

PIPEX PHARMACEUTICALS, INC.
Form 10KSB
April 02, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

**FORM 10-KSB
ANNUAL REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2006

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934
For the transition period from _____ to _____

Commission File Number: 333-139354

PIPEX PHARMACEUTICALS, INC.

(Name of small business issuer in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)
3985 Research Park Drive
Ann Arbor, MI
(Address of principal executive offices)

13-3808303
(IRS Employer Identification Number)

48108
(Zip Code)

Registrant's telephone number, including area code:
(734) 332-7800

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, \$0.001 par value per share
(Title of Class)

Indicate by check mark 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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of issuer'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

State issuer's revenues for its most recent fiscal year: \$0

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

The aggregate market value of the issuer's common stock held by non-affiliates of the registrant as of March 21, 2007, was approximately \$31,088,557, based on \$1.31, the price at which the registrant's common stock was last sold on that date.

As of March 21, 2006, the issuer had 50,966,912 shares of common stock outstanding.

Documents incorporated by reference: None.

Transitional Small Business Disclosure Format (Check one): Yes No

PIPEX PHARMACEUTICALS, INC.

FORM 10-KSB
TABLE OF CONTENTS

	Page
PART I.	
Item 1. Business	3
Item 1A. Risk Factors	12
Item 2. Properties	30
Item 3. Legal Proceedings	30
Item 4. Submission of Matters to a Vote of Security Holders	30
PART II.	
Item 5. Market for Registrant's Common Equity and Related Stockholder Matters	31
Item 6. Management's Discussion and Analysis of Financial Condition and Results of Operations	32
Item 7. Financial Statements and Supplementary Data	39
Item 8. Changes in and Discussions with Accountants on Accounting and Financial Disclosure	65
Item 8A. Controls and Procedures	65
Item 8B. Other Information	65
PART III.	
Item 9. Directors and Executive Officers of the Registrant	66
Item 10. Executive Compensation	71
Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	73
Item 12. Certain Relationships and Related Transactions	74
Item 13. Principal Accountant Fees and Services	75
PART IV.	
Item 14. Exhibits and Financial Statement Schedules and Reports on Form 8-K	77
SIGNATURES	79

PART I.**Forward-Looking Statements**

Most of the matters discussed within this report include forward-looking statements on our current expectations and projections about future events. In some cases you can identify forward-looking statements by terminology such as “may,” “should,” “potential,” “continue,” “expects,” “anticipate,” “intends,” “plans,” “believes,” “estimates,” and similar expressions. These statements are based on our current beliefs, expectations, and assumptions and are subject to a number of risks and uncertainties. Actual results and events may vary significantly from those discussed in the forward-looking statements.

Except as otherwise provided, Pipex shall mean Pipex Pharmaceuticals and its subsidiaries, Pipex Therapeutics Inc., Effective Pharmaceuticals, Inc., CD4 Biosciences, Inc. and Solovax, Inc.

These forward-looking statements are made as of the date of this report, and we assume no obligation to update these forward-looking statements whether as a result of new information, future events, or otherwise, other than as required by law. In light of these assumptions, risks, and uncertainties, the forward-looking events discussed in this report might not occur.

ITEM 1. BUSINESS**General**

Pipex Pharmaceuticals, Inc. (together with its subsidiaries, “Pipex” or the “Company”) is a development-stage, specialty pharmaceutical company that is developing proprietary, late-stage drug candidates for the treatment of neurologic and fibrotic diseases. Our strategy is to exclusively in-license proprietary, clinical-stage drug candidates that have demonstrated preliminary efficacy in human clinical trials and to complete the further clinical testing, manufacturing and other regulatory requirements sufficient to seek marketing authorizations via the filing of a New Drug Application (NDA) with the FDA and a potential Marketing Application Authorization (MAA) with the European Medicines Evaluation Agency (EMA).

Below is a table of our product candidates, therapeutic indication(s) and their respective stage of development:

PRODUCT	THERAPEUTIC INDICATION	STAGE OF DEVELOPMENT
COPREXA™ (oral tetrathiomolybdate)	Initially Presenting Neurologic Wilson’s Disease	Phase III Clinical Trial (complete) NDA in preparation
COPREXA™ (oral tetrathiomolybdate)	Refractory Idiopathic Pulmonary Fibrosis (IPF)	Phase IIa Clinical Trial (complete)
COPREXA™ (oral tetrathiomolybdate)	Primary Biliary Cirrhosis (PBC)	Phase II Clinical Trial (on-going)
TRIMESTA™ (oral estriol)	Relapsing-Remitting Multiple Sclerosis	Phase II Clinical Trial (complete)
Anti-CD4 802-2	Prevention of Severe Graft Vs. Host Disease	Phase I/II Clinical Trial (ongoing)
Anti-CD4 802-2	Autoimmune Diseases	Preclinical studies
CORRECTA™ (clotrimazole enema)	Refractory Acute Pouchitis	Phase II Clinical Trial (ongoing)
EFFIRMA™ (oral flupirtine)	Fibromyalgia	Phase II Clinical Trial (planned)

Product Summary

The following is a summary of each of the clinical stage drug candidates that we are developing:

COPREXA™ (oral tetrathiomolybdate)

Our lead product candidate, COPREXA™, is an oral, small-molecule, anticopper agent that is highly specific for lowering the levels of free copper in serum. Free copper in serum represents the toxic form of copper, as opposed to the essential form of copper which is found tightly bound to appropriate copper proteins, such as ceruloplasmin. Free copper in serum readily crosses the blood-brain barrier (BBB) and is generally at equilibrium with free copper levels in the central nervous system (CNS). The brain is the organ most sensitive to the toxic effects of free copper. By lowering the levels of toxic free copper in serum, COPREXA™ demonstrated in two pivotal clinical trials the ability to reduce toxic free copper levels and substantially improve clinical outcomes in initially presenting neurologic Wilson's disease patients. We believe that COPREXA's unique mechanism of action and specificity for free copper makes it ideally suited for the treatment of other CNS diseases in which abnormal serum and CNS copper homeostasis are implicated.

COPREXA™ for Neurologic Wilson's Disease

COPREXA™ has successfully completed two pivotal clinical trials for the treatment of neurologically-presenting Wilson's disease, a genetic disease characterized by psychiatric and neurologic disorders caused by impaired hepatic copper excretion which results in elevated levels of toxic free copper in the systemic circulation and CNS. Based upon the positive results of these two pivotal clinical trials and communication from the FDA, we intend to submit an NDA with the FDA and an MAA with the EMEA to market COPREXA™ in the U.S. and Europe for the initial indication of neurologically-presenting Wilson's disease. Wilson's disease is an orphan drug indication. There are approximately 6,000 Wilson's disease patients in the U.S., of which approximately half are diagnosed with neurologic symptoms and half with hepatic symptoms. It is estimated that several hundred of them annually are newly diagnosed, neurologically-presenting patients who are suitable candidates for treatment with COPREXA™. Wilson's disease is an inherited genetic disease in which affected patients have an impaired ability to properly excrete copper via the liver and stool. Due to the rarity of Wilson's disease and the fact that it is easily mistaken for psychosis, patients typically are not diagnosed until the presentation of neurodegenerative symptoms.

Psychiatric symptoms of neurologically-presenting Wilson's patients will generally precede neurologic symptoms by months or years and may include loss of emotional control, temper tantrums, emotional outbursts, bouts of crying, severe depression, suicidal ideation, loss of inhibitions, delusions, hallucinations and loss of ability to focus on tasks. Neurologic symptoms later develop as a result of neurodegeneration in the basal ganglia of the brain and include impaired speech, tremor, dystonia, incoordination and dysphasia. Crippling movement disorders may ultimately occur. Without proper treatment, Wilson's disease is usually fatal by the age of 30. However, if treatment is begun early enough, symptomatic recovery is usually complete and a life of normal length and quality can be expected.

Current Therapies for Wilson's Disease

Therapy for Wilson's disease can be divided into two broad categories: (1) initial therapy in acutely ill patients, and (2) maintenance therapy. Initial therapy relates to the first few weeks to months of therapy, during which a newly presenting patient is still suffering from acute copper toxicity. Once the copper levels have been brought down to a subtoxic threshold, maintenance therapy is provided for the remainder of the patient's life to prevent recurrence of copper accumulation and further copper toxicity. However, the currently approved therapies for Wilson's disease offer suboptimal treatment

options for newly-diagnosed Wilson's patients and indeed the FDA approved chelators, penicillamine and trientine, may be contraindicated due to the high incidence of irreversible neurologic worsening attributable to the mechanism of these agents.

Three drugs are currently available for the treatment of various forms of Wilson's disease: penicillamine (Cupramin[®]), trientine (Syprine[®]), and zinc acetate (Galzin[®]). Zinc acetate's use for Wilson's disease maintenance therapy was invented and developed by our scientific founder, Dr. George Brewer, the inventor of COPREXA[™]. Penicillamine, a copper chelator in use since the 1950's, is currently the first-line therapy. As noted above, approximately 50% of Wilson's disease patients initially present with neurologic and psychiatric symptoms. According to published literature, approximately 50% of patients who receive penicillamine as first-line therapy, suffer further neurologic deterioration upon initiation of the drug. It is estimated that about half of these patients who worsen, or about 25% of the neurologically-presenting Wilson's patients treated with penicillamine, never recover to their pre-penicillamine baseline. There is also evidence that even pre-symptomatic patients can develop neurologic disease after being initiated on penicillamine. Accordingly, treatment with penicillamine may induce additional, irreversible neurological damage.

Trientine (Syprine[®]), another copper chelator, is FDA approved as second-line therapy for Wilson's disease patients who have become resistant to penicillamine. The mechanism of action of trientine is similar to that of penicillamine, and it has been found to cause similar symptoms of neurological worsening when used as initial therapy. However, the incidence of neurologic deterioration in patients treated with trientine is approximately 25-30%, as compared to an estimated 50% incidence in patients treated with penicillamine. The neurologic worsening attributable to penicillamine and trientine may be explained by the fact that penicillamine and trientine are non-selective chelators that mobilize additional free copper from tissues and organs where copper is normally stored. Such uncontrolled chelation increases the levels of free copper in the serum, tissues and CNS, thereby causing further copper toxicity in the brain. The brain is very sensitive to the toxic effects of free copper and has adapted a very tightly regulated system of copper chaperones and copper transporters to deliver, utilize and clear excess copper.

Galzin[®] (zinc acetate capsules) was approved by the FDA in 1997 and EMEA in 2001. Galzin[®] is the standard maintenance therapy for Wilson's disease, but it is not ideal for patients who initially present with neurologic symptoms because it has a relatively slow onset of action and may take up to six months to produce effects. Furthermore, because Galzin[®] acts by partially blocking the absorption of additional copper via the intestines, it neither complexes nor chelates copper and therefore has little or no effect on circulating levels of toxic free copper present in the body. Unless circulating levels of toxic free copper are brought down to a subtoxic threshold, Wilson's patients are at risk for further copper toxicity and worsening of their disease.

Pivotal Clinical Trials of COPREXA in Neurologically-Presenting Wilson's Disease

The first pivotal clinical trial of COPREXA[™] was conducted on an open label basis in 55 neurologically-presenting Wilson's disease patients. Galzin[®] maintenance therapy followed for a period of two years. During that follow-up period, neurologic function was assessed with scored neurologic and speech tests. A highly statistically significant improvement was achieved in these patients in annual quantitative neurologic scores ($p < 0.002$) as compared to baseline. Annual quantitative speech scores also yielded a highly statistically significant result ($p < 0.001$) as compared to baseline. Importantly, only 2 of the 55 patients, or 3.6% of the patients treated with COPREXA[™] showed further neurologic deterioration. This compares very favorably with historical controls of an estimated 52% incidence of neurologic deterioration in patients treated with penicillamine, the first line therapy.

In a second double-blind, randomized comparator, pivotal clinical trial, 48 newly diagnosed, neurologically-presenting Wilson's patients were treated with either trientine (Syprine[®]), a copper chelator having a similar mechanism of action to that of penicillamine and approved for use as second

line therapy for Wilson's disease, versus COPREXATM. The primary endpoint of this comparator study was the incidence of neurological worsening between the two groups. This comparator trial demonstrated a statistically significant reduction in the incidence of neurologic worsening in favor of COPREXATM (p<0.05). Twenty-six percent (26%) of trientine treated patients (6 of 23) experienced neurologic worsening compared to only four percent (4.0%) of COPREXATM treated patients (1 of 25). Importantly, in addition to the high incidence of irreversible neurologic deterioration associated with trientine, this pivotal comparator trial also suggested that neurologic deterioration during the initial treatment phase with trientine is an important prognostic indicator of death in this patient group.

The clinical development of COPREXATM has been supported by grants from the Orphan Products Group of the FDA.

COPREXATM for Idiopathic Pulmonary Fibrosis (IPF)

In order to broaden the therapeutic utility of COPREXATM, we are also developing it as a highly potent oral antifibrotic agent. This research is based upon the observation that the fibrotic disease process is dependent upon the availability of endogenous free copper. COPREXATM has demonstrated the ability to inhibit fibrosis in a number of well established animal models through the sequestration of available copper and inhibition of key fibrotic cytokines, including secreted protein acid rich in cysteine (SPARC), NF-kappaB, TGF-β, FGF-2, IL-1, IL-6, IL-8, connective tissue growth factor (CTGF) and collagen.

IPF is a fatal respiratory disease characterized by progressive loss of lung function due to extensive fibrosis of lung tissues that are essential for respiration and life. It affects an estimated 124,000 patients in the U.S., resulting in approximately 30,000 deaths in the U.S. annually. This represents more deaths annually than either breast or prostate cancer.

Phase II Clinical Trials of COPREXA in Refractory IPF Patients

Based upon the successful animal experiments described above, an one-year, open-label, phase II clinical trial of COPREXATM was completed for the treatment of refractory IPF. The prospectively defined primary endpoint of the study was the percentage of patients capable of maintaining clinically stable pulmonary function as determined by forced vital capacity (FVC), an accepted measurement of pulmonary function in IPF. These results are being prepared for publication. This phase II trial was partially supported by a grant from the Coalition for Pulmonary Fibrosis, a non-profit organization.

COPREXATM for Primary Biliary Cirrhosis (PBC)

Primary biliary cirrhosis (PBC) is an autoimmune and fibrotic disease which targets the bile ducts of the liver. PBC is a relatively rare disease affecting approximately 20,000 patients in the U.S. Progression of PBC is somewhat variable. Some patients die or require transplant within 5 years, while others have a more protracted course of disease.

Phase II Clinical Trial of COPREXATM in Primary Biliary Cirrhosis

Based on positive animal experiments, we have initiated a 50-patient, three-year, double-blind, placebo-controlled, phase II clinical trial of COPREXATM for the treatment of PBC. This study is being supported by an \$850,000 grant from the Orphan Products Division of the FDA. Therapies currently approved for PBC, such as ursodiol (Urso[®]) offer only palliative relief of the symptoms of PBC and do not alter the course of the disease.

COPREXA™ for Alzheimer's Disease (AD)

An increasing body of evidence points to dysfunctional copper homeostasis in the pathogenesis of AD. Recently, a published prospective clinical study conducted in 3718 patients in the U.S. over six years, which included subjects that consumed a vitamin containing copper supplement (1.6mg of copper a day) when taken together with a high saturated and trans fat diet resulted in an equivalent of 19 years of mental decline.

A separate European clinical study conducted in 53 patients correlated the levels of the highly reactive "free copper" pool in serum to disease severity in AD patients versus aged-matched control patients. These results demonstrated that the "free copper" serum pool was highly increased in AD patients.

These clinical studies are complemented by preclinical studies that show that AD amyloid-a plaques when treated with copper chelating agents in-vitro loosen and reverse fibril formation as determined by spectroscopy. Other investigations have shown that reduction in intracellular neuronal copper levels downregulates the expression of amyloid precursor protein (APP), a hallmark AD protein.

COPREXA's specificity and unique mechanism of action for rapidly lowering toxic free copper levels, combined with its history of success in completed pivotal clinical trials of neurologically presenting Wilson's disease, may position COPREXA™ as the first available therapeutic agent capable of correcting the serum and CNS free copper dyshomeostasis that might represent an important fundamental cause of AD.

The National Institute of Health (NIH) granted COPREXA™ a grant in the amount of \$306,172 in February 2007 in order to support the testing of its utility for the treatment of AD.

TRIMESTA™ (oral estriol)

We are developing TRIMESTA™ as an oral immunomodulatory and anti-inflammatory agent for the North American market. Estriol has been approved and marketed throughout Europe and Asia as a mild estrogenic agent for over 40 years for the treatment of post-menopausal hot flashes. Estriol is an important endogenous hormone that is produced in the placenta by women during pregnancy. Maternal levels of estriol increase in a linear fashion throughout the third trimester of pregnancy until birth, whereupon they abruptly fall to near zero. Our scientific collaborator of TRIMESTA™ is a leading authority on the role that estriol plays in affording immunologic privilege to the fetus so as to prevent its rejection by the mother. It is a widely observed phenomenon that pregnant women with autoimmune diseases (such as multiple sclerosis) experience high rates of spontaneous remission during pregnancy (especially in the third trimester) as well as high rates of relapse during the post-partum period (especially in the three-month post-partum period). Based upon these insights, our scientific collaborator of TRIMESTA™ has conducted initial clinical trials of TRIMESTA™ in multiple sclerosis patients and has demonstrated encouraging results.

TRIMESTA™ for Relapsing-Remitting Multiple Sclerosis (MS)

Current Therapies for Relapsing-Remitting MS.

There are currently five FDA-approved therapies for the treatment of relapsing-remitting multiple sclerosis: Betaseron®, Rebif®, Avonex®, Copaxone® and Tysabri®. These therapies provide only a modest benefit for patients with relapsing-remitting MS and therefore serve to only delay progression of the disease. All of these drugs require frequent (daily, weekly & monthly) injections (or infusions) on an ongoing basis and are associated with unpleasant side effects (such as flu-like symptoms), high rates of non-compliance among users, and eventual loss of efficacy due to the appearance of resistance in approximately 30% of patients. An estimated two-thirds of MS patients are women.

Phase II Clinical Trial Results of TRIMESTA™ in Relapsing-Remitting MS

TRIMESTA™ has completed an initial 10-patient, 16-month, single-agent, crossover, phase IIA clinical trial in the U.S. for the treatment of MS. The results of this study were encouraging.

Decrease in Volume and Number of Myelin Lesions

In relapsing-remitting MS patients treated, the total volume and number of pathogenic gadolinium enhancing myelin lesions (an established neuroimaging measurement of disease activity in MS) decreased during the treatment period as compared to a six-month pre-treatment baseline period. The median total enhancing lesion volumes decreased by 79% (p =0.02) and the number of lesions decreased by 82% (p =0.09) within the first three months of treatment with TRIMESTA™. Over the next three months, lesion volumes decreased by 82% (p =0.02) and the number of lesions decreased by 82% (p =0.02) compared to baseline. During a three-month re-treatment phase of this clinical trial, relapsing-remitting MS patients again showed a decrease in enhancing lesion volumes (88%) (p =0.008) and a decrease in the number of lesions (48%) (p =0.04) compared to baseline.

Market Opportunities for TRIMESTA™

Multiple Sclerosis

MS is a progressive neurological disease in which the body loses the ability to transmit messages along nerve cells, leading to a loss of muscle control, paralysis, and, in some cases, death. Currently, more than 2.5 million people worldwide (approximately 400,000 patients in the US), mainly young adults aged 18-50, are afflicted with MS and 66% of these patients are women. The most common form of MS is relapsing-remitting MS, which accounts for approximately 75% of MS patients.

MS exacts a heavy toll on our healthcare system. According to a published study, the total annual cost for all people with MS in the U.S. is estimated to be more than \$9 billion. The average annual cost of MS is approximately \$44,000 to \$95,625 per person. These figures include lost wages and healthcare costs (care giving, hospital and physician costs, pharmaceutical therapy and nursing home care). The cost of treating patients with later-stage progressive forms of MS is approximately \$65,000 per year per person. The average lifetime costs for people with MS are more than \$2.2 million per person.

During 2005, sales estimates of FDA-approved MS therapies, which include Avonex®, Betaseron®, Copaxone®, and Rebif®, totaled approximately \$5.0 billion, with Avonex® accounting for \$1.5 billion in worldwide sales (\$935 million were in the U.S.).

ANTI-CD4 802-2

We are developing a series of small molecule and peptide based inhibitors of the T-cell CD4 co-receptor. The CD4 co-receptor is central to a number of autoimmune disorders such as MS.

Our lead anti-CD4 molecule, named 802-2, has demonstrated efficacy in a number of animal models of autoimmune disease models, and it is currently being evaluated in a phase I/II clinical trial for the prevention of graft-vs.-host disease. Anti-CD4 802-2 may represent the first clinical stage, non-antibody-based molecule capable of inducing immune tolerance for a variety of CD4-mediated autoimmune diseases.

Market Opportunity for Anti-CD4 802-2 and Small Molecule CD4 Inhibitors

From a commercial perspective, anti-CD4 802-2 and our other anti-CD4 molecules address an autoimmune disease market projected to be \$21 billion in 2006 with an anticipated annual growth rate of 15% thereafter. Autoimmune diseases represent the third-largest category of illness in the

industrialized world, after heart disease and cancer. A partial list of such diseases includes MS, psoriasis, and rheumatoid arthritis, as well as “non-typical” CD4-mediated diseases such as allergy and asthma.

CORRECTA™ (clotrimazole enema)

We are developing CORRECTA™, a proprietary retention enema formulation of the widely used topical antifungal agent clotrimazole, for the treatment of acute refractory pouchitis, a subset of inflammatory bowel disease (IBD) and ulcerative colitis (UC) market. CORRECTA™ is currently the subject of a double-blind, placebo-controlled, multi-center, one-month, phase II clinical trial for acute pouchitis. This study, called the “CAPTURE” study, is currently being funded by a \$750,000 grant from the FDA’s Orphan Drug Group.

Market Opportunity for CORRECTA™

Pouchitis

Pouchitis is a debilitating complication that can develop following corrective surgical treatment of ulcerative colitis, wherein an ileal reservoir (or pouch) is constructed to enable normal bowel movements after removal of the diseased colon. This ileal reservoir can become inflamed, leading to debilitating gastrointestinal symptoms including diarrhea, incontinence, bleeding, fever and urgency. Currently, there are no approved treatments for pouchitis. Published scientific data suggest that there are approximately 30,000 to 45,000 pouchitis patients and between 5,000 to 10,000 refractory pouchitis patients in the U.S.

EFFIRMA™ (oral flupirtine)

We are developing EFFIRMA™ (oral flupirtine), a novel, centrally-active, oral therapy for the treatment of fibromyalgia and we plan to conduct a limited, controlled phase II pilot clinical trial in this indication. Fibromyalgia is a common, centrally-mediated pain disorder characterized by chronic diffuse pain and other symptoms. The active ingredient of EFFIRMA™, flupirtine, was originally developed by Asta Medica and has been approved in Europe since 1984 for the treatment of chronic lower back pain, although it has never been introduced to the U.S. market for any indication.

EFFIRMA™ for Fibromyalgia

Our scientific collaborator has demonstrated preliminary anecdotal efficacy of EFFIRMA™ for the treatment of Fibromyalgia in a small number of U.S. patients suffering from Fibromyalgia that were refractive to other analgesics and therapies. EFFIRMA™ was well tolerated by patients with no untoward side effects. In addition, substantial improvement in signs and symptoms was demonstrated in this difficult-to-treat Fibromyalgia patient population.

Intellectual Property

Our goal is to (a) obtain, maintain, and enforce patent protection for our products, formulations, processes, methods, and other proprietary technologies, (b) preserve our trade secrets, and (c) operate without infringing on the proprietary rights of other parties, worldwide. We seek, where appropriate, the broadest intellectual property protection for product candidates, proprietary information, and proprietary technology through a combination of contractual arrangements and patents.

We have exclusively licensed from various universities more than 45 patent and patent applications, including foreign equivalents relating to our product candidates.

We have also obtained various regulatory exclusivities, such as “Orphan Drug” designations for two of our product candidates, COPREXATM and CORRECTATM. Orphan Drug designations provide 7 years of market exclusivity in the U.S. and 10 years of marketing exclusivity in Europe. Specifically, we have obtained orphan drug protection for the use of COPREXATM in the treatment of neurologic Wilson’s disease. We have also obtained orphan drug protection for the use of CORRECTATM for the treatment of acute pouchitis. These regulatory exclusivities combined with our patents and patent applications provide for supplemental intellectual property protection for our products against competitors.

Below is a description of our license and development agreements relating to our product candidates:

University of Michigan (UM) Exclusive License Agreement

We have entered into an exclusive worldwide license agreement with the University of Michigan (UM) for all uses of U.S. Patent No. 6,855,340, corresponding international applications, and a related corresponding patent application that relates to various uses of anticopper therapeutics, including COPREXATM, to treat inflammatory and fibrotic diseases. Pursuant to this agreement, we will use our best efforts to commercialize COPREXATM for the therapeutic uses embodied in the issued patent and pending patent application; reimburse UM for patent expenses; pay UM royalties equal to 2% of net sales of COPREXATM for uses covered by the UM patents; issue UM 1,261,492 shares of our common stock; pay UM success-based milestone fees totaling \$350,000 (the first of which is due when we file an NDA and the second of which is due when we receive FDA approval for COPREXATM in an indication covered by the UM patents), and indemnify UM against certain liabilities.

Collaborative Research and Development Agreement with UM

During September 2005, we entered into a three-year sponsored research agreement with UM relating to expanding the therapeutic utility of COPREXATM to treat other copper mediated diseases. Pursuant to that agreement, we sponsor approximately \$450,000 per annum, payable in monthly installments. This agreement can be extended for an additional two-year period.

Consulting Agreement with Dr. George Brewer

We have entered into a three-year consulting agreement with Dr. George Brewer, inventor of the COPREXATM technology. Pursuant to this agreement, we pay Dr. Brewer a quarterly fee of \$30,000. We also issued to Dr. Brewer options to acquire 650,000 shares of our common stock and agreed to pay Dr. Brewer a royalty on sales of COPREXATM equal to 3% of net sales for 17 years. On November 22, 2006, we issued Dr. Brewer an additional 650,000 options to acquire our common stock. This agreement has a provision for a two-year extension.

McLean Hospital Exclusive License Agreement

We have entered into an exclusive license agreement with the McLean Hospital, a Harvard University hospital, relating to U.S. Patent No. 6,610,324 and its foreign equivalents, entitled “Flupirtine in the treatment of fibromyalgia and related conditions.” Pursuant to this agreement, we agreed to pay McLean royalties on net sales of flupirtine equal to 3.5% of net sales of flupirtine for indications covered by the issued patents, reduced to 1.75% if we have a license to other intellectual property covering those indications; use our best efforts to commercialize flupirtine for the therapeutic uses embodied in the patent applications; reimburse back patent costs of approximately \$41,830; and pay the following milestone payments: \$150,000 upon the initiation of a pivotal phase III clinical trial of flupirtine; \$300,000 upon the filing of an NDA for flupirtine; and \$600,000 upon FDA approval of flupirtine.

University of Southern California Agreement

Through our majority owned subsidiary Solovax we have an exclusive option agreement, as amended, with the University of Southern California (USC) to license U.S. Patent Application serial nos. 09/156509 and 10/773356 and its foreign equivalents entitled "T-Cell Vaccination for the Treatment of Multiple Sclerosis." Under this agreement we are required to reimburse USC's patent expenses and pay USC royalties of 4% of net sales relating to the vaccine. We have until December 2007 to exercise our option and enter into an exclusive license. If we wish to enter into an exclusive license, we will have to issue to USC stock representing a 10% ownership interest of our Solovax subsidiary.

Children's Hospital-Boston Agreement

Our majority owned subsidiary Effective Pharmaceuticals, Inc. (EPI), has entered into an exclusive worldwide license agreement with Children's Hospital Medical Corporation, an affiliate of Children's Hospital-Boston, relating to a certain pending patent application covering all gastrointestinal, hepatic, and rectal uses of the clotrimazole technology, including CORRECTA™. Pursuant to this agreement, we paid a \$150,000 upfront payment in two installments, as well as annual maintenance fees, milestone payments totaling \$3 million that are payable on issuance of U.S. and European patents covering the clotrimazole technology, on initiation of a pivotal phase III clinical trial, on filing of a New Drug Application (NDA), and on approval of an NDA with the FDA and European Medical Agency, as well as royalties on net sales of the clotrimazole technology covered by the licensed patents. We may be permitted to partially pay milestone payments in the form of equity. We also acquired rights to valuable data generated under an investigational new drug (IND) application filing with the FDA and an orphan drug designation. These data include all preclinical and clinical data know-how relating to the clotrimazole technology. We would also be required to indemnify Children's Hospital and its employees against certain liabilities.

Thomas Jefferson University License Agreement

Our majority-owned subsidiary CD4 Biosciences Inc., has entered into an exclusive worldwide license agreement with Thomas Jefferson University (TJU) relating to certain U.S. and foreign issued patents and patent applications relating to all uses of anti-CD4 802-2 and CD4 inhibitor technology. We are obligated to pay annual maintenance fees, milestone payments upon the filing of an NDA and approval of an NDA with the FDA, as well as royalties on net sales of anti-CD4 802-2 and other anti-CD4 molecules covered by the licensed patents. We also received rights to valuable data generated under any IND application filing, which includes toxicology and manufacturing information relating to anti-CD4 802-2. As partial consideration for this license, TJU was issued shares representing 5% of the common stock of CD4 Biosciences Inc. We also agreed that TJU would receive anti-dilution protection on those CD4 shares through the first \$2 million in financing to CD4. We also agree to indemnify TJU against certain liabilities.

The Regents of University of California License Agreement

We have an exclusive worldwide license agreement with the Regents of the University of California relating to an issued US Patent No. 6,936,599 and pending patent applications covering the uses of the TRIMESTA™ technology. Pursuant to this agreement, we paid an upfront license fee of \$20,000, reimbursed patent expenses of \$41,000 and agreed to pay a license fee of \$25,000 during 2006, as well as annual maintenance fees, milestone payments totaling \$750,000 that are payable on filing a NDA, and on approval of an NDA with the FDA, as well as royalties on net sales of the TRIMESTA™ technology covered by the licensed patents. If we become public or are acquired by a public company, we may be permitted to partially pay milestone payments in the form of equity.

Asset Purchase Agreement for TRIMESTA™

Through an asset purchase agreement and the approval of the stockholders of EPI and General Fiber, Inc., a related party company controlled by Accredited Ventures, we have an option to acquire an exclusive license to TRIMESTA™.

Agreement to Acquire EPI

During December 2005, we acquired 65.47% of EPI from two of our directors for no additional consideration. During January 2007, we merged with EPI, thus acquiring the 34.53% of EPI's outstanding common and Series B, convertible preferred stock for approximately 2.3 million shares of our common stock, assumption of 206,573 warrants, and 104,056 options to purchase common stock. EPI is now a wholly-owned subsidiary.

Manufacturing

We utilize contract manufacturing firms to produce the bulk active ingredients for COPREXA™, TRIMESTA™, CORRECTA™, Anti-CD4 802-2, and EFFIRMA™ in accordance with "current good manufacturing processes" (cGMP) guidelines outlined by the FDA. During January 2007, we leased a 6000 square foot facility in Ann Arbor, MI which will be used to produce oral capsule products for under GMP conditions. We plan to initially manufacture COPREXA™ at this site.

Sales and Marketing

We plan to establish our own in-house neuroscience sales and marketing effort in the United States to market our neurology products, specifically, COPREXA™ and TRIMESTA™. As we expand the use of COPREXA™ and TRIMESTA™ into larger CNS diseases, we will be able to utilize our existing marketing infrastructure to market these products. We may choose to enter into a co-promotion or licensing agreement for specific territories with biotechnology or pharmaceutical companies to market CORRECTA™, Anti-CD4 802-2, EFFIRMA™, SOLOVAX™, and certain uses of COPREXA™.

ITEM 1A. RISK FACTORS

An investment in our securities is highly speculative and involves a high degree of risk. Therefore, in evaluating us and our business you should carefully consider the risks set forth below, which are only a few of the risks associated with investing in our common stock. You should be in a position to risk the loss of your entire investment.

Risks Relating to Our Business

We are a development stage company. We currently have no product revenues and will need to raise additional capital to operate our business.

We are a development stage company that has experienced significant losses since inception and has a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. To date, we have generated no product revenues. As of December 31, 2006, we have expended approximately \$7.4 million on a consolidated basis acquiring and developing our current product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Therefore, for the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees, and grants. We will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable

terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we do the following:

- continue to undertake pre-clinical development and clinical trials for our product candidates;
- seek regulatory approvals for our product candidates;
- implement additional internal systems and infrastructure;
- lease additional or alternative office facilities; and
- hire additional personnel, including members of our management team.

We also expect to experience negative cash flow for the foreseeable future as we fund our technology development with capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock and underlying securities.

We have a limited operating history on which investors can base an investment decision.

We are a development-stage company and have not demonstrated our ability to perform the functions necessary for the successful commercialization of any of our product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

- continuing to undertake pre-clinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our company, acquiring, developing, and securing our proprietary technology, and undertaking pre-clinical trials and Phase I/II and Phase II clinical trials of our principal product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

We may not obtain the necessary U.S. or worldwide regulatory approvals to commercialize our product(s).

We will need FDA approval to commercialize our product candidates in the U.S. and approvals from equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval for any of our product candidates, we must submit to the FDA a new drug application, or “NDA,” demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as “pre-clinical studies,” as well as human tests, which are referred to as “clinical trials.” We will also need to file additional investigative new drug applications and protocols in order to initiate clinical testing of our drug candidates in new therapeutic indications and delays in obtaining required FDA and institutional review board approvals to commence such studies may delay our initiation of such planned additional studies.

Satisfying the FDA’s regulatory requirements typically takes many years, depending on the type, complexity, and novelty of the product candidate, and requires substantial resources for research, development, and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action, or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may do the following:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize our product candidate for sale outside the United States.

We may not be able to retain rights licensed to us by others to commercialize key products and may not be able to establish or maintain the relationships we need to develop, manufacture, and market our products.

We currently rely on an exclusive worldwide license agreement with the University of Michigan relating to various uses of COPREXA™. We also have an exclusive license agreement with the McLean Hospital relating to the use of EFFIRMA™ to treat fibromyalgia syndrome; an exclusive license agreement with Thomas Jefferson University relating to our anti-CD4 inhibitors; an exclusive license agreement with the Regents of the University of California relating to our TRIMESTA™ technology; an exclusive license agreement with the Children’s Hospital-Boston relating to our CORRECTA™ technology and an exclusive option agreement to license our T-cell vaccine program from the University of Southern California (USC) which expires during December 2007. Each of these agreements requires us to use our best efforts to commercialize each of the technologies as well as

meet certain diligence requirements and timelines in order to keep the license agreement in effect. In the event we are not able to meet our diligence requirements, we may not be able to retain the rights granted under our agreements or renegotiate our arrangement with these institutions on reasonable terms, or at all.

Furthermore, we currently have very limited product development capabilities and no manufacturing, marketing or sales capabilities. For us to research, develop, and test our product candidates, we would need to contract with outside researchers, in most cases those parties that did the original research and from whom we have licensed the technologies.

We can give no assurances that any of our issued patents licensed to us or any of our other patent applications will provide us with significant proprietary protection or be of commercial benefit to us. Furthermore, the issuance of a patent is not conclusive as to its validity or enforceability, nor does the issuance of a patent provide the patent holder with freedom to operate without infringing the patent rights of others.

Developments by competitors may render our products or technologies obsolete or non-competitive.

Companies that currently sell or are developing both generic and proprietary pharmaceutical compounds to treat central-nervous-system, inflammatory, autoimmune and fibrotic diseases include: Pfizer, Inc., GlaxoSmithKline Pharmaceuticals, Shire Pharmaceuticals, Plc., Merck & Co., Eli Lilly & Co., Serono, SA, Biogen Idec, Inc., Achillion, Ltd., Active Biotech, Inc., Panteri Biosciences, Meda, Merrimack Pharmaceuticals, Inc., Schering AG, Forest Laboratories, Inc., Attenuon, LLC, Cypress Biosciences, Inc., Axcan Pharma, Inc., Teva Pharmaceuticals, Inc., Intermune, Inc. Fibrogen, Inc., Rare Disease Therapeutics, Inc., Prana Biotechnology, Inc., Merz & Co., AstraZeneca Pharmaceuticals, Inc., Chiesi Pharmaceuticals, Inc., Targacept, Inc., and Johnson & Johnson, Inc. Alternative technologies are being developed to treat autoimmune inflammatory, fibrotic, Alzheimer's and Wilson's diseases, several of which are in early and advanced clinical trials, such as, pifrenidone, milnacipram, Actimmune TM and other interferon preparations. Unlike us, many of our competitors have significant financial and human resources. In addition, academic research centers may develop technologies that compete with our CORRECTA™, TRIMESTA™, anti-CD4 inhibitors, EFFIRMA™ and COPREXA™ technologies. We are aware that other companies are developing competitive anti-copper therapies that are in various stages of clinical trial.

We may not succeed in enforcing our orphan drug designations.

COPREXA™ has been designated by the FDA as an "orphan drug" for the treatment of Wilson's disease patients presenting with neurologic complications. CORRECTA™ has also been designated by the FDA as an "orphan drug" for the treatment of pouchitis patients. We intend to file for "orphan drug" designations in the EMEA (the European equivalent of the FDA) for both COPREXA™ and CORRECTA™ for similar uses. Pursuant to our agreements with our scientific inventors and universities, we have acquired these designations. Orphan drug designation is an important element of our competitive strategy because there are no composition of matter patents for COPREXA™, TRIMESTA™ or CORRECTA™. Any company that obtains the first FDA approval for a designated orphan drug for a rare disease generally receives marketing exclusivity for use of that drug for the designated condition for a period of seven years in the United States and ten years in the European Union.

To be successful in enforcing this designation, our new drug application would need to be the first NDA approved to use COPREXA™ to treat Wilson's disease. While we are not aware of any other companies that have sought orphan drug designation for COPREXA™ or its active ingredient, tetrathiomolybdate, for this indication, other companies may in the future seek it and may obtain FDA marketing approval before we do. In addition, the FDA may permit other companies to market

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

a form of tetrathiomolybdate to treat Wilson's disease patients with neurologic complication if their product demonstrates clinical superiority. This could create a more competitive market for us.

Competitors could develop and gain FDA approval of our products for a different indication.

A competitor could develop our products in a similar format, but for a different indication. For example, other companies could manufacture and develop COPREXA™ and its active ingredient, tetrathiomolybdate, and secure approvals for different indications. We are aware that a potential competitor has an exclusive license from the University of Michigan (UM) to an issued U.S. patent that relates to the use of tetrathiomolybdate to treat angiogenic diseases (the "Angiogenic Patent") and is currently in phase I and phase II clinical trials for the treatment of various forms of cancer. To our knowledge, this competitor and UM have filed additional patent applications claiming various analog structures and formulations of tetrathiomolybdate to treat various diseases. While our use of COPREXA™ and its active ingredient, tetrathiomolybdate, is in a more advanced state of clinical development, having completed two pivotal clinical trials, we cannot predict whether or not one or more patent applications corresponding to the Angiogenic Patent will be filed or if any U.S. patents will be issued which might prevent us from expanding the commercial applications of COPREXA™. Further, we cannot predict whether our competitor might seek to develop their version of tetrathiomolybdate for Wilson's disease and file for FDA or EMEA approval before us and saturate the market. We also cannot predict whether, if issued, any patent corresponding to the Angiogenic Patent may prevent us from conducting our business or result in lengthy and costly litigation or the need for a license. Furthermore, if we need to obtain a license to these or other patents in order to conduct our business, we may find that it is not available to us on commercially reasonable terms, or is not available to us at all.

If the FDA approves other tetrathiomolybdate products to treat indications other than those covered by our issued or pending patent applications, physicians may elect to prescribe a competitor's tetrathiomolybdate to treat Wilson's disease—this is commonly referred to as "off-label" use. While under FDA regulations a competitor is not allowed to promote off-label uses of its product, the FDA does not regulate the practice of medicine and, as a result, cannot direct physicians as to which source it should use for the tetrathiomolybdate they prescribe to their patients. Consequently, we might be limited in our ability to prevent off-label use of a competitor's tetrathiomolybdate to treat Wilson's disease or inflammatory or fibrotic disease, even if we have orphan drug exclusivity. Our competitor might seek FDA or EMEA approval to market tetrathiomolybdate for any therapeutic indication, including Wilson's disease or idiopathic pulmonary fibrosis (IPF). If we are not able to obtain and enforce these patents, a competitor could use tetrathiomolybdate for a treatment or use not covered by any of our patents.

We rely primarily on method patents and patent applications and various regulatory exclusivities to protect the development of our technologies, and our ability to compete may decrease or be eliminated if we are not able to protect our proprietary technology.

Our competitiveness may be adversely affected if we are unable to protect our proprietary technologies. Currently, there are no composition of matter patents for TRIMESTA™, EFFIRMA™, CORRECTA™, COPREXA™ or their respective active ingredients estriol, flupirtine, clotrimazole and tetrathiomolybdate. Additionally, we do not have an issued patent for COPREXA™'s use to treat Wilson's disease, although we do have Orphan Drug Designation for this indication. Orphan Drug Designation provides protection for seven years of marketing exclusivity for that product in that disease indication in the U.S. We also expect to rely on patent protection from an issued U.S. Patent for the use of COPREXA™ and related compounds to treat inflammatory and fibrotic diseases (U.S. Patent No 6,855,340) and we have received a notice of allowance for the use of COPREXA™ and related compounds to treat Alzheimer's disease. Both of these patents have been exclusively licensed to us. We have also filed various pending patent applications which cover various formulations, packaging, distribution & monitoring methods for COPREXA™. We rely on issued patent and

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

pending patent applications for use of TRIMESTA™ to treat MS (issued U.S. Patent No. 6,936,599) and various other therapeutic indications which have been exclusively licensed to us. We have also exclusively licensed an issued patent for the treatment of fibromyalgia with EFFIRMA™ and have pending patent applications for our uses of CORRECTA™.

We also expect to rely on regulatory exclusivities, such as the Orphan Drug Designation with the FDA and EMEA (“Orphan Drug”) to protect COPREXA™ and CORRECTA™ for certain therapeutic indications and our other future products. Orphan Drug protection provides for seven years of marketing exclusivity for that disease indication in the U.S. and ten years of marketing exclusivity for that disease indication in Europe. We have received an Orphan Drug Designation for the use of CORRECTA™ to treat pouchitis as well as an Orphan Drug Designation for the use of COPREXA™ to treat neurologically presenting Wilson’s disease and are in the process of filing similar designations in Europe. Orphan Drug Designation is an important element of our competitive strategy for COPREXA™ and CORRECTA™. To be successful in enforcing this designation, our NDA would need to be the first NDA approved to use COPREXA™ and CORRECTA™ for that indication. While we are not aware of any other companies that have sought orphan drug designation for COPREXA™ and CORRECTA™ for any indication, other companies may in the future seek it and may obtain FDA marketing approval before we do.

After the Orphan Drug exclusivity period expires, assuming our patents are validly issued, we still expect to rely on our issued and pending method of use patent applications to protect our proprietary technology with respect to the development of COPREXA™, TRIMESTA™ and CORRECTA™. The patent positions of pharmaceutical companies are uncertain and may involve complex legal and factual questions. We may incur significant expense in protecting our intellectual property and defending or assessing claims with respect to intellectual property owned by others. Any patent or other infringement litigation by or against us could cause us to incur significant expense and divert the attention of our management.

We may also rely on the United States Drug Price Competition and Patent Term Restoration Act, commonly known as the “Hatch-Waxman Amendments,” to protect some of our current product candidates, specifically COPREXA™, TRIMESTA™, Anti-CD4 802-2, EFFIRMA™ and other future product candidates we may develop. Once a drug containing a new molecule is approved by the FDA, the FDA cannot accept an abbreviated NDA for a generic drug containing that molecule for five years, although the FDA may accept and approve a drug containing the molecule pursuant to an NDA supported by independent clinical data. Recent amendments have been proposed that would narrow the scope of Hatch-Waxman exclusivity and permit generic drugs to compete with our drug.

Others may file patent applications or obtain patents on similar technologies or compounds that compete with our products. We cannot predict how broad the claims in any such patents or applications will be, and whether they will be allowed. Once claims have been issued, we cannot predict how they will be construed or enforced. We may infringe intellectual property rights of others without being aware of it. If another party claims we are infringing their technology, we could have to defend an expensive and time consuming lawsuit, pay a large sum if we are found to be infringing, or be prohibited from selling or licensing our products unless we obtain a license or redesign our product, which may not be possible.

We also rely on trade secrets and proprietary know-how to develop and maintain our competitive position. Some of our current or former employees, consultants, or scientific advisors, or current or prospective corporate collaborators, may unintentionally or willfully disclose our confidential information to competitors or use our proprietary technology for their own benefit. Furthermore, enforcing a claim alleging the infringement of our trade secrets would be expensive and difficult to prove, making the outcome uncertain. Our competitors may also independently develop similar knowledge, methods, and know-how or gain access to our proprietary information through some other means.

We may fail to retain or recruit necessary personnel, and we may be unable to secure the services of consultants.

As of December 31, 2006, we have eight full-time employees, including Steve H. Kanzer, our co-founder, Chairman and CEO and Dr. Charles Bisgaier, our President. We have also engaged regulatory consultants to advise us on our dealings with the FDA. We intend to recruit certain key executive officers, including a vice president of finance, a vice president of regulatory affairs, and other key executive officers. Our future performance will depend in part on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management.

Certain of our officers, directors, (including Mr. Stergis, our Vice Chairman & former Chief Operating Officer and Dr. Rudick, our Chief Medical Officer) scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies. We can expect this to also be the case with personnel that we engage in the future. We can give no assurances that any such other companies will not have interests that are in conflict with our interests.

Losing key personnel or failing to recruit necessary additional personnel would impede our ability to attain our development objectives. There is intense competition for qualified personnel in the drug-development field, and we may not be able to attract and retain the qualified personnel we would need to develop our business.

We rely on independent organizations, advisors, and consultants to perform certain services for us, including handling substantially all aspects of regulatory approval, clinical management, manufacturing, marketing, and sales. We expect that this will continue to be the case. Such services may not always be available to us on a timely basis when we need them.

We may experience difficulties in obtaining sufficient quantities of our products or other compounds.

In order to successfully commercialize our product candidates, we must be able to manufacture our products in commercial quantities, in compliance with regulatory requirements, at acceptable costs, and in a timely manner. Manufacture of the types of biopharmaceutical products that we propose to develop present various risks. For example, manufacture of the active ingredient in COPREXA™ is a complex process that can be difficult to scale up for purposes of producing large quantities. This process can also be subject to delays, inefficiencies, and poor or low yields of quality products. Furthermore, the active ingredient of COPREXA™ is known to be subject to a loss of potency as a result of prolonged exposure to moisture and other normal atmospheric conditions. We are developing proprietary formulations and specialty packaging solutions to overcome this stability issue, but we can give no assurances that we will be successful in meeting the stability requirements required for approval by regulatory authorities such as the FDA. Additionally, our SOLOVAX T-cell vaccine technology is complex to manufacture. The vaccine is manufactured through the procurement of a patient's own T-cells derived from the patient's plasma. This manufacturing process involves incubation of T-cells, irradiation and refrigeration of the cells. We plan to develop a revised manufacturing procedure which will streamline quality control of the vaccine.

Historically, our manufacturing has been handled by contract manufacturers and compounding pharmacies. We can give no assurances that we will be able to continue to use our current manufacturer or be able to establish another relationship with a manufacturer quickly enough so as not to disrupt commercialization of any of our products, or that commercial quantities of any of our products, if approved for marketing, will be available from contract manufacturers at acceptable costs.

In addition, any contract manufacturer that we select to manufacture our product candidates might fail to maintain a current "good manufacturing practices" (cGMP) manufacturing facility.

During January 2007, we decided to establish a commercial manufacturing facility for our products in Ann Arbor MI and we would require substantial additional funds in order to hire and train significant numbers of employees and comply with the extensive regulations applicable to such a facility. We might find that we are unable to develop a cGMP manufacturing facility that is able to manufacture quantities of products required for all clinical trials, as well as commercial-scale manufacturing.

The cost of manufacturing certain products may make them prohibitively expensive. In order to successfully commercialize our product candidates we may be required to reduce the costs of production, and we may find that we are unable to do so. We may be unable to obtain, or may be required to pay high prices for compounds manufactured or sold by others that we need for comparison purposes in clinical trials and studies for our products.

Clinical trials are very expensive, time-consuming, and difficult to design and implement.

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 would 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. Commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing;
- 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 submissions or conduct of our trials.

The results of our clinical trials may not support our product candidate claims.

Even if our clinical trials are completed as planned, we cannot be certain that the results will support our product-candidate claims. Success in pre-clinical testing and phase II clinical trials does not ensure that later clinical trials will be successful. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and pre-clinical testing. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. Any such failure could cause us to abandon a product candidate and might delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay our obtaining FDA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

Physicians and patients may not accept and use our technologies.

Even if the FDA approves our product candidates, physicians and patients may not accept and use them. Acceptance and use of our product will depend upon a number of factors, including the following:

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

- the perception of members of the health care community, including physicians, regarding the safety and effectiveness of our drugs;
- the cost-effectiveness of our product relative to competing products;
- availability of reimbursement for our products from government or other healthcare payers; and
- the effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

We depend on researchers who are not under our control.

We depend upon independent investigators and scientific collaborators, such as universities and medical institutions, to conduct our pre-clinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs or the timing of their procurement of clinical-trial data. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking those programs ourselves. Failing to devote sufficient time and resources to our drug-development programs, or substandard performance, could result in delay of any FDA applications and our commercialization of the drug candidate involved.

These collaborators may also have relationships with other commercial entities, some of which may compete with us. Our collaborators assisting our competitors at our expense, could harm our competitive position. For example, we depend on scientific collaborators for our TRIMESTA™, SOLOVAX™, CORRECTA™, anti-CD4 802-2, EFFIRMA™ and COPREXA™ development programs. Specifically, all of the clinical trials have been conducted under physician-sponsored investigational new drug applications (INDs), not corporate-sponsored INDs. We are also dependent on government and private grants to fund certain of our clinical trials for our product candidates. If we are unable to maintain these grants, we might be forced to scale back development of these product candidates. We have experienced difficulty in collecting the data or transferring these programs to corporate-sponsored INDs.. Additionally, we are aware that all of our scientific collaborators also act as advisors to our competitors.

We have no experience selling, marketing, or distributing products and do not have the capability to do so.

We currently have no sales, marketing, or distribution capabilities. We do not anticipate having resources in the foreseeable future to allocate to selling and marketing our proposed products. Our success will depend, in part, on whether we are able to enter into and maintain collaborative relationships with a pharmaceutical or a biotechnology company charged with marketing one or more of our products. We may not be able to establish or maintain such collaborative arrangements or to commercialize our products in foreign territories, and even if we do, our collaborators may not have effective sales forces.

If we do not, or are unable to, enter into collaborative arrangements to sell and market our proposed products, we will need to devote significant capital, management resources, and time to establishing and developing an in-house marketing and sales force with technical expertise. We may be unsuccessful in doing so.

If we fail to maintain positive relationships with particular individuals, we may be unable to successfully develop our product candidates, conduct clinical trials, and obtain financing.

If we fail to maintain positive relationships with members of our management team or if these individuals decrease their contributions to our company, our business could be adversely impacted. We do not carry key employee insurance policies for any of our key employees.

We also rely greatly on employing and retaining other highly trained and experienced senior management and scientific personnel. The competition for these and other qualified personnel in the biotechnology field is intense. If we are not able to attract and retain qualified scientific, technical, and managerial personnel, we probably will be unable to achieve our business objectives.

We may not be able to compete successfully for market share against other drug companies.

The markets for our product candidates are characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval, they will compete with existing and future drugs and therapies developed, manufactured, and marketed by others. Competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies, or other public and private research organizations. Many of these competitors have therapies to treat autoimmune fibrotic and central nervous system diseases already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research-and-development programs than we do, have substantially greater financial resources than we do, and have significantly greater experience in the following areas:

- developing drugs;
- undertaking pre-clinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, as well as costs associated with frivolous lawsuits.

If any other person files patent applications, or is issued patents, claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention. We, or our licensors, may also need to participate in interference proceedings involving our issued patents and pending applications of another entity.

We cannot guarantee that the practice of our technologies will not conflict with the rights of others. In some foreign jurisdictions, we could become involved in opposition proceedings, either by opposing the validity of another's foreign patent or by persons opposing the validity of our foreign patents.

We may also face frivolous litigation or lawsuits from various competitors or from litigious securities attorneys. The cost to us of any litigation or other proceeding relating to these areas, even if resolved

in our favor, could be substantial and could distract management from our business. Uncertainties resulting from initiation and continuation of any litigation could have a material adverse effect on our ability to continue our operations.

If we infringe the rights of others we could be prevented from selling products or forced to pay damages.

If our products, methods, processes, and other technologies are found to infringe the proprietary rights of other parties, we could be required to pay damages, or we may be required to cease using the technology or to license rights from the prevailing party. Any prevailing party may be unwilling to offer us a license on commercially acceptable terms.

Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our drugs, alone or with collaborators, will depend in part on the extent to which reimbursement is available from government and health administration authorities, private health maintenance organizations, health insurers, and other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage may not be available, or may be inadequate, to cover the cost of our drugs. This could affect our ability to commercialize our products.

We may not be able to obtain adequate insurance coverage against product liability claims.

Our business exposes us to the product liability risks inherent in the testing, manufacturing, marketing, and sale of human therapeutic technologies and products. Even if it is available, product liability insurance for the pharmaceutical and biotechnology industry generally is expensive. Adequate insurance coverage may not be available at a reasonable cost.

Risks Relating to Our Stock

We will seek to raise additional funds in the future, which may be dilutive to shareholders or impose operational restrictions.

We expect to seek to raise additional capital in the future to help fund development of our proposed products. If we raise additional capital through the issuance of equity or debt securities, the percentage ownership of our current shareholders will be reduced. We may also enter into strategic transactions that may be dilutive. Our shareholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our common stock. If we cannot raise additional funds, we will have to delay development activities of our products candidates.

We are controlled by our current officers, directors, and principal stockholders.

Currently, our directors, executive officers, and principal stockholders beneficially own a majority of our common stock. As a result, they will be able to exert substantial influence over the election of our board of directors and the vote on issues submitted to our stockholders.

Our common stock may be thinly traded and its price volatile. This may make it difficult for shareholders to sell their shares of our common stock.

There may be significant volatility in the market price for our common stock. The stock market has from time to time experienced significant price and volume fluctuations that have particularly affected the market prices of pharmaceuticals companies and that may be unrelated to our operating performance. General market conditions could materially affect the market price of our common stock. The market price of our shares could also be subject to significant fluctuations in response to, and may be adversely effected by, among other factors, government regulatory actions, variations in our quarterly operating results, developments in the global pharmaceuticals industry, and general stock market conditions.

Because we will be subject to the “penny stock” rules, broker-dealers may find it harder to sell the shares of our common stock.

Our common stock is quoted on the OTCBB (as opposed to NASDAQ or AMEX) and the price of the common stock is below \$5.00 per share, we are therefore subject to “penny stock” regulation. The penny stock rules impose additional sales practice requirements on broker-dealers who sell such securities to persons other than established customers and accredited investors (generally those with assets in excess of \$1,000,000 or annual income exceeding \$200,000 or \$300,000 together with a spouse). For transactions covered by these rules, the broker-dealer must make a special suitability determination for the purchase of such securities and have received the purchaser’s written consent to the transaction prior to the purchase. Additionally, for any transaction involving a penny stock, unless exempt, the rules require the delivery, prior to the transaction, of a disclosure schedule prescribed by the Securities and Exchange Commission relating to the penny stock market. The broker-dealer also must disclose the commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements must be sent disclosing recent price information on the limited market in penny stocks. Consequently, the “penny stock” rules may restrict the ability of broker-dealers to sell shares of our common stock. The market price of our common stock would likely suffer as a result.

Because we became public by means of a “reverse merger”, we may not be able to attract the attention of major brokerage firms.

Additional risks may exist since we became public through a “reverse merger.” Securities analysts of major brokerage firms may not provide coverage of us since there is little incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to conduct any secondary offerings on behalf of our company in the future.

Our compliance with the Sarbanes-Oxley Act and SEC rules concerning internal controls may be time consuming, difficult and costly.

Although individual members of our management team have experience as officers of publicly traded companies, much of that experience came prior to the adoption of the Sarbanes-Oxley Act of 2002. It may be time consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by Sarbanes-Oxley. We may need to hire additional financial reporting, internal controls and other finance staff in order to develop and implement appropriate internal controls and reporting procedures. If we are unable to comply with Sarbanes-Oxley’s internal controls requirements, we may not be able to obtain the independent accountant certifications that Sarbanes-Oxley Act requires publicly-traded companies to obtain.

There is not now, and there may not ever be, an active market for our common stock.

There currently is no market for our common stock. Further, although our common stock may be quoted on the OTC Bulletin Board, trading of our common stock may be extremely sporadic. For example, several days may pass before any shares may be traded. There can be no assurance that a more active market for the common stock will develop.

We cannot assure you that the common stock will become liquid or that it will be listed on a securities exchange.

We cannot assure you that we will be able to meet the listing standards of any stock exchange, such as the American Stock Exchange or the Nasdaq National Market, or that we will be able to maintain any such listing. Such exchanges require companies to meet certain initial listing criteria including certain minimum bid prices per share. We may not be able to achieve or maintain such minimum bid prices or may be required to effect a reverse stock split to achieve such minimum bid prices. Until the common stock is listed on an exchange, we expect that it would be eligible to be quoted on the OTC Bulletin Board, another over-the-counter quotation system, or in the "pink sheets." In those venues, however, an investor may find it difficult to obtain accurate quotations as to the market value of the common stock. In addition, if we failed to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling the common stock, which may further affect its liquidity. This would also make it more difficult for us to raise additional capital.

There may be issuances of shares of preferred stock in the future.

Although we currently do not have preferred shares outstanding, the board of directors could authorize the issuance of a series of preferred stock that would grant holders preferred rights to our assets upon liquidation, the right to receive dividends before dividends would be declared to common stockholders, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. To the extent that we do issue preferred stock, the rights of holders of common stock could be impaired thereby, including without limitation, with respect to liquidation.

We have never paid dividends.

We have never paid cash dividends on our common stock and do not anticipate paying any for the foreseeable future.

Risks Related to Our Industry

Government Regulation

The FDA, comparable foreign regulators and state and local pharmacy regulators impose substantial requirements upon clinical development, manufacture and marketing of pharmaceutical products. These and other entities regulate research and development and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising, and promotion of our products. The drug approval process required by the FDA under the Food, Drug, and Cosmetic Act generally involves:

- Preclinical laboratory and animal tests;
- Submission of an IND, prior to commencing human clinical trials;

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

- Adequate and well-controlled human clinical trials to establish safety and efficacy for intended use;
- Submission to the FDA of a NDA; and
- FDA review and approval of a NDA.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, and animal studies to assess potential safety and efficacy. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. In some cases, long-term preclinical studies are conducted concurrently with clinical studies.

We will submit the preclinical test results, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we begin human clinical trials. The IND automatically becomes effective 30 days after filing, unless the FDA raises questions about conduct of the trials outlined in the IND and imposes a clinical hold, in which case, the IND sponsor and FDA must resolve the matters before clinical trials can begin. It is possible that our submission may not result in FDA authorization to commence clinical trials.

Clinical trials must be supervised by a qualified investigator in accordance with good clinical practice regulations, which include informed consent requirements. An independent Institutional Review Board (“IRB”) at each medical center reviews and approves and monitors the study, and is periodically informed of the study’s progress, adverse events and changes in research. Progress reports are submitted annually to the FDA and more frequently if adverse events occur.

Human clinical trials typically have three sequential phases that may overlap:

Phase I: The drug is initially tested in healthy human subjects or patients for safety, dosage tolerance, absorption, metabolism, distribution, and excretion.

Phase II: The drug is studied in a limited patient population to identify possible adverse effects and safety risks, determine efficacy for specific diseases and establish dosage tolerance and optimal dosage.

Phase III: When phase II evaluations demonstrate that a dosage range is effective with an acceptable safety profile, phase III trials to further evaluate dosage, clinical efficacy and safety, are undertaken in an expanded patient population, often at geographically dispersed sites.

We cannot be certain that we will successfully complete phase I, phase II, or phase III testing of our product candidates within any specific time period, if at all. Furthermore, the FDA, an IRB or the IND sponsor may suspend clinical trials at any time on various grounds, including a finding that subjects or patients are exposed to unacceptable health risk.

Concurrent with these trials and studies, we also develop chemistry and physical characteristics data and finalize a manufacturing process in accordance with good manufacturing practice (“GMP”) requirements. The manufacturing process must conform to consistency and quality standards, and we must develop methods for testing the quality, purity, and potency of the final products. Appropriate packaging is selected and tested, and chemistry stability studies are conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

Results of the foregoing are submitted to the FDA as part of a NDA for marketing and commercial shipment approval. The FDA reviews each NDA submitted and may request additional information.

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

Once the FDA accepts the NDA for filing, it begins its in-depth review. The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted. The process may be significantly extended by requests for additional information or clarification regarding information already provided. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians. Manufacturing establishments often are inspected prior to NDA approval to assure compliance with GMPs and with manufacturing commitments made in the application.

Submission of a NDA with clinical data requires payment of a fee (for fiscal year 2004, \$573,500). In return, the FDA assigns a goal of ten months for issuing its "complete response," in which the FDA may approve or deny the NDA, or require additional clinical data. Even if these data are submitted, the FDA may ultimately decide the NDA does not satisfy approval criteria. If the FDA approves the NDA, the product becomes available for physicians prescription. Product approval may be withdrawn if regulatory compliance is not maintained or safety problems occur. The FDA may require post-marketing studies, also known as phase IV studies, as a condition of approval, and requires surveillance programs to monitor approved products that have been commercialized. The agency has the power to require changes in labeling or prohibit further marketing based on the results of post-marketing surveillance.

Satisfaction of these and other regulatory requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures on our activities. We cannot be certain that the FDA or other regulatory agencies will approve any of our products on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from pre-clinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications or uses. Even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing FDA regulation, including record-keeping requirements, reporting of adverse experiences, submitting periodic reports, drug sampling and distribution requirements, manufacturing or labeling changes, record-keeping requirements, and compliance with FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their facilities with the FDA and state agencies, and are subject to periodic unannounced inspections for GMP compliance, imposing procedural and documentation requirements upon us and third-party manufacturers. Failure to comply with these regulations could result, among other things, in suspension of regulatory approval, recalls, suspension of production or injunctions, seizures, or civil or criminal sanctions. We cannot be certain that we or our present or future subcontractors will be able to comply with these regulations.

The FDA regulates drug labeling and promotion activities. The FDA has actively enforced regulations prohibiting the marketing of products for unapproved uses. The FDA permits the promotion of drugs for unapproved uses in certain circumstances, subject to stringent requirements. We and our product candidates are subject to a variety of state laws and regulations which may hinder our ability to market our products. Whether or not FDA approval has been obtained, approval by foreign regulatory authorities must be obtained prior to commencing clinical trials, and sales and marketing efforts in those countries. These approval procedures vary in complexity from country to country, and the processes may be longer or shorter than that required for FDA approval. We may incur significant costs to comply with these laws and regulations now or in the future.

The FDA's policies may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Increased attention to the containment of health care costs worldwide could result in new government regulations materially adverse to our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Other Regulatory Requirements

The U.S. Federal Trade Commission and the Office of the Inspector General of the U.S. Department of Health and Human Services ("HHS") also regulate certain pharmaceutical marketing practices. Government reimbursement practices and policies with respect to our products are important to our success.

We are subject to numerous federal, state and local laws relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with these laws and regulations. The regulatory framework under which we operate will inevitably change in light of scientific, economic, demographic and policy developments, and such changes may have a material adverse effect on our business.

European Product Approval

Prior regulatory approval for human healthy volunteer studies (phase I studies) is required in member states of the European Union (E.U.). Summary data from successful phase I studies are submitted to regulatory authorities in member states to support applications for phase II studies. E.U. authorities typically have one to three months (which often may be extended in their discretion) to raise objections to the proposed study. One or more independent ethics committees (similar to U.S. IRBs) review relevant ethical issues.

For E.U. marketing approval, we submit to the relevant authority for review a dossier, or MAA (Market Authorization Application), providing information on the quality of the chemistry, manufacturing and pharmaceutical aspects of the product as well as non-clinical and clinical data.

Approval can take several months to several years, and can be denied, depending on whether additional studies or clinical trials are requested (which may delay marketing approval and involve unbudgeted costs) or regulatory authorities conduct facilities (including clinical investigation site) inspections and review manufacturing procedures, operating systems and personnel qualifications. In many cases, each drug manufacturing facility must be approved, and further inspections may occur over the product's life. The regulatory agency may require post-marketing surveillance to monitor for adverse effects or other studies. Further clinical studies are usually necessary for approval of additional indications. The terms of any approval, including labeling content, may be more restrictive than expected and could affect the marketability of a product.

Failure to comply with these ongoing requirements can result in suspension of regulatory approval and civil and criminal sanctions. European renewals may require additional data, resulting in a license being withdrawn. E.U. regulators have the authority to revoke, suspend or withdraw approvals, prevent companies and individuals from participating in the drug approval process, request recalls, seize violative products, obtain injunctions to close non-compliant manufacturing plants and stop shipments of violative products.

Pricing Controls

Pricing for products under approval applications is also subject to regulation. Requirements vary widely between countries and can be implemented disparately intra-nationally. The E.U. generally

provides options for member states to control pricing of medicinal products for human use, ranging from specific price-setting to systems of direct or indirect controls on the producer's profitability. U.K. regulation, for example, generally provides controls on overall profits derived from sales to the U.K. National Health Service that are based on profitability targets or a function of capital employed in servicing the National Health Service market. Italy generally utilizes a price monitoring system based on the European average price over the reference markets of France, Spain, Germany and the U.K. Italy typically establishes price within a therapeutic class based on the lowest price for a medicine belonging to that category. Spain generally establishes selling price based on prime cost plus a profit margin within a range established yearly by the Spanish Commission for Economic Affairs.

There can be no assurance that price controls or reimbursement limitations will result in favorable arrangements for our products.

Third-Party Reimbursements

In the U.S., the E.U. and elsewhere, pharmaceutical sales are dependent in part on the availability and adequacy of reimbursement from third party payers such as governments and private insurance plans. Third party payers are increasingly challenging established prices, and new products that are more expensive than existing treatments may have difficulty finding ready acceptance unless there is a clear therapeutic benefit.

In the U.S., consumer willingness to choose a self-administered outpatient prescription drug over a different drug or other form of treatment often depends on the manufacturer's success in placing the product on a health plan formulary or drug list, which results in lower out-of-pocket costs. Favorable formulary placement typically requires the product to be less expensive than what the health plan determines to be therapeutically equivalent products, and often requires manufacturers to offer rebates. Federal law also requires manufacturers to pay rebates to state Medicaid programs in order to have their products reimbursed by Medicaid. Medicare, which covers most Americans over age 65 and the disabled, has adopted a new insurance regime that will offer eligible beneficiaries' limited coverage for outpatient prescription drugs effective January 1, 2006. The prescription drugs that will be covered under this insurance will be specified on a formulary published by Medicare. As part of these changes, Medicare is adopting new payment formulas for prescription drugs administered by providers, such as hospitals or physicians, that are generally expected to lower reimbursement.

The E.U. generally provides options for member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement. Member states can opt for a "positive" or "negative" list, with the former listing all covered medicinal products and the latter designating those excluded from coverage. The E.U., the U.K. and Spain have negative lists, while France uses a positive list. Canadian provinces establish their own reimbursement measures. In some countries, products may also be subject to clinical and cost effectiveness reviews by health technology assessment bodies. Negative determinations in relation to our products could affect prescribing practices. In the U.K., the National Institute for Clinical Excellence ("NICE") provides such guidance to the National Health Service, and doctors are expected to take it into account when choosing drugs to prescribe. Health authorities may withhold funding from drugs not given a positive recommendation by NICE. A negative determination by NICE may mean fewer prescriptions. Although NICE considers drugs with orphan status, there is a degree of tension on the application of standard cost assessment for orphan drugs, which are often priced higher to compensate for a limited market. It is unclear whether NICE will adopt a more relaxed approach toward the assessment of orphan drugs.

We cannot assure you that any of our products will be considered cost effective, or that reimbursement will be available or sufficient to allow us to sell them competitively and profitably.

Fraud and Abuse Laws

The U.S. federal Medicare/Medicaid anti-kickback law and similar state laws prohibit remuneration intended to induce physicians or others either to refer patients, or to acquire or arrange for or recommend the acquisition of health care products or services. While the federal law applies only to referrals, products or services receiving federal reimbursement, state laws often apply regardless of whether federal funds are involved. Other federal and state laws prohibit anyone from presenting or causing to be presented false or fraudulent payment claims. Recent federal and state enforcement actions under these statutes have targeted sales and marketing activities of prescription drug manufacturers. As we begin to market our products to health care providers, the relationships we form, such as compensating physicians for speaking or consulting services, providing financial support for continuing medical education or research programs, and assisting customers with third-party reimbursement claims, could be challenged under these laws and lead to civil or criminal penalties, including the exclusion of our products from federally-funded reimbursement. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition. We intend to consult counsel concerning the potential application of these and other laws to our business and to our sales, marketing and other activities to comply with them. Given their broad reach and the increasing attention given them by law enforcement authorities, however, we cannot assure you that some of our activities will not be challenged.

Patent Restoration and Marketing Exclusivity

The U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) permits the FDA to approve Abbreviated New Drug Applications (“ANDAs”) for generic versions of innovator drugs, as well as NDAs with less original clinical data, and provides patent restoration and exclusivity protections to innovator drug manufacturers.

The ANDA process permits competitor companies to obtain marketing approval for drugs with the same active ingredient and for the same uses as innovator drugs, but does not require the conduct and submission of clinical studies demonstrating safety and efficacy. As a result, a competitor could copy any of our drugs and only need to submit data demonstrating that the copy is bioequivalent to gain marketing approval from the FDA.

Hatch-Waxman requires a competitor that submits an ANDA, or otherwise relies on safety and efficacy data for one of our drugs, to notify us and/or our business partners of potential infringement of our patent rights. We and/or our business partners may sue the company for patent infringement, which would result in a 30-month stay of approval of the competitor’s application. The discovery, trial and appeals process in such suits can take several years. If the litigation is resolved in favor of the generic applicant or the challenged patent expires during the 30-month period, the stay is lifted and the FDA may approve the application.

Hatch-Waxman also allows competitors to market copies of innovator products by submitting significantly less clinical data outside the ANDA context. Such applications, known as “505(b)(2) NDAs” or “paper NDAs,” may rely on clinical investigations not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use and are subject to the ANDA notification procedures described above.

The law also restores a portion of a product’s patent term that is lost during clinical development and NDA review, and provides statutory protection, known as exclusivity, against FDA approval or acceptance of certain competitor applications. Restoration can return up to five years of patent term for a patent covering a new product or its use to compensate for time lost during product development and regulatory review. The restoration period is generally one-half the time between the effective date of an IND and submission of an NDA, plus the time between NDA submission and its

approval (subject to the five-year limit), and no extension can extend total patent life beyond 14 years after the drug approval date. Applications for patent term extension are subject to U.S. Patent and Trademark Office ("USPTO") approval, in conjunction with FDA. Approval of these applications takes at least six months, and there can be no guarantee that it will be given at all.

Hatch-Waxman also provides for differing periods of statutory protection for new drugs approved under an NDA. Among the types of exclusivity are those for a "new molecular entity" and those for a new formulation or indication for a previously-approved drug. If granted, marketing exclusivity for the types of products that we are developing, which include only drugs with innovative changes to previously-approved products using the same active ingredient, would prohibit the FDA from approving an ANDA or 505(b)(2) NDA relying on safety and efficacy data for three years. This three-year exclusivity, however, covers only the innovation associated with the original NDA. It does not prohibit the FDA from approving applications for drugs with the same active ingredient but without our new innovative change. These marketing exclusivity protections do not prohibit FDA from approving a full NDA, even if it contains the innovative change.

ITEM 2. PROPERTIES

Our primary offices are located at 3985 Research Park Drive, Ann Arbor, Michigan 48108. We currently rent approximately 5,500 square feet of office, laboratory and production space for monthly rent of \$6,250. This lease expires on November 1, 2007, but includes an option to extend for an additional six month term. During the first quarter of 2007, we entered into a one year lease for \$9,223 per month for commercial scale manufacturing, laboratory and office space which totals 13,182 square feet. This lease has an option to renew for an additional two years. Our phone number is (734) 332-7800 and our facsimile number is (734) 332-7878. Our website is www.pipexpharma.com.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any pending legal proceeding, nor are we aware of any proceeding contemplated by any governmental authority involving us.

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

No matters were submitted to a vote of stockholders during the last quarter of the year ended December 31, 2006.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED SHAREHOLDER MATTERS

Our common stock currently trades on the OTC Bulletin Board under the symbol "PPXP" which was changed from "SFPH" on December 18, 2006. The following table states the range of the high and low bid-prices per share of our common stock for each of the calendar quarters during the last two fiscal years, as reported by the National Quotation Bureau Incorporated and the OTC Bulletin Board. These quotations represent inter-dealer prices, without retail mark-up, markdown, or commission, and may not represent actual transactions. The last price of our common stock as reported on the OTC Bulletin Board on December 31, 2006 was \$5.75 per share. As of December 31, 2006, there were approximately 366 shareholders of record of our common stock, this number does not include beneficial owners from whom shares are held by nominees in street name.

	<u>High</u>	<u>Low</u>
YEAR ENDED DECEMBER 31, 2006		
Fourth quarter	\$6.50	\$0.56
Third quarter	\$1.10	\$1.00
Second quarter	\$1.60	\$1.25
First quarter	\$1.02	\$0.01
YEAR ENDED DECEMBER 31, 2005		
Fourth quarter	\$3.00	\$0.00
Third quarter	\$2.50	\$0.03
Second quarter	\$0.03	\$0.02
First quarter	\$0.01	\$0.00

We have not paid any cash dividends on our common stock to date, and we have no intention of paying cash dividends in the foreseeable future. Whether we declare and pay dividends is determined by our board of directors at their discretion, subject to certain limitations imposed under Delaware corporate law. The timing, amount and form of dividends, if any, will depend on, among other things, our results of operations, financial condition, cash requirements and other factors deemed relevant by our board of directors.

Recent Sales of Unregistered Securities; Uses of Proceeds from Registered Securities

During October and November of 2006, the Company completed private placements of its stock, which resulted in the issuance of 20,702,794 shares of common stock and 10,351,979 warrants. Each unit consisted of 148,525 shares of common stock and a warrant to purchase 74,263 shares of common stock. Of the total, 6,757,518 shares were part of the share exchange in the reverse merger in connection with the issuance of 34,000,000 shares by Sheffield. The remaining 13,946,440 shares of common stock reflected issuances post reverse merger. The net proceeds from the private placements were approximately \$12,766,000, which was net of cash paid as direct offering costs totaling \$1,160,418. In connection with the private placements, the Company engaged a company, which is controlled by the Company's Chairman and Chief Executive Officer, as the placement agent for the transaction. Of the total \$1,160,418 in direct offering costs, the Company paid the placement agent the sum of approximately \$1,033,800. Additionally the placement agent was paid non-cash compensation of 2,874,831 warrants with an aggregate fair value of \$4,555,457. In December 2006, the Company filed a Registration Statement under the Securities Act of 1933, as amended, to register the resale of these shares by the purchasers of such shares. The Registration Statement was declared effective by the Securities and Exchange Commission on February 13, 2007. The proceeds are being used to fund

operations, for working capital and for general corporate purposes, which may include capital expenditures, clinical development, research, manufacturing and/or in-licensing of technology.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this prospectus. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements.

Financial Operations Overview

Since our inception during January 2001, our efforts and resources have been focused primarily on acquiring and developing our pharmaceutical technologies, raising capital and recruiting personnel. We are a development stage company and have no product sales to date and we will not receive any product sales until we receive approval from the FDA or receive approval from equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates. Our major sources of working capital have been proceeds from cash for equity financings from our Chairman and Chief Executive Officer and various private financings, primarily involving private sales of our common stock and other equity securities.

Our company resulted from the October 2006 merger of a newly-created wholly owned subsidiary of Sheffield Pharmaceuticals, Inc. ("Sheffield"), a Delaware corporation incorporated in September 1993, and Pipex Therapeutics, Inc., a Delaware corporation ("Pipex Therapeutics"). In connection with that transaction, a wholly owned subsidiary of Sheffield merged with and into Pipex Therapeutics, with Pipex Therapeutics remaining as the surviving corporation and a wholly-owned subsidiary of Sheffield. On December 11, 2006, Sheffield changed its name to Pipex Pharmaceuticals, Inc. ("Pipex"). In exchange for their shares of capital stock in Pipex Therapeutics, the former stockholders of Pipex Therapeutics received shares of capital stock of Sheffield representing approximately 98 percent of the outstanding equity of Sheffield on a primary diluted basis after giving effect to the transaction, with Sheffield assuming Pipex's outstanding options and warrants. In addition, the board of directors of Sheffield was reconstituted shortly following the effective time of the transaction such that the directors of Sheffield were replaced by our current directors, all of whom were previously directors of Pipex Therapeutics. Further, upon the effective time of the merger, the business of Sheffield was abandoned and the business plan of Pipex Therapeutics was adopted. The transaction was therefore accounted for as a reverse acquisition with Pipex Therapeutics, as the acquiring party and Sheffield as the acquired party. Accordingly, when we refer to our business and financial information relating to periods prior to the merger, we are referring to the business and financial information of Pipex Therapeutics, unless the context indicates otherwise.

Research and development expenses consist primarily of manufacturing costs, license fees, salaries and related personnel costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and organizational affairs and other expenses relating to the design, development, testing, and enhancement of our product candidates. We expense our research and development costs as they are incurred.

General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development and general legal activities.

Our results include non-cash compensation expense as a result of the issuance of stock and stock option grants. Compensation expense for options granted to employees represents the difference between the fair value of our common stock and the exercise price of the options at the date of grant. We account for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and comply with the disclosure provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock- Based Compensation." Compensation for options granted to consultants has been determined in accordance with SFAS No. 123 as the fair value of the equity instruments issued. APB Opinion No. 25 has been applied in accounting for fixed and milestone-based stock options to employees and directors as allowed by SFAS No. 123. This amount is being recorded over the respective vesting periods of the individual stock options. The expense is included in the respective categories of expense in the statement of operations. We expect to record additional non-cash compensation expense in the future, which may be significant. However, because some of the options are milestone-based, the total expense is uncertain.

Critical Accounting Policies

In December 2001, the SEC requested that all registrants discuss their most "critical accounting policies" in management's discussion and analysis of financial condition and results of operations. The SEC indicated that a "critical accounting policy" is one which is both important to the portrayal of the company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

Results of Operations

Years Ended December 31, 2006 and 2005.

Research and development expenses. For the year ended December 31, 2006, research and development expense was \$2,665,555 as compared to \$946,065 for the year ended December 31, 2005. The increase of \$1,719,490 is due primarily to an increase of approximately \$745,800 associated with payments related to further the development of our licensed clinical drug candidates, an increase in salaries of approximately \$304,800, an increase of stock based compensation and stock issued for license fees of approximately \$543,400 and an increase in patent expenses of approximately \$42,400.

General and administrative expenses. For the year ended December 31, 2006, general and administrative expense was \$1,439,022 as compared to \$373,145 for the year ended December 31, 2005. The increase of \$1,065,877 is due primarily to an increase in stock based compensation of approximately \$582,800, an increase to professional fees of approximately \$233,600 and an increase in salaries of approximately \$152,900.

Other income (expense), net. For the year ended December 31, 2006, interest income was \$17,982 as compared to \$868 for the year ended December 31, 2005. Interest income was higher in 2006 as compared to 2005, due to the higher levels of cash available for investment in the fourth quarter of 2006.

Net loss. Net loss for the year ended December 31, 2006, was \$4,860,095 as compared to \$1,546,092 for the year ended December 31, 2005. This increase in net loss is attributable primarily to an increase in research and development expenses of \$1,719,490, an increase in general and administrative expenses of \$1,065,877 and an increase of \$570,750 of a preferred stock dividend issued by a subsidiary.

Liquidity and Capital Resources

During the year ended December 31, 2006, we had a net increase in cash of \$11,034,636. Total cash resources as of December 31, 2006 was \$12,192,426. Cash proceeds in 2006 resulted primarily from private placements of common stock by which we raised net proceeds of \$12,765,994 and proceeds from a related party loan, subsequently converted to equity, in the amount of \$1,365,344, offset by \$2,365,819 to fund operations. During the years ended December 31, 2006 and 2005, net cash used in operating activities was \$2,365,819 and \$1,082,109, respectively. This cash was used to fund our net losses for the periods, adjusted for non-cash expenses and changes in operating assets and liabilities.

Net cash used in investing activities for the years ended December 31, 2006 and 2005 was \$710,833 and \$0, respectively. The net cash used in investing activities for the year ended December 31, 2006 resulted from the acquisition of a corporate shell in the reverse merger and the acquisition of property and equipment.

Net cash proceeds from financing activities were \$14,111,288 and \$2,234,853 for the years ended December 31, 2006 and 2005, respectively. The net cash proceeds from financing activities for the year ended December 31, 2006 resulted from \$12,765,994 raised in the private placements in the fourth quarter, net of offering costs, and proceeds from a related party loan of \$1,365,344, offset by \$20,000 of repayments on the loan to the related party. The net cash proceeds from financing activities for the year ended December 31, 2005 resulted from the issuance of preferred stock in a subsidiary, totaling \$1,750,300, net of offering costs, and proceeds from a related party loan of \$684,553, offset by \$200,000 of repayments on the loan.

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing. Such additional funds may not become available on acceptable terms and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term. We will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs.

Current and Future Financing Needs

We have incurred an accumulated deficit of \$8,774,363 through December 31, 2006. We have incurred negative cash flow from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts. Based on our current plans, we believe that our cash will be sufficient to enable us to meet our planned operating needs at least for the next 18 months.

However, the actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our pre-clinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;

- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our shares or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

License and Contractual Agreement Obligations

Below is a table of our contractual obligations for the years 2007, 2008 and 2009.

Agreements	Year			
	Total	2007	2008	2009
License Agreements	\$ 272,830	\$ 89,000	\$ 88,830	\$ 95,000
Research and Development Agreements	\$ 765,833	\$ 459,500	\$ 306,333	\$ 0
Consulting Agreements	\$ 207,500	\$ 137,500	\$ 70,000	\$ 0
<i>COPREXA™ (oral tetrathiomolybdate)</i>				

Based on completed pivotal clinical trials using COPREXA™ for the treatment of initially presenting neurologic Wilson's disease and communication with the FDA, we plan to file an NDA during 2007. In order to expand the therapeutic utility of COPREXA™, we have completed a phase II clinical trial using COPREXA™ for the treatment of refractory Idiopathic Pulmonary Fibrosis (IPF), a fatal lung disease for which there is no FDA approved therapy. We have also initiated a phase II clinical trial using COPREXA™ in the treatment of primary biliary cirrhosis (PBC), a fatal liver disease. The primary purposes for these studies is to evaluate the safety and efficacy of COPREXA™ when administered intravenously to patients with IPF and PBC and who have failed curative or survival prolonging therapy or for whom no such therapies exist, establish the maximum tolerated dose, and identify dose limiting toxicities.

COPREXA™ has received clinical development grants from the FDA's Orphan Products group. These grants have covered the predominant cost of pre-clinical efficacy and safety testing, and Phase II and Phase III clinical program. PBC is currently supported by a \$950,000 orphan drug grant funded by the FDA. Through December 31, 2006, we have incurred approximately \$1,211,000 of costs related to our development of COPREXA™, of which approximately \$150,000 was incurred in fiscal 2005, and approximately \$1,061,000 was incurred for the year ending December 31, 2006.

TRIMESTA™ (oral estriol)

During 2007, we plan to initiate a multicenter, placebo controlled 130 patient phase II/III clinical trial using TRIMESTA™ for the treatment of relapsing-remitting Multiple Sclerosis (MS). This phase II/III clinical trial builds upon our encouraging results from our earlier phase IIa clinical trial. The primary

purpose of this study will be to evaluate the safety and efficacy of TRIMESTA™ in a larger MS patient population. The preclinical and clinical development of TRIMESTA™ has been primary financed by grants from the NIH and various non-profit foundations. Through December 31, 2006, we have incurred approximately \$235,000 of costs related to our development of TRIMESTA™ of which approximately \$49,500 was incurred in fiscal 2005, and \$185,500 was incurred in the year ending December 31, 2006.

Anti-CD4 802-2

During 2007, we plan to complete our phase I/II clinical trial of anti-CD4 802-2 in the prevention of graft-vs-host disease as well as complete our preclinical animal studies of anti-CD4 802-2. The primary purpose of these preclinical studies is to evaluate the molecules potential efficacy in different disease settings. If successful, we may choose to initiate clinical studies in these diseases. The preclinical and clinical development of anti-CD4 802-2 has been primary financed by grants from the NIH and various non-profit foundations. Through December 31, 2006, we have incurred \$1,261,100 of costs related to our development of anti-CD4 802-2 of which \$57,800, \$331,800, \$303,300, \$295,100, \$112,500 was incurred in fiscal 2001, 2002, 2003, 2004 and 2005 respectively and \$160,600 has been incurred in the year ended December 31, 2006.

CORRECTA™ (clotrimazole emema)

During 2007, we plan to continue the phase II clinical trial of CORRECTA™ in the treatment of acute refractory pouchitis, a gastrointestinal disease (the "CAPTURE study"). The primary purpose of this double blind, placebo-controlled phase II clinical trial is to test CORRECTA's safety and efficacy in treating acute refractory pouchitis. The CAPTURE study is supported by a \$750,000 orphan drug grant from the FDA.

The preclinical and clinical development of CORRECTA™ has been primarily financed by grants from the FDA's orphan drug products group and various non-profit foundations. Through December 31, 2006, we have incurred approximately \$210,000 of costs related to our development of CORRECTA™ of which approximately \$103,000 was incurred in fiscal 2005, and \$107,000 has been incurred in 2006.

Solovax

During 2007, we plan to analyze the data from our phase II clinical trial of SOLAVAX™ in the treatment of secondary progressive MS, as well as develop a new manufacturing procedure for SOLAVAX™.

If successful, we may choose to initiate a phase IIb clinical study in this disease. The preclinical and clinical development of SOLOVAX has been primarily financed by grants from the NIH and various non-profit foundations totaling \$5.5 million. Through December 31, 2006, we have incurred approximately \$679,900 of costs related to our development of SOLAVAX of which \$106,900, \$157,700, \$164,300, \$162,800, and \$66,900 was incurred in fiscal 2001, 2002, 2003, 2004, and 2005 respectively, and \$21,300 has been incurred in 2006.

We believe we currently have sufficient capital to fund development activities of COPREXA™, TRIMESTA™, anti-CD4 802-2, CORRECTA™ and SOLOVAX™ during 2006 and 2007 and 2008. Assuming our NDA for COPREXA™ is filed, accepted and ultimately approved for market in 2008, we will generate cash flow from the sales of COPREXA™. However, if our business does not generate any cash flow, we will need to raise additional capital to continue development of the product beyond 2009. To the extent additional capital is not available when we need it, we may be forced to sublicense our rights to our product candidates, abandon our development efforts altogether, or lose our licenses to our product candidates, any of which would have a material adverse effect on

the prospects of our business. See also the risks identified under the section entitled "Risk Factors" in this report.

Additional Licenses

We may enter into additional license agreements relating to new drug candidates.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect certain reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

ITEM 7. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS

PIPEX PHARMACEUTICALS, INC. AND SUBSIDIARIES
(A Development Stage Company)

TABLE OF CONTENTS

	Page
Report of Independent Registered Public Accounting Firm	40
Consolidated Balance Sheet	41
Consolidated Statements of Operations	42
Consolidated Statements of Changes in Stockholders' Equity	43
Consolidated Statements of Cash Flows	44
Notes to Consolidated Financial Statements	45

39

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of:
Pipex Pharmaceuticals, Inc.
(A Development Stage Company)

We have audited the accompanying consolidated balance sheet of Pipex Pharmaceuticals, Inc. and Subsidiaries (a development stage company) as of December 31, 2006 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years ended December 31, 2006 and 2005 and for the period from January 8, 2001 (inception) to December 31, 2006. These consolidated financial statements are the responsibility of the Company'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 the 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 misstatement. 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 Pipex Pharmaceuticals, Inc. and Subsidiaries (a development stage company) as of December 31, 2006, and the consolidated results of their operations, changes in stockholders' equity and cash flows for the years ended December 31, 2006 and 2005, and for the period from January 8, 2001 (inception) to December 31 2006, in conformity with accounting principles generally accepted in the United States of America.

/s/ Berman & Company, P.A.

Boca Raton, Florida
February 23, 2007

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Consolidated Balance Sheet
December 31, 2006

Assets

Current Assets:

Cash	\$	12,192,426
Prepaid expenses		25,702

Total Current Assets		12,218,128
-----------------------------	--	-------------------

Equipment, net of accumulated depreciation of \$32,935		297,288
--	--	---------

Total Assets	\$	12,515,416
---------------------	-----------	-------------------

Liabilities and Stockholders' Equity

Current Liabilities:

Accounts payable	\$	540,120
Accrued liabilities		188,899

Total Current Liabilities		729,019
----------------------------------	--	----------------

Commitments and Contingencies (See Note 6)

Stockholders' Equity

Preferred stock, \$0.001 par value; 10,000,000 shares authorized, none issued and outstanding		—
---	--	---

Common stock, \$0.001 par value, 100,000,000 shares authorized, 48,683,912 shares issued and outstanding		48,684
--	--	--------

Additional paid-in capital		20,512,076
----------------------------	--	------------

Deficit accumulated during the development stage		(8,774,363)
--	--	-------------

Total Stockholders' Equity		11,786,397
-----------------------------------	--	-------------------

Total Liabilities and Stockholders' Equity	\$	12,515,416
---	-----------	-------------------

See accompanying notes to consolidated financial statements

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Consolidated Statements of Operations

For the years ended December 31,

	2006	2005	For the Period from January 8, 2001 (Inception) to December 31, 2006
Operating Expenses:			
Research and development	2,665,555	946,065	4,833,069
General and administrative	1,439,022	373,145	2,982,893
Merger costs	12,500	37,500	50,000
Total Operating Expenses	4,117,077	1,356,710	7,865,962
Loss from Operations	(4,117,077)	(1,356,710)	(7,865,962)
Other Income (Expense):			
Interest income	17,982	868	44,582
Other expense	—	—	(1,733)
Total Other Income, net	17,982	868	42,849
Net Loss	\$ (4,099,095)	\$ (1,355,842)	\$ (7,823,113)
Less: Preferred stock dividend—subsidiary	(761,000)	(190,250)	(951,250)
Net Loss Applicable to Common Shareholders	\$ (4,860,095)	\$ (1,546,092)	\$ (8,774,363)
Net Loss Per Share—Basic and Diluted	\$ (0.50)	\$ (1.71)	\$ (1.76)
Weighted average number of shares outstanding during the year/period — basic and diluted	9,733,629	906,253	4,989,483

See accompanying notes to consolidated financial statements

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Consolidated Statements of Changes in Stockholders' Equity
For the years ended December 31, 2006 and 2005 and for the period from January 8, 2001 (inception) to December 31, 2006

	Series A Convertible Preferred Stock \$0.001 Par Value		Common Stock \$0.001 Par Value		Additional Paid-in Capital	Defecit accumulated during development stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance, January 8, 2001 (inception)	—	\$ —	—	\$ —	\$ —	\$ —	\$ —
Issuance of common stock to founders in exchange for subscription receivables \$0.00001/share)	—	—	4,716,411	4,716	(4,366)	—	350
Issuance of preferred stock to founder for cash (\$0.01844/share)	16,264,661	16,265	—	—	283,735	—	300,000
Issuance of preferred and common stock to founder for cash—subsidiaries	—	—	—	—	850,540	—	850,540
Net loss for the period ended December 31, 2001	—	—	—	—	—	(277,868)	(277,868)
Balance, December 31, 2001	16,264,661	16,265	4,716,411	4,716	1,129,909	(277,868)	873,022
Issuance of common stock for compensation and consulting—subsidiary	—	—	—	—	119	—	119
Grant of stock options for consulting services—subsidiary	—	—	—	—	5,890	—	5,890
Net loss for the year ended December 31, 2002	—	—	—	—	—	(768,508)	(768,508)
Balance, December 31, 2002	16,264,661	16,265	4,716,411	4,716	1,135,918	(1,046,376)	110,523
Grant of stock options for compensation—subsidiary	—	—	—	—	17,984	—	17,984
Net loss for the year ended December 31, 2003	—	—	—	—	—	(719,307)	(719,307)
Balance, December 31, 2003	16,264,661	16,265	4,716,411	4,716	1,153,902	(1,765,683)	(590,800)
Issuance of common stock for cash—subsidiary	—	—	—	—	50	—	50
	—	—	—	—	10,437	—	10,437

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

Grant of stock options for consulting services—subsidiary								
Net loss for the year ended December 31, 2004							(602,493)	(602,493)
Balance, December 31, 2004	16,264,661	16,265	4,716,411	4,716	1,164,389	(2,368,176)	(1,182,806)	
Recognition of stock based consulting in connection with stock options grants					59,960			59,960
Recognition of stock based compensation in connection with stock option grants					10,493			10,493
Recognition of deferred compensation—subsidiary					14,057			14,057
Issuance of Series B, convertible preferred stock for cash—subsidiary					1,902,500			1,902,500
Cash paid as direct offering costs in connection with sale of Series B, convertible preferred stock—subsidiary					(152,200)			(152,200)
10% in-kind Series B, convertible preferred stock dividend—subsidiary					190,250	(190,250)		
Net loss for the year ended December 31, 2005							(1,355,842)	(1,355,842)
Balance, December 31, 2005	16,264,661	16,265	4,716,411	4,716	3,189,449	(3,914,268)	(703,838)	
Conversion of related party loan to common stock (\$0.67268/share)			4,995,633	4,996	3,269,732			3,274,728
Issuance of common stock for cash—private placement (\$0.67340/share)			20,702,794	20,703	13,905,660			13,926,363
Cash paid as direct offering costs in private placements					(1,160,418)			(1,160,418)
Issuance of common stock for license fees (\$.30679/share)			1,266,941	1,267	387,424			388,691
Conversion of accrued expenses to contributed capital—former related party					3,017			3,017
Deemed issuance to shareholders of legal acquiror and recapitalization			737,472	737	(665,737)			(665,000)
Conversion of Series A, convertible preferred stock to common stock	(16,264,661)	(16,265)	16,264,661	16,265				

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

Recognition of stock based consulting in connection with stock option grants	—	—	—	—	411,310	—	411,310
Recognition of stock based compensation in connection with stock option grants	—	—	—	—	410,639	—	410,639
10% in-kind Series B, convertible preferred stock dividend—subsidiary	—	—	—	—	190,250	(190,250)	—
30% in-kind Series B, convertible preferred stock dividend—subsidiary	—	—	—	—	570,750	(570,750)	—
Net loss for the year ended December 31, 2006	—	—	—	—	—	(4,099,095)	(4,099,095)
Balance, December 31, 2006	—	\$ —	48,683,912	\$ 48,684	\$ 20,512,076	\$ (8,774,363)	\$ 11,786,397

See accompanying notes to consolidated financial statements

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Consolidated Statements of Cash Flows

	<u>For the years ended December 31,</u>		For the Period from January 8, 2001 (Inception) to December 31, 2006
	<u>2006</u>	<u>2005</u>	
Cash Flows From Operating Activities:			
Net loss	\$ (4,099,095)	\$ (1,355,842)	\$ (7,823,113)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	410,639	24,550	453,523
Stock-based consulting	411,310	59,960	487,716
Stock issued for license fees	388,691	—	388,691
Depreciation	30,675	2,260	32,935
Changes in operating assets and liabilities:			
Prepaid expenses and other	(25,702)	—	(25,702)
Accounts payable	325,746	186,963	540,120
Accrued liabilities	191,917	—	191,917
Net Cash Used In Operating Activities	(2,365,819)	(1,082,109)	(5,753,913)
Cash Flows From Investing Activities:			
Purchases of property and equipment	(45,833)	—	(45,833)
Cash paid to acquire shell in reverse merger	(665,000)	—	(665,000)
Net Cash Used In Investing Activities	(710,833)	—	(710,833)
Cash Flows From Financing Activities:			
Proceeds from sale of common stock and warrants in private placement	13,926,362	—	13,926,362
Cash paid as direct offering costs in private placements	(1,160,418)	—	(1,160,418)
Proceeds from issuance of Series B, convertible preferred stock - subsidiary	—	1,902,500	1,902,500
Direct offering costs in connection with issuance of series B, convertible preferred stock - subsidiary	—	(152,200)	(152,200)
Proceeds from issuance of preferred and common stock	—	—	1,150,590
Proceeds from loans payable - related party	1,365,344	684,553	3,210,338
Repayments of loans payable - related party	(20,000)	(200,000)	(220,000)
Net Cash Provided By Financing Activities	14,111,288	2,234,853	18,657,172
Net increase in cash	11,034,636	1,152,744	12,192,426
Cash at beginning of year/period	1,157,790	5,046	—
Cash at end of year/period	\$ 12,192,426	\$ 1,157,790	\$ 12,192,426

Supplemental disclosures of cash flow information:

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

Cash paid during the period for interest	\$ —	\$ —	\$ —
Cash paid for taxes	\$ —	\$ —	\$ —
Supplemental disclosure of non-cash investing and financing activities:			
Pipex Therapeutics acquired equipment in exchange for a loan with a related party	\$ —	\$ 284,390	\$ 284,390
EPI declared a 10% and 30% in-kind dividend on its Series B, convertible preferred stock	\$ 761,000	\$ 190,250	\$ 951,250
The Company issued shares and warrants in connection with the conversion of certain related party debt	\$ 3,274,728	\$ —	\$ 3,274,728
Conversion of accrued liabilities to contributed capital - former related party	\$ 3,017	\$ —	\$ 3,017

See accompanying notes to consolidated financial statements

**Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)**

Notes to Consolidated Financial Statements

Note 1 Organization and Nature of Operations

(A) Description of the Business

Pipex Pharmaceuticals, Inc. ("Pipex") is a development-stage pharmaceutical company that is developing proprietary, late-stage drug candidates for the treatment of neurologic and fibrotic diseases.

(B) Corporate Structure and Basis of Presentation

The Company has four majority owned subsidiaries, Pipex Therapeutics, Inc. (Pipex Therapeutics), Solovax, Inc. (Solovax), Effective Pharmaceuticals, Inc. (EPI) and CD4 Biosciences, Inc. (CD4).

The Company consists of four separate entities previously under common control. As of December 31, 2006, all of the entities were majority owned subsidiaries of Pipex. The combinations of these entities were accounted for in a manner similar to a pooling of interests.

For financial reporting purposes, the outstanding preferred stock and common stock of the Company is that of Pipex. All statements of operations, stockholders' deficit and cash flows for each of the entities are presented as consolidated since inception (January 8, 2001) due to the existence of common control since that date. All of our subsidiaries were incorporated January 8, 2001 under the laws of the State of Delaware, except for EPI which was incorporated on December 12, 2000.

(C) Reverse Merger and Recapitalization

On October 31, 2006, Sheffield Pharmaceuticals, Inc. ("Sheffield"), a shell corporation, entered into a Merger Agreement ("Merger") with Pipex Therapeutics, a privately owned Delaware company, whereby Pipex Therapeutics was the surviving corporation. This transaction was accounted for as a reverse merger since Sheffield did not have any operations and a recapitalization of Pipex Therapeutics. Since Pipex Therapeutics acquired a controlling voting interest, it was deemed the accounting acquirer, while Sheffield was deemed the legal acquirer. The historical financial statements of the Company are those of Pipex Therapeutics, EPI, Solovax and CD4 since inception, and of the consolidated entities from the date of Merger and subsequent. On December 11, 2006, Sheffield changed its name to Pipex Pharmaceuticals, Inc.

Since the transaction is considered a reverse merger and recapitalization, the guidance in SFAS No. 141 does not apply for purposes of presenting pro-forma financial information.

Pursuant to the Merger Agreement, Sheffield issued 34,000,000 shares of common stock for all of the outstanding Series A, convertible preferred and common stock of Pipex Therapeutics and Sheffield assumed all of Pipex Therapeutics's outstanding options and warrants, but did not assume the options and warrants outstanding within Pipex Therapeutics's majority owned subsidiaries. On October 31, 2006, concurrent with the Merger, Pipex Therapeutics executed a private stock purchase agreement to purchase an additional 2,426,300 shares of common stock held by Sheffield's sole officer and director; these shares were immediately cancelled and retired. Aggregate consideration paid for Sheffield was \$665,000. Upon the closing of the reverse merger, shareholders of Sheffield retained an aggregate 737,472 shares of common stock. As a result of these transactions, Pipex Therapeutics acquired approximately 98% ownership of the issued and outstanding common shares of Sheffield.

**Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)**

Notes to Consolidated Financial Statements

(D) Contribution Agreements — Consolidation of Entities under Common Control

1. EPI's Acquisition of CD4

On December 31, 2004, EPI acquired 91.61% of the issued and outstanding common stock of CD4 in exchange for 825,000 shares of common stock having a fair value of \$825. EPI assumed certain outstanding accounts payable and loans of CD4 of approximately \$664,000. The fair value of the exchange was equivalent to the par value of the common stock issued. CD4 shareholders retained 119,000 shares (8.39%) of the issued and outstanding common stock of CD4; these shareholders comprise the non-controlling shareholder base of CD4.

2. Pipex Therapeutic's Acquisition of Solovax

On July 31, 2005, Pipex Therapeutics acquired 96.9% of the aggregate voting preferred and common stock of Solovax. Pipex Therapeutics assumed all outstanding liabilities of approximately \$310,000, the transfer of 1,000,000 shares of Series A Convertible Preferred Stock owned by Solovax's president and 250,000 shares of common stock owned by Solovax's COO. The fair value of the exchange was equivalent to the par value of the common stock received pursuant to the terms of the contribution.

3. Pipex Therapeutic's Acquisition of EPI/CD4

On December 31, 2005, Pipex Therapeutics acquired 65.47% of the aggregate voting preferred and common stock of EPI and its majority owned subsidiary CD4. In addition, Pipex Therapeutics assumed \$583,500 of outstanding liabilities of EPI. The fair value of the exchange was equivalent to the par value of the common stock received pursuant to the terms of the contribution.

In the consolidated financial statements at December 31, 2006, each of these transactions was analogous to a recapitalization with no net change to equity since the entities were under common control at the date of the transaction.

Note 2 Summary of Significant Accounting Policies

(A) Principles of Consolidation

The consolidated financial statements include the accounts of Pipex Pharmaceuticals, Inc. and its majority owned subsidiaries, Pipex Therapeutics, Solovax, EPI, and CD4. All significant inter-company accounts and transactions have been eliminated in consolidation.

For financial accounting purposes, the Company's inception is deemed January 8, 2001. The activity of EPI for the period from December 12, 2000 to January 7, 2001 was nominal. Therefore, there is no financial information presented for this period.

(B) Development Stage

For the period from inception (January 8, 2001) to date, the Company has been a development stage enterprise, and accordingly, the Company's operations have been directed primarily toward the acquisition and creation of intellectual properties and certain research and development activities to improve current technological concepts. As the Company is devoting its efforts to research and development, there has been no revenue generated from sales, license fees or royalties. Additionally, the Company continually seeks sources of debt or equity based funding to further its intended research and development activities. The Company has experienced net losses since its inception, and

**Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)**

Notes to Consolidated Financial Statements

had an accumulated deficit of \$8,774,363 at December 31, 2006. The Company's consolidated financial statements are presented as statements of a development stage enterprise. Additionally, the Company continually seeks sources of debt or equity based funding to further its intended research and development activities.

(C) Use of Estimates

In preparing financial statements in conformity with generally accepted accounting principles, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and revenues and expenses during the periods presented. Actual results may differ from these estimates.

Significant estimates during 2006 and 2005 include depreciable lives of property, valuation of stock options and warrants granted for services or compensation pursuant to SFAS No. 123R, existence and recording of research and development expenditures as expenses in connection with the provisions of SFAS No. 2, estimates of the probability and potential magnitude of contingent liabilities and the valuation allowance for deferred tax assets.

(D) Cash

The Company minimizes its credit risk associated with cash by periodically evaluating the credit quality of its primary financial institution. The balance at times may exceed federally insured limits. At December 31, 2006, the balance exceeded the federally insured limit by \$11,792,261.

(E) Equipment

Equipment is stated at cost, less accumulated depreciation. Costs greater than \$1,000 are capitalized and depreciated on a straight-line basis over the estimated useful lives, which is generally ten years. Equipment consists primarily of equipment used in connection with research and development. Expenditures for maintenance and repairs are charged to expense as incurred.

(F) Long Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. There were no impairment charges taken during the years ended December 31, 2006 and 2005 and for the period from January 8, 2001 (inception) to December 31, 2006.

(G) Derivative Liabilities

In connection with the reverse merger, all outstanding convertible preferred stock of Pipex was cancelled and retired, as such, the provisions of EITF No. 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" do not apply. The Company's majority owned subsidiaries also contain issued convertible preferred stock; however, none of these instruments currently contains any provisions that require the recording of a derivative liability. In connection with the acquisition of EPI on January 5, 2007 (See Note 9(A)), all issued and outstanding shares of Series A and B, convertible preferred stock were cancelled and retired. As such, no potential derivative liabilities will exist pertaining to these instruments.

**Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)**

Notes to Consolidated Financial Statements

(H) Net Loss per Share

Basic earnings (loss) per share is computed by dividing the net income (loss) less preferred dividends for the period by the weighted average number of common shares outstanding. Diluted earnings per share is computed by dividing net income (loss) less preferred dividends by the weighted average number of common shares outstanding including the effect of share equivalents. Since the Company reported a net loss at December 31, 2006 and 2005 and for the period from January 8, 2001 (inception) to December 31, 2006, respectively, all common stock equivalents would be anti-dilutive; as such there is no separate computation for diluted earnings per share.

The Company's net loss per share for the years ended December 31, 2006 and 2005 and for the period from January 8, 2001 (inception) to December 31, 2006 was computed assuming the recapitalization associated with the reverse merger, as such all share and per share amounts have been retroactively restated to reflect the weighted average shares outstanding for the legal acquirer. Additionally, the numerator for computing net loss per share was adjusted for preferred stock dividends recorded during the years ended December 31, 2006 and 2005 in connection with certain provisions relating to the sale of EPI's Series B, convertible preferred stock. (See Note 5(C)(1))

(I) Research and Development Costs

The Company expenses all research and development costs as incurred for which there is no alternative future use. These costs also include the expensing of employee compensation and employee stock based compensation.

(J) Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. (See Note 7)

(K) Fair Value of Financial Instruments

The carrying amounts of the Company's short-term financial instruments, including accounts payable, and accrued liabilities, approximate fair value due to the relatively short period to maturity for these instruments.

(L) Stock Based Compensation

In December 2004, the FASB issued SFAS No. 123(R), "*Share-Based Payment*," which replaces SFAS No. 123 and supersedes APB Opinion No. 25. Under SFAS No. 123(R), companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share-based compensation arrangements include stock options, stock warrants, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. In March 2005, the SEC issued Staff Accounting Bulletin No. 107, or "SAB 107". SAB 107 expresses views of the staff regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods. On April 14, 2005, the SEC adopted a rule amending the compliance dates for SFAS 123R. Companies may elect to apply this statement either prospectively, or

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Notes to Consolidated Financial Statements

on a modified version of retrospective application under which financial statements for prior periods are adjusted on a basis consistent with the pro forma disclosures required for those periods under SFAS No. 123. The Company has elected to retroactively adopt the provisions of SFAS No. 123R.

All share-based payments to employees since inception have been recorded and expensed in the statements of operations as applicable.

(M) Recent Accounting Pronouncements

In February 2006 the FASB issued SFAS 155, "Accounting for Certain Hybrid Financial Instruments" (SFAS 155), which amends SFAS No. 133, "Accounting for Derivatives Instruments and Hedging Activities" (SFAS 133) and SFAS No. 140, "Accounting for Transfers and Servicing of Financial Assets and Extinguishment of Liabilities" (SFAS 140). SFAS 155 amends SFAS 133 to narrow the scope exception for interest-only and principal-only strips on debt instruments to include only such strips representing rights to receive a specified portion of the contractual interest or principal cash flows. SFAS No. 155 also amends SFAS No. 140 to allow qualifying special-purpose entities to hold a passive derivative financial instrument pertaining to beneficial interests that it is a derivative financial instrument. The Company will adopt SFAS No. 155 on January 1, 2007 and does not expect it to have a material effect on its financial position, results of operations, or cash flows.

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, ("FIN 48") "*Accounting for uncertainty in income taxes — an interpretation of SFAS No. 109.*" This Interpretation provides guidance for recognizing and measuring uncertain tax positions, as defined in FASB No. 109, "*Accounting for income taxes.*" FIN 48 prescribes a threshold condition that a tax position must meet for any of the benefit of an uncertain tax position to be recognized in the financial statements. Guidance is also provided regarding de-recognition, classification and disclosure of uncertain tax positions. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company does not expect that this Interpretation will have a material impact on their financial position, results of operations or cash flows.

In September 2006, the FASB issued SFAS No. 157 ("SFAS 157"); *Fair Value Measurements.* SFAS 157 clarifies the principle that fair value should be based on the assumptions that market participants would use when pricing an asset or liability. Additionally, it establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company does not expect the adoption of SFAS 157 to have a material impact on their financial position, results of operations or cash flows.

In September 2006, the FASB issued SFAS No. 158 ("SFAS 158"); *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans, an amendment of FASB Statements No. 87, 88, 106, and 132(R).* SFAS 158 requires employers to recognize the under-funded or over-funded status of a defined benefit postretirement plan as an asset or liability in its statement of financial position and to recognize changes in the funded status in the year in which the changes occur through accumulated other comprehensive income. Additionally, SFAS 158 requires employers to measure the funded status of a plan as of the date of its year-end statement of financial position. The new reporting requirements and related new footnote disclosure rules of SFAS 158 are effective for fiscal years ending after December 15, 2006. The new measurement date requirement applies for fiscal years ending after December 15, 2008. The Company does not expect the adoption of SFAS 158 to have a material impact on their financial position, results of operations or cash flows.

In September 2006, the U.S. Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin ("SAB No. 108"), which expresses the views of the SEC staff regarding the

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Notes to Consolidated Financial Statements

process of quantifying financial statement misstatements. SAB No. 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. The guidance of this SAB is effective for annual financial statements covering the first fiscal year ending after November 15, 2006, which is December 31, 2006 for the Company. SAB No. 108 did not have an impact on the Company's financial position, results of operations or cash flows.

Note 3 Equipment

At December 31, 2006, equipment consisted primarily of laboratory equipment that is being depreciated on a straight-line basis over its estimated useful life of ten years. Depreciation expense in the years ended December 31, 2006 and 2005, and in the period from inception (January 8, 2001) to December 31, 2006, was \$30,675, \$2,260 and \$32,935, respectively. During 2005, the Company acquired equipment in exchange for a related party note payable. (See Note 4)

Note 4 Loans Payable — Related Party

An affiliate of the Company's founder, President and CEO has advanced working capital to or on behalf of the Company. Loan activity for the Company was as follows since inception:

<u>Total loans / (repayments) per year</u>	<u>Amount</u>
Year ended December 31, 2001 — loans	\$ —
Year ended December 31, 2002 — loans	130,520
Year ended December 31, 2003 — loans	244,640
Year ended December 31, 2004 — loans	785,281
Year ended December 31, 2005 — loans	968,943
Year ended December 31, 2005 — repayments	(200,000)
Year ended December 31, 2006 — loans	1,365,344
Year ended December 31, 2006 — repayments	(20,000)
Year ended December 31, 2006 — conversion to equity	(3,274,728)
	<hr/>
Balance, December 31, 2006	\$ —
	<hr/>

During 2005, the Company acquired \$284,390 in equipment in exchange for an increase in loans payable— related party. This advance is the non-cash component of the \$968,943 in 2005. (See Note 3)

On October 31, 2006, the non-interest bearing loans payable to the Company's founder, Chairman and Chief Executive Officer, which amounted to \$3,274,728, were converted into 4,995,633 shares of common stock and 2,497,817 warrants to purchase common stock. (See Note 5(D))

Note 5 Stockholders' Equity and Non-Controlling Interest

All issuances for Pipex Therapeutics, Inc. have been retroactively restated to reflect the recapitalization due to reverse merger.

**Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)**

Notes to Consolidated Financial Statements

(A) Preferred Stock Issuances

1. For the Year Ended December 31, 2001

On January 4, 2001, EPI issued 3,000,000 shares of Series A Convertible Preferred Stock to the Founder serving as the CEO and Chairman of the Board of EPI in exchange for \$250,000 (\$0.08 per share).

On January 15, 2001, Pipex Therapeutics issued 16,264,661 shares of Series A Convertible Preferred Stock (pursuant to the October 31, 2006 reverse merger and recapitalization) to a founder serving as the President, CEO and Chairman of the Board of Pipex in exchange for \$300,000 (\$0.01844 per share). On October 31, 2006, pursuant to the reverse merger with Sheffield, these shares of Series A Convertible Preferred Stock were cancelled and retired.

On January 31, 2001, Solovax issued 1,000,000 shares of Series A Convertible Preferred Stock to the Founder serving as the President, CEO and Chairman of the Board of Solovax in exchange for \$300,000 (\$0.30 per share).

On February 7, 2001, CD4 issued 1,000,000 shares of Series A Convertible Preferred Stock, to an affiliate of a founder serving as the CEO and Chairman of the Board of CD4 in exchange for \$300,000 (\$.30 per share).

2. For the Year Ended December 31, 2005

On March 10, 2005, EPI's board of directors and stockholders voted to authorize the designation of a Series B Convertible Preferred Stock. (See Note 5(C))

From March through June 2005, EPI issued 1,902,500 shares of Series B Convertible Preferred Stock, at \$1 per share, for proceeds of \$1,902,500. In connection with this offering, EPI paid \$152,200 of offering costs that were charged against additional paid in capital. The Company also granted 171,225 warrants as compensation in connection with this equity raise. (See Note 5(H)(1))

See Note 9(A) regarding acquisition of remaining non-controlling interest.

4. CD4 Biosciences, Inc.

(B) Series A Convertible Preferred Stock

The Company and its majority owned subsidiaries has each authorized and issued Series A Convertible Preferred Stock. (See Note 1(C)) for conversion of Pipex Series A convertible preferred stock.

The terms of the Series A Convertible Preferred Stock for the Company and its majority owned subsidiaries is summarized below. The terms are the same for each of the entities.

1. Dividends

Each share of Series A Convertible Preferred Stock is entitled to receive dividends in an amount equal to dividends declared and paid with respect to that number of shares of common stock into which one share of Series A Convertible Preferred Stock is then convertible. For the period from January 8, 2001 (inception) to December 31, 2006, neither the Company, nor any of its majority owned subsidiaries has declared any Series A Convertible Preferred Stock dividends.

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Notes to Consolidated Financial Statements

2. Liquidation Preference

Upon liquidation, holders of the Series A Convertible Preferred Stock will be entitled to the greater of (1) a per share amount equal to the original purchase price plus any dividends accrued but not paid and (2) the amount that the holder would receive in respect of a share of Series A, preferred if immediately prior to dissolution and liquidation, all shares of Series A Convertible Preferred Stock were converted into shares of common stock.

3. Conversion

Each share of Series A Convertible Preferred Stock is immediately convertible on a one for one basis at the option of the holder. The conversion ratio is determined by dividing the original issue price of the Series A Convertible Preferred Stock by the conversion price for the Series A, convertible preferred stock in effect on the date the certificate is surrendered for conversion. The conversion price will initially be the original issue price, which is subject to future adjustment. Therefore, at December 31, 2006, the conversion ratio is 1.00.

4. Voting Rights

Each holder of Series A, convertible preferred stock is entitled to one vote for each share of common stock into which each share of Series A Convertible Preferred Stock could then be converted.

5. Beneficial Conversion Feature and Derivative Liability

The Company and its majority owned subsidiaries has reviewed each of the provisions of its Series A Convertible Preferred Stock and noted no required accounting for a beneficial conversion feature pursuant to the guidance in EITF No.'s 98-5 or 00-27. Upon issuance, the original issue price, its fair value, and conversion price were equivalent.

Additionally, there is no required accounting or financial statement impact for derivative instruments. None of the Company or its majority owned subsidiaries Series A Convertible Preferred Stock has embedded features requiring such treatment.

(C) Series B Convertible Preferred Stock

Only Pipex and EPI have authorized Series B Convertible Preferred Stock.

At December 31, 2006, Pipex has not issued any of its Series B Convertible Preferred Stock. Pipex has not yet designated their Series B Convertible Preferred Stock as it pertains to dividends, liquidation preference, conversion, voting rights, and other rights and preferences.

At December 31, 2006, the only Series B Convertible Preferred Stock of the consolidated group of companies, that has been issued was in EPI. The consolidated balance sheet reflects these transactions as a component of equity and the par value is eliminated in consolidation. (See Note 1(B)). EPI's Series B Convertible Preferred Stock was cancelled and retired in connection with the January 5, 2007 merger agreement to acquire the remaining portion of the non-controlling voting interest in EPI by Pipex (See Note 9(A))

The terms of the Series B Convertible Preferred Stock for EPI are summarized below.

1. Dividends

If the common stock of the company trades on a national securities exchange (a "Trading Event") or the company completes an initial public offering of EPI common stock (an "IPO"), or the conversion

**Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)**

Notes to Consolidated Financial Statements

of all of the outstanding shares of Series B Convertible Preferred Stock, each share of Series B Convertible Preferred Stock will be entitled to receive a dividend in additional shares of Series B Convertible Preferred Stock at the rate of 10% of the Series B purchase price per year, with those dividends being payable only in a number of shares equal to the dollar amount of those dividends divided by the Series B original purchase price (as adjusted for any stock dividends, consolidations, splits, recapitalizations, and the like). Dividends accrue on each share of Series B Convertible Preferred Stock, whether or not earned or declared and regardless of when any share of Series B Convertible Preferred Stock was issued. During the years ended December 31, 2006 and 2005, the Company issued 190,250 and 190,250 shares, respectively for the 10% PIK dividend having a fair value of \$190,250 and \$190,250, respectively.

Each share of Series B Convertible Preferred Stock is also entitled to receive an additional dividend at the rate of 30% of the Series B original purchase price if within 18 months from the final closing (this occurred effective June 30, 2005) of this offering there has occurred neither an IPO nor a Trading Event. These dividends are payable only in a number of shares equal to the dollar amount of those dividends divided by the Series B original purchase price. At December 31, 2006, since none of the conditions were met within the allotted 18-month time frame, the Company recorded a 30% paid in kind dividend for 570,750 shares having a fair value of \$570,750.

At December 31, 2006 and 2005, EPI recorded preferred stock dividends aggregating 761,000 and 190,250 shares, respectively, having a fair value of \$761,000 and \$190,250, respectively. For the period from January 8, 2001 (inception) to December 31, 2006, the Company recorded preferred stock dividends aggregating 951,250 shares having a fair value of \$951,250.

2. Liquidation Preference

Upon liquidation, holders of the shares of Series B Convertible Preferred Stock will be entitled to receive in preference to holders of shares of any junior stock an amount per share of Series B Convertible Preferred Stock equal to the greater of (1) an amount equal to the Series B original purchase price (as adjusted for any stock dividends, consolidations, splits, recapitalizations and the like) plus any dividends accrued on a share of Series B Convertible Preferred Stock but not paid and (2) the current market price of our common stock multiplied by the number of shares of common stock into which a share of Series B Convertible Preferred Stock could be converted immediately prior to dissolution and liquidation. After payment of the liquidation amount to holders of shares of Series B Convertible Preferred Stock the remaining assets will be distributed to holders of shares of common stock.

3. Conversion

Each share of Series B Convertible Preferred Stock is convertible at the option of the holder at any time into one share of common stock, subject to adjustment.

Upon consummation of an IPO or a Trading Event, all shares of Series B Convertible Preferred Stock will be deemed automatically converted into that number of fully paid and non-assessable shares of common stock into which those shares would have then been convertible in the event of optional conversion. In the event of a merger in which our shareholders constitute a majority of the voting power of the surviving corporation, or our common stock trades at 300% of the Series B original purchase price, then all of the shares of Series B Convertible Preferred Stock then outstanding will convert into shares of common stock.

**Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)**

Notes to Consolidated Financial Statements

4. Voting Rights

Each holder of shares of Series B Convertible Preferred Stock is entitled to one vote for each share of common stock into which each share of Series B Convertible Preferred Stock could then be converted and is entitled to vote together with our shares of Series A Convertible Preferred Stock and common stock.

5. Beneficial Conversion Feature and Derivative Liability

EPI's Series B Convertible Preferred Stock has no required accounting for a beneficial conversion feature pursuant to the guidance in EITF No.'s 98-5 or 00-27. Upon issuance, the original issue price, its fair value, and conversion price were equivalent.

Additionally, there is no required accounting or financial statement impact for derivative instruments. EPI's Series B Convertible Preferred Stock has no embedded features requiring such treatment.

6. Anti-dilution Protection

If EPI issues any shares of common stock (with certain exceptions) without consideration or for a consideration per share less than the "Conversion Price" (as defined in the certificate of amendment containing the terms of the Series B Convertible Preferred Stock) in effect immediately prior to the issuance of those shares, holders of shares of Series B Convertible Preferred Stock will be entitled to weighted-average anti-dilution protection. EPI has not issued or granted any common stock or common stock equivalents since the issuance of the Series B Convertible Preferred Stock during 2005.

(D) Common Stock Issuances of Issuer

During October and November of 2006, the Company completed private placements of its stock, which resulted in the issuance of 20,702,794 shares of common stock and 10,351,979 warrants. The net proceeds from the private placements were approximately \$12,766,000, which included cash paid as direct offering costs of approximately \$1,160,000. In connection with the private placements, the Company engaged a company, which is controlled by the Company's Chairman and Chief Executive Officer, as the placement agent for the transaction. Of the total approximate \$1,160,000 in direct offering costs, the Company paid the placement agent the sum of approximately \$1,033,800. Additionally the placement agent was paid non-cash compensation of 2,874,831 warrants with an aggregate fair value of \$4,555,457. (See Note 5 (G)).

On October 31, 2006, the loans payable to the Company's founder, President and CEO were converted into 4,995,633 shares of common stock and 2,497,817 warrants. (See Note 4). The warrants have an exercise price of \$0.74 and each warrant has a life of 5 years.

During October 2006, the Company converted all of its 16,264,661 shares of Series A, convertible preferred stock in exchange for equivalent common shares. The fair value of the exchange was based upon par value with a net effect of \$0 to the statement of equity.

During October 2006, the Company issued 1,266,941 shares of common stock to an unrelated third party in connection with the terms of a license agreement. The fair value was \$388,691 based upon recent cash offering price and was charged to research and development expense.

(E) Common Stock Issuances of Subsidiaries

During the period from January 8, 2001 (inception) to December 31, 2004, the Company's majority owned subsidiaries; CD4, Solovax and EPI issued an aggregate 590,000 shares of common stock for \$590. Additionally, EPI issued 825,000 shares of common stock at par value to acquire a controlling

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Notes to Consolidated Financial Statements

interest in CD4. Finally, an aggregate 119,000 shares of common stock was issued for compensation and consulting services rendered having a fair value of \$119.

(F) Stock Option Plan

During 2001 (the "Effective Date"), Pipex Therapeutics' Board and stockholders adopted the 2001 Stock Incentive Plan (the "Plan"). This plan was assumed by Pipex in the merger, in the fourth quarter of 2006. As of the date of the merger there were a total of 4,468,059 options issued and outstanding. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period shall not exceed 1,250,000 (not affected for stock split). All awards pursuant to the Plan shall terminate upon the termination of the grantee's employment for any reason.

Pursuant to the provisions of SFAS No. 123R, in the event of termination, the Company will cease to recognize compensation expense. There is no deferred compensation recorded upon initial grant date, instead, the fair value of the share-based payment is recognized ratably over the stated vesting period.

Awards include options, restricted shares, stock appreciation rights, performance shares and cash-based awards (the "Awards"). The Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined in the Plan. The Plan provides for a Committee of the Board (the "Committee") to grant awards and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the awards, including acceleration of the vesting of an award at any time.

The Company has followed fair value accounting and the related provisions of SFAS No. 123R for all share based payment awards since inception. The fair value of each option or warrant granted is estimated on the date of grant using the Black-Scholes option-pricing model. All option and warrant grants are expensed in the appropriate period based upon vesting terms, in each case with an offsetting credit to additional paid in capital. The Black-Scholes assumptions used in the years ended December 31, 2006 and 2005 are as follows:

	Year Ended December 31,	
	2006	2005
Exercise price	\$0.03 - \$4.00	\$0.03
Expected dividends	0%	0%
Expected volatility	93.09% - 200%	200%
Risk free interest rate	4.43% - 4.99%	3.03% - 4.52%
Expected life of option	3-10 years	10 years

All option and grants are expensed in the appropriate period based upon vesting terms, in each case with an offsetting credit to additional paid in capital. The stock-based compensation expense recorded by the Company for the years ended December 31, 2006 and 2005 and the period from inception to December 31, 2006 with respect to awards under the Plan is as follows:

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Notes to Consolidated Financial Statements

	Year Ended December 31,		Inception to December 31, 2006
	2006	2005	
Research and development:			
employees	\$ 226,909	\$ 12,275	\$ 239,184
non-employees	—	59,960	59,960
General and administrative:			
employees	183,730	12,275	196,005
non-employees	\$ 411,310	—	411,310
	<u>\$ 226,909</u>	<u>\$ 84,510</u>	<u>\$ 906,459</u>

Pursuant to FAS 123R, the Company records stock based compensation based upon the stated vested provisions in the related agreements. The vesting provisions for these agreements have various terms as follows: immediate vesting, half vesting immediately and the remainder over three years, quarterly over three years, annually over three years, one-third immediate vesting and remaining annually over two years, and one half immediate vesting with remaining vesting over six months.

A summary of stock option activity for the years ended December 31, 2006 and 2005 is as follows:

	Number of Shares	Weighted Average Exercise Price
Balance at December 31, 2004	—	\$ —
Granted	764,384	\$ 0.03
Exercised	—	\$ —
Forfeited	—	\$ —
Balance at December 31, 2005	764,384	\$ 0.03
Granted	4,092,182	\$ 0.73
Exercised	—	\$ —
Forfeited	(15,000)	\$ 0.30
Balance at December 31, 2006	4,841,566	\$ 0.62

Of the total options granted, 1,925,516 are fully vested, exercisable and non-forfeitable.

Of the 4,092,182 options granted in 2006, 3,606,094 were granted to related parties of which 1,060,188 are fully vested.

The options outstanding and exercisable at December 31, 2006 are as follows:

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Notes to Consolidated Financial Statements

Options Outstanding			Options Exercisable		
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.03	764,384	7.29 Years	\$0.03	764,384	\$0.03
\$0.06	211,425	9.35 Years	\$0.06	40,659	\$0.06
\$0.61	1,992,756	9.42 Years	\$0.61	332,126	\$0.61
\$0.67	813,175	9.84 Years	\$0.67	271,058	\$0.67
\$0.74	298,507	9.92 Years	\$0.74	174,129	\$0.74
\$1.00	686,319	4.07 Years	\$1.00	343,160	\$1.00
\$4.00	75,000	9.97 Years	\$4.00	—	\$4.00
	4,841,566	7.91 Years	\$0.62	1,925,516	\$0.45

(G) Stock Warrants

In October and November 2006, the Company issued warrants to purchase 10,351,979 shares of common stock as part of the private placement offering. The warrants have an exercise price of \$0.74 and each warrant has a life of 5 years.

In addition, as part of the private placements, the Company issued warrants to purchase 2,874,831 shares of common stock to the placement agent, which is a company that is controlled by the Company's Chairman and CEO. The warrants have an exercise price of \$0.74. The fair value of the warrants totals \$4,555,457 and was determined by using the Black-Scholes model with the following assumptions: expected dividend yield of 0%; expected volatility of 79.4%; risk-free interest rate of 4.54% and an expected life of ten years. Since these warrants were granted as compensation in connection with an equity raise, the Company has treated these warrants as a direct offering cost. The result of the transaction has a \$0 net effect to equity. The warrants are fully vested and non-forfeitable.

On October 31, 2006, the loans payable to the Company's founder, President and CEO were converted into 4,995,633 shares of common stock and 2,497,817 warrants to purchase common stock. The warrants have an exercise price of \$0.74 and a life of 5 years. (See Note 4)

12,849,796 of the warrants are callable by Pipex in the event that Pipex's common stock trades at \$1.85 per share for 20 of 30 consecutive days. Accordingly, net proceeds of approximately \$9,500,000 may be realized by Pipex in the event that all of the warrants are exercised.

A summary of warrant activity for the years ended December 31, 2006 and 2005 is as follows:

	Number of Shares
Balance as December 31, 2005	—
Granted	15,724,627
Exercised	—
Forfeited	—
Balance as December 31, 2006	15,724,627

(H) Options and Warrants of Subsidiaries**(1) EPI**

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Notes to Consolidated Financial Statements

The following tables summarize all stock option and warrant grants to employees and non-employees of EPI as of December 31, 2006 and 2005, and the related changes during these periods is presented below.

	<u>Number of Options/Warrants</u>	<u>Weighted Average Exercise Price</u>
Stock Options/Warrants		
Balance at December 31, 2004	292,500	\$ 0.04
Granted	171,225	\$ 1.10
Exercised	—	\$ —
Forfeited	—	\$ —
	<u>463,725</u>	
Balance at December 31, 2005	463,725	\$ 0.43
Granted	—	\$ —
Exercised	—	\$ —
Forfeited	—	\$ —
	<u>463,725</u>	
Balance at December 31, 2006	463,725	\$ 0.43
	<u>257,479</u>	
Options exercisable at December 31, 2006	257,479	\$ 0.75
		<u>\$ —</u>
Weighted average fair value of options granted during 2005		\$ —

Of the total options granted, 86,254 are fully vested, exercisable and non-forfeitable. Of the 292,500 options granted, 262,500 were granted to a related party of which 56,254 are fully vested. See Note 9(A)

Of the total warrants granted, all 171,225 are fully vested, exercisable and non-forfeitable and 144,590 were issued to related parties.

The following table summarizes information about stock options/warrants for EPI at December 31, 2006:

Range of Exercise Price	Options/Warrants Outstanding			Options/Warrants Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.03	262,500	7.71 Years	\$0.03	56,254	\$0.03
\$0.10	30,000	7.76 Years	\$0.20	30,000	\$0.20
\$1.10	171,225	8.42 Years	\$1.10	171,225	\$1.10
	<u>463,725</u>	8.19 Years	\$0.43	<u>257,479</u>	\$0.75

(2) CD4

The following tables summarize all stock option grants to employees and non-employees of CD4 as of December 31, 2006 and 2005, and the related changes during these periods is presented below.

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Notes to Consolidated Financial Statements

	<u>Number of Options</u>	<u>Weighted Average Exercise Price</u>
Stock Options		
Balance at December 31, 2004	30,000	\$ 0.20
Granted	—	\$ —
Exercised	—	\$ —
Forfeited	—	\$ —
	<u>30,000</u>	
Balance at December 31, 2005	30,000	\$ 0.20
Granted	—	\$ —
Exercised	—	\$ —
Forfeited	—	\$ —
	<u>30,000</u>	
Balance at December 31, 2006	30,000	\$ 0.20
	<u>30,000</u>	<u>\$ 0.20</u>
Options exercisable at December 31, 2006	30,000	\$ 0.20
	<u>30,000</u>	<u>\$ 0.20</u>
Weighted average fair value of options granted during 2006		\$ —
	<u>30,000</u>	

Of the total options granted, all 30,000 are fully vested, exercisable and non-forfeitable and are issued to non-related parties.

The following table summarizes information about stock options for CD4 at December 31, 2006:

<u>Options Outstanding</u>				<u>Options Exercisable</u>	
<u>Range of Exercise Price</u>	<u>Number Outstanding</u>	<u>Weighted Average Remaining Contractual Life</u>	<u>Weighted Average Exercise Price</u>	<u>Number Exercisable</u>	<u>Weighted Average Exercise Price</u>
\$0.20	30,000	1.48 Years	\$0.20	30,000	\$0.20

(I) Non-Controlling Interest

Since the Company's majority owned subsidiaries have never been profitable and present negative equity, there has been no establishment of a positive non-controlling interest. Since this value cannot be presented as a deficit balance, the accompanying consolidated balance sheet reflects a \$0 balance.

Note 6 Commitments and Contingencies

(A) License Agreements

Since inception, the Company has entered into various option and license agreements for the use of patents and their corresponding applications. These agreements have been entered into with various educational institutions and hospitals. These agreements contain payment schedules or stated amounts due for (a) option and license fees, (b) expense reimbursements, and (c) achievement of success milestones. All expenses related to these agreements have been recorded as research and development. In connection with these agreements, the Company had approximately \$78,100 outstanding as accounts payable and \$181,400 outstanding as accrued liabilities, as of December 31, 2006.

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

In connection with these agreements, the Company may be obligated to make milestone payments up to an amount of \$6,675,000. Some of these payments may be fulfilled through the issuance of the Company's common stock, at the Company's option. There have been no such milestones achieved or

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Notes to Consolidated Financial Statements

payments made during the years ending December 31, 2006, 2005, and for the period from January 8, 2001 (inception) to December 31, 2006. At the present time, the Company can give no assurances that any such milestones will be achieved. In addition to the milestone payments, the Company may be obligated to make royalty payments on future sales pursuant to the agreements. The schedule below does not include the value of these commitments.

(B) Consulting Agreements

In August 2005, Pipex entered into an agreement with an individual to provide consulting services for the Company's research and development. The consultant was paid \$25,000 upon the execution of the agreement. The consultant will receive annual consulting fees of \$120,000 for each of the next three years. The consultant also received 200,000 options having a fair value \$59,960 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 200%, risk free interest rate of 1.81% and an expected life of 10 years.

In December 2006, Pipex entered into an agreement with a Company to provide consulting services relating to the Company's business management and development. The consultant will be paid \$16,666 per month over a six-month term. The consultant also received 298,507 stock options having a fair value of \$705,103, and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 93.09%, risk free interest rate of 4.43% and an expected life of 10 years.

(C) Employment Agreements

In January 2005, the Company entered into a four-year employment agreement with the Company's Chairman and Chief Executive Officer. Pursuant to this agreement, Pipex will pay an annual base salary of \$297,000, an annual bonus equal to 30% of base salary and a ten-year option to acquire 813,175 shares of common stock at the completion of the Company's private placement that occurred on October 31, 2006. As of December 31, 2006, 271,058 options have vested, with the remainder vesting annually over the next two years. The fair value of the options totaled \$568,491 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 200%, risk free interest rate of 4.61% and an expected life of 10 years.

The Company entered into an employment agreement with its President on May 24, 2006. Pursuant to this agreement, Pipex will pay an annual base salary of \$295,000 and a guaranteed bonus of one-third of base salary. Pipex has also granted a ten-year option to purchase 1,992,756 shares of common stock, of which 332,126 have vested as of December 31, 2006. The remainder of these options will vest quarterly over a three-year period. In event of a termination without just cause, Pipex will provide six months severance, payable over a six-month period.

The following schedule shows committed amounts due for license fees, patent cost reimbursements, sponsored research agreements, employment agreements and consulting fees as of December 31, 2006:

2007:	\$	1,546,000
2008:		1,325,163
2009:		758,333
2010:		95,000
2011:		95,000
Each Year Thereafter:		95,000
		<hr style="border-top: 1px solid black;"/>
Total:	\$	3,914,496
		<hr style="border-top: 1px solid black;"/>

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Notes to Consolidated Financial Statements

Note 7 Income Taxes

There was no income tax expense for the years ended December 31, 2006 and 2005 due to the Company's net losses.

The Company's tax expense differs from the "expected" tax expense for the years ended December 31, 2006 and 2005, (computed by applying the Federal Corporate tax rate of 34% to loss before taxes and 5.5% for State Corporate taxes, the blended rate used was 37.63%), as follows:

	<u>2006</u>	<u>2005</u>
Computed "expected" tax expense (benefit) — Federal	\$ (1,317,039)	\$ (435,632)
Computed "expected" tax expense (benefit) — State	(225,450)	(74,571)
Change in valuation allowance	1,542,489	510,203
	<u>\$ —</u>	<u>\$ —</u>

The effects of temporary differences that gave rise to significant portions of deferred tax assets at December 31, 2006 are as follows:

Deferred tax assets:		
Non-deductible stock based compensation	\$	(495,031)
Net operating loss carryforward		(2,448,806)
		<u>(2,943,837)</u>
Total gross deferred tax assets		(2,943,837)
Less valuation allowance		2,943,837
		<u>\$ —</u>

At December 31, 2006, the Company has a net operating loss carry-forward of \$6,507,590 available to offset future taxable income expiring 2026. Utilization of these net operating losses may be limited due to potential ownership changes under Section 382 of the Internal Revenue Code.

The valuation allowance at December 31, 2005 was \$1,401,348. The net change in valuation allowance during the year ended December 31, 2006 was an increase of \$1,542,489. In assessing the reliability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on consideration of these items, Management has determined that enough uncertainty exists relative to the realization of the deferred income tax asset balances to warrant the application of a full valuation allowance as of December 31, 2006.

Note 8 Related Party Transactions

During January 2001, Pipex sold approximately \$1.1 million of Series A Preferred Stock to a company controlled by our Chairman and Chief Executive Officer. From 2002 until October 2006, we relied on non-interest bearing bridge loans from a company controlled by our Chairman and Chief Executive Officer. During this 5-year period, the Chairman loaned us \$3,274,728 for no additional consideration. In connection with the private placement during October 2006, the Chairman agreed to convert these loans into units in the offering. As a result of the conversion of these loans, we issued 4,995,633 shares of common stock and 2,497,817 warrants to purchase common stock.

**Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)**

Notes to Consolidated Financial Statements

During January 2006, the Company entered into an agreement with an affiliate of one of the Company's directors to write an executive information report for a fee of \$35,000. As of December 31, 2006, the Company has paid \$17,500 for these services.

In connection with private placements in October and November 2006, we engaged a company that is controlled by our Chairman and Chief Executive Officer as our placement agent. At the closing of the private placement during October and November 2006, Pipex paid the placement agent the sum of \$1,033,800 as commissions for its services. The placement agent also received a warrant to purchase 2,874,831 shares of common stock. (See Note 5 (G)) Two of our directors and officers are representatives of the placement agent.

As part of the October 2006 private placement, the Company sold 297,310 shares of its common stock and 148,655 warrants to purchase common stock for total proceeds of \$200,000 to entities controlled by our President. As part of the same private placement, Pipex sold 148,655 shares of its common stock and 74,327 warrants to purchase common stock for total proceeds of \$100,000 to a related family member of our Chairman and CEO. The terms on which their purchases were made were identical to the terms in which the other investors in these offerings purchased shares.

Note 9 Subsequent Events

(A) Acquisition of EPI

On January 5, 2007, EPI merged with and into a wholly owned subsidiary of Pipex, Effective Acquisition Corp. In the transaction, Pipex issued 2,283,000 shares of common stock having a fair value of \$15,181,950 based upon the quoted closing trading price of \$6.65 per share. As consideration for the share issuance, EPI, exchanged its outstanding Series B, convertible preferred stock at 120% of total shares held prior to the exchange. Therefore, 1,902,500 shares of Series B, convertible preferred stock were equivalent to 2,283,000 shares for purposes of the exchange. The additional 951,250 shares of Series B dividends were cancelled and retired and were not contemplated in the exchange. The Company also cancelled and retired 3,000,000 shares of Series A, convertible preferred stock as well as 825,000 shares of common stock.

In connection with this exchange, and pursuant to EITF 98-3, "*Determining whether a Non-Monetary Transaction involves the receipt of Productive Assets or of a Business*" EPI was classified as a development stage company and thus was not considered a business. As a result, SFAS No. 141 purchase accounting rules did not apply. Additionally, the Company applied the provisions of EITF 86-32, "*Early Extinguishment of a Subsidiary's Mandatorily Redeemable Preferred Stock*" and has determined that even though the preferred stock of EPI was not mandatorily redeemable, this transaction would be considered a capital transaction, and there would be no resulting gain or loss.

Finally, in connection with EITF Topic D-42, "*The Effect on the Calculation of Earnings Per Share for the Redemption or Induced Conversion of Preferred Stock*", The Company has determined that the fair value of the consideration transferred to the holders of EPI Series B, convertible preferred stock over the carrying amount of the preferred stock represents a return to the preferred stockholders. The difference is \$12,328,200, which is included as a component of paid in-kind dividends. At the Company's next reporting period, this difference will be treated as an additional reduction in net loss applicable to common shareholders for purposes of computing loss per share.

The Company granted an aggregate 463,725 options and warrants in a one for one exchange for the outstanding options and warrants with EPI option and warrant holders. These new options and warrants will continue to vest according to their original terms. Pursuant to SFAS No. 123R and fair value accounting, the Company treated the exchange as a modification of an award of equity

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Notes to Consolidated Financial Statements

instruments. As such, incremental compensation cost shall be measured as the excess of the fair value of the replacement award over the fair value of the cancelled award at the cancellation date. In substance, Pipex repurchased the EPI instruments by issuing a new instrument of equal or greater value.

The Company has used the following weighted average assumptions for the fair value of the replacement award:

Expected dividends	0%
Expected volatility	196.10%
Expected life	7-8 years
Risk free interest rate	4.65%
Exercise prices ranged from	\$0.033 - \$1.10

The Company has used the following weighted average assumptions for the fair value of the cancelled award at the cancellation date:

Expected dividends	0%
Expected volatility	200.00%
Expected life	7-8 years
Risk free interest rate	4.65%
Exercise prices ranged from	\$0.033 - \$1.10

The fair value of the replacement award required an incremental increase in compensation expense of approximately \$300.

(B) Stock Option Grants

During January and February 2007, the Company issued 610,000 stock options to new-hire employees, board directors and a consultant having a fair value of \$1,287,244. The Company used the following weighted average assumptions:

Expected dividends	0%
Expected volatility	103.29% - 195.16%
Expected life	5-10 years
Risk free interest rate	4.66% - 4.90%
Exercise prices ranged from	\$1.29 - \$7.50

(C) Employment Agreements

During January and February 2007, the Company entered into six separate employment agreements. Pursuant to the terms of the agreements, these employees are paid annual salaries and were issued a total of 310,000 stock options. These options have been included as a component of the aggregate 610,000 options in Note 9(B). Of the total, 150,000 options were granted to board directors.

(D) Consulting Agreement

On February 15, 2007, the Company executed an agreement with an unrelated third party to provide certain services. Pursuant to the terms of the agreement, the Company will pay \$9,000 per month for a period of twelve months and grant 300,000 stock options with a cashless exercise provision. These options vest upon various milestones as well as over the life of the contract.

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)

Notes to Consolidated Financial Statements

(E) Option Agreement

On January 2, 2007, the Company entered into an option agreement for licensing a new drug candidate. Pursuant to the terms of the agreement, the Company paid \$50,000 as a non-refundable fee that gave the Company an exclusive six-month option period in which the Company can enter into a definitive license agreement. If upon executing a definitive license agreement, the Company will be required to pay certain milestones such as cash for royalties, reimbursement for previously incurred patent expenses and stock options.

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

There have been no disagreements on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure with our independent auditors for the period ended December 31, 2006.

ITEM 8A. CONTROLS AND PROCEDURES

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the Company's reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms and that such information is accumulated and communicated to the Company's management, including its Chief Executive Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Commission Rule 13a-15(b), the company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the year covered by this Report. Based on the foregoing, the Company's Chief Executive Officer concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in the Company's internal control over financial reporting during the Company's most recent fiscal year that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company is not an "accelerated filer" for the 2006 fiscal year because it is qualified as a "small business issuer". Hence, under current law, the internal controls certification and attestation requirements of Section 404 of the Sarbanes-Oxley act will not apply to the Company.

ITEM 8B. OTHER INFORMATION

Not applicable.

PART III

ITEM 9. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Below is certain information regarding our directors and executive officers. The following table states who are our directors and officers, as well as biographical information regarding our directors and management.

Name	Age	Position
Steve H. Kanzer, CPA, Esq.	43	Chairman and Chief Executive Officer
Charles L. Bisgaier, Ph.D.	53	President and Director
Jeffrey J. Kraws	42	Director
A. Joseph Rudick, M.D.	50	Chief Medical Officer and Director
Nicholas Stergis, M.S.	32	Vice Chairman and Director
John S. Althaus, M.S., M.B.A.	53	Vice President, Advanced Technology
Jeff Wolf, Esq.	43	Director
Daniel J. Dorman	44	Director
James S. Kuo, M.D., M.B.A.	42	Director

Steve H. Kanzer, CPA, Esq.

Mr. Kanzer, 43, is our co-founder and has served as President since our inception in February 2001 until May 2006. In September 2004, Mr. Kanzer assumed the additional roles of Chairman and Chief Executive Officer and serves on a full-time basis at our corporate headquarters in Ann Arbor, Michigan. Mr. Kanzer has also been a director and officer of our subsidiaries, including Solovax, Inc., Effective Pharmaceuticals, Inc., Putney Drug Corp. and CD4 Biosciences, Inc. Since December 2000, he has served as co-founder and Chairman of Accredited Ventures Inc. and Accredited Equities Inc., a venture capital firm and NASD-member investment bank, respectively, which both specialize in the biotechnology industry. Mr. Kanzer was co-founder, Chairman, President and Chief Executive Officer of Developmental Therapeutics, Inc., a cardiovascular drug development company which was developing an oral thyroid hormone analog, DITPA, for congestive heart failure. Developmental Therapeutics was acquired in October 2003 by Titan Pharmaceuticals, Inc., a publicly traded biopharmaceutical company. Prior to founding Accredited Ventures and Accredited Equities in December 2000, Mr. Kanzer served as Senior Managing Director-Head of Venture Capital at Paramount Capital from 1991 until December 2000. While at Paramount Capital, Mr. Kanzer was involved in the formation and financing of a number of biotechnology companies and held various positions in these companies. From 1995 through 1999, Mr. Kanzer was founding Chairman of the Board of Discovery Laboratories, Inc., a public biotechnology company that has a pending NDA for a drug called SURFAXIN[®] which Mr. Kanzer licensed in 1995. From 1997 until 2000, Mr. Kanzer was founding President of PolaRx Biopharmaceuticals, Inc., a biopharmaceutical company that licensed and developed TRISENOX[®] (arsenic trioxide), a leukemia drug that was approved by the FDA in 2000 and which currently holds the FDA record for fastest drug ever developed from IND filing until NDA approval (30 months). PolaRx was merged with Cell Therapeutics Inc. (NASDAQ:CTIC) in January 2000, and Cephalon acquired the rights to TRISENOX[®] in 2005 for \$165 million. Since 1996, Mr. Kanzer has served as a member of the board of directors of DOR BioPharma, Inc., a public biotechnology company that has a pending NDA for orBec[®] (oral beclomethasone dipropionate), a drug that Mr. Kanzer licensed in 1997. Mr. Kanzer currently serves as non-executive Vice Chairman of the Board of DOR and also served as Interim President from June 2002 until January 2003. In March 1998, Mr. Kanzer led the privatization of the Institute for Drug Research Kft. (IDR) in Budapest, Hungary, a 400-employee, 26 acre pharmaceutical research and development center. Since 1950, IDR operated as the central pharmaceutical R&D center for the country of Hungary, served the active pharmaceutical ingredients (API) needs of Eastern Europe, and performed original drug discovery research, resulting in the registration of over 80 API products. Mr. Kanzer served as Chief Executive Officer of IDR from March 1998 and led the sale of IDR to IVAX Corporation in October 1999. Mr.

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

Kanzer has also been a co-founder and director of 23 biotechnology companies, including Avigen, Inc., XTLBio, Boston Life Sciences, Inc. and Titan Pharmaceuticals, Inc., all publicly traded companies. Prior to joining Paramount Capital in 1992, Mr. Kanzer was an attorney at the law firm of Skadden, Arps, Slate, Meagher & Flom in New York where he specialized in mergers and acquisitions. Mr. Kanzer received his J.D. from New York University School of Law in 1988 and a B.B.A. in Accounting from Baruch College in 1985, where he was a Baruch Scholar. Mr. Kanzer is active in university-based pharmaceutical technology licensing and has served as Co-Chair of the New York Chapter of the Licensing Executives Society.

Charles L. Bisgaier, Ph.D.

Dr. Bisgaier, 53, is our President and a director. Prior to joining Pipex, Dr. Bisgaier was the Senior Director of Pharmacology at Esperion Therapeutics, a Division of Pfizer Global Research and Development in Ann Arbor, Michigan. In 1998, Dr. Bisgaier co-founded Esperion Therapeutics and served as the Vice President of Pharmacology. At Esperion he played an active role in the discovery, pre-clinical or clinical development of product candidates, including ETC-216 (ApoA-IMilano), ETC-588, ETC-642 and small molecule lipid regulators, that may have utility for the treatment and prevention of cardiovascular diseases. ETC-216 was the first agent every to show rapid regression of artery plaques in humans. In 2004, Esperion Therapeutics was acquired by Pfizer for \$1.3 billion.

Prior to Esperion Therapeutics, Dr. Bisgaier was an Associate Research Fellow in the Department of Vascular and Cardiac Disease at Warner-Lambert/Parke-Davis, where he played a role in discovery and development of pharmaceuticals that modulate lipoprotein and cholesterol metabolism. There he participated in the discovery and development of pharmaceutical agents including Gemfibrozil (Lopid®), Atorvastatin calcium (Lipitor®), Avasimibe and Gemcabene. He also lead the discovery efforts for lipid regulating agents including cholesteryl ester transfer protein inhibitors, fatty acid mimetics and cholesterol esterase inhibitors. He has carried out basic research on HDL and its associated proteins including studies on apolipoprotein synthesis, paraoxonase, oxidation, and cholesteryl ester transfer protein function.

He has published over 70 peer reviewed articles and reviews and is a named inventor on numerous patents and patent applications. He currently holds an adjunct position in Pharmacology at the University of Michigan. He is also the Editor-in-Chief of Current Medicinal Chemistry Immunology, Endocrine and Metabolic Agents. Dr. Bisgaier serves as a member of the Michigan Society of Medical Research Board as well as the ProNAI Therapeutics Scientific Board (Kalamazoo, MI).

Dr. Bisgaier received a B.A. (1974) in Biology from the State University College at Oneonta, NY, and a M.S. (1977) and Ph.D. (1981) in Biochemistry from George Washington University. Following his doctorate, he studied lipoprotein metabolism within a Specialized Center of Research (SCOR) for atherosclerosis at Columbia University College of Physicians and Surgeons prior to joining Warner-Lambert/Parke-Davis in 1990.

Jeffrey J. Kraws

Mr. Kraws, 42, is a director of Pipex. Mr. Kraws is Chief Executive Officer and co-founder of Crystal Research Associates. Well known and respected on Wall Street, Mr. Kraws has received some of the most prestigious awards in the industry. Among other awards, he was given a "5-Star Rating" in 2001 by Zacks and was ranked the number one analyst among all pharmaceutical analysts for stock performance in 2001 by Starmine.com. Prior to founding Crystal Research Associates, Mr. Kraws served as co-president of The Investor Relations Group (IRG), a firm representing primarily under-followed, small-capitalization companies. Previously, Mr. Kraws served as a managing director of healthcare research for Ryan Beck & Co. and as director of research/senior pharmaceutical analyst and managing director at Gruntal & Co., LLC (prior to its merger with Ryan Beck & Company). Mr. Kraws served as managing director of the healthcare research group and senior pharmaceutical analyst at First Union Securities (formerly EVEREN Securities); as senior U.S. pharmaceutical analyst for the Swedish-Swiss conglomerate Asea Brown Boveri; and as managing director and president of the Brokerage/Investment Banking operation of ABB Aros Securities, Inc. He also served as senior

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

pharmaceutical analyst at Nationsbank Montgomery Securities, BT Alex Brown & Sons, and Buckingham Research. Mr. Kraws also has industry experience, having been responsible for competitive analysis within the treasury group at Bristol-Myers-Squibb Company. He holds an MBA from Cornell University and a B.S. degree from State University of New York-Buffalo. During 2006, Mr. Kraws served as our Vice President of Business Development, on a part-time basis. Mr. Kraws only devotes a portion of his time to our business.

A. Joseph Rudick, M.D.

Dr. Rudick, 50, was appointed to the board of directors of Pipex during December 2004. Dr. Rudick currently serves as our Chief Medical Officer and is president and chief medical officer of our subsidiary Effective Pharmaceuticals, Inc.

Dr. Rudick was Chief Executive Officer and President of Atlantic Technology Ventures, Inc. (Atlantic), a public drug-development company, as well as a member of its board of directors from May 1999 until its merger with Manhattan Pharmaceuticals, Inc. in February 2003. He was also a founder of Atlantic and two of its majority-owned subsidiaries, Optex Ophthalmologics, Inc. and Channel Therapeutics, Inc. During his tenure at Atlantic, he structured a corporate partnership with Bausch & Lomb for development of Atlantic's novel cataract removal device, named Catarex™, as well as a partnership with Indevus Pharmaceuticals, Inc. for development of their novel clinical-stage neuropathic pain compound, now known as IP-571. From 1994 to 2001, Dr. Rudick was a vice president of Paramount Capital, Inc., an investment bank specializing in the biotechnology and biopharmaceutical industries, where he participated in numerous private equity financings.

Since 1988, he has been a partner of Associate Ophthalmologists P.C., a private ophthalmology practice located in New York, and from 1993 to 1998 he served as a director of Healthdesk Corporation, a publicly traded medical information company of which he was a co-founder. Dr. Rudick earned a B.A. in Chemistry, with the distinction of Phi Beta Kappa, from Williams College and a Doctorate of Medicine, with the distinction of Alpha Omega Alpha, from the University of Pennsylvania. Dr. Rudick is also a registered representative of Accredited Equities Inc.

John S. Althaus, M.S., M.B.A.

Mr. Althaus, 53, currently serves as the Vice President, Advanced Technology for Pipex. Mr. Althaus' professional career spans 30 + years of scientific research and development in academia and industry and business development in industry. His industry experience includes employment in pharmaceutical, biotechnology and medical device businesses. Mr. Althaus was a faculty research associate at the University of Virginia, Department of Anesthesiology, where he investigated the impact of anesthesia on neurotransmitter mechanisms in peripheral and central nervous systems. While at Pharmacia & Upjohn and the Upjohn Companies, Mr. Althaus became an expert in free-radical-dependent drug therapies in the treatment of neurological diseases and traumatic brain injury. He was a member of the discovery, research and development team that produced the drug Mirapex, a treatment for Parkinson's disease. He was also a member of the discovery, research and development team that produced the drug Freedox, a treatment for brain hemorrhage. Mr. Althaus presented lectures nationally and internationally as the scientific liaison for marketing regarding the promotion of Freedox.

While at Parke-Davis/Pfizer, Mr. Althaus designed, built and managed a bioanalytical research laboratory. The goal of the laboratory was the discovery, development and use of biomarkers to evaluate drug efficacy in clinical trials. Tyrosine nitration and halogenation as biomarkers of disease-dependent free radical injury were found to be diagnostic in atherosclerosis, Parkinson's disease and broncopulmonary dysplasia. Mr. Althaus next joined HandyLab, Inc., a microfluidic biotechnology company that manufactures DNA diagnostic medical devices. Mr. Althaus was the main author and principal investigator of a \$2 million NIST ATP grant to develop and commercialize electrochemical detection of DNA diagnostic medical devices.

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

Prior to his position with Pipex, Mr. Althaus was the founder of Holomics, Inc., a diagnostic device company. In addition, he was also the President of General Fiber, a biotechnology company that develops innovative fibers to address unmet health needs. Mr. Althaus is a co-inventor on eight patents and patent applications and a co-author on 52 peer-reviewed publications. Mr. Althaus received his MS in biochemistry from the University of Maryland and his MBA in general studies from Western Michigan University.

Nicholas Stergis, M.S.

Mr. Stergis, 32, is our co-founder, and Vice Chairman of our board of directors. Mr. Stergis has served as our Chief Operating Officer from our founding during 2001 until March 2007. Prior to co-founding Pipex, Mr. Stergis was a co-founder, Chief Operating Officer and director of Developmental Therapeutics, Inc., a cardiovascular drug development company, until its acquisition in October 2003 by Titan Pharmaceuticals, Inc. (AMEX: TTP), a publicly-traded pharmaceutical company.

Mr. Stergis is also a co-founder and Managing Director of Accredited Ventures Inc., a venture capital firm specializing in the biotechnology and pharmaceutical industries. Mr. Stergis is also Managing Director of Accredited Equities, Inc., a NASD member firm. Prior to co-founding Accredited Ventures, Mr. Stergis was the Interim Director of Corporate Development for Corporate Technology Development, Inc. (CTD), a biopharmaceutical company based in Miami, Florida, until its merger with DOR BioPharma, Inc. (DOR), a publicly traded biotechnology company. During his tenure at CTD, he was responsible for all development tasks associated with the company's lead product, orBe®, which has completed a pivotal Phase III clinical trial and is pending NDA and MAA approval. He was also instrumental in CTD's divestiture of important botulinum toxin intellectual property to Allergan, Inc. (NYSE:AGN), a publicly traded specialty pharmaceutical companies. Prior to joining CTD, Mr. Stergis was a Technology Associate at Paramount Capital, a New York based private equity, venture capital, investment banking and asset management group specializing in the biotechnology and pharmaceutical industries. There, he participated in the startup, acquisition and financing of various biotechnology companies, including CTD. Mr. Stergis received his M.S. in Biology from New York University as well as a B.S. in Biology from the University at Albany, State University of New York. Mr. Stergis is also a director and interim officer of several privately held biopharmaceutical companies such as General Fiber, Inc. which are engaged in the in-licensing of biopharmaceutical candidates. As such, Mr. Stergis devotes a portion of his time to the business of the company.

Jeffrey Wolf, Esq.

Mr. Wolf, 43, currently serves as one of the directors of Pipex. Mr. Wolf has substantial experience in creating, financing, nurturing and growing new ventures based upon breakthrough research and technology. Mr. Wolf is the founding partner of Seed-One Ventures, LLC, a venture capital group focused on seed-stage technology-based investments. Mr. Wolf has been a founder of Elusys Therapeutics, Inc., an antibody-based therapeutic company, Tyrx Pharma, Inc., a biopolymer-based company, Sensatex, Inc., a medical device company and Generation Mobile, Inc. a telecommunications company. Prior to founding Seed-One Ventures, Mr. Wolf served as the Managing Director of The Castle Group, Ltd., a biomedical venture capital firm. At both organizations, Mr. Wolf was responsible for supervising the formation and funding of new technology, biomedical, and service oriented ventures. Mr. Wolf currently sits on the board of Elusys Therapeutics and Netli, Inc. Mr. Wolf received his MBA from Stanford Business School, his JD from New York University School of Law and his BA with honors in Economics from the University of Chicago.

Daniel J. Dorman

Mr. Dorman, 44, was appointed to our board of directors on February 20, 2007. Mr. Dorman is the President of D. J. Dorman & Co., Inc. and its predecessor companies since 1989. D. J. Dorman & Co., Inc. originates, structures, acquires and manages investments in private equity and buyout opportunities on behalf of several entities. Mr. Dorman is also Chairman and CEO of Dorman

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

Industries, LLC which is a privately owned multi-industry holding company. Additionally, Mr. Dorman is a director of Kux Manufacturing Company, Inc., an architectural engineering and manufacturing company; Chairman of Kroll International, LLC, a wholesaler of law enforcement, homeland defense and public safety equipment; Chairman of Versatile Processing Group, Inc., a holding company for various non-ferrous metal processing and utility service companies serving the industrial and electric utility industries and a director of an international private equity fund, AFA Private Equity Fund I. Mr. Dorman is a graduate of Ferris State University where he holds a Bachelor in Business Administration.

James S. Kuo, M.D., M.B.A.

Dr. Kuo, 42, was appointed to our board of directors on February 20, 2007. Dr. Kuo is the President and Chief Executive Officer of Cysteine Pharma, Inc. From 2003 to 2006, he served as founder, Chairman and Chief Executive Officer of BioMicro Systems, Inc. a private venture-backed, microfluidics company. From 2001 to 2002, he served as President and Chief Executive Officer of Microbiotix, Inc., a private, anti-infectives drug development company. Prior to that time, Dr. Kuo was co-founder, President and Chief Executive Officer of Discovery Laboratories, Inc. where he raised over \$22 million in initial private funding and took the company public. He has held senior licensing and business development positions at Pfizer, Inc., and Myriad Genetics, Inc. Dr. Kuo has also been the Managing Director of Venture Analysis at HealthCare Ventures, LLC and Vice President at Paramount Capital Investments, LLC. Dr. Kuo is further a founder of ArgiNOx Pharmaceuticals, Inc., and Monarch Labs. LLC., and is non-executive Chairman of DOR BioPharma, Inc., a publicly traded pharmaceutical company. Dr. Kuo simultaneously received his M.D. from the University of Pennsylvania School of Medicine and his M.B.A. from the Wharton School of Business.

Our directors are paid \$2,000 per board meeting that they attend in person, \$1,000 per telephonic board meeting and \$500 per committee meeting.

We also reimburse our directors for travel and other out-of-pocket expenses incurred in attending board of director or committee meeting.

Directors' Term of Office

Directors will hold office until the next annual meeting of shareholders and the election and qualification of their successors. Officers are elected annually by our board of directors and serve at the discretion of the board of directors.

Audit Committee and Audit Committee Financial Expert

The audit committee is comprised of Jeff Wolf and Dr. James Kuo. The audit committee is responsible for recommending the Company's independent public accounting firm and reviewing management's actions in matters relating to audit functions. The Committee reviews with the Company's independent public accountants the scope and results of its audit engagement and the Company's system of internal controls and procedures. The Committee also reviews the effectiveness of procedures intended to prevent violations of laws. The Committee also reviews, prior to publication, our reports on Form 10-KSB and Form 10-QSB. Our board has determined that all audit committee members are independent under applicable SEC regulations. Our board of directors has determined that Dr. Kuo qualifies as an "audit committee financial expert" as that term is used in Section 407 of the Sarbanes-Oxley Act of 2002.

To date, we have conducted research and development operations and generated no revenue since inception. In light of the foregoing, and upon evaluating our internal controls, our board of directors determined that our internal controls are adequate to insure that financial information is recorded, processed, summarized and reported in a timely and accurate manner in accordance with applicable rules and regulations of the SEC.

Our Compensation Committee consists of Daniel Dorman and Jeff Wolf. Our Nominating Committee consists of Jeff Wolf and Dr. James Kuo. These committees perform several functions, including

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

reviewing all forms of compensation provided to our executive officers, directors, consultants and employees, including stock compensation, and recommending appointments to the board and appointment of executive officers.

ITEM 10. EXECUTIVE COMPENSATION

The following table discloses the total compensation we paid to principal executive officer and two other most highly compensated executive officers in our 2006 and 2005 fiscal years.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Annual Compensation			All Other Annual Compensation	Total
		Salary(\$)	Bonus(\$)	Option Awards (1)		
Steve H. Kanzer, CPA, Esq. Chairman & Chief Executive Officer	2006	0	0	\$ 568,491	0	\$ 568,491
	2005	0	0	0	0	0
Charles Bisgaier, Ph.D. President	2006	\$ 170,192	0	\$ 545,804	0	\$ 715,996
	2005	0	0	0	0	0
A. Joseph Rudick, M.D. Chief Medical Officer	2006	\$ 175,000	0	0	0	\$ 175,000
	2005	\$ 116,666	\$ 25,000	0	0	\$ 141,666

(1) The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model. The weighted average assumptions used for the valuation of these option awards are as follows: Expected dividends 0%; Expected volatility 200%; Risk free interest rate ranging from 4.57% - 4.99%; Expected life of options ranging from 3 to 10 years. The assumptions are also disclosed in Note 5 in the Notes to the Consolidated Financial Statements for the Year ended December 31, 2006 included in this report.

The following table contains information relating to grants of stock options made during the fiscal year ended December 31, 2006, to our senior executive officers. No stock options were exercised by our senior executive officers during the last fiscal year.

OPTION/SAR GRANTS IN LAST FISCAL YEAR

Name and Principal Position	Number of securities underlying options/SARs granted (#)	Percent of total options/SARs granted to employees in fiscal year	Exercise Price (\$/Sh)	Expiration date
Steve H. Kanzer, CPA, Esq. Chairman & Chief Executive Officer	813,175	18.68%	\$.67	11/21/2016
Charles Bisgaier, Ph.D. President	1,992,756(1)	45.77%	\$.61	5/30/2016
A. Joseph Rudick, M.D. Chief Medical Officer	0	0	0	0
John Althaus, M.S. Vice President, Advanced Technology	162,635(1)	3.74%	\$.06	2/6/2010
Jeffrey Kraws Director	686,320(1)	15.76%	\$.03	1/26/2010

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

(1) These options were issued by Pipex Therapeutics during the last fiscal year and exchanged on October 31, 2006 for options of Pipex Pharmaceuticals in connection with the merger of Pipex Therapeutics and a subsidiary of Pipex Pharmaceuticals.

The following table discloses information regarding outstanding equity awards as of December 31, 2006 for each of our senior executive officers.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

Name and Principal Position	Number of Securities Underlying Unexercised Options/Exercisable (1)	Number of Securities Underlying Unexercised Options/Unexercisable (1)	Option Exercise Price	Option Expiration date
Steve H. Kanzer Chairman & Chief Executive Officer	271,058	542,117	\$.67	11/21/2016
Charles Bisgaier, Ph.D. President	332,126	1,660,630	\$.61	5/30/2016
A. Joseph Rudick, M.D. Chief Medical Officer, President of EPI	0	0	—	—
John Althaus, M.S. Vice President, Advanced Technology	40,659	121,976	\$.06	2/16/2010

(1) These options were issued during 2006 by Pipex Therapeutics and exchanged on October 31, 2006 for options of Pipex Pharmaceuticals in connection with the merger of Pipex Therapeutics and a subsidiary of Pipex Pharmaceuticals.

Employment Agreements

Pipex entered into an employment agreement with Dr. Charles L. Bisgaier on May 24, 2006. Pursuant to this agreement, Pipex will pay Dr. Bisgaier an annual base salary of \$295,000 and a guaranteed bonus of one-third of his base salary. Pipex has also granted Dr. Bisgaier a ten year option to purchase 1,992,756 shares of common stock, of which 332,126 have already vested. The remainder of this option will vest quarterly over a three year period. In event of a termination without just cause, Pipex will provide Dr. Bisgaier with six months severance, payable over a six month period.

During January 2006, Pipex has entered into an employment letter agreement with Jeffrey Kraws, a director to serve as Vice President of Business Development, pursuant to which we will pay him an annual base salary of \$75,000 following the closing of a financing and have granted him an option to purchase 686,320 shares of common stock, at an exercise price of \$0.03 per share, with 343,160 vested upon execution of his employment agreement and the remainder vesting annually over three years. During March 2007, we entered into an amended agreement with Mr. Kraws whereby he forgo any cash compensation and continue as a director in exchange for 114,386 options vesting. As of the date of this report, we have not paid Mr. Kraws under this agreement.

Pursuant to an employment letter agreement, our majority-owned subsidiary, EPI agreed to pay Dr. Rudick \$175,000 per annum, pay life and disability insurance on behalf of Dr. Rudick and he received an option to purchase 262,500 shares of EPI common stock. Following the acquisition of EPI, Dr. Rudick agreed to reduce his annual base salary to \$95,000 per annum, forgo any life or disability reimbursement from the Company and agree to cancel an unvested option to purchase 294,071 shares of our common stock. During March 2007, Dr. Rudick was appointed as President & Chief Medical

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

Officer of Pipex Neurosciences Inc., a majority owned subsidiary in which Dr. Rudick will receive five percent equity ownership.

In January 2005, we entered into a four year employment agreement with Steve H. Kanzer to serve as our Chairman and Chief Executive Officer. We agreed to pay him an annual base salary of \$297,000, an annual bonus equal to 30% of his base salary and issue him a ten-year option to acquire 813,175 shares of our common stock, vesting annually over a three year period commencing at the completion of our private placement financing. As of the date of this report, we have not paid Mr. Kanzer.

During November 2005, we entered into an employment agreement as amended with John Althaus, MS, our Vice President of Advanced Technology. We currently pay Mr. Althaus \$100,000 per year and we issued him 162,635 options to acquire our common stock.

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

The following table sets forth certain information regarding beneficial ownership of our common stock and warrants to purchase shares of common stock as of February 6, 2007 by (i) each person (or group of affiliated persons) who is known by us to own more than five percent of the outstanding shares of our common stock, (ii) each director and executive officer, and (iii) all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. The principal address of each of the stockholders listed below except as indicated is c/o Pipex Pharmaceuticals, Inc., 3985 Research Park Drive, Ann Arbor, MI 48108. We believe that all persons named in the table have sole voting and investment power with respect to shares beneficially owned by them. All share ownership figures include shares issuable upon exercise of options or warrants exercisable within 60 days of February 6, 2006, which are deemed outstanding and beneficially owned by such person for purposes of computing his or her percentage ownership, but not for purposes of computing the percentage ownership of any other person.

Principal Stockholders Table

Name of Owner	Shares Owned	Percentage of Shares Outstanding
Accredited Venture Capital, LLC	23,756,955(1)	44.42%
Steve H. Kanzer	25,172,274(2)	45.84%
Ridgeback Capital Investment Ltd.	5,569,686(3)	10.54%
Firebird Capital	4,459,648(4)	8.5%
Nicholas Stergis	5,105,131(5)	9.81%
Charles Bisgaier, Ph.D.	778,091(6)	1.60%
Jeffrey J. Kraws	457,547(7)	*
A. Joseph Rudick, M.D.	569,375(8)	1.11%
Jeffrey Wolf, Esq.	75,000(9)	*
Daniel J. Dorman	2,358,574(10)	4.55%
James S. Kuo	75,000(11)	*
All officers and directors as a group (8 persons)	34,590,992	58.74%

* represents less than 1% of our common stock

(1) Consists of 21,259,138 shares of common stock,, warrants to purchase 2,497,817 shares of common stock.

(2) Consists of the 21,259,138 shares of common stock and 2,497,817 warrants, registered in the name of Accredited Venture Capital, LLC, and 195,238 common shares, 1,039,255 warrants to purchase

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

common stock and 180,826 options to purchase common stock held directly by Mr. Kanzer. Pharmainvestors, LLC is the managing member of Accredited Venture Capital, LLC. Mr. Kanzer is the managing member of Pharmainvestors, LLC. As such, Mr. Kanzer may be considered to have control over the voting and disposition of the shares registered in the name of Accredited Venture Capital, LLC. Mr. Kanzer disclaims beneficial ownership of those shares, except to the extent of his pecuniary interest. Excludes 542,477 options that will vest annually over two years.

(3) Consists of 3,713,129 of shares of common stock and 1,856,564 warrants to purchase common stock issued to Ridgeback Capital Investment Ltd. Ridgeback Capital Investment Ltd.'s address is 430 Park Avenue, 12th Floor, New York, New York 10022.

(4) Consists of 1,486,549 of shares of common stock and 743,275 warrants to purchase common stock issued to Firebird Global Master Fund, Ltd and 1,486,549 of shares of common stock and 743,275 warrants to purchase common stock issued to Firebird Global Master Fund II, Ltd. Firebird's address is 152 West 57th Street, 24th Floor, New York, New York 10019.

(5) Consists of 4,065,876 shares of common stock, and a warrant to purchase 1,039,255 shares of common stock, issued to Mr. Stergis. Mr. Stergis's business address is 801 Brickell Avenue, 9th Floor, Miami, Florida 33131.

(6) Consists of 332,126 vested options to purchase common stock, 148,655 shares of common stock and 74,327 warrants to purchase common stock issued to Bisgaier Family LLC, a company of which Dr. Bisgaier is the managing member; 148,655 shares of common stock and 74,327 warrants to purchase common stock issued to two trusts for which Dr. Bisgaier has control of. Excludes 1,660,618 unvested options to purchase common stock vesting over three years.

(7) Assumes the exercise of a vested option to purchase 343,160 shares of our common stock. This option is exercisable within 60 days of the date of this filing. Excludes an unvested option to purchase 228,773 shares of common stock which will vest annually over two years. Mr. Kraw's business address is 800 Third Avenue, 17th Fl., New York, NY 10022.

(8) Consists of 90,483 shares of common stock, an option to purchase 149,180 shares of common stock and a warrant to purchase 329,712 shares of common stock. Dr. Rudick's business address is 150 Broadway, Suite 1800, New York, NY 10128.

(9) Assumes the exercise of an option to purchase 75,000 shares of our common stock. Mr. Wolf's business address is c/o Seed-One Ventures, LLC, 1205 Lincoln Road, Suite 216, Miami Beach, Florida 33139.

(10) Consists of 37,131 shares of common stock registered in the name of Red Metal Capital, LLC, of which Mr. Dorman is the Managing Member, 1,485,251 shares of common stock registered in the name of AFA Private Equity Fund I, of which Mr. Dorman is a partner, 18,566 warrants to purchase common stock registered in the name of Red Metal Capital, LLC, 742,626 warrants to purchase common stock registered in the name of AFA Private Equity Fund I, and 75,000 options to purchase common stock held directly by Mr. Dorman.

(11) Consists of 75,000 options to purchase common stock.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

During January 2001, we sold approximately \$1.1 million of Series A Preferred Stock to Accredited Venture Capital, LLC, a company controlled by Steve H. Kanzer, our Chairman and Chief Executive Officer. From 2002 until October 2006, we relied on non-interest bearing bridge loans from Accredited Ventures, Inc. (AVI), a company controlled Steve H. Kanzer, our Chairman and Chief Executive Officer and the managing member of our largest stockholder, Accredited Venture Capital, LLC. During this 5 year period, AVI loaned us \$3,363,494 for no additional consideration. In connection with the private placement during October 2006, AVI agreed to convert these loans into units in the offering. As a result of the conversion of these loans, we issued 4,995,634 million shares of common

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

stock and 2,497,817 warrants to purchase common stock. In the merger, all shares of preferred stock were converted into common stock of the Registrant.

In connection with a private placement in October and November 2006, we engaged Accredited Equities Inc. (AEI), a company controlled by Steve H. Kanzer, our Chairman and Chief Executive Officer as our placement agent. At the closing of our private placement during October and November 2006, we paid AEI the sum of approximately \$639,844 as commissions for its services and the selected dealer was paid a cash fee of \$327,950. AEI also received a non-accountable expense allowance of \$75,000 and a warrant to purchase 2,874,831 shares of common stock. Dr. Joseph Rudick, our director, Chief Medical Officer is a registered representative of AEI. Mr. Nicholas Stergis, our co-founder and Chief Operating Officer, is the managing director of AEI and AVI.

As part of the October 2006 private placement, Pipex sold 297,310 shares of its common stock and 148,655 warrants to purchase common stock for total proceeds of \$200,000 to entities controlled by Dr. Charles Bisgaier, our President. As part of the same private placement, Pipex sold 148,655 shares of its common stock and 74,327 warrants to purchase common stock for total proceeds of \$100,000 to the father of our Chairman and CEO. The terms on which their purchases were made were identical to the terms in which the other investors in these offerings purchased shares.

In connection with our acquisition of Effective Pharmaceuticals Inc. (EPI), Accredited Venture Capital, LLC and Mr. Stergis, both directors of Pipex contributed their 65.47% equity ownership in EPI to Pipex for no additional consideration. During 2005, EPI paid \$152,200 to AEI for placement agent services rendered in connection with the issuance of its Series B preferred stock. EPI also issued a warrant to purchase 171,225 shares of common stock to designees of AEI, including Mr. Kanzer, Dr. Rudick and Mr. Stergis, all members of our board of directors. During March 2005, EPI repaid AVI for loans totaling \$200,000 and AVI agreed to defer repayment of loans totaling \$513,886 until the next financing or a merger of EPI. These EPI loans were converted into Units as part of our October 2006 private placement. Mr. Stergis had been paid \$6,000 per month which increased to \$8,166 per month on November 1, 2006, which was increased to \$12,500 per month as of March 2007. During 2006, we paid \$2,150 per month to AVI and we currently pay AVI \$1,000 per month for office space. As of March 31, 2007, we no longer pay rent to AVI.

On January 5, 2007, we acquired the remaining 34.53% interest in our subsidiary EPI in exchange for 2,385,742 shares of our common stock and assumed a total of 398,126 options to purchase our common stock and 206,573 warrants to purchase our common stock. In connection therewith, Messrs. Kanzer and Stergis each exchanged their existing EPI warrants for 22,953 warrants to purchase our common stock, and Dr. Rudick exchanged EPI common stock for 90,483 shares of our common stock and exchanged his existing EPI options for 361,933 options to purchase our common stock, a majority of which is unvested, and exchanged his EPI warrants for 128,585 warrants to purchase our common stock.

We have entered into an agreement with Crystal Research Associates, LLC, a firm in which Mr. Kraws one of our directors and VP of Business Development is the CEO to write an executive information overview. Pursuant to this agreement, we have paid Crystal Research Associates \$35,000 for the generation of the report.

We have employment agreements with Drs. Rudick, Bisgaier, Mr. Kraws and Mr. Kanzer, all directors and executive officers of the company. See "Employment Agreements" section of this filing for further descriptive information on employment compensation.

ITEM 13. PRINCIPAL ACCOUNTANT FEES AND SERVICES

During 2006 Berman & Company, P.A., our registered public accounting firm, billed us a total of \$90,400 for audit and other services as follows:

- Audit fees of \$63,400 which consist of fees related to professional services rendered in connection with the audit of our consolidated financial statements from inception through the period ending December 31, 2005;

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

- Audit-related fees of \$27,000 which consist of fees for assurance and related services that are reasonably related to the performance of the audit and the review of our financial statements and which are not reported under "Audit Fees." In 2006, these services related to the registration statement on Form SB-2 dated December 14, 2006 in connection with resale of shares issued in our private placement and merger.

PART IV

ITEM 14. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) Financial Statements

1. These financial statements are set forth in Item 8.
2. No financial statement schedules are required.

(b) Reports on Form 8-K

A report on Form 8-K was filed on February 22, 2007 under Item 5.02 Departure of Directors and Certain Officers; Election of Directors.

A report on Form 8-K was filed on December 1, 2006 under Item 1.01 Entry into a Material Definitive Agreement, Item 3.02 Unregistered Sales of Equity Securities and Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

3.1 Certificate of Incorporation (1)

3.2 By-Laws (1)

4.1 Form of Warrant Certificate (2)

10.1 Employment Agreement with Charles L. Bisgaier (3)

10.2 Consulting Agreement with George J. Brewer (3)

10.3 License Agreement with the Regents of the University of Michigan (3)

10.4 Research Agreement with the Regents of the University of Michigan (3)

10.5 Option and License Agreement between University of Southern California and Solovax, Inc. (3)

10.6 First Amendment to Option and License Agreement between University of Southern California and Solovax, Inc. (3)

10.7 License Agreement between Children's Medical Center Corporation and Effective Pharmaceuticals, Inc. (3)

10.8 License Agreement between Thomas Jefferson University and CD4 Biosciences, Inc. (3)

10.9 First Amendment to License Agreement between Thomas Jefferson University and CD4 Biosciences, Inc. (3)

10.10 Private Stock Purchase Agreement with Michael Manion (3)

10.11 Lock-up Agreement with Michael Manion (3)

10.12 Lock-up Agreement with Accredited Venture Capital, LLC (3)

10.13 Lock-up Agreement with Nicholas Stergis (3)

10.14 Lock-up Agreement with Joseph Rudick (3)

10.15 Lock-up Agreement with Jeffrey Kraws (3)

10.16 Lock-up Agreement with Jeffrey Wolf (3)

10.17 Lock-up Agreement with Charles Bisgaier (3)

10.18 Unit Purchase Agreement (2)

31.1 Certification pursuant to Rule 13a-14(a)/15d-14(a) (4)

Edgar Filing: PIPEX PHARMACEUTICALS, INC. - Form 10KSB

32.1 Certification pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002. (4)

(1) Incorporated by reference to the Registrant's Form 10-KSB for the fiscal year ended December 31, 1996.

(2) Incorporated by reference to the Registrant's Form 8-K filed on December 1, 2006.

(3) Incorporated by reference to the Registrant's Form 8-K filed on November 6, 2006.

(4) Filed herewith.

SIGNATURES

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

PIPEX PHARMACEUTICALS, INC.

By: /s/ Steve H. Kanzer

Steve H. Kanzer

Chairman & Chief Executive Officer

(Principal Executive Officer and Principal Financial Officer)

Date: April 2, 2007

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

Date: April 2, 2007

By: /s/ Steve H. Kanzer

Steve H. Kanzer

Chairman and Chief Executive Office

(Principal Executive Officer and Principal Financial Officer)

Date: April 2, 2007

By: /s/ Jeffrey J. Kraws

Jeffrey J. Kraws

Director

Date: April 2, 2007

By: /s/ Nicholas Stergis

Nicholas Stergis

Director

Date: April 2, 2007

By: /s/ A. Joseph Rudick

Joseph Rudick

Director

Date: April 2, 2007

By: /s/ Charles Bisgaier

Charles Bisgaier

Director

Date: April 2, 2007

By: /s/ Jeff Wolf

Jeff Wolf

Director

Date: April 2, 2007

By: /s/ Daniel J. Dorman

Daniel J. Dorman

Director

Date: April 2, 2007

By: /s/ James S. Kuo

James S. Kuo

Director