference from the information provided in the Company's Proxy Statement under the discussion of the Company Audit Committee and under the item regarding shareholder ratification of the Company's independent accountants.

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.

SIGNATURES

OPEXA THERAPEUTICS, INC.

By: /s/ DAVID B. MCWILLIAMS
David B. McWilliams, President and Chief Executive Officer

Date: March 15, 2007

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ DAVID B. MCWILLIAMS</u> David B. McWilliams	President, Chief Executive Officer And Director	March 15, 2007
<u>/s/LYNNE HOHLFELD</u> Lynne Hohlfeld	Chief Financial Officer and Principal Accounting Officer	March 15, 2007
<u>/s/ GREGORY H. BAILEY</u> Gregory H. Bailey	Director	March 15, 2007
<u>/s/ DAVID HUNG</u> David Hung	Director	March 15, 2007
<u>/s/ MICHAEL RICHMAN</u> Michael Richman	Director	March 15, 2007
<u>/s/ SCOTT B. SEAMAN</u> Scott B. Seaman	Director	March 15, 2007

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

I, David B. McWilliams, certify that:

1. I have reviewed this annual report on Form 10-KSB of Opexa Therapeutics, Inc. (the "small business issuer");
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 small business issuer as of, and for, the periods presented in this report;
4. The small business issuer'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 small business issuer 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 small business issuer, 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 small business issuer'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 small business issuer's internal control over financial reporting that occurred during the small business issuer's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and
5. The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer'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 small business issuer'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 small business issuer's internal control over financial reporting.

/s/ DAVID B. MCWILLIAMS

David B. McWilliams
President and Chief Executive Officer

Date: March 15, 2007

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

I, Lynne Hohlfeld, certify that:

1. I have reviewed this annual report on Form 10-KSB of Opexa Therapeutics, Inc. (the "small business issuer");
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 small business issuer as of, and for, the periods presented in this report;
4. The small business issuer'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 small business issuer 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 small business issuer, 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 small business issuer'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 small business issuer's internal control over financial reporting that occurred during the small business issuer's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting; and
5. The small business issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer'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 small business issuer'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 small business issuer's internal control over financial reporting.

/s/ LYNNE HOHLFELD

Lynne Hohlfeld

Chief Financial Officer and Principal Accounting Officer

Date: March 15, 2007

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

Pursuant to 18 U.S.C. Section 1350, the undersigned Officer of Opexa Therapeutics, Inc.(the "Company"), hereby certifies, to such officer's knowledge, that the Company's Annual Report on Form 10-KSB for the year ended December 31, 2006 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ DAVID B. MCWILLIAMS

David B. McWilliams

President and Chief Executive Officer

Date: March 15, 2007

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

Pursuant to 18 U.S.C. Section 1350, the undersigned Officer of Opexa Therapeutics, Inc. (the "Company"), hereby certifies, to such officer's knowledge, that the Company's Annual Report on Form 10-KSB for the year ended December 31, 2006 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ LYNNE HOHLFELD

Lynne Hohlfeld
Chief Financial Officer and Principal Accounting Officer

Date: March 15, 2007