

SHEFFIELD PHARMACEUTICALS INC

Form 8-K

November 06, 2006

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): October 31, 2006

Sheffield Pharmaceuticals, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction of incorporation)

01-12584

(Commission File Number)

13-3808303

(IRS Employer Identification No.)

**3985 Research Park Drive
Ann Arbor, MI 48108**

(Address of principal executive offices and zip code)

(734) 332-7800

(Registrant's telephone number including area code)

Sheffield Pharmaceuticals, Inc.
1220 Glenmore Drive
Apopka, FL 32712

(Former Name and Former Address)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12(b))
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this Form 8-K that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These include statements about the Registrant's expectations, beliefs, intentions or strategies for the future, which are indicated by words or phrases such as "anticipate," "expect," "intend," "plan," "will," "the Registrant believes," "management believes" and similar words or phrases. The forward-looking statements are based on the Registrant's current expectations and are subject to certain risks, uncertainties and assumptions. The Registrant's actual results could differ materially from results anticipated in these forward-looking statements. All forward-looking statements included in this document are based on information available to the Registrant on the date hereof, and the Registrant assumes no obligation to update any such forward-looking statements.

Item 1.01 Entry into a Material Definitive Agreement.

On October 31, 2006 (the "Closing Date"), the Registrant entered into a merger agreement (the "Merger Agreement") by and among Pipex Therapeutics, Inc., a privately owned Delaware corporation ("Pipex"), and Pipex Therapeutics Acquisition Corp, a Delaware corporation and wholly owned subsidiary of the Registrant ("Acquisition Sub"). Acquisition Sub was formed on October 27, 2006 for the purpose of pursuing the merger transaction contemplated by the Merger Agreement (the "Merger"). On October 31, 2006, prior to entry into the Merger Agreement, Pipex purchased 2,426,300 shares of common stock pursuant to a Private Stock Purchase Agreement with Michael Manion, an individual holding a total of 2,766,300 shares of the Registrant's common stock. A copy of the Stock Purchase Agreement is incorporated herein by reference and is filed as an exhibit to this Form 8-K. Such shares were retired contemporaneous with the Merger so that at the time of the Merger the Registrant had 737,717 shares of common stock issued and outstanding excluding the shares issued to the shareholders of Pipex. Upon closing of the Merger Agreement, Pipex merged with Acquisition Sub with Pipex being the surviving entity. The Merger Agreement was duly considered and approved by the board of directors of the Registrant as well as the board of directors and majority stockholders of Pipex. A copy of the Merger Agreement is incorporated herein by reference and is filed as an exhibit to this Form 8-K.

In accordance with the Merger Agreement, all outstanding shares of common and preferred stock of Pipex were converted into the right to receive, at Closing and thereafter, an aggregate of 34,000,000 shares of newly issued common stock of the Registrant. Pursuant to the Merger Agreement, the Registrant also assumed the outstanding warrants to purchase an additional 6,893,737 common shares and stock options to acquire an additional 4,915,332 common shares. On November 2, 2006, a Certificate of Merger with the State of Delaware was filed consummating the Merger.

As a result of the Merger, Pipex became a wholly-owned subsidiary of the Registrant and the shareholders of Pipex shall have acquired approximately 97.87% of the Registrant's issued and outstanding stock. The Registrant currently has a total of 34,737,717 issued and outstanding shares of Common Stock. In the Merger, the Registrant also assumed Pipex's warrants and options. Pipex has three majority-owned subsidiaries, Effective Pharmaceuticals, Inc, CD4 BioSciences, Inc. and Solovax, Inc.

In connection with the Merger and related transactions, the Registrant, pursuant to a Registration Rights Agreement has agreed to file, within 45 days of the Closing Date, a registration statement registering for resale certain shares exchanged by the Registrant. A form of the Registration Rights Agreement is incorporated herein by reference and is filed as an exhibit to this Form 8-K and a copy of the Lock-Up agreement of the affiliated investor is incorporated herein by reference and is filed as an exhibit to this Form 8-K.

Concurrent with the Merger, the directors and officers of Pipex and Sheffield entered into lock-up agreements for a period of 12 months from the date of the merger.

The description of the transactions contemplated by the Merger Agreement set forth herein does not purport to be complete and is qualified in its entirety by reference to the full text of the exhibit filed herewith and incorporated by this reference.

Overview

A summary of the business of Pipex is described herein. As used herein, unless the context otherwise requires, "Pipex" refers to the Delaware legal entity having that name, "Pipex Therapeutics Inc." and "the Company" (and "we", "our" and similar expressions) refer to the business of Pipex before the Merger and the Registrant after the Merger, and the "Registrant" refers to Sheffield Pharmaceuticals, Inc.. The Registrant intends to seek stockholder approval in the near future to change the name of the Registrant to Pipex Therapeutics, Inc.

ITEM 2.01. COMPLETION OF ACQUISITION OR DISPOSITION OF ASSETS.

Prior to the merger of Pipex Therapeutics Acquisition Corp. with Pipex Therapeutics, Inc., Sheffield Pharmaceuticals, Inc. was a shell company as defined in Rule 12b-2 of the Securities Exchange Act of 1934. Pursuant to Item 2.01 (f) of Form 8-K, we are required to include in this Report the information that we would be required to provide if we were filing a general form for registration of securities on Form 10-SB. This information is set forth below and is organized in accordance with the Items set forth in Form 10-SB.

Item 4.01 Changes in Registrant's Certifying Accountant

(a) On November 3, 2006, the Registrant ended the engagement of Michael Cronin CPA ("Cronin") as its independent certified public accountants effective as of December 31, 2005. The decision was approved by the Board of Directors of the Registrant.

The report of Cronin on the Registrant's financial statements for the fiscal years ended December 31, 2005 and 2004 did not contain an adverse opinion or disclaimer of opinion. During the Registrant's fiscal years ended December 31, 2005 and 2004 and the subsequent interim period preceding the termination, there were no disagreements with Cronin on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Cronin, would have caused Cronin to make reference to the subject matter of the disagreements in connection with its report on the financial statements for such years or subsequent interim periods.

The Registrant requested that Cronin furnish it with a letter addressed to the Registrant confirming its dismissal and whether or not it agrees with the Registrant's financial statements. A copy of the letter furnished by Cronin in response to that request, dated November 3, 2006, is filed as Exhibit 16.1 to this Form 8-K.

(b) On November 3, 2006, Berman & Company, P.A. ("Berman") was engaged as the Registrant's new independent certified accountants. During the two most recent fiscal years and the interim period preceding the engagement of Berman, the Registrant has not consulted with Berman regarding either: (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Registrant's financial statements; or (ii) any matter that was either the subject of a disagreement or event identified in paragraph (a)(1)(iv) of Item 304 of Regulation S-B.

ITEM 5.01. CHANGES IN CONTROL OF REGISTRANT.

See Item 1.01 of this Form 8-K.

ITEM 5.02. DEPARTURE OF DIRECTORS OR PRINCIPAL OFFICERS; ELECTION OF DIRECTORS;
APPOINTMENT OF PRINCIPAL OFFICERS.

On October 16, 2006, Nicholas Stergis, M.S. was appointed to the Board of Directors of Sheffield and on October 27, 2006 to the Board of Directors of Pipex Therapeutics Corp. Mr. Stergis currently serves as the Chief Operating Officer of Pipex. A Form 8-K including the biography of Mr. Stergis was filed by the Company on October 16, 2006. On November 1, 2006, Mr. Michael Manion tendered his resignation to the board of directors of the Company effective November 3, 2006 and the board of directors accepted his resignation.

COMPANY SUMMARY

Pipex Therapeutics, Inc. (“Pipex”, “we”, or “our”) 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 Applications (NDA) with the FDA and a potential Marketing Application Authorization (MAA) with the European Medicines Evaluation Agency (EMA).

A key component of our strategy encompasses the efficient and timely development of our clinical-stage drug candidates through the selection of initial indications representing high unmet medical needs and which may therefore benefit from both a fast-track and priority review regulatory review process as well as premium pricing for such indications. If approved for marketing, we may pursue additional indications for our investigation la agents via a Supplemental New Drug Applications (SNDAs) while benefiting from the expedited and lower clinical trial costs associated with the clinical testing of already approved agents as compared to investigational agents not yet approved. Our lead drug candidate, COPREXA™, is a novel, oral, anticopper therapeutic that during the last 18 years has completed two clinical trials in neurologically-presenting Wilson’s disease that we believe have demonstrated sufficient safety and efficacy to support a NDA with the FDA as well as a MAA with the European Medicines Evaluation Agency.

In order to expand the therapeutic utility of our oral agent, COPREXA™ beyond initially presenting neurological Wilson's disease our investigators have recently completed an initial 12 month, 16 patient, open label phase II clinical trial for the treatment of refractory Idiopathic Pulmonary Fibrosis (IPF), a pregressive fibrotic lung disease associated with high rates of mortality and for which there is no currently approved therapy. IPF is estimated to result in 30,000 deaths annually in the U.S., which exceeds the annual number of deaths attributable to breast and prostate cancer

PRODUCT	THERAPEUTIC INDICATION	STAGE OF DEVELOPMENT
COPREXA Ô (oral tetrathiomolybdate)	Neurologic Wilson's Disease	Phase III Clinical Trial (complete) NDA in preparation
COPREXA Ô (oral tetrathiomolybdate)	Refractory Idiopathic Pulmonary Fibrosis (IPF)	Phase IIa Clinical Trial (complete)
COPREXA Ô (oral tetrathiomolybdate)	Primary Biliary Cirrhosis (PBC)	Phase II Clinical Trial (on-going)
TRIMESTA Ô (oral estriol)	Relapsing-Remitting Multiple Sclerosis	Phase IIb Clinical Trial
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 Ô (clotrimazole enema)	Refractory Acute Pouchitis	Phase II Clinical Trial (ongoing)
EFFIRMA™ (oral flupirtine)	Fibromyalgia	Phase II Clinical Trial (planned)
SOLOVAX™ (MS T-cell vaccine)	Multiple Sclerosis Vaccine	Phase II Clinical Trial (complete)

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 chaperone 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 phase III 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 CNS diseases in which abnormal serum and CNS copper homeostasis are implicated, such as Alzheimer's disease.

COPREXA™ for 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, 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. and 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. There are an estimated 6,000 currently diagnosed Wilson's patients in the U.S. with many more that are currently misdiagnosed. Due to the impaired ability to incorporate and excrete copper, elevated levels of toxic free copper enter the systemic circulation, passively cross the blood-brain-barrier and enter the cerebral spinal fluid (CSF) of the brain and interfere with normal synaptic function and ultimately neurodegeneration of the brain typically presenting after twenty years of age. 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.

Currently, approximately half of newly-diagnosed Wilson's patients initially present with neurologic symptoms while interestingly, the prevalence of neurologic Wilson's disease is greatly increased in patients carrying one the apolipoprotein 4 (apoE4) phenotype gene, a significant risk factor for Alzheimer's disease. The remaining Wilson's disease patients will generally initially present with hepatic 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 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 Wilson's disease: penicillamine (Cupramine®), 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™ for neurologic Wilson's disease. 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. 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 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 developed by our scientific founder, Dr. George Brewer, and was approved by the FDA (1997) and EMEA (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. Brewer GJ et. Al., Treatment of Wilson disease with ammonium tetrathiomolybdate: III. Initial therapy in a total of 55 neurologically affected patients and follow-up with zinc therapy. *Arch Neurol.* 2003 Mar; 60(3):379-85.

In a second double-blind, randomized comparator, pivotal clinical trial, 48 newlydiagnosed, 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 COPREXA™. 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 COPREXA™ ($p < 0.05$). Twenty-six percent (26%) of trientine treated patients (6 of 23) experienced neurologic worsening compared to only four percent (4.0%) of COPREXA™ 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 results of this trial were published in April of this year, (Brewer, G.J., Askari, F., Lorincz, M.T., Carlson, M., Schilsky, M., Kluin, K.J., Hedera, P., Moretti, P., Fink, J.K., Tankanow, R. 2006. Treatment of Wilson disease with ammonium tetrathiomolybdate: IV. Comparison of tetrathiomolybdate and trientine in a double-blind study of treatment of the neurologic presentation of Wilson disease. *Arch Neurol* 63:521-527)

The clinical development of COPREXA has been supported by grants from the Orphan Products Division of the FDA.

COPREXA™ for Idiopathic Pulmonary Fibrosis (IPF)

We are developing COPREXA™ as a highly potent oral antifibrotic agent based upon the observation that the fibrotic disease process is dependent upon the availability of endogenous free copper. COPREXA™ 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- κ B, 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 80,000 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.

Preclinical IPF Model Using COPREXA™

Our scientific collaborator tested COPREXA™ in the bleomycin mouse model, a model of pulmonary fibrosis. In this model, bleomycin is instilled in the trachea of the mouse and produces a marked inflammatory reaction in the lungs after seven days. By day 21, this inflammatory reaction is followed by a marked fibrosis at which point the experiment is terminated. COPREXA™ treatment was found to strongly inhibit fibrosis in this model, even when treatment was not initiated until after day 7 (i.e., after the fibrotic disease process had already begun). These results suggest that COPREXA™ is capable of specifically inhibiting chronic fibrotic disease processes in the lung (which are believed to be analogous to the chronic fibrotic disease processes that result in the scarring, loss of pulmonary function and respiratory failure characterized by IPF) as opposed to merely inhibiting acute inflammatory reactions caused by acute lung insult.

Phase II Clinical Trials of COPREXA™ in Refractory IPF Patients

Based upon the successful animal experiments described above, a 16-patient, one-year, open-label, phase II clinical trial of COPREXA™ 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), the accepted measurement of pulmonary function in IPF. After six months of therapy with oral COPREXA™, 93.3% of patients had stable disease and after twelve months of therapy with oral COPREXA™, 75% of patients had stable disease. These results compare favorably to published historical controls which show stable disease after six months in only 68% of patients and stable disease after twelve months in only 46% of patients. This phase II trial was partially supported by a grant from the Coalition for Pulmonary Fibrosis, a non-profit organization.

COPREXA™ 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 COPREXA™ 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 COPREXA™ 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.

Anti-Copper therapies and other neurodegenerative diseases

Alzheimer's disease (AD) is a disease for which a growing body of evidence implicates elevated levels of toxic free copper in the serum and CNS as central to the disease process and severity of disease making AD potentially analogous to a latent form of Wilson's disease. We believe that COPREXA's specificity and unique mechanism of action for lowering toxic free copper, combined with its history of success in 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 we believe represents the most important fundamental cause of neurodegenerative diseases, such as AD. AD is a growing societal epidemic that currently affects approximately 4.5 million people in the U.S. and approximately 50% of persons over the age of 85.

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 inventor 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 Th1-mediated 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 non-pregnant female multiple sclerosis patients and has demonstrated encouraging results.

TRIMESTA™ for Relapsing-Remitting Multiple Sclerosis (MS)

Current Therapies for Relapsing-Remitting MS.

We are developing TRIMESTA™ as an oral immunomodulatory therapy for female relapsing-remitting MS patients that can be used either alone or in combination with other agents or during the post-partum period following pregnancy. There are currently five FDA-approved first line therapies for the treatment of relapsing-remitting multiple sclerosis: Betaseron®, Rebif®, Avonex® and Copaxone®. Tysabri®, was reintroduced during 2006 to the marketplace, but is only approved for refractory MS patients. 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 II 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 the relapsing-remitting MS patient group, 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.

Improvement in PASAT cognitive testing scores

During this phase II clinical trial, a 14% improvement in Paced Auditory Serial Addition Test (“PASAT”) cognitive testing scores was observed in the relapsing-remitting MS group. PASAT is a routine cognitive test performed in patients with a wide variety of neuropsychological disorders such as MS. PASAT cognitive testing was conducted during the three-month period prior to the initiation of treatment and again at month 12 following therapy. The PASAT scores were expressed as a mean percent change from baseline and were significantly improved in the relapsing-remitting group (p=0.04). PASAT scores were unchanged in the secondary progressive (SP) group.

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 (caregiving, 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 (cnsnqic-cyclic)

We are developing a series of rationally-designed, small molecule/peptidomimetic inhibitors of the T-cell CD4 co-receptor. The CD4 co-receptor is central to a number of autoimmune disorders such as MS. Our anti-CD4 molecules are designed to selectively block the dimerization and oligomerization of adjacent CD4 receptors via the D1 domains of such receptors. CD4 dimerization is believed to be necessary for the proper formation of the immunological synapse between antigen presenting cells (APCs) and T-cells, which results in the achievement of the critical threshold signaling required for CD4 T-Cell activation.

By selectively blocking critical threshold signaling, our anti-CD4 molecules display the important advantage of causing apoptosis (via activation-induced cell death (AICD)) and/or anergy of CD4 T-cells. Our anti-CD4 molecules are selective for otherwise active CD4 T-cells and demonstrate the ability to modify the course of CD4-mediated diseases through the selective deletion of pathogenic memory T-cells, thereby inducing immune tolerance. As opposed to monoclonal antibody approaches, our anti-CD4 molecules are non-T-cell depleting, non-immunogenic and potentially orally available.

Our lead anti-CD4 molecule, 802-2 (cnsnqic-cyclic), has demonstrated efficacy in a number of animal models of MS and other autoimmune disease models, and it is currently being evaluated in a phase I/II clinical trial for the prevention of severe 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. We believe that the recent withdrawal of several wide-selling anti-inflammatory agents that offered patients only palliative therapy exemplifies the need to develop new, convenient approaches to modify the course of CD4-mediated autoimmune diseases through the induction of immune tolerance. We believe that our anti-CD4 molecules have the lead as nonbiologic agents capable of inducing immune tolerance. In addition, they are accompanied by broadly issued patents covering the selective inhibition of CD4 by small molecules. 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. The important role of CD4+ T-cells is just beginning to be understood and appreciated as a therapeutic target to potentially induce tolerance.

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 that is related to ulcerative colitis (UC). 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. We have expanded this study to five centers and are in the process of reviewing CORRECTATM's utility for other distal gastrointestinal market opportunity.

Phase II Clinical Trial for CORRECTA™ in Refractory Pouchitis

A phase II clinical trial to test CORRECTA™ is currently enrolling approximately 30 patients with active pouchitis for whom currently available standard therapies have failed. The primary goal of this phase II study is to test the safety and efficacy of CORRECTA™ at four different dose levels versus the current standard of care in the treatment of pediatric and adult patients with pouchitis. The primary endpoint of this trial is a reduction in the pouchitis disease activity index (PDAI), a composite index of clinical, gross, and histologic parameters that represents an established and previously validated continuous-scoring system for this indication. We will rate each subject's pouchitis disease severity before and after study (or placebo) therapy. As such, the primary outcome for this study will be a determination of whether the average change in PDAI scores (measured pre- and post-therapy) is different in placebo and active treatment groups. We are currently enrolling the cohort B portion of the CAPTURE study, which will treat patients at two higher dose levels of CORRECTA™, specifically 6,000mg and 7,500mg per day as compared to placebo.

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 syndrome (FMS) and we plan to conduct a limited, controlled phase II pilot clinical trial in this indication. FMS is a common, centrally-mediated pain disorder characterized by chronic diffuse pain and other symptoms. We have exclusively licensed an issued U.S. patent and pending foreign equivalents covering the use of flupirtine for the treatment of FMS. 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 FMS

Our scientific collaborator has demonstrated preliminary anecdotal efficacy of EFFIRMA™ for the treatment of FMS in a small number of U.S. patients suffering from FMS 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 FMS patient population.

MATERIAL AGREEMENTS

University of Michigan 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 COPREXA™, to treat inflammatory and fibrotic diseases, including Alzheimer's disease. Pursuant to this agreement, we will use our best efforts to commercialize COPREXA™ 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 COPREXA™ for uses covered by the UM patents; issue UM 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 COPREXA™ in an indication covered by the UM patents, and indemnify UM and Dr. Brewer against certain claims.

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 COPREXA™ 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 COPREXA™ technology. Pursuant to this agreement, we pay Dr. Brewer a quarterly fee of \$30,000. We also issued to Dr. Brewer options to acquire 650,540 shares of our common stock and agreed to pay Dr. Brewer a royalty on sales of COPREXA™ equal to 3% of net sales for 17 years. At the closing of our Merger, we issued Dr. Brewer an additional 650,540 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; 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 a NDA for flupirtine; and \$600,000 upon FDA approval of flupirtine.

University of Southern California Agreement

During August 2001, through our majority owned subsidiary Solovax we have an exclusive option agreement 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

During August 2005, we have 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 \$75,000 upfront payment and have agreed to pay \$75,000 on August 31, 2006, 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. 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. 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

During February 2002, our majority-owned subsidiary named CD4 Biosciences Inc., we 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 antidilution 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 for patent expenses of \$41,000 and agreed to pay a license fee of \$25,000 in September 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.

Oregon Health & Sciences University License Agreement

During 2005, we have an exclusive worldwide license agreement with Oregon Health & Sciences University relating to pending U.S. and international patent applications covering the use of low dose estrogens to treat immune pathologies including the active ingredient of TRIMESTA™. Pursuant to this agreement, we paid an upfront license fee of \$1,500, reimbursed for patent expenses of \$41,000; and agreed to pay annual maintenance fees, potential regulatory and patent milestone payments totaling \$375,000, which are covered by the patent rights, as well as royalties on net sales of products covered by the licensed patent applications.

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™.

Employment Agreement with Dr. A. Joseph Rudick

On September 15, 2004, our majority owned subsidiary EPI entered into, and subsequently amended, an employment agreement with Dr. A. Joseph Rudick to serve as the Chief Medical Officer and President of EPI. During 2005, the company paid Dr. Rudick a \$25,000 bonus and we agreed to pay him an annual base salary of \$175,000. In the merger with EPI, we will grant Dr. Rudick options to acquire 691,235 shares of our common stock, over a ten-year term, vesting over a three year period being at the closing of the Merger (assuming Dr. Rudick raises at least \$10 million in gross proceeds to Pipex and completes the EPI acquisition), so long as Dr. Rudick is employed as a director or officer of Pipex and issue 53,270 warrants to purchase EPI common stock at \$1.10 per share.

Employment Agreement with Steve H. Kanzer

In January 2005, we entered into a four year employment agreement with Steve H. Kanzer to serve as our Chairman, President and Chief Executive Officer. Upon the consummation of a financing, 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, assuming Mr. Kanzer raises at least \$10 million in gross proceeds to Pipex.

Letter of Intent to Merge with BCY LifeSciences, Inc.

On January 19, 2006, we entered into a letter of intent to merge with BCY LifeSciences, Inc., a publicly traded biopharmaceutical company listed on the TSX Venture Exchange in Canada (TSXV: BCY). Pursuant to this letter of intent, we provided a bridge loan of \$50,000 to BCY. This letter of intent expired without renewal during June 2006. The \$50,000 was not repaid, nor is it expected to be repaid and represents a failed merger cost expense.

Agreement to Acquire EPI

Pursuant to a share exchange agreement, we acquired 65.47% of Effective Pharmaceuticals, Inc. (EPI). Following the closing of our acquisition by Registrant, we plan to consummate a merger with EPI in which Pipex will acquire the 34.53% of EPI's outstanding Series B, convertible preferred stock that we do not currently own. We plan to complete this merger during the forth quarter of 2006. However, we can give no assurances that we will be able to consummate this merger with EPI (see "Risk Factors—we may not be able to consummate the merger of EPI into our company"). Upon the closing of this merger, EPI would become a wholly-owned subsidiary and there will be no minority interest.

MANUFACTURING

We plan to 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.

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™, and certain uses of COPREXA™.

FACILITIES

Our primary offices are located at 3985 Research Park Drive, Ann Arbor, MI 48108. We currently rent approximately 5,500 square feet of office, laboratory and production space on a month-to-month basis for monthly rent of \$5,500. Our phone number is (734) 332-7800 and our facsimile number is (734) 332-7878. Our website is located at www.pipexinc.com. We also have additional offices in Miami, Florida, which we share with Accredited Ventures, Inc., EPI, and CD4.

CORPORATE INFORMATION

We were incorporated in the State of Delaware on January 8, 2001. We have two majority owned subsidiaries, Solovax, Inc. (“Solovax”) and Effective Pharmaceuticals, Inc. (“EPI”). EPI in turn owns 91.6% of the outstanding shares of CD4 Biosciences, Inc. (“CD4”). We currently own an aggregate 65.47% of the outstanding voting Series B, convertible preferred and common shares of EPI.

Our primary offices and laboratories are located at 3985 Research Park Drive, Ann Arbor, MI 48108. Our phone number is (734) 332-7800 and our facsimile number is (734) 332-7878. Our website is located at www.pipexinc.com.

RISK FACTORS

An investment in our securities is speculative and involves a high degree of risk. You should not invest in our securities if you cannot bear the economic risk of your investment for an indefinite period of time and cannot afford to lose your entire investment. You should carefully consider the following risk factors associated with the offering, as well as other information contained elsewhere in this memorandum, before investing.

This Form 8-K contains certain forward-looking statements within the meaning of section 27A of the Securities Act and section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are based on current expectations, estimates and projections about our industry, management’s beliefs, and assumptions made by management. Words such as “anticipates,” “expects,” “intends,” “plans,” “believes,” “seeks,” “estimates,” variations of such and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Accordingly, actual results may differ materially from those expressed or forecasted in any such forward-looking statements. Such risks and uncertainties include those risk factors and such other uncertainties noted in this Form 8-K. We assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events, or otherwise.

RISKS RELATED 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 June 30, 2006, we have expended approximately \$5.3 million on a consolidated basis acquiring and developing our current product

candidates. Until such time as we receive approval from the U.S. Federal Drug Administration 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 the net proceeds of this offering, cash on hand, licensing fees, and grants. We will need to seek additional sources of financing in addition to the proceeds of this offering, 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, and we may never achieve or maintain profitability. 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 candidates.

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 and Oregon Health and Science University 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). 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 will 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 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 inflammatory, fibrotic, Alzheimer's and Wilson's diseases, several of which are in early and advanced clinical trials, such as, pirfenidone, milnacipram, Actimmune® 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, flupirtine and COPREXATM technologies. We are aware that Pharmafrontiers and BayHill Therapeutics are developing competitive T-cell vaccine therapies for the treatment of multiple sclerosis and are planning to initiate a phase II and phase III clinical trials.

We may not succeed in enforcing our orphan drug designations.

COPREXATM has been designated by the FDA as an "orphan drug" for the treatment of Wilson's disease patients presenting with neurologic complications. CORRECTATM has also been designated by the FDA as an "orphan drug" for the treatment of pouchitis patients. We intend to file an "orphan drug" designation from the EMEA (the European equivalent of the FDA) for both COPREXATM and CORRECTATM for similar uses. Pursuant to our agreements with our scientific inventors, we have acquired these designations. Orphan drug designation is an important element of our competitive strategy because there is no composition of matter patent for COPREXATM TRIMESTA™ or CORRECTATM. 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 the COPREXATM to treat this indication. While we are not aware of any other companies that have sought orphan drug designation for COPREXATM 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 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 COPREXATM 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 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 more advanced states of clinical development, having completed two phase III clinical trials, we cannot predict whether or not one or more U.S. patents will be issued corresponding to the Angiogenic Patent and patent applications 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). It may be more difficult to establish contributory infringement of methods of formulation or use patents as compared to a patent on a compound. 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 ingredient, 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. If granted by the FDA, Orphan Drug Designation would provide 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 if issue, would cover various formulations, packaging, distribution & monitoring methods for COPREXA™. We rely on issued patent and 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 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 Act 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.

We currently 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. Following the completion of this offering, we intend to recruit certain key executive officers, including a vice president of finance, a vice president of regulatory affairs, and other 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 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.

If we decide to establish a full-scale commercial manufacturing facility, we would require substantial additional funds, we would need 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 issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

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

- 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 if their performance is substandard, that 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 TRIMESTATM, CORRECTATM, anti-CD4 802-2, EFFIRMATM and COPREXATM development programs. Specifically, all of the clinical trials have been conducted under physician-sponsored investigational new drug applications (INDs), not corporate-sponsored INDs. 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 the 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 and central nervous systems 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. 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.

Certain interlocking relationships may present potential conflicts of interest.

Members of our management are also officers of the placement agent or its affiliate, Accredited Ventures, Inc., a merchant banking and venture capital firm that identifies, evaluates, and pursues investment opportunities in the biomedical and biopharmaceutical sectors, whether technologies, products, or companies.

Steve H. Kanzer, our co-founder, Chairman, President and Chief Executive Officer and an affiliate of our largest stockholder, is Chairman and Chief Executive Officer of the placement agent and Accredited Ventures. Nicholas Stergis, our Chief Operating Officer, Treasurer, Secretary, and director, is also a managing director of Accredited Ventures and managing director of the Placement Agent. Additionally, Dr. A. Joseph Rudick, a member of our board of directors and Chief Medical Officer, is a registered representative of the placement agent.

None of our affiliates, including Accredited Ventures, the placement agent, or any of our directors or officers, is obligated under any agreement or understanding with us to make any additional products or technologies available to us. Similarly, we can give no assurances, and we do not expect and purchasers of our shares should not expect, that any biomedical or pharmaceutical product or technology identified by any of our affiliates in the future would be made available to us.

Certain of our current or future officers and directors may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies that are developing products and technologies to treat central nervous system, autoimmune, and fibrotic diseases. We can give no assurances that such other companies will not have interests that conflict with ours.

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 RELATED TO OUR Merger with Registrant

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. 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.

We may not be able to consummate the merger of EPI into our company.

We intend to complete the merger of our majority owned subsidiary EPI into Pipex. That merger would require the approval of the 34.53% of the aggregate outstanding series B convertible, preferred and common stock of IP that we do not currently own. If holders of these Series B shares do not approve the merger, they will remain outstanding. These shares of Series B are entitled to an annual 10% paid-in kind dividend on June 30, 2005 and June 30, 2006. The holders of the series B, convertible preferred stock are also entitled to a one time 30% payment-in-kind dividend of shares of Series B preferred stock that is payable December 2006. EPI is required to pay these dividends until a merger or trading event of the common stock of EPI in which the shares of Series B preferred stock would be automatically converted. Payment of that dividend will result in a reduction in our ownership interest in EPI and could result in our losing voting control of EPI.

There is a limited public market for the Registrant's common stock and there is no assurance that one will develop.

The Registrant is required to file a registration statement on Form SB-2 within 45 days of the closing of our Merger under the Securities Act to permit the resale of shares received by Pipex shareholders in the acquisition by Registrant. Former Pipex shareholders would, however, only be able to sell their Registrant shares under the registration statement once it becomes effective, and we can give no assurances as to when the registration statement would become effective, if at all. In the event that we do not file a registration statement within 45 days and cause it to go effective within 150 days, we will pay a 2% penalty payable in cash per month to the subscribers in this offering. We are required to maintain this registration statement effective for a period of 2 years from the date of closing.

The shares of Registrant common stock that has been issued to Pipex shareholders in the merger with Registrant has not be registered under the Securities Act of 1933. Therefore, these shares would have to be held indefinitely unless they were subsequently registered under the Securities Act or unless an exemption from the registration requirements of the Securities Act was available. Rule 144 promulgated under the Securities Act, which provides an exemption from registration for dispositions of unregistered securities under certain circumstances, would not then be available with respect to any of Registrant securities, at the time of the merger Registrant will not be a reporting company under the Securities Exchange Act. Certificates representing Registrant shares issued to Pipex shareholders in the acquisition would bear a legend with respect to such restrictions on subsequent transfers.

Furthermore, we can give no assurances that a market for our common stock will develop or that the price of the shares in the market will be equal to or greater than the price per share investors pay in this offering. In fact, the price of our shares in any market that may develop could be significantly lower.

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 Registrant common stock issued in the merger with Registrant.

Our Registrant’s 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 be 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.

We are subject to the reporting requirements of federal securities laws, which can be expensive.

We are a public reporting company in the U.S. and, accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, and the compliance obligations of the Sarbanes-Oxley Act. The costs of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC and furnishing audited reports to stockholders will cause our expenses to be higher than they would be if we remained a privately-held company. In addition, we will incur substantial expenses in connection with the preparation of the registration statement and related documents with respect to the registration of resales of the shares and the reporting of the ,Merger.

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 will become 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 after the closing of the Merger. 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.

When the Registration Statement becomes effective, there will be a significant number of shares of common stock eligible for sale, which could depress the market price of such stock.

Following the effective date of the Registration Statement, a large number of shares of common stock will become available for sale in the public market, which could harm the market price of our stock. Further, shares may be offered from time to time in the open market pursuant to Rule 144, and these sales may have a depressive effect as well. In general, a person who has held restricted shares for a period of one year may, upon filing a notification with the SEC on Form 144, sell common stock into the market in an amount equal to the greater of one percent of the outstanding shares or the average weekly trading volume during the last four weeks prior to such sale.

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 plan to list our common stock on the American Stock Exchange or the NASDAQ National Market as soon as practicable. However, we cannot assure you that we will be able to meet the initial listing standards of either of those or of any other stock exchange, or that it will be able to maintain any such listing. 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;
- 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. 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 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.

The E.U. provides two different, elective authorization routes: centralized and decentralized. For NB S101 we have selected the centralized route, leading in one marketing authorization the entire E.U., in which our application will be reviewed by members of the Committee for Proprietary Medicinal Products ("CPMP"), on behalf of EMEA. Based on that review, EMEA will provide an opinion on safety, quality and efficacy to the European Commission, which makes the decision to grant or refuse authorization.

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 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 Pipex is 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.

MANAGEMENT AND BOARD OF DIRECTORS

Our management will succeed the management of Sheffield. Pipex’s directors, Steve H. Kanzer, Dr. Charles L. Bisgaier, Jeffrey Wolf, Jeffrey Kraws, Nicholas Stergis, and Dr. A. Joseph Rudick, will continue to serve as directors of the surviving company.

The following table states who are directors and officers of Sheffield, as well as biographical information regarding our directors and management.

Name	Age	Position
Steve H. Kanzer, CPA, Esq.	42	Chairman and Chief Executive Officer
Charles L. Bisgaier, Ph.D.	52	President and Director
Jeffrey J. Kraws	41	Vice President, Business Development and Director
A. Joseph Rudick, M.D.	49	Chief Medical Officer and Director
Nicholas Stergis, M.S.	32	Chief Operating Officer and Director
John S. Althaus, M.S., M.B.A.	52	Vice President, Advanced Technology
Jeff Wolf, Esq.	41	Director

Steve H. Kanzer, CPA, Esq.

Mr. Kanzer, 42, is a co-founder of Pipex Therapeutics, Inc. and has served as President since our inception in February 2001. In September 2004, Mr. Kanzer assumed the additional roles of Chairman, President 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. 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. Accredited Ventures has funded substantially all of our operations to date. 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 co-founded Paramount Capital, Inc. in 1991 and served as Senior Managing Director-Head of Venture Capital at Paramount Capital 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. Mr. Kanzer was founding Chairman of the Board of Discovery Laboratories, Inc. from 1995 through 1999. 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, resulting in CTIC becoming the second best performing stock for the year 2000. Cephalon acquired the rights to TRISENOX® in 2005 for \$165 million and currently markets the drug. Since 1996, Mr. Kanzer has served as a member of the board of directors of DOR BioPharma, Inc., a public biotechnology company that is preparing to file an 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. 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 (LES).

Charles L. Bisgaier, Ph.D.

Dr. Bisgaier, 52, 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 is a director of Pipex and our Vice President of Business Development. 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 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. Mr. Kraws only devotes a portion of his time to our business.

A. Joseph Rudick, M.D.

Dr. Rudick 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 majority-owned 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 the placement agent.

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

Mr. Althaus 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 bronchopulmonary 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.

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 is a co-founder, Chief Operating Officer and a member of the board of directors of Pipex and was appointed to the board of directors of Sheffield on October 14, 2006. Mr. Stergis is also a co-founder and Interim Chief Operating Officer and director of our majority-owned subsidiary Effective Pharmaceuticals, Inc. 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., an 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, orBec®, which has completed a pivotal Phase III clinical trial and is pending NDA submission. 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 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 a co-founding partner of Seed-One Venture Partners, LLC, a venture capital group focused on seed-stage biomedical investments. Mr. Wolf has been a co-founder of Elusys Therapeutics, Inc., an antibody-based therapeutic company, Tyrx Pharma, Inc., a biopolymer-based company and Sensatex, Inc., a medical device company. Prior to founding Seed-One Venture Partners, 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, Tyrx Pharma and Sensatex. 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.

PROPRIETARY RIGHTS

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other relevant proprietary technologies, and to preserve our trade secrets and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy has been to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents.

We also depend upon the skills, knowledge, and experience of our scientific and technical personnel, as well as that of our advisors, consultants, and other contractors, none of which is patentable. To help protect our proprietary know-how which is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

We currently have certain exclusive license agreements with the University of Michigan, Thomas Jefferson University, the Regents of the University of California, Children's Hospital, Boston and the McLean Hospital, and an exclusive option agreement with the University of Southern California under We also have similar rights to a number of related foreign patents and patent applications filed under Patent Cooperation Treaties (PCT).

Item 5.06 Change in Shell Company Status.

On October 31, 2006, the Registrant entered a Merger Agreement pursuant to which the parties agreed that the Registrant acquired all of the issued and outstanding shares of stock of Pipex Therapeutics, Inc. in exchange for the issuance in the aggregate of 34 million of the Registrant's shares of common stock (the "Exchange").

Pipex Therapeutics, Inc. became a wholly-owned operating subsidiary of the Registrant and, upon the issuance of the Shares and completion of related transactions. The Registrant currently has a total of 34,737,717 issued and outstanding shares of Common Stock and 46,546,786 shares outstanding on a fully diluted basis including shares of Common Stock issuable upon the exercise of options and warrants.

As the result of the completion of the Exchange, the Registrant believes it is no longer a shell company as that term is defined in Rule 405 of the Securities Act and Rule 12b-2 of the Securities Exchange Act of 1934, as amended.

LEGAL PROCEEDINGS

Pipex is not a party to any material legal proceedings nor is Pipex aware of any circumstance that may reasonably lead a third party to initiate legal proceedings against Pipex.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information regarding beneficial ownership of Pipex's common stock and warrants to purchase shares of common stock as of October 31, 2006 following the Merger 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 Therapeutics, Inc., 3985 Research Park Drive, Suite 4, 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 October 31, 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 ⁽¹⁾⁽²⁾
Accredited Venture Capital, LLC (1)	23,756,955	63.80%
Steve H. Kanzer (1)	23,756,955	63.80%
Firebird Capital (2)	4,459,648	12.57%
Nicholas Stergis (3)	4,065,876	11.70%
Charles Bisgaier, Ph.D. (4)	612,028	1.75%
Jeffrey J. Kraws (5)	363,160	*
A. Joseph Rudick, M.D. (6)	81,318	*

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Jeffrey Wolf, Esq. (7)	32,527	*
All officers and directors as a group (6 persons)	28,891,864	83.17%

* represents less than 1% of our common stock

- (1) Consist of 21,259,138 shares of common stock and a warrant to purchase 2,497,817 shares of common stock issued to Accredited Venture Capital, LLC, a company in which Pharmainvestors, LLC, is the managing member and a partial beneficial owner. Steve H. Kanzer is the Managing Member of Pharmainvestors, LLC. As such, Mr. Kanzer may be considered to have control over the voting and disposition of those shares. Mr. Kanzer disclaims beneficial ownership of those shares, except to the extent of his pecuniary interest. Excludes an unvested option to purchase 250,000 shares of common stock at \$2 per share (which will vest if Mr. Kanzer raises at least \$10 million in this financing), which will vest annually over three years. Excludes Placement Agent warrants to purchase common stock. Mr. Kanzer's business address is 3985 Research Park Drive, Suite 4, Ann Arbor, MI 48108.
- (2) 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.
- (3) Consists of 4,065,876 shares of common stock issued to Mr. Stergis. Excludes Placement Agent warrants to purchase common stock. Mr. Stergis's business address is 801 Brickell Avenue, 9th Floor, Miami, Florida 33131.
- (4) Consists of 166,063 vested options to purchase common stock, 148,655 shares of common stock and 74,327 warrant to common stock issued to Bisgaier Family LLC, a company Dr. Bisgaier is the managing member; 148,655 shares of common stock and 74,327 warrant to common stock issued to two trusts for which Dr. Bisgaier has control of. Excludes 1,826,681 unvested options to common stock vesting over three years. Dr. Bisgaier's business address is 3985 Research Park Drive, Suite 4, Ann Arbor, MI 48108.
- (5) 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 343,160 common stock which will vest annually over three years. Mr. Kraws's business address is 800 Third Avenue, 17th Fl., New York, NY 10022.
- (6) Includes an option to purchase 81,318 shares of common stock. This does not include an option to purchase 691,235 shares of common stock, vesting annually over three years if Dr. Rudick raises at least \$10 million in gross proceeds to Pipex and Dr. Rudick completes the EPI acquisition. This option is not exercisable within 60 days of the date of this report. Dr. Rudick's business address is 150 Broadway, Suite 1800, New York, NY 10128.
- (7) Assumes the exercise of an option to purchase 32,527 shares of our common stock. This option is exercisable within 60 days of the date of this report. Mr. Wolf's business address is c/o Seed-One Ventures, LLC, 1205 Lincoln Road, Suite 216, Miami Beach, Florida 33139.

Item 9.01 Financial Statements and Exhibits.

- (a) Financial statements of business acquired.
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Audited consolidated financial statements of the Company as of and for the years ended December 31, 2005 and 2004 and for the period from January 8, 2001 (Inception) to December 31, 2005 and unaudited condensed consolidated financial statements as of June 30, 2006 appear elsewhere herein, commencing on page F-1.

(b) Pro Forma Financial Information.

Pro forma financial statements are not required to be filed with this Current Report.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Sheffield Pharmaceuticals, Inc.

(Registrant)

By: /s/ Steve H. Kanzer

Name: Steve H. Kanzer

Title: Chief Executive Officer

November 5, 2006

List of Exhibits

- 2.1 Merger Agreement with the Registrant and Pipex Therapeutics Inc.
 - 10.1 Employment Agreement between Pipex Therapeutics, Inc. and Charles L. Bisgaier
 - 10.2 Consulting Agreement between Pipex, Inc. and George J. Brewer
 - 10.3 License Agreement between Pipex, Inc. the Regents of the University of Michigan
 - 10.4 Research Agreement between Pipex, Inc. and the Regents of the University of Michigan
 - 10.5 Option and License Agreement between University of Southern California and Autoimmune Vaccines, Inc.
 - 10.6 First Amendment to Option and License Agreement between University of Southern California and Solovax, Inc. (formerly Autoimmune Vaccines, Inc.)
 - 10.7 License Agreement between Children's Medical Center Corporation and Effective Pharmaceuticals, Inc.
 - 10.8 License agreement between Thomas Jefferson University and Quantas Biopharmaceuticals, Inc.
 - 10.9 First Amendment to License Agreement between Thomas Jefferson University and CD4 Biosciences, Inc.
 - 10.10 Private Stock Purchase Agreement between Pipex Therapeutics Inc and Michael Manion
 - 10.11 Lock-Up Agreement with Mr. Michael Manion
 - 10.12 Lock-Up Agreement with Accredited Venture Capital, LLC
 - 10.13 Lock-Up Agreement with Nicholas Stergis
 - 10.14 Lock-Up Agreement with Joseph Rudick, M.D.
 - 10.15 Lock-Up Agreement with Jeffrey Kraws
 - 10.16 Lock-Up Agreement with Jeffrey Wolf
 - 10.17 Lock-Up Agreement with Charles Bisgaier, PhD.
-

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

Consolidated Financial Statements

**Years Ended December 31, 2005, 2004, and
for the period from January 8, 2001 (Inception)
to December 31, 2005**

Index to Financial Statements for December 31, 2005

Index to Financial Statements for June 30, 2006

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of:

Pipex Therapeutics, Inc.

(A Development Stage Company)

We have audited the accompanying consolidated balance sheet of Pipex Therapeutics, Inc. and Subsidiaries (a development stage company) as of December 31, 2005 and the related consolidated statements of operations, changes in stockholders' deficit and cash flows for the years ended December 31, 2005 and 2004 and for the period from January 8, 2001 (inception) to December 31, 2005. 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 Therapeutics, Inc. and Subsidiaries (a development stage company) as of December 31, 2005, and the consolidated results of their operations, changes in stockholders' deficit and cash flows for the years ended December 31, 2005 and 2004, and for the period from January 8, 2001 (inception) to December 31, 2005, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has a net loss of \$1,355,842 and net cash used in operations of \$1,082,109, respectively for the year ended December 31, 2005 and a working capital deficit of \$985,968, deficit accumulated during the development stage of \$3,914,268 and a stockholders' deficit of \$703,838 at December 31, 2005. These factors raise substantial doubt about its ability to continue as a going concern. Management's plan in regards to these matters is also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Berman & Company, P.A.
Certified Public Accountants

Boca Raton, Florida

July 20, 2006 except for Note 8(E) as to which the date is November 2, 2006

Pipex Therapeutics, Inc. and Subsidiaries
(A Development Stage Company)
Consolidated Balance Sheet
December 31, 2005

ASSETS

Current Assets

Cash	\$ 1,157,790
Total Current Assets	1,157,790

Equipment, net of accumulated depreciation of \$2,260	282,130
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Total Assets	\$ 1,439,920
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LIABILITIES AND STOCKHOLDERS' DEFICIT

Current Liabilities

Accounts payable	\$ 214,374
Loans payable - related party	1,929,384
Total Current Liabilities	2,143,758

Commitments and Contingencies (See Note 6)

Stockholders' Deficit

Series A, convertible preferred stock, \$0.001 par value; 5,000,000 shares authorized, issued and outstanding	5,000
Series B, convertible preferred stock, \$0.001 par value; 10,000,000 shares authorized, none issued and outstanding	-
Common stock, \$0.001 par value; 10,000,000 shares authorized, 1,450,000 shares issued and outstanding	1,450
Additional paid-in capital	3,203,980
Deficit accumulated during the development stage	(3,914,268)
Total Stockholders' Deficit	(703,838)
Total Liabilities and Stockholders' Deficit	\$ 1,439,920

See accompanying notes to consolidated financial statements.

Pipex Therapeutics, Inc. and Subsidiaries
(A Development Stage Company)
Consolidated Statements of Operations

	For the year ended December 31,		For the Period from January 8, 2001 (Inception) to December 31, 2005
	2005	2004	
Operating Expenses			
Research and development	\$ 946,065	\$ 349,551	\$ 2,167,514
General and administrative	285,701	221,612	1,280,105
Compensation	87,444	31,333	263,766
Merger costs	37,500	-	37,500
Total Operating Expenses	1,356,710	602,496	3,748,885
Loss from Operations	(1,356,710)	(602,496)	(3,748,885)
Other Income (Expense)			
Interest income	868	3	26,600
Other expense	-	-	(1,733)
Total Other Income, net	868	3	24,867
Net Loss	\$ (1,355,842)		