PIPEX PHARMACEUTICALS, INC.
Form 10KSB/A
August 29, 2008
UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-KSB/A
AMENDMENT No. 1
ANNUAL REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

For the fiscal year ended December 31, 2007

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934

For the transition period from_____
to_____

Commission File Number: 333-139354

PIPEX PHARMACEUTICALS, INC.
(Name of small business issuer in its charter)

Delaware	13-3808303
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification Number)
3930 Varsity Drive Ann Arbor, MI	48108
(Address of principal executive offices)	(Zip Code)

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

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

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

Common Stock, $0.001 par value per share

(Title of Class)

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

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

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

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

The aggregate market value of the issuer's common stock held by non-affiliates of the registrant as of March 24, 2008, was approximately $7,246,715 based on $0.89, the price at which the registrant's common stock was last sold on that date.

As of March 24, 2008, the issuer had 20,472,855 shares of common stock outstanding.

Documents incorporated by reference: None.

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

PIPEX PHARMACEUTICALS, INC.

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EXPLANATORY NOTE

The purpose of this Amendment No. 1 on Form 10-KSB/A is to include the internal control over financial reporting information in the certification of the principal executive officer and principal financial officer of Pipex Pharmaceuticals, Inc. (the "Company"), as required by Section 302 of the Sarbanes-Oxley Act of 2002, that was inadvertently omitted from the certification contained in the previously filed Annual Report on Form 10-KSB for the year ended December 31, 2007, filed with the Securities and Exchange Commission on March 31, 2008 (the "Original Form 10-KSB"). This certification is included as Exhibit 31.1 to this Amended Report.

There are no other changes to the Original Form 10-KSB other than those outlined above. Except as required to reflect the change noted above, this Amendment No. 1 on Form 10-KSB does not purport to provide a general update or discussion of any other developments involving the Company subsequent to the filing of the Original Form 10-KSB. Accordingly, this Amendment No. 1 should be read in conjunction with the Original Form 10-KSB and the Company's filings made with the Securities and Exchange Commission subsequent to the date of the Original Form 10-KSB.

PART I.

Forward-Looking Statements

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

These forward-looking statements are made as of the date of this report, and we assume no obligation to explain the reason why actual results may differ. In light of these assumptions, risks, and uncertainties, the forward-looking events discussed in this report might not occur.

ITEM 1. BUSINESS

GENERAL

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

Our drug candidates address the following pharmaceutical market opportunities: multiple sclerosis, fibromyalgia, Huntington's disease, Alzheimer's disease, dry age related macular degeneration (AMD), neurologic Wilson's disease and idiopathic pulmonary fibrosis (IPF).

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

Product	Therapeutic Indication	Stage of Development

TRIMESTATM (oral, once-daily estriol)	Relapsing Remitting Multiple Sclerosis	Phase II/III (on-going)
EFFIRMATM (oral flupirtine)	Fibromyalgia	Phase II (planned)
Oral TTM (oral tetrathiomolybdate)	Neurologically Presenting Wilson's Disease	NDA filed Nov. 28, 2007 FDA refusal to file Jan. 28, 2008
Oral TTM (oral tetrathiomolybdate)	Idiopathic Pulmonary Fibrosis (IPF)	Phase II (completed)
Oral TTM (oral tetrathiomolybdate)	Alzheimer’s Disease	Phase II (initiated)
Oral TTM (oral tetrathiomolybdate)	Huntington’s Disease	Preclinical Studies (Ongoing)
Oral TTM (oral tetrathiomolybdate)	Primary Biliary Cirrhosis	Phase II (ongoing)
Zincmonocysteine (zinc-monocysteine)	Dry Age Related Macular Degeneration	Phase II (completed)
Anti-CD4 802-2	Prevention of Severe GvHD	Phase I (complete)
CORRECTATM (clotrimazola enema)	Refractory Pouchitis	Phase II (ongoing)

Product Summary

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

TRIMESTA TM (oral, once-daily estriol)

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

Phase II/III Clinical Trial of TRIMESTA TM in Relapsing-Remitting MS
TRIMESTATM is currently the subject of an ongoing 150 patient double-blind phase II/III clinical in relapsing remitting MS patients. TRIMESTATM will be given in combination with subcutaneously injected Copaxone®, a standard treatment for MS. The primary endpoint is evaluating effects of the treatment combination on relapse rates using several clinical and magnetic resonance imaging measures of disability progression. This clinical trial has received a $5 million grant from the National Multiple Sclerosis Society (NMSS) in partnership with the National MS Society's Southern California chapter, with support from the National Institutes of Health (NIH).

TRIMESTATM for Relapsing-Remitting Multiple Sclerosis (MS)

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

Phase II Clinical Trial Results of TRIMESTA in Relapsing-Remitting MS
TRIMESTATM has completed an initial 10-patient, 16-month, single-agent, crossover, phase IIA clinical trial in the U.S. for the treatment of MS. The results of this study were encouraging.

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

Market Opportunities for TRIMESTA TM

Multiple Sclerosis

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

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

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

EFFIRMATM (oral flupirtine)

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

Our oral flupirtine has been approved as a treatment of pain in Europe since 1984, but has never been approved for any indication in the US. Flupirtine, a non-opiate analgesic, has been used in Europe for more than 20 years for post-surgical pain, cancer pain, trauma pain, pain associated with liver disease, and other nocioceptive pain states. Preclinical data and clinical experience suggests that flupirtine should also be effective for neuropathic pain since it acts in the central nervous system via a mechanism of action distinguishable from most marketed analgesics. Flupirtine is especially attractive because it operates through non-opiate pain pathways, exhibits no known abuse potential, and lacks withdrawal effects. In addition, no tolerance to its antinocioceptive effects has been observed. One common link between neuroprotection, nocioception, and flupirtine may be the NMDA (N-methyl-D-aspartate) glutamate system, a major receptor subtype for the excitotoxic neurotransmitter, glutamate. Flupirtine has strong inhibitory actions on NMDA-mediated neurotransmission.

EFFIRMA TM for Fibromyalgia

Our scientific collaborator has demonstrated preliminary anecdotal efficacy of EFFIRMATM for the treatment of Fibromyalgia in a small number of U.S. patients suffering from fibromyalgia that were refractive to other analgesics and therapies. EFFIRMATM was well tolerated by patients with no untoward side effects. In addition, substantial improvement in signs and symptoms was demonstrated in this difficult-to-treat fibromyalgia patient population. Our scientific collaborator filed an investigator initiated IND with the FDA to conduct a phase II clinical trial in fibromyalgia patients with oral flupirtine. This IND was placed on hold pending the outcome of certain chemistry, manufacturing and controls concerns. We along with our scientific collaborator have responded to the FDA’s concerns regarding manufacturing concerns.

Market Opportunity for EFFIRMA
Fibromyalgia is an arthritis-related condition that is characterized by generalized muscular pain and fatigue. It is a chronic and debilitating condition characterized by widespread pain and stiffness throughout the body, accompanied by severe fatigue, insomnia and mood symptoms. It is estimated to affect between two and four percent of the world's population and after, osteoarthritis, is the most commonly diagnosed disorder in rheumatology clinics.

We estimate that there are approximately 6 million Americans with fibromyalgia. During 2007, Lyrica® which is marketed by Pfizer, is the only FDA-approved medication for fibromyalgia, recorded $1.8 billion in sales and $1.2

billion during its first year on the market.

oral TTM (oral tetrathiomolybdate)

Oral TTM is an oral, small-molecule, anticopper agent that is highly specific for lowering the levels of free copper in serum. Free copper in serum represents the toxic form of copper, as opposed to the essential form of copper which is found tightly bound to appropriate copper proteins, such as ceruloplasmin. Free copper in serum readily crosses the blood-brain barrier (BBB) and is generally at equilibrium with free copper levels in the central nervous system (CNS). The brain is the organ most sensitive to the toxic effects of free copper. By lowering the levels of toxic free copper in serum, oral TTM demonstrated the ability to reduce toxic free copper levels in initially presenting neurologic Wilson's disease patients. We have also demonstrated oral TTM's ability to reduce levels of free copper in animal models of other CNS diseases, such as Alzheimer's disease and Huntington's disease. Oral TTM's unique mechanism of action and specificity for free copper may make it ideally suited for the treatment of other CNS diseases in which abnormal serum and CNS copper homeostasis are implicated.

Oral TTM for Idiopathic Pulmonary Fibrosis (IPF)

Oral TTM has also demonstrated an ability in various animal models to be a potent oral antifibrotic agent. This research is based upon the observation that the fibrotic disease process is dependent upon the availability of endogenous free copper. Oral TTM has demonstrated the ability to inhibit fibrosis in a number of well established animal models through the sequestration of available copper and inhibition of key fibrotic cytokines, including secreted protein acid rich in cysteine (SPARC), NF-kappaB, TGF- , FGF-2, IL-1, IL-6, IL-8, connective tissue growth factor (CTGF) and collagen.

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

Phase II Clinical Trials of oral TTM in Refractory IPF Patients

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

Oral TTM for Alzheimer's Disease (AD)

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

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

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

Oral TTM's specificity and unique mechanism of action for rapidly lowering toxic free copper levels, combined with its history of success in completed pivotal clinical trials of neurologically presenting Wilson's disease, may position oral TTM as the first available therapeutic agent capable of correcting the serum and CNS fee copper dyshomeostasis that might represent an important fundamental cause of AD. The National Institute of Health (NIH) granted COPREXA TM a grant in the amount of $306,172 in February 2007 in order to support the testing of its utility for the treatment of AD. During November 2007, our scientific collaborator reported preliminary results of the use of oral TTM in Alzheimer's disease animal studies, oral TTM demonstrated a 40% reduction ($p<0.05$) in insoluble amyloid-beta, a key Alzheimer's disease protein.

During January 2008, we initiated a phase II clinical trial with oral TTM in Alzheimer's disease patients. We plan to pre-select patients with elevated levels of "free" copper. This clinical trial received partial support from the Italian Ministry of Health. Based on the manufacturing issue raised in the clinical hold letter, we are currently evaluating the manufacturing issues raised within the hold letter as it relates to the oral TTM batches prepared for this phase II study.

Since receipt of the written clinical hold letter, we have informed our clinical collaborators for this study not to enroll anyone into the study until further notice. We cannot provide any assurances that we will be able to readily solve the manufacturing issues in the hold letter and continue with this clinical trial.

Oral TTM TM in for Neurologic Wilson’s Disease

Based upon receipt of written clinical hold letter communicated to a collaborator's IND from the FDA and forwarded to us on March 26, 2008, the FDA communicated concerns previously disclosed regarding the adequacy of the evidence of clinical efficacy, safety, study quality, data collection and overall risk/benefit profile of oral TTM for the treatment of neurologic Wilson's disease as represented by the two completed clinical trials of TTM for neurologic Wilson's disease that formed the basis of the previous NDA submission. In the written clinical hold letter for the Wilson's disease IND, the FDA raised additional chemistry, manufacturing and controls questions, regarding the identity, strength and purity of oral TTM that will need to be resolved to the satisfaction of the FDA before the clinical hold is lifted. In the written clinical hold letter the FDA also provided non-clinical hold feedback including the reference that the clinical endpoints, design and conduct of the dose comparator study that has enrolled 40 patients to date will not be sufficient for a NDA of oral TTM for neurological Wilson's disease. Based on this written FDA communication, we believe that at the present time it appears that the FDA will not deem the three existing clinical trials of oral TTM to be sufficient for an NDA for this indication. Pipex plans to have a Type B meeting with the FDA to discuss next steps for oral TTM development in neurologic Wilson's disease.

ANTI-CD4 802-2

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

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

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

From a commercial perspective, anti-CD4 802-2 and our other anti-CD4 molecules address an autoimmune disease market projected to be $21 billion in 2006 with an anticipated annual growth rate of 15% thereafter. Autoimmune diseases represent the third-largest category of illness in the industrialized world, after heart disease and cancer. A partial list of such diseases includes MS, psoriasis, and rheumatoid arthritis, as well as “non−typical” CD4-mediated diseases such as allergy and asthma.

CORRECTATM (clotrimazole enema)

We are developing CORRECTATM, a proprietary retention enema formulation of the widely used topical antifungal agent clotrimazole, for the treatment of acute refractory pouchitis, a subset of inflammatory bowel disease (IBD) and ulcerative colitis (UC) market. CORRECTATM is currently the subject of a double-blind, placebo-controlled, multi-center, one-month, phase II clinical trial for acute pouchitis.

Market Opportunity for CORRECTATM
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.

FreeboundTM (metals diagnostic device)

We are developing a proprietary diagnostic device, FreeboundTM capable of measuring levels of free and bound metals in biological samples. In order to improve the manufacturing process of Freebound's disposable assay component while at the same time preserving capital, in the first quarter of 2008 we suspended testing of Freebound pursuant to the Pre-IDE protocol that we filed with the FDA in October 2007 and have entered into a research and supply agreement with a supplier and have initiated limited testing of these newly supplied disposable assay components.

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

We have exclusively licensed from various universities issued patent and patents applications, including foreign equivalents relating to our product candidates. We also file patent applications for inventions invented or discovered by us.

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

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

University of Michigan (UM) Exclusive License Agreement

We have entered into an exclusive worldwide license agreement with the University of Michigan (UM) for all uses of U.S. Patent No. 6,855,340, corresponding international applications, and a related corresponding patent application that relates to various uses of anti-copper therapeutics, including oral TTM, to treat inflammatory and fibrotic diseases. Pursuant to this agreement, we will use our best efforts to commercialize oral TTM 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 oral TTM for uses covered by the UM patents; issue UM 422,314 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 oral TTM in an indication covered by the UM patents), and indemnify UM against certain liabilities.

Collaborative Research and Development Agreement with UM

During September 2005, we entered into a three-year sponsored research agreement with UM relating to expanding the therapeutic utility of oral TTM 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. This agreement initially expires August 30, 2008. As part of our corporate restructuring during March 2008, we provided notice of termination of this agreement.

Consulting Agreement with Dr. George Brewer

We have entered into a three-year consulting agreement with Dr. George Brewer, inventor of the oral TTM technology. Pursuant to this agreement, we pay Dr. Brewer a quarterly fee of $30,000. We also issued to Dr. Brewer options to acquire 433,314 shares of our common stock and agreed to pay Dr. Brewer a royalty on sales of oral TTM equal to 3% of net sales for 17 years. This agreement has a provision for a two-year extension.

McLean Hospital Exclusive License Agreement

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

University of Southern California Agreement

Through our majority owned subsidiary Solovax we have an exclusive license agreement, as amended, with the University of Southern California (USC) to license U.S. Patent Application serial nos. 09/156509 and 10/773356 and its foreign equivalents entitled “T-Cell Vaccination for the Treatment of Multiple Sclerosis.” Under this agreement we are required to reimburse USC’s patent expenses and pay USC royalties of 4% of net sales relating to the vaccine.

Children’s Hospital-Boston Agreement

Our subsidiary Effective Pharmaceuticals, Inc. (EPI), has entered into an exclusive worldwide license agreement with Children’s Hospital Medical Corporation, an affiliate of Children’s Hospital-Boston, relating to a certain pending patent application covering all gastrointestinal, hepatic, and rectal uses of the clotrimazole technology, including

CORRECTATM. Pursuant to this agreement, we owe a $150,000 upfront payment in two equal installments, of which the first installment has been paid, as well as annual maintenance fees, milestone payments totaling $3 million that are payable on issuance of U.S. and European patents covering the clotrimazole technology, on initiation of a pivotal phase III clinical trial, on filing of a New Drug Application (NDA), and on approval of an NDA with the FDA and European Medical Agency, as well as royalties on net sales of the clotrimazole technology covered by the licensed patents. We may be permitted to partially pay milestone payments in the form of equity. We also acquired rights to valuable data generated under an investigational new drug (IND) application filing with the FDA and an orphan drug designation. These data include all preclinical and clinical data know-how relating to the clotrimazole technology. We would also be required to indemnify Children's Hospital and its employees against certain liabilities.

Thomas Jefferson University License Agreement

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

The Regents of University of California License Agreement

We have an exclusive worldwide license agreement with the Regents of the University of California relating to an issued US Patent No. 6,936,599 and pending patent applications covering the uses of the TRIMESTATM technology. Pursuant to this agreement, we paid an upfront license fee of $20,000, reimbursed patent expenses of $41,000 and agreed to pay a license fee of $25,000 during 2006, as well as annual maintenance fees, milestone payments totaling $750,000 that are payable on filing an NDA, and on approval of an NDA with the FDA, as well as royalties on net sales of the TRIMESTA TM 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 License Agreement

We have an exclusive worldwide license agreement with Oregon Health & Sciences University relating to various doses of estrogens in combination with immunotherapeutics for the treatment of autoimmune diseases. Pursuant to this agreement, we paid an upfront license fee of $1,500 and reimbursed patent expenses of $38,160. Milestone payments totaling $575,000 may be due upon the achievement of certain milestones, as well as minimum royalty payments of $210,000 and royalties on net sales for the technology covered by the licensed patents. We have the ability to make these milestone payments in the form of equity.

Maine Medical Institute License Agreement

We have an exclusive worldwide license agreement with Maine Medical Institute relating to various uses of anti-copper therapies. Pursuant to this agreement, we paid in equity, an upfront license fee of $20,000 made in two installments will reimburse patent expenses of $45,000 over a three year period. Milestone payments totaling $350,000 that are payable on filing an NDA, and on approval of an NDA with the FDA, as well as royalties on net sales for the technology covered by the licensed patents. We have the ability to make these milestone payments in the form of equity. As part of our corporate restructuring during March 2008, we provided notice of termination of this agreement.

Manufacturing

We utilize contract manufacturing firms to produce the bulk active ingredients for oral TTM, TRIMESTATM, Zinc-monocysteine, CORRECTATM, Anti-CD4 802-2, and EFFIRMATM in accordance with “current good manufacturing processes” (cGMP) guidelines outlined by the FDA. During February 2007, we leased a 17,600 square foot facility in Ann Arbor, MI which will be used to produce oral capsule products under GMP conditions. We have manufactured oral TTM at this site.

Sales and Marketing

We plan to establish our own in-house neuroscience sales and marketing effort in the United States to market our neurology products, specifically oral TTM and TRIMESTA TM. As we expand the use of our products 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 CORRECTATM, Anti-CD4 802-2, EFFIRMATM, Zinc-monocysteine, SOLOVAX, TM and certain uses of oral TTM.

ITEM 1A. RISK FACTORS

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

RISKS RELATING TO OUR BUSINESS

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

We are a development stage company that has experienced significant losses since inception and has a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. To date, we have generated no product revenues. As of December 31, 2007, we have expended approximately $17.3 million on a consolidated basis acquiring and developing our current product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Therefore, for the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees, and grants. We will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We are not currently profitable and may never become profitable.

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

- continue to undertake pre-clinical development and clinical trials for our product candidates;

- seek regulatory approvals for our product candidates;

- implement additional internal systems and infrastructure;

- lease additional or alternative office facilities; and

- hire additional personnel, including members of our management team.

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

achieve or maintain profitability could negatively impact the value of our common stock and underlying securities.

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

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

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

Our operations have been limited to organizing and staffing our company, acquiring, developing, and securing our proprietary technology, and undertaking pre-clinical trials and Phase I/II, and Phase II and Phase III 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.

Our NDA for oral TTM has not been accepted for filing and/or we may not obtain the necessary U.S. or worldwide regulatory approvals to commercialize oral TTM or one of our product(s).

On November 28, 2007, we filed a New Drug Application (NDA) with the Food and Drug Administration (FDA) seeking approval to market oral TTM (oral tetrathiomolybdate) for initially presenting neurologic Wilson's disease. On January 28, 2008 representing sixty (60) days from the date of NDA filing we received notification from the FDA that our NDA has not been accepted for further review and the FDA issued a refusal to file letter ("RTF"). In the RTF letter the FDA cited various deficiencies in the NDA filing, including, the formatting and presentation of the data, preliminary assessments concerning the adequacy and quality of the clinical evidence to support the safety and efficacy of oral TTM, the necessity to conduct a Segment III preclinical reproductive toxicology study as well as chemistry, manufacturing and controls issues regarding the identity, strength and purity of oral TTM. Given the receipt of the RTF letter, we will face substantial delays in our ability to prepare and re-file a new NDA, if at all, and potential approval to market oral TTM.

On February 26, 2008, we completed a Type A meeting with the FDA to discuss the deficiencies raised in the RTF letter. Based on this meeting with the FDA, Pipex believes it reached an understanding with the FDA on a course of action to resolve all of the filing issues raised in the RTF letter. Nevertheless, the FDA raised concerns regarding the adequacy of the evidence of clinical efficacy, safety, study quality, data collection and overall risk/benefit profile of oral TTM for neurologic Wilson's disease as represented by the two completed clinical trials of oral TTM for neurologic Wilson's disease that formed the basis of the NDA. Even if Pipex is successful in preparing and filing a revised NDA, Pipex cannot provide any assurances that a newly filed NDA will be accepted for filing or that upon review of the NDA by the FDA, Pipex will be successful in overcoming such FDA concerns and that oral TTM for initially presenting neurologic Wilson's disease will be approved by the FDA. The clinical trials for oral TTM which formed the basis of the NDA filing were conducted over a period of 18 years from 1998 to 2005 prior to entering into our license agreement for oral TTM and were conducted under an investigator initiated IND by our scientific advisor and consultant, Dr. George Brewer under grant support from various non-profit foundations and governmental agencies including the FDA’s Orphan Products Group. In the event that we are able to prepare, file and obtain FDA acceptance of a new NDA filing for oral TTM, we cannot provide any assurances that after the FDA reviews our new submission, that the new NDA submission will overcome the FDA's concerns raised in the RTF letter sufficient for approval of oral TTM or that the FDA will not upon further review raise additional concerns regarding manufacturing, clinical, or nonclinical which may impact the potential approvability of oral TTM for the treatment of neurologic Wilson’s disease.

In order to enhance a resubmitted NDA filing for oral TTM for the treatment of neurologic Wilson’s disease, at the February 26, 2008 Type A meeting Pipex discussed with the FDA Pipex’s plans to schedule a Type B meeting with the FDA to discuss the utility of providing the FDA with additional efficacy data from an ongoing double-blind, comparator, dose optimization clinical trial of oral TTM for the treatment of neurologic Wilson’s disease. To date, this third study has enrolled and completed dosing in approximately 40 neurologically presenting Wilson’s disease patients. At the Type B meeting to be scheduled, Pipex intends to present potential, available pharmacokinetic and pharmacodynamic data (such as and including oral TTM's effects on lowering serum free copper levels in patients) from this third clinical trial as well as a summarization of the data from the previously completed clinical trials with oral TTM for neurologic Wilson’s disease. The feedback from this Type B meeting with the FDA will determine the timing of any potential NDA resubmission for oral TTM for this indication and may result in Pipex discontinuing the NDA refiling process for oral TTM as well as potentially our planned MAA filing in Europe. Additionally, depending on the analysis of additional data, the FDA may request a separate pharmacokinetic study or additional clinical

studies.

On March 17, 2008, Dr. George Brewer informed us that pursuant to a teleconference between Dr. Brewer and the FDA of the same date, Dr. Brewer's physician sponsored investigational new drug application (IND) for oral tetrathiomolybdate for Wilson's disease had been placed on clinical hold pending the potential resolution, if any, of items described in the RTF. The IND that is the subject of the clinical hold includes an active dose optimization comparator protocol of oral tetrathiomolybdate that to date has enrolled and treated approximately 40 neurologically presenting Wilson's disease patients the data from which we intend to collect, analyze and present to the FDA at a Type B meeting to be requested to discuss a potential revised New Drug Application submission. We cannot provide any assurance that Dr. Brewer will be successful in lifting the clinical hold imposed by the FDA, that we will be successful in preparing and filing a revised NDA, that any such newly filed NDA will be accepted for filing or that upon review of any such NDA by the FDA, we will be successful in overcoming the concerns raised by the FDA and that oral tetrathiomolybdate for initially presenting neurologic Wilson's disease will be approved by the FDA. Based upon receipt of a written clinical hold letter communicated to Dr. Brewer from the FDA and forwarded to us on March 26, 2008, the FDA detailed its issues and concerns that are required to be addressed in order to lift the clinical hold, including chemistry, manufacturing and control (CMC) issues concerning the identity, strength and purity of oral TTM. We presently intend to assist Dr. Brewer in resolving the CMC issues raised by the FDA and do not presently intend to initiate patient dosing in our Italian clinical trial of oral TTM for Alzheimer's disease until such issues are resolved to the satisfaction of the FDA. We cannot provide any assurance that we will be successful in overcoming such CMC issues to the satisfaction of the FDA. The written clinical hold letter also provided feedback not related to the clinical hold per se including the reference that the clinical endpoints, design and conduct of the dose comparator clinical study that has enrolled 40 patients to date will most likely not be sufficient for a NDA of oral TTM for neurologic Wilson's disease. Based on this communication, Pipex plans to have a Type B meeting with the FDA to discuss next steps for oral TTM development in neurologic Wilson's disease. Given the issues raised by the FDA in its RTF letter of January 28, 2008 as well as the FDA's written clinical hold letter to Dr. George Brewer forwarded to us on March 26, 2008, at the present time it appears that the FDA will not deem the three existing clinical trials of oral TTM to be sufficient for a New Drug Application of oral TTM for initially presenting neurologic Wilson's disease. Given the limited number of patients afflicted by this disease, an additional clinical trial of oral TTM for this indication will necessarily take a substantial amount of time and resources to plan, enroll and complete. The design of such further study is also uncertain given that existing drugs approved for Wilson's disease appear to be contraindicated for initially presenting neurologic Wilson's disease or too slow acting for this critically ill patient population. Should we elect to abandon our efforts to seek U.S. and/or European approval of oral TTM for neurologically presenting Wilson's disease we will most likely not have sufficient resources to pursue all of the additional indications for oral TTM that are the subject of our research and development, including, idiopathic pulmonary fibrosis, Alzheimer's disease, primary biliary cirrhosis and Huntington's disease. We may elect to abandon our efforts to develop oral TTM for any or all of these indications, including, Wilson's disease.

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 an NDA, demonstrating that the product candidate is safe for humans and effective for its intended use and that the product candidate can be consistently manufactured and is stable. This demonstration requires significant research and animal tests, which are referred to as "pre-clinical studies," human tests, which are referred to as "clinical trials" as well as the ability to manufacture the product candidate, referred to as "chemistry manufacturing control" or "CMC." 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.

In addition to our own patent applications, we also currently rely on an exclusive worldwide license agreement with the University of Michigan relating to various uses of oral TTM. We also have an exclusive license agreement with the McLean Hospital relating to the use of EFFIRMATM to treat fibromyalgia syndrome; an exclusive license agreement with Thomas Jefferson University relating to our anti-CD4 inhibitors; an exclusive license agreement with the Regents of the University of California relating to our TRIMESTATM technology; an exclusive license agreement with the Children's Hospital-Boston relating to our CORRECTATM technology and an exclusive license 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 limited marketing or sales capabilities. For us to research, develop, and test our product candidates, we would need to contract with outside researchers, in most cases those parties that did the original research and from whom we have licensed the technologies.

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

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

Companies that currently sell or are developing both generic and proprietary pharmaceutical compounds to treat central-nervous-system, inflammatory, autoimmune and fibrotic diseases include: Pfizer, Inc., Aton Pharma, 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., Novartis, 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 or alternative delivery or dosages of already approved therapies are being developed to treat autoimmune inflammatory, Fibromyalgia, MS, fibrotic, Alzheimer's and Wilson's diseases, several of which may be approved or are in early and advanced clinical trials, such as pirfenidone, milnacipram, Lyrica, Cymbalta, Effexor, 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 CORRECTATM, TRIMESTA TM, zincmonocysteine, anti-CD4 inhibitors, EFFIRMATM and oral TTM technologies. We are aware that other companies are developing competitive anti-copper therapies that are in various stages of clinical trials or have been approved by regulatory authorities. For example, trientine, d–-pennicillamine and zinc based therapies, all FDA approved anti-copper agents have been or are being tested in various treatment regiments for the treatment of Wilson's disease. Should clinicians or regulatory authorities view these therapeutic regiments as or more effective than oral TTM in the treatment of neurologic Wilson's disease, this might delay or prevent us from obtaining regulatory approval for oral TTM, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid and private insurers.

We may not succeed in enforcing our orphan drug designations.

Oral TTM 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 for "orphan drug" designations in the EMEA (the European equivalent of the FDA) for both oral TTM and CORRECTATM for similar uses. Pursuant to our agreements with our scientific inventors and universities, we have acquired these designations. Orphan drug designation is an important element of our competitive strategy because there are no composition of matter patents for oral TTM 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 oral TTM to treat Wilson's disease. While we are not aware of any other companies that have sought orphan drug designation for oral TTM 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 oral TTM and its active ingredient, tetrathiomolybdate, and secure approvals for different indications. We are aware that a potential competitor has an exclusive license from the University of Michigan (UM) to an issued U.S. patent that relates to the use of tetrathiomolybdate to treat angiogenic diseases (the "Angiogenic Patent") and is currently in phase I and phase II clinical trials for the treatment of various forms of cancer. To our knowledge, this competitor and UM have filed additional patent applications claiming various analog structures and formulations of tetrathiomolybdate to treat various diseases. Further, we cannot predict whether our competitor might obtain approval in the U.S. or Europe to market tetrathiomolybdate for cancer or another indication ahead of us. We also cannot predict whether, if issued, any patent corresponding to the Angiogenic Patent may prevent us from conducting our business or result in lengthy and costly litigation or the need for a license. Furthermore, if we need to obtain a license to these or other patents in order to conduct our business, we may find that it is not available to us on commercially reasonable terms, or is not available to us at all.

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

Since we do not have composition of matter patent claims for oral TTM, EFFIRMA TM, and TRIMESTA TM, others may obtain approvals for other uses of these products. For example, the active ingredients in both EFFIRMA TM and TRIMESTA TM have been approved for marketing in overseas countries for different uses. Other companies, including the original developers or affiliates of these products may seek to develop EFFIRMA TM or TRIMESTA TM for these uses in the US or any country we are seeking approval for. We cannot provide any assurances that any other company may obtain FDA approval for products that contain EFFIRMATM or TRIMESTATM that might adversely affect our ability to develop and market these products in the US.

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. Other than anti-CD4 802-2 and zinc-monocysteine, there are no composition of matter patents for TRIMESTATM, EFFIRMATM, CORRECTATM, Solovax, oral TTM or their respective active and zinc-monocysteine ingredients estriol, flupirtine, clotrimazole and tetrathiomolybdate. Additionally, we do not have an issued patent for oral TTMs use to treat Wilson's disease, although we do have Orphan Drug Designation for this indication. Orphan Drug Designation provides protection for seven years of marketing exclusivity for that product in that disease indication in the U.S. We also expect to rely on patent protection from an issued U.S. Patent for the use of oral TTM and related compounds to treat inflammatory and fibrotic diseases (U.S. Patent No 6,855,340). These patents have been exclusively licensed to us. We have also filed various pending patent applications which cover various formulations, packaging, distribution & monitoring methods for oral TTM. We rely on issued patent and pending patent applications for use of TRIMESTATM to treat MS (issued U.S. Patent No. 6,936,599) and various other therapeutic indications which have been exclusively licensed to us. We have also exclusively licensed an issued patent for the treatment of fibromyalgia with EFFIRMATM and have pending patent applications for our uses of CORRECTA TM.

Our zinc-monocysteine (z-monocys) product candidate is exclusively licensed from its inventors, David A. Newsome and David Tate. Z-monocys is the subject of two issued U.S. patents, 7,164,035 and 6,586,611 and pending U.S. patent application ser. no. 11/621,380.

In March 2008, we received an English translation of a Russian disclosure, Zegzhda et. al. Chemical Abstracts Vol. 85 Abstract No. 186052 (1976) that was recently cited by the U.S. patent examiner during our prosecution of the pending U.S. patent application Ser. No. 11/621,390. The translation of such disclosure appears to describe an insoluble non-zinc-salt zinc monocysteine complex which may impact the validity of claim 1 of U.S. patent 7,164,035.

We also expect to rely on regulatory exclusivities, such as the Orphan Drug Designation with the FDA and EMEA ("Orphan Drug") to protect oral TTM, CORRECTATM and our other future products for certain therapeutic indications. 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 CORRECTATM to treat pouchitis as well as an Orphan Drug Designation for the use

of oral TTM 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 oral TTM and CORRECTATM. To be successful in enforcing this designation, our NDA would need to be the first NDA approved to use oral TTM and CORRECTATM for that indication. While we are not aware of any other companies that have sought orphan drug designation for oral TTM and CORRECTATM 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 oral TTM, TRIMESTATM and CORRECTATM. 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 oral TTM, TRIMESTATM, zincmonocystine, Anti-CD4 802-2, EFFIRMATM 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.

In July 2007 our exclusively licensed European patent covering our multivalent T-cell vaccine, SolvaxTM, was opposed and revoked. In order to save resources, we have elected not to appeal such ruling and may elect to abandon the license with USC.

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

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

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

As of March 31, 2008, we have 12 full-time employees. We have also engaged regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. We intend to recruit certain key executive officers, including a Chief Financial Officer and Vice President of Regulatory Affairs during 2008. Our future performance will depend in part on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management.

Certain of our officers, directors, (including Mr. Stergis, our Vice Chairman of the Board and former Chief Operating Officer, Dr. Rudick, a director and former Chief Medical Officer, Jeffrey Kraws, a director and former VP of Business Development, Jeffrey Wolf, a director, and Dr. Kuo, a director) scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies which might be developing competitive products to ours. None 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 stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by any of our directors or affiliates in the future would be made available to us.

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 oral TTM 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 oral TTM 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 or the requirements that our new proprietary formulations and drug product will demonstrate satisfactory comparability to less stable formulations utilized in prior clinical trials. We may experience delays in demonstrating satisfactory stability requirements and drug product comparability requirements that could delay acceptance or approval of our planned NDA for oral TTM.

Our SOLOVAX T-cell vaccine technology is complex to manufacture. The vaccine is manufactured through the procurement of a patient's own T-cells derived from the patient's plasma. This manufacturing process involves incubation of T-cells, irradiation and refrigeration of the cells. We plan to develop a revised manufacturing procedure which will streamline quality control of the vaccine.

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

In addition, any contract manufacturer that we select to manufacture our product candidates might fail to maintain a current "good manufacturing practices" (cGMP) manufacturing facility. During February 2007, we established a commercial manufacturing facility for oral TTM product in Ann Arbor, MI and we have hired and trained our employees to comply with the extensive regulations applicable to such a facility. Upon FDA inspection our facility and/or cGMP procedures may require changes that could delay our intended product launch of oral TTM and other products that might develop.

The cost of manufacturing certain product candidates 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 product candidates.

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

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We estimate that clinical trials of our product candidates would take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;

- determination of dosing;

- lack of effectiveness during clinical trials;

- slower than expected rates of patient recruitment;

- inability to monitor patients adequately during or after treatment; and

- inability or unwillingness of medical investigators to follow our clinical protocols.

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

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

Even if our clinical trials are completed as planned, we cannot be certain that the results will support our product-candidate claims. Success in pre-clinical testing and phase II clinical trials does not ensure that later phase II or phase III 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 substandard performance, could result in delay of any FDA applications and our commercialization of the drug candidate involved.

Our oral TTM program is highly dependent on Dr. George Brewer, Professor Emeritus at the University of Michigan. Dr. Brewer was the principal investigator and conducted the clinical trials over an 18 year period on the oral TTM clinical trials which formed the basis of our NDA filing. We have retained Dr. Brewer, age 76 as an advisor and consultant to Pipex. In the event of Dr. Brewer's untimely death or disability, may significantly hamper our developement capabilities of oral TTM.

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, SOLOVAXTM, CORRECTATM, anti-CD4 802-2, EFFIRMATM and oral TTM development programs. Specifically, all of the clinical trials have been conducted under physician-sponsored investigational new drug applications (INDs), not corporate-sponsored INDs. Additionally, the clinical trials for oral TTM for the treatment of neurologic Wilson's disease have been conducted and completed prior to us licensing this technology from the University of Michigan. Due to various patient privacy regulations and other administrative matters, we have experienced delays and/or an inability to obtain clinical trial data relating to oral TTM. As such, this delay or inability to obtain any data might result our inability to obtain regulatory approvals for oral TTM and our products. We are also dependent on government and private grants to fund certain of our clinical trials for our product candidates. For example, TRIMESTA has received a $5 million grant from the Southern Chapter of the National Multiple Sclerosis Society which funds a majority of our ongoing phase II/III clinical trial in relapsing remitting multiple sclerosis. If we are unable to maintain these grants, we might be forced to scale back development of these product candidates. We have experienced difficulty in collecting the data or transferring these programs to corporate-sponsored INDs. Additionally, we are aware that all of our scientific collaborators may also act as advisors to our competitors.

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

We currently have no sales, marketing, or distribution capabilities. We do not anticipate having resources in the foreseeable future to allocate to selling and marketing our proposed products. Our success will depend, in part, on whether we are able to enter into and maintain collaborative relationships with a pharmaceutical or a biotechnology

company charged with marketing one or more of our products. We may not be able to establish or maintain such collaborative arrangements or to commercialize our products in foreign territories, and even if we do, our collaborators may not have effective sales forces.

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

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

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

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

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

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

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

- developing drugs;

- undertaking pre-clinical testing and human clinical trials;

- obtaining FDA and other regulatory approvals of drugs;

- formulating and manufacturing drugs; and

- launching, marketing and selling drugs.

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

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

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

We may also face frivolous litigation or lawsuits from various competitors or from litigious securities attorneys. The cost to us of any litigation or other proceeding relating to these areas, even if resolved in our favor, could be substantial and could distract management from our business. Uncertainties resulting from initiation and continuation

of any litigation could have a material adverse effect on our ability to continue our operations.

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

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

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

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

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

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

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

RISKS RELATING TO OUR STOCK

We will seek to raise additional funds in the future, which may be dilutive to stockholders 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 stockholders will be reduced. We may also enter into strategic transactions, issue equity as part of license issue fees to our licensors, compensate consultants using equity that may be dilutive. Our stockholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our common stock. If we cannot raise additional funds, we will have to delay development activities of our products candidates.

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

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

Our shares of common stock are from time to time thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares to raise money or otherwise desire to liquidate their shares.

Our common stock has from time to time been “thinly-traded,” meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non−existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give stockholders any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

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

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

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

We cannot assure you that we will be able to maintain the listing standards of the American Stock Exchange. The American Stock Exchange requires companies to meet certain listing criteria including certain minimum stockholders and equity prices per share. We may not be able to maintain such minimum prices or may be required to effect a reverse stock split to maintain such minimum prices.

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 2008, $1,178,500). In return, the FDA assigns a goal of ten months for issuing its "complete response," in which the FDA may approve or deny the NDA, or require additional clinical data. Even if these data are submitted, the FDA may ultimately decide the NDA does not satisfy approval criteria. If the FDA approves the NDA, the product becomes available for physicians prescription. Product approval may be withdrawn if regulatory compliance is not maintained or safety problems occur. The FDA may require post-marketing studies, also known as phase IV studies, as a condition of approval, and requires surveillance programs to monitor approved products that have been commercialized. The agency has the power to require changes in labeling or prohibit further marketing based on the results of post-marketing surveillance.

Satisfaction of these and other regulatory requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures on our activities. We cannot be certain that the FDA or other regulatory agencies will approve any of our products on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from pre-clinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications or uses.

Even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing FDA regulation, including record-keeping requirements, reporting of adverse experiences, submitting periodic reports, drug sampling and distribution requirements, manufacturing or labeling changes, record-keeping requirements, and

compliance with FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their facilities with the FDA and state agencies, and are subject to periodic unannounced inspections for GMP compliance, imposing procedural and documentation requirements upon us and third-party manufacturers. Failure to comply with these regulations could result, among other things, in suspension of regulatory approval, recalls, suspension of production or injunctions, seizures, or civil or criminal sanctions. We cannot be certain that we or our present or future subcontractors will be able to comply with these regulations.

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

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

Other Regulatory Requirements

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

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

European Product Approval

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

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

Approval can take several months to several years, and can be denied, depending on whether additional studies or clinical trials are requested (which may delay marketing approval and involve unbudgeted costs) or regulatory authorities conduct facilities (including clinical investigation site) inspections and review manufacturing procedures, operating systems and personnel qualifications. In many cases, each drug manufacturing facility must be approved, and further inspections may occur over the product's life.

The regulatory agency may require post-marketing surveillance to monitor for adverse effects or other studies. Further clinical studies are usually necessary for approval of additional indications. The terms of any approval, including labeling content, may be more restrictive than expected and could affect the marketability of a product.

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

Pricing Controls

Pricing for products under approval applications is also subject to regulation. Requirements vary widely between countries and can be implemented disparately intra-nationally. The E.U. generally provides options for member states to control pricing of medicinal products for human use, ranging from specific price-setting to systems of direct or

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

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

Third-Party Reimbursements

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

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

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

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

Fraud and Abuse Laws

The U.S. federal Medicare/Medicaid anti-kickback law and similar state laws prohibit remuneration intended to induce physicians or others either to refer patients, or to acquire or arrange for or recommend the acquisition of health care products or services. While the federal law applies only to referrals, products or services receiving federal reimbursement, state laws often apply regardless of whether federal funds are involved. Other federal and state laws prohibit anyone from presenting or causing to be presented false or fraudulent payment claims. Recent federal and state enforcement actions under these statutes have targeted sales and marketing activities of prescription drug manufacturers. As we begin to market our products to health care providers, the relationships we form, such as compensating physicians for speaking or consulting services, providing financial support for continuing medical education or research programs, and assisting customers with third-party reimbursement claims, could be challenged under these laws and lead to civil or criminal penalties, including the exclusion of our products from federally-funded reimbursement. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition. We intend to consult counsel concerning the potential application of these and other laws to our business and to our sales, marketing and other activities to comply with them. Given their broad reach and the increasing attention given them

by law enforcement authorities, however, we cannot assure you that some of our activities will not be challenged.

Patent Restoration and Marketing Exclusivity

The U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) permits the FDA to approve Abbreviated New Drug Applications ("ANDAs") for generic versions of innovator drugs, as well as NDAs with less original clinical data, and provides patent restoration and exclusivity protections to innovator drug manufacturers. The ANDA process permits competitor companies to obtain marketing approval for drugs with the same active ingredient and for the same uses as innovator drugs, but does not require the conduct and submission of clinical studies demonstrating safety and efficacy. As a result, a competitor could copy any of our drugs and only need to submit data demonstrating that the copy is bioequivalent to gain marketing approval from the FDA. Hatch-Waxman requires a competitor that submits an ANDA, or otherwise relies on safety and efficacy data for one of our drugs, to notify us and/or our business partners of potential infringement of our patent rights. We and/or our business partners may sue the company for patent infringement, which would result in a 30-month stay of approval of the competitor's application. The discovery, trial and appeals process in such suits can take several years. If the litigation is resolved in favor of the generic applicant or the challenged patent expires during the 30-month period, the stay is lifted and the FDA may approve the application. Hatch-Waxman also allows competitors to market copies of innovator products by submitting significantly less clinical data outside the ANDA context. Such applications, known as "505(b)(2) NDAs" or "paper NDAs," may rely on clinical investigations not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use and are subject to the ANDA notification procedures described above.

The law also restores a portion of a product's patent term that is lost during clinical development and NDA review, and provides statutory protection, known as exclusivity, against FDA approval or acceptance of certain competitor applications. Restoration can return up to five years of patent term for a patent covering a new product or its use to compensate for time lost during product development and regulatory review. The restoration period is generally one-half the time between the effective date of an IND and submission of an NDA, plus the time between NDA submission and its approval (subject to the five-year limit), and no extension can extend total patent life beyond 14 years after the drug approval date. Applications for patent term extension are subject to U.S. Patent and Trademark Office ("USPTO") approval, in conjunction with FDA. Approval of these applications takes at least six months, and there can be no guarantee that it will be given at all.

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

ITEM 2. PROPERTIES

Our primary offices are located at 3930 Varsity Drive, Ann Arbor, MI 48108. We currently rent approximately 17,675 square feet of office, laboratory and production space for monthly rent of $14,327.62. This lease expires on February 28, 2011 extendable at our option for an additional three years. We believe our current offices will be adequate for the foreseeable future. Our phone number is (734) 332-7800 and our facsimile number is (734) 332-7878. Our website is located at www.pipexinc.com.

ITEM 3. LEGAL PROCEEDINGS

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

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

The following matters were submitted to a vote of our stockholders at our 2007 Annual Meeting of Stockholders held on November 2, 2007 and approved by the requisite vote of our stockholders as follows:

1. Election of the following director nominees to serve for the following year and until his successor is elected:

	Number of Shares	
Nominee	For	Withheld
Steve H. Kanzer	10,788,781	30,698
Charles L. Bisgaier	10,788,781	30,698
Jeffrey J. Kraws	10,788,748	30,731
A. Joseph Rudick	10,788,814	30,665
Nicholas Stergis	10,788,814	30,665
Jeff Wolf	10,790,381	29,098
Daniel J. Dorman	10,790,348	29,131
James S. Kuo	10,790,348	29,131

2. Approval of the Pipex Pharmaceuticals, inc. 2007 Stock Incentive Plan:

	Number of Shares	
For	Against	Abstain
9,397,760	44,850	1,434

3. Ratification of the selection of Berman & Company, P.A. as the Company's independent registered public accounting firm for our fiscal year ending December 31, 2007:

	Number of Shares	
For	Against	Abstain
10,794,684	23,594	1,201

The number of shares of our common stock eligible to vote as of the record date of October 9, 2007 was 16,998,076 shares.

PART II

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

Our common stock has traded on the American Stock Exchange under the symbol "PP" since July 2007. We were previously listed on the OTC Bulletin Board under the name "PPXP" beginning on December 18, 2006. The following table states the range of the high and low bid-prices per share of our common stock for each of the calendar quarters during the last two fiscal years while our common stock was quoted on the OTC Bulletin Board and the high and sale price while our common stock has traded on the American Stock Exchange. These quotations represent inter-dealer prices, without retail mark-up, markdown, or commission, and may not represent actual transactions. The last price of our common stock as reported on the American Stock Exchange on March 24, 2008 was $0.89 per share. As of March 24, 2008, there were approximately 386 stockholders of record of our common stock. This number does not include beneficial owners from whom shares are held by nominees in street name.

	High	Low
YEAR ENDED DECEMBER 31, 2007		
Fourth quarter	$ 7.10	$ 4.68
Third quarter	$ 8.00	$ 4.30
Second quarter	$ 8.10	$ 3.71
First quarter	$ 30.00	$ 3.06
YEAR ENDED DECEMBER 31, 2006		
Fourth quarter	$ 6.50	$ 0.56
Third quarter	$ 1.10	$ 1.00
Second quarter	$ 1.60	$ 1.25
First quarter	$ 1.02	$ 0.01

Dividend Policy

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

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

From October through November 2007, the Company issued a total of 3,274,566 shares of our common stock to a total of 50 warrant holders pursuant to a warrant call. These warrants had been previously issued in connection with the Company's 2006 private placement transaction. In connection with this warrant call, the Company appointed Noble International Investments, Inc. ("Noble") as the Company's exclusive warrant solicitation agent. The Company paid Noble $579,569 and issued Noble 327,456 warrants to purchase 327,456 share of common stock. The Warrants have a term of five years and are exercisable at $6.36 per share. This offering and sale of shares of common stock qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuance did not involve a public offering. The offering was not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the offering. In addition, these investors had the necessary investment intent as required by Section 4(2) since they agreed to, and received, share certificates bearing a legend stating that such shares are restricted. This restriction ensures that these shares will not be immediately redistributed into the market and therefore not be part of a public offering. This offering was done with no general

solicitation or advertising by us. Each investor made representations regarding his or her financial sophistication and had an opportunity to ask questions of our management.

From May 17, 2007 through September 30, 2007, the Registrant issued a total of 127,406 shares of our common stock to a total of three holders of our warrants upon the exercise of those warrants. This offering and sale of shares of common stock qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuance did not involve a public offering. The offering was not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the offering. In addition, these investors had the necessary investment intent as required by Section 4(2) since they agreed to, and received, share certificates bearing a legend stating that such shares are restricted. This restriction ensures that these shares will not be immediately redistributed into the market and therefore not be part of a public offering. This offering was done with no general solicitation or advertising by us. Each investor made representations regarding his or her financial sophistication and had an opportunity to ask questions of our management.

On January 5, 2007, the Registrant issued 795,248 shares of its common stock, and assumed a total of 34,685 options to purchase its common stock and a total of 68,858 warrants to purchase its common stock in connection with its acquisition of the remaining 34.53% interest in its subsidiary EPI. This offering and sale of securities qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuance did not involve a public offering. The offering was not a public offering as defined in Section 4(2) because of the manner of the offering. The investors had the necessary investment intent as required by Section 4(2) since they agreed to, and received, share certificates bearing a legend stating that such shares are restricted. This restriction ensures that these shares will not be immediately redistributed into the market and therefore not be part of a public offering. This offering was done with no general solicitation or advertising by the Registrant. Based on an analysis of the above factors, the Registrant has met the requirements to qualify this offering and sale for exemption under Section 4(2) of the Securities Act of 1933.

During October and November of 2006, the Company completed private placements of its stock, which resulted in the issuance of 6,900,931 shares of common stock and 3,451,524 warrants. Each unit consisted of 49,508 shares of common stock and a warrant to purchase 24,754 shares of common stock. Of the total, 2,252,506 shares were part of the share exchange in the reverse merger in connection with the issuance of 11,333,333 shares by Sheffield. The remaining 4,648,813 shares of common stock reflected issuances post reverse merger. The net proceeds from the private placements were approximately $12,766,000, which was net of cash paid as direct offering costs totaling $1,160,418. In connection with the private placements, the Company engaged a company, which is controlled by the Company’s Chairman and Chief Executive Officer, as the placement agent for the transaction. Of the total $1,160,418 in direct offering costs, the Company paid the placement agent the sum of approximately $1,033,800. Additionally the placement agent was paid non-cash compensation of 958,277 warrants with an aggregate fair value of $4,555,457. In December 2006, the Company filed a Registration Statement under the Securities Act of 1933, as amended, to register the resale of these shares by the purchasers of such shares. The Registration Statement was declared effective by the Securities and Exchange Commission on February 13, 2007. The proceeds are being used to fund operations, for working capital and for general corporate purposes, which may include capital expenditures, clinical development, research, manufacturing and/or in-licensing of technology.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the audited financial statements and notes thereto for the fiscal year ended December 31, 2007, found in this report. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward looking statements by using words such as "anticipate," "believe," "intends," or similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in Part I, Item 1A of this Report.

Overview

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

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

Critical Accounting Policies

In December 2001, the SEC requested that all registrants discuss their most "critical accounting policies" in management's discussion and analysis of financial condition and results of operations. The SEC indicated that a "critical accounting policy" is one which is both important to the portrayal of the company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We believe that the following discussion regarding research and development expenses, general and administrative expenses and non-cash compensation expense involve our most critical accounting policies.

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

General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development and general legal activities, as well as an allocation of overhead expenses incurred by the Company. We expense our general and administrative expenses as they are incurred.

Our results include non-cash compensation expense as a result of the issuance of stock and stock option grants. Compensation expense for options granted to employees represents the fair value of the award at the date of grant. All share-based payments to employees since inception have been recorded and expensed in the statements of operations as applicable under SFAS No. 123R “Share-Based Payment”.

This amount is being recorded over the respective vesting periods of the individual stock options. The expense is included in the respective categories of expense in the statement of operations. We expect to record additional non-cash compensation expense in the future, which may be significant. However, because some of the options are milestone-based, the total expense is uncertain.

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

Results of Operations

Year Ended December 31, 2007 and 2006.

Research and Development Expenses. For the year ended December 31, 2007, research and development expense was $6,327,726 as compared to $2,665,555 for the year ended December 31, 2006. The increase of $3,662,171 is due primarily to an increase in salaries and payroll taxes of approximately $1,157,000, an increase in stock based compensation charges of approximately $1,146,000 and an increase of approximately $952,000 associated with payments related to further the development of our licensed clinical drug candidates.

General and Administrative Expenses. For the year ended December 31, 2007, general and administrative expense was $3,810,585 as compared to $1,451,522 for the year ended December 31, 2006. The increase of $2,359,063 is due primarily to an increase in stock based compensation charge of approximately $791,000, an increase to professional fees of approximately $638,000 and an increase in salaries and payroll taxes of approximately $437,000.

Other Income (Expense), net. For the year ended December 31, 2007, other income-net was $245,878 compared to $17,982 for the year ended December 31, 2006. For the year ended December 31, 2007, interest income was $298,807 as compared to $17,982 for the year ended December 31, 2006. Interest income was higher for the period in 2007 as compared to the same period in 2006, due to the higher levels of cash in interest bearing accounts. For the year ended December 31, 2007, interest expense was $52,929 as compared to $0 for the year ended December 31, 2006. Interest expense for the period in 2007 relates to interest paid on the notes payable which did not exist for the same period in 2006. These notes were repaid in March 2008.

Net Loss. Net loss for the year ended December 31, 2007, was $9,892,433 as compared to $4,099,095 for the year ended December 31, 2006. This increase in net loss is attributable primarily to an increase in research and development expenses of $3,662,171 and an increase in general and administrative expenses of $2,359,063 as discussed above.

Net Loss Applicable to Common Shareholders. The net loss applicable to common shareholders for the year ended December 31, 2007 includes a non-cash charge of $12,409,722 related to the acquisition of Effective Pharmaceuticals, Inc (“EPI”). The net loss applicable to common shareholders for the year ended December 31, 2006 includes a non-cash charge of $761,000 related to Series B Preferred Stock dividends issued from EPI. The total of the non-cash charges was reflected through equal and offsetting adjustments to additional paid-in-capital with no net impact on stockholders’ equity. These amounts were considered in the determination of the Company’s loss per common share amounts for the year ended December 31, 2007 and 2006 and for the period from January 8, 2001 (inception) to December 31, 2007.

Liquidity and Capital Resources

During the year ended December 31, 2007, we had a net decrease in cash of $699,624. Total cash resources as of December 31, 2007 was $11,492,802. During the year ended December 31, 2007 and 2006, net cash used in operating activities was $6,606,859 and $2,365,819 respectively. This cash was used to fund our operations for the periods, adjusted for non-cash expenses and changes in operating assets and liabilities.

Net cash used in investing activities for the year ended December 31, 2007 and 2006 was $1,965,574 and $710,833, respectively. The net cash used in investing activities for the year ended December 31, 2007 resulted from the acquisition of property and equipment. The net cash used in investing activities for the year ended December 31, 2006 resulted from $665,000 paid to acquire Sheffield Pharmaceuticals, Inc. in the reverse acquisition and $45,833 for the purchase of property and equipment.

Net cash proceeds from financing activities were $7,872,809 and $14,111,288 for the years ended December 31, 2007 and 2006, respectively. The net cash proceeds from financing activities for the year ended December 31, 2007 resulted from $7,552,378 for proceeds from the exercise of warrants, less $579,569 paid as direct offering costs. In addition, the Company raised $1,100,000 in proceeds from notes payable under term loans, less $200,000 of repayments under these loans. The net cash proceeds from financing activities for the year ended December 31, 2006 resulted from proceeds from the sale of common stock and warrants in private placement offerings of $13,926,362 less cash paid as direct offering costs of $1,160,418 and proceeds from a related party loan of $1,365,344, less $20,000 of repayments under the loan.

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

Current and Future Financing Needs

We have incurred an accumulated deficit of $31,076,518 through December 31, 2007. We have incurred negative cash flow from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts. Based on our current plans, we believe that our cash will be sufficient to enable us to meet our planned operating needs at least for the next 12 months.

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

• the progress of our research activities;

• the number and scope of our research programs;

• the progress of our pre-clinical and clinical development activities;

• the progress of the development efforts of parties with whom we have entered into research and development agreements;

• our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;

• our ability to achieve our milestones under licensing arrangements;

• the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and

• the costs and timing of regulatory approvals.

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

License and Contractual Agreement Obligations

Below is a table of our contractual obligations for the years 2008 through 2011 as of December 31, 2007.

	Year				
Agreements	2008	2009	2010	2011	Total
Research and Development	$ 306,333	$ 0	$ 0	$ 0	$ 306,333
Lease Agreements	$ 141,375	$ 145,733	$ 150,152	$ 25,148	$ 462,408
License Agreements	$ 223,830	$ 125,000	$ 130,000	$ 132,500	$ 611,330
Consulting Agreements	$ 91,661	$ 3,332	$ 0	$ 0	$ 94,993
	$ 763,199	$ 274,065	$ 280,152	$ 157,648	$ 1,475,064

Product Candidates

TRIMESTA TM (oral estriol)

In June 2007, a two year seven U.S. center, placebo controlled 150 patient phase II/III clinical trial using TRIMESTATM for the treatment of relapsing-remitting Multiple Sclerosis (MS) was initiated under a $5 million grant from the Southern California Chapter of the National Multiple Sclerosis Society and NIH. This phase II/III clinical trial builds upon our encouraging results from an earlier phase IIa clinical trial. The primary purpose of this study is to evaluate the safety and efficacy of TRIMESTA TM in a larger MS patient population with a one year blinded interim analysis. The preclinical and clinical development of TRIMESTA TM has been primary financed by grants from the NIH and various non-profit foundations. Through December 31, 2007, we have incurred approximately $429,000 of costs related to our development of TRIMESTA TM of which approximately $49,500 and $185,500 was incurred in fiscal years 2005 and 2006, respectively, and approximately $194,000 was incurred in 2007.

EFFIRMA TM (oral flupirtine)

Our scientific collaborator has filed an IND with the FDA to conduct a phase II clinical trial with EFFIRMA in fibromyalgia patients. If our IND is approved, we plan to fund the phase II clinical study. Through December 31, 2007, we have incurred approximately $85,000 of costs related to our development of EFFIRMA TM, all of which was incurred during 2007.

Oral TTM (oral tetrathiomolybate)

Through December 31, 2007, we have incurred approximately $2,887,000 of costs related to our development of oral TTM , of which approximately $150,000 and $1,061,000 was incurred in fiscal years 2005 and 2006, respectively, and approximately $1,676,000 was incurred for the year ended December 31, 2007.

During 2008, we plan to hold a Type B meeting with the FDA to discuss an approval pathway for oral TTM. The feedback from that meeting with the FDA will determine if we pursue an NDA filing for oral TTM in neurologic Wilson’s disease. We plan to continue to explore additional therapeutic indications of oral TTM through collaborative arrangements or discontinue them altogether.

Anti-CD4 802-2

Through December 31, 2007, we have incurred $1,383,000 of costs related to our development of anti-CD4 802-2 of which $58,000, $332,000, $303,000, $295,000, $113,000 and $161,000 was incurred in fiscal years 2001, 2002, 2003, 2004, 2005 and 2006 respectively and approximately $121,000 has been incurred in 2007.

CORRECTA TM (clotrimazole emema)

During 2008, we plan to continue the phase II clinical trial of CORRECTA in the treatment of acute refractory pouchitis, a gastrointestinal disease (the "CAPTURE study"). The primary purpose of this double blind, placebo-controlled phase II clinical trial is to test CORRECTA's safety and efficacy in treating acute refractory pouchitis. The preclinical and clinical development of CORRECTA TM has been primarily financed by grants from the FDA's orphan drug products group and various non-profit foundations. Through December 31, 2007, we have incurred approximately $246,000 of costs related to our development of CORRECTA TM of which approximately $103,000 and $107,000 was incurred in fiscal years 2005 and 2006, respectively, and $36,000 has been incurred during 2007.

SolovaxTM (multivalent T-cell vaccine for MS)

During 2008, we plan to further analyze the data from our phase II clinical trial of SOLOVAX TM in the treatment of secondary progressive MS, as well as develop a new manufacturing procedure for SOLOVAX TM in Ann Arbor Michigan that more closely resembles the process utilized in the initial published clinical trial of SOLOVAX TM . On July 11, 2007 at an opposition hearing in Munich, Germany brought by a competitor, Opexa Therapeutics, Inc., our third auxiliary request to amend claims to our exclusively licensed issued European patent number EP1015025 was denied on the basis of time and as a result such patent was revoked. We intend to vigorously continue to prosecute, defend and protect our pending corresponding U.S. patent application and will be updating the public on our future plans to develop SOLOVAX TM for multiple sclerosis. On December 21, 2007 we converted our exclusive agreement with the University of Southern California (USC) to a full exclusive license agreement and issued to USC ten percent (10%) of the common stock of Solovax Inc., our subsidiary that is developing our Multivalent T-cell vaccine for MS upon issuance of the written opinion of the European Patent Office associated with such opposition proceeding. We plan to seek a corporate partner in the cellular therapy field to further develop the Solovax technology.

If successful, we may choose to initiate a phase IIb clinical study in this disease. The preclinical and clinical development of SOLOVAX has been primarily financed by grants from the NIH and various non-profit foundations totaling $5.5 million. Through December 31, 2007, we have incurred approximately $688,000 of costs related to our development of SOLOVAX of which $107,000, $158,000, $164,000, $163,000, $67,000 and $21,000 was incurred in fiscal 2001, 2002, 2003, 2004, 2005 and 2006, respectively, and $8,000 has been incurred during 2007.

Z-monocys

In July 2007 licensed the rights for the manufacture, distribution and marketing of products based on patented zinc-monocysteine complexes ("Z-monocys"). We plan to initially develop Z-monocys as an oral treatment for dry age-related macular degeneration ("dry AMD"). Z-monocys has completed a six month double blind randomized placebo controlled trial in 80 dry AMD patients with statistically significant improvements in visual acuity, contrast sensitivity and photorecovery times. A manuscript describing these results has been submitted to a leading peer-reviewed ophthalmic journal. Through December 31, 2007, we have incurred approximately $154,000 of costs related to our development of Z-monocys of which all has been incurred during 2007.

Based on our current capital expenditures, we believe we currently have sufficient capital to fund development activities of oral TTM, TRIMESTATM , anti-CD4 802-2, CORRECTA TM, SOLOVAX TM , Z-monocys and EFIRMATM during 2007 and 2008. However, if our business does not generate any cash flow through corporate partnering transactions, we will need to raise additional capital to continue development of the product beyond 2009. To the extent additional capital is not available when we need it, we may be forced to sublicense our rights to our product candidates, abandon our development efforts altogether, or lose our licenses to our product candidates, any of which would have a material adverse effect on the prospects of our business. See also the risks identified under the section entitled “Risk Factors” in this report.

Additional Licenses

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

ITEM 7. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS

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

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of:
Pipex Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Pipex Pharmaceuticals, Inc. and Subsidiaries (a development stage company) as of December 31, 2007 and 2006 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years ended December 31, 2007 and 2006 and for the period from January 8, 2001 (inception) to December 31, 2007. 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included the consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly in all material respects, the consolidated financial position of Pipex Pharmaceuticals, Inc. and Subsidiaries (a development stage company) as of December 31, 2007 and 2006, and the consolidated results of their operations, changes in stockholders' equity and cash flows for the years ended December 31, 2007 and 2006, and for the period from January 8, 2001 (inception) to December 31 2007, in conformity with accounting principles generally accepted in the United States of America.

/s/ Berman & Company, P.A.
Boca Raton, Florida
March 11, 2008

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

Assets	December 31, 2007	2006
Current Assets		
Cash	$ 11,492,802	$ 12,192,426
Prepaid expenses	63,636	25,702
Total Current Assets	11,556,438	12,218,128
Property and Equipment, net of accumulated depreciation of $232,564 and $32,935	2,063,233	297,288
Deposits and other assets	13,381	-
Total Assets	$ 13,633,052	$ 12,515,416
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 728,119	$ 540,120
Accrued liabilities	59,409	188,899
Notes payable	900,000	-
Total Current Liabilities	1,687,528	729,019
Commitments (See Note 6)		
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 20,433,467 and 16,227,971 shares issued and outstanding	20,433	16,228
Additional paid-in capital	43,001,609	20,544,532
Deficit accumulated during the development stage	(31,076,518)	(8,774,363)
Total Stockholders' Equity	11,945,524	11,786,397
Total Liabilities and Stockholders' Equity	$ 13,633,052	$ 12,515,416

See accompanying notes to consolidated financial statements

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

	For the years ended December 31,		For the period from January 8, 2001 (inception) to December 31,
	2007	2006	2007
Operating Expenses:			
Research and development	$ 6,327,726	$ 2,665,555	$ 11,160,795
General and administrative	3,810,585	1,451,522	6,845,211
Total Operating Expenses	10,138,311	4,117,077	18,006,006
Loss from Operations	(10,138,311)	(4,117,077)	(18,006,006)
Other Income (Expense):			
Interest income	298,807	17,982	343,389
Interest expense	(52,929)	-	(52,929)
Total Other Income, net	245,878	17,982	290,460
Net Loss	$ (9,892,433)	$ (4,099,095)	$ (17,715,546)
Less: Preferred stock dividend - subsidiary	-	(761,000)	(951,250)
Less: Merger dividend	(12,409,722)	-	(12,409,722)
Net Loss Applicable to Common Shareholders	$ (22,302,155)	$ (4,860,095)	$ (31,076,518)
Net Loss Per Share - Basic and Diluted	$ (1.27)	$ (1.50)	$ (7.60)
Weighted average number of shares outstanding during the year/period - basic and diluted	17,597,120	3,244,543	4,089,820

See accompanying notes to consolidated financial statements

Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Consolidated Statements of Stockholders' Equity
For the years ended December 31, 2007 and 2006 and for the period from January 8, 2001 (inception) to December 31, 2007

	Series A, Convertible Preferred Stock $0.001 Par Value		Common Stock $0.001 Par Value		Additional Paid-in Capital	Deficit accumulated during development stage	Total Stockholde Equity
	Shares	Amount	Shares	Amount			
Balance, January 8, 2001 (inception)	-	$ -	-	$ -	$ -	$ -	$
Issuance of common stock to founders in exchange for subcription receivable ($0.00003/share)	-	-	1,572,136	1,572	(1,222)	-	
Issuance of preferred stock to founder for cash ($0.055/share)	5,421,554	5,422	-	-	294,578	-	300
Issuance of preferred and common stock to founder for cash - subsidiaries	-	-	-	-	850,540	-	850
Net loss for the period ended December 31, 2001	-	-	-	-	-	(277,868)	(277
Balance, December 31, 2001	5,421,554	5,422	1,572,136	1,572	1,143,896	(277,868)	873
	-	-	-	-	119	-	

Issuance of common stock for compensation and consulting - subsidiary							
Grant of stock options for consulting services - subsidiary	-	-	-	-	5,890	-	5
Net loss for the year ended December 31, 2002	-	-	-	-	-	(768,508)	(768
Balance, December 31, 2002	5,421,554	5,422	1,572,136	1,572	1,149,905	(1,046,376)	110
Grant of stock options for compensation - subsidiary	-	-	-	-	17,984	-	17
Net loss for the year ended December 31, 2003	-	-	-	-	-	(719,307)	(719
Balance, December 31, 2003	5,421,554	5,422	1,572,136	1,572	1,167,889	(1,765,683)	(590
Issuance of common stock for cash - subsidiary	-	-	-	-	50	-	
Grant of stock options for consulting services - subsidiary	-	-	-	-	10,437	-	10
Net loss for the year ended December 31, 2004	-	-	-	-	-	(602,493)	(602

Balance, December 31, 2004	5,421,554	5,422	1,572,136	1,572	1,178,376	(2,368,176)	(1,182
Recognition of stock based consulting in connection with stock options grants	-	-	-	-	59,960	-	59
Recognition of stock based compensation in connection with stock option grants	-	-	-	-	10,493	-	10
Recognition of deferred compensation - subsidiary	-	-	-	-	14,057	-	14
Issuance of Series B, convertible preferred stock for cash - subsidiary	-	-	-	-	1,902,500	-	1,902
Cash paid as direct offering costs in connection with sale of Series B, convertible preferred stock - subsidiary	-	-	-	-	(152,200)	-	(152
10% in-kind Series B, convertible preferred stock dividend - subsidiary	-	-	-	-	190,250	(190,250)	
Net loss for the year ended December 31, 2005	-	-	-	-	-	(1,355,842)	(1,355

Balance, December 31, 2005	5,421,554	5,422	1,572,136	1,572	3,203,436	(3,914,268)	(703
Conversion of related party loan to common stock ($2.02/share)	-	-	1,665,211	1,665	3,273,063	-	3,274
Issuance of common stock for cash - private placement ($2.02/share)	-	-	6,900,931	6,901	13,919,462	-	13,926
Cash paid as direct offering costs in private placements	-	-	-	-	(1,160,418)	-	(1,160
Issuance of common stock for license fees ($0.92/share)	-	-	422,314	422	388,269	-	388
Conversion of accrued expenses to contributed capital - former related party	-	-	-	-	3,017	-	3
Deemed issuance to shareholders of legal acquiror and recapitalization	-	-	245,824	246	(665,246)	-	(665
Conversion of Series A, convertible preferred stock to common stock	(5,421,554)	(5,422)	5,421,554	5,422	-	-	
Recognition of stock based consulting in connection with stock option grants	-	-	-	-	411,310	-	411
	-	-	-	-	410,639	-	410

Recogntion of stock based compensation in connection with stock option grants							
10% in-kind Series B, convertible preferred stock dividend - subsidiary	-	-	-	-	190,250	(190,250)	
30% in-kind Series B, convertible preferred stock dividend - subsidiary	-	-	-	-	570,750	(570,750)	
Net loss for the year ended December 31, 2006	-	-	-	-	-	(4,099,095)	(4,099
Balance, December 31, 2006	-	-	16,227,970	16,228	20,544,532	(8,774,363)	11,786
Recognition of stock based compensation in connection with stock option grants	-	-	-	-	1,483,123	-	1,483
Recognition of stock based consulting in connection with stock option grants	-	-	-	-	673,271	-	673
Issuance of common stock for consideration of common shares in EPI acquistion ($19.95/share)	-	-	30,161	30	601,682	-	601

Contributed services - related party					275,645	-	275
Issuance of common stock for license fees ($6.85/share)	-	-	2,920	3	19,997	-	20
Issuance of common stock for milestone payment ($4.90/share)	-	-	5,102	5	24,995	-	25
Issuance of common stock in connection with warrants exercise ($2.22/share)	-	-	3,401,967	3,402	7,548,976	-	7,552
Cash paid as direct offering costs in private placements	-	-	-	-	(579,569)	-	(579
Issuance of common stock for consideration of preferred shares in EPI acquistion ($19.95/share)	-	-	765,087	765	12,408,957	(12,409,722)	
Rounding of shares due to reverse split			260	-	-	-	
Net loss for the year ended December 31, 2007	-	-	-	-	-	(9,892,433)	(9,892
Balance, December 31, 2007	-	$ -	20,433,467	$ 20,433	$ 43,001,609	$ (31,076,518)	$ 11,945

See accompanying notes to consolidated financial statements

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Pipex Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Consolidated Statements of Cash Flows

	For the year ended December 31,		For the Period from January 8, 2001 (Inception) to December 31, 2007
	2007	2006	
Cash Flows From Operating Activities:			
Net loss	$ (9,892,433)	$ (4,099,095)	$ (17,715,546)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	1,483,123	410,639	1,936,646
Stock-based consulting	673,271	411,310	1,160,987
Stock issued as compensation in acquisition of subsidiary	601,712	-	601,712
Contributed services - related party	275,645	-	275,645
Stock issued for license fee	20,000	388,691	408,691
Stock issued for milestone payment	25,000	-	25,000
Depreciation	199,629	30,675	232,564
Changes in operating assets and liabilities:			
Prepaid expenses and other	(37,934)	(25,702)	(63,636)
Deposits and other assets	(13,381)	-	(13,381)
Accounts payable	187,999	325,746	728,119
Accrued liabilities	(129,490)	191,917	62,427
Net Cash Used In Operating Activities	(6,606,859)	(2,365,819)	(12,360,772)
Cash Flows From Investing Activities:			
Purchases of property and equipment	(1,965,574)	(45,833)	(2,011,407)
Cash paid to acquire shell in reverse merger	-	(665,000)	(665,000)
Net Cash Used In Investing Activities	(1,965,574)	(710,833)	(2,676,407)
Cash Flows From Financing Activities:			
Proceeds from loans payable - related party	-	1,365,344	3,210,338
Repayments of loans payable - related party	-	(20,000)	(220,000)
Proceeds from note payable	1,100,000	-	1,100,000
Repayments of note payable	(200,000)	-	(200,000)
Proceeds from issuance of preferred and common stock	-	-	1,150,590
Proceeds from sale of common stock and warrants in private placements	-	13,926,362	13,926,362
Proceeds from sale of common stock in connection with warrants exercise	7,552,378	-	7,552,378
Cash paid as direct offering costs in warrant call and private placements	(579,569)	(1,160,418)	(1,739,987)
Proceeds from issuance of Series B, convertible preferred stock - subsidiary	-	-	1,902,500

Direct offering costs in connection with issuance of series B, convertible preferred stock - subsidiary	-	-	(152,200)
Net Cash Provided By Financing Activities	7,872,809	14,111,288	26,529,981
Net increase (decrease) in cash	(699,624)	11,034,636	11,492,802
Cash at beginning of year/period	12,192,426	1,157,790	-
Cash at end of year/period	$ 11,492,802	$ 12,192,426	$ 11,492,802
Supplemental disclosures of cash flow information:			
Cash paid for interest	$ 52,929	$ -	$ 52,929
Cash paid for taxes	$ -	$ -	$ -
Supplemental disclosure of non-cash investing and financing activities:			
Exchange of EPI preferred stock into Pipex common stock in acquisition	$ 12,409,722	$ -	$ 12,409,722
Pipex acquired equipment in exchange for a loan with a related party	$ -	$ 284,390	$ 284,390
EPI declared a 10% and 30% in-kind dividend on its Series B, convertible preferred stock.	$ -	$ 761,000	$ 951,250
The Company issued shares and warrants in connection with the conversion of certain related party debt.	$ -	$ 3,274,728	$ 3,274,728
Conversion of accrued liabilities to contributed capital - former related party	$ -	$ 3,017	$ 3,017

See accompanying notes to consolidated financial statements

Pipex Pharmaceuticals, Inc. and Subsidiaries
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December 31, 2007 and 2006

Note 1 Organization and Nature of Operations

(A) Description of the Business

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

(B) Corporate Structure, Basis of Presentation and Non-Controlling Interest

The Company has four subsidiaries, Pipex Thereapeutics, Inc. ("Pipex Therapeutics"), Effective Pharmaceuticals, Inc. ("EPI"), Solovax, Inc. ("Solovax") and CD4 Biosciences, Inc. ("CD4") which were previously under common control. As of December 31, 2007 EPI is wholly owned and Pipex Therapeutics, Solovax and CD4 are majority owned. The combinations of these entities were accounted for in a manner similar to a pooling of interests.

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

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

The Company's ownership in its subsidiaries requires the Company to account for the related non-controlling interest. Under generally accepted accounting principles, when losses applicable to the minority interest in a subsidiary exceed the minority interest in the equity capital of the subsidiary, the excess is not charged to the minority interest since there is no obligation of the minority interest to make good on such losses. The Company, therefore, has included losses applicable to the minority interest against its interest. Since the Company's subsidiaries have never been profitable and present negative equity, there has been no establishment of a positive non-controlling interest. This value is not presented as a deficit balance in the accompanying consolidated balance sheet.

(C) Reverse Stock Split

In January 2007, and effective on April 25, 2007, the Company's Board of Directors approved a 3 for 1 reverse stock split of all outstanding common stock, stock options and stock warrants of Pipex. All share and per share amounts have been retroactively restated to reflect this reverse stock split.

See Note 2(H) as it pertains to the retroactive effect of the share and per share amounts pursuant to the reverse acquisition and recapitalization discussed in Note 1(D).

(D) Reverse Acquisition and Recapitalization

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

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

Pursuant to the agreement, Sheffield issued 34,000,000 shares of common stock for all of the outstanding Series A, convertible preferred and common stock of Pipex Therapeutics, and Sheffield assumed all of Pipex Therapeutics’s outstanding options and warrants, but did not assume the options and warrants outstanding within any of Pipex Therapeutics’s subsidiaries (EPI, CD4 and Solovax). On October 31, 2006, concurrent with the Merger, Pipex Therapeutics executed a private stock purchase agreement to purchase an additional 2,426,300 shares of common stock held by Sheffield’s sole officer and director; these shares were immediately cancelled and retired. Aggregate consideration paid for Sheffield was $665,000. Upon the closing of the reverse acquisition, shareholders of Sheffield retained an aggregate 245,824 shares of common stock. As a result of these two stock purchase transactions, Pipex Therapeutics acquired approximately 99% ownership of the issued and outstanding common shares of Sheffield.

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

1. EPI's Acquisition of CD4

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

2. Pipex Therapeutic's Acquisition of Solovax

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

3. Pipex Therapeutic's Acquisition of EPI/CD4

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

In the consolidated financial statements at December 31, 2007, each of these transactions described in Notes 1(E)(1), 1(E)(2) and 1(E)(3), was analogous to a recapitalization with no net change to equity since the entities were under common control at the date of the transaction.

4. Pipex Pharmaceutical's Acquisition of EPI, Share Issuances and Paid-in Kind Merger Dividend

On January 5, 2007, EPI merged with and into a wholly owned subsidiary of Pipex, Effective Acquisition Corp. In the transaction, Pipex issued an aggregate 795,248 shares of common stock having a fair value of $15,865,198 based upon the quoted closing trading price of $19.95 per share. As consideration for the share issuance, EPI exchanged 1,902,501 shares of Series B Convertible Preferred stock and 75,000 shares of common stock into 765,087 and 30,161, shares of Pipex common stock, respectively.

See additional discussion below for the issuance of the 765,087 shares, the Company recorded a paid-in kind/merger dividend.

In connection with the issuance of the 30,161 shares, the Company recorded additional compensation expense of $601,712 as the stock was issued to an officer and director of the Company.

During 2006, EPI declared a 10% and 30% preferred stock dividend, respectively, on its outstanding Series B, convertible preferred stock. During 2005, EPI declared a 10% preferred stock dividend on its outstanding Series B, convertible preferred stock. In total, 951,250 shares of additional Series B, convertible preferred stock were issued to the holders of record at the declaration date. These 951,250 shares of outstanding Series B preferred stock dividend were cancelled and retired and were not contemplated in the exchange with Pipex. EPI also cancelled and retired all of the issued and outstanding 3,000,000 shares of Series A Convertible Preferred stock as well as 750,000 shares of common stock

In connection with this exchange and pursuant to Securities and Exchange Commission Regulation S-X, Rule 11-01(d) and EITF 98-3, “Determining whether a Non-Monetary Transaction involves the receipt of Productive Assets or of a Business” EPI was classified as a development stage company and thus was not considered a business. As a result, SFAS No. 141 purchase accounting rules did not apply. Additionally, the Company applied the provisions of EITF 86-32, “Early Extinguishment of a Subsidiary’s Mandatorily Redeemable Preferred Stock” and has determined that even though the preferred stock of EPI was not mandatorily redeemable, this transaction is analogous to a capital transaction, and there would be no resulting gain or loss.

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Finally, in connection with EITF Topic D-42, "The Effect on the Calculation of Earnings Per Share for the Redemption or Induced Conversion of Preferred Stock", The Company has determined that the fair value of the consideration transferred to the holders of EPI Series B, convertible preferred stock over the carrying amount of the preferred stock represents a return to the preferred stockholders. The difference is $12,409,722, which is included as a component of paid in-kind dividends. This amount is included as an additional reduction in net loss applicable to common shareholders for purposes of computing loss per share in the accompanying financial statements for the years ended December 31, 2007 and 2006 and for the period from January 8, 2001 (inception) to December 31, 2007.

As part of the acquisition of EPI, the Company granted an aggregate 68,858 warrants and 34,685 options for the outstanding warrants and options held by the EPI warrant and option holders. These new warrants and options will continue to vest according to their original terms. Pursuant to SFAS No. 123R and fair value accounting, the Company treated the exchange as a modification of an award of equity instruments. As such, incremental compensation cost was measured as the excess of the fair value of the replacement award over the fair value of the cancelled award at the cancellation date. In substance, Pipex repurchased the EPI instruments by issuing a new instrument of greater value.

The Company used the following weighted average assumptions for the fair value of the replacement award: expected dividend yield of 0%; expected volatility of 196.10%; risk-free interest rate of 4.65%, an expected life ranging from seven to eight years and exercise prices ranging from $0.09 - $3.30.

The Company has the following weighted average assumptions for the fair value of the cancelled award at the cancellation date: expected dividend yield of 0%; expected volatility of 200%; risk-free interest rate of 4.65%, an expected life ranging from seven to eight years and exercise prices ranging from $0.09 -$3.30.

The fair value of the replacement award required an increase in compensation expense of approximately $352,734.

Note 2 Summary of Significant Accounting Policies

(A) Principles of Consolidation

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

(B) Development Stage

The Company's consolidated financial statements are presented as those of a development stage enterprise. For the period from January 8, 2001 (inception) to date, the Company has been a development stage enterprise, and accordingly, the Company's operations have been directed primarily toward the acquisition and creation of intellectual properties and certain research and development activities to improve current technological concepts. As the Company is devoting its efforts to research and development, there have been no sales, license fees or royalties earned. Additionally, the Company continually seeks sources of debt or equity based funding to further its intended research and development activities. The Company has experienced net losses since its inception, and had an accumulated deficit of $31,076,518 at December 31, 2007.

(C) Use of Estimates

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

Significant estimates during 2007 and 2006 include depreciable lives of property, valuation of warrants and stock options granted for services or compensation pursuant to EITF No. 96-18 and SFAS No. 123R, respectively, estimates of the probability and potential magnitude of contingent liabilities and the valuation allowance for deferred tax assets due to continuing operating losses.

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(D) Cash

The Company minimizes its credit risk associated with cash by periodically evaluating the credit quality of its primary financial institution. The balance at times may exceed federally insured limits. At December 31, 2007, the balance exceeded the federally insured limit by $11,009,126.

(E) Property and Equipment

Property and equipment is stated at cost, less accumulated depreciation. Expenditures for maintenance and repairs are charged to expense as incurred. Items of property and equipment with costs greater than $1,000 are capitalized and depreciated on a straight-line basis over the estimated useful lives, as follows:

Description	Estimated Useful Life
Office equipment and furniture	5 years
Laboratory equipment	10 years
Manufacturing equipment	10 years
Leasehold improvements and fixtures	Lesser of estimated useful life or life of operating lease

(F) Long Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. There were no impairment charges taken during the years ended December 31, 2007 and 2006 and for the period from January 8, 2001 (inception) to December 31, 2007.

(G) Derivative Liabilities

In connection with the reverse acquisition, all outstanding convertible preferred stock of Pipex was cancelled and retired, as such, the provisions of EITF No. 00-19, “Accounting for Derivative Financial Instruments Index to, and Potentially Settled in, a Company’s Own Stock” do not apply. The Company’s majority owned subsidiaries also contain issued convertible preferred stock; however, none of these instruments currently contains any provisions that require the recording of a derivative liability. In connection with the acquisition of EPI on January 5, 2007 (See Notes 1(D) and 1(E)(4), all issued and outstanding shares of Series A and B, convertible preferred stock were cancelled and retired. As such, no potential derivative liabilities will exist pertaining to these instruments.

(H) Net Loss per Share

Basic earnings (loss) per share is computed by dividing the net income (loss) less preferred dividends for the period by the weighted average number of common shares outstanding. Diluted earnings per share is computed by dividing net

income (loss) less preferred dividends by the weighted average number of common shares outstanding including the effect of share equivalents. Since the Company reported a net loss at December 31, 2007 and 2006 and for the period from January 8, 2001 (inception) to December 31, 2007, respectively, all common stock equivalents would be anti-dilutive; as such there is no separate computation for diluted earnings per share.

The Company's net loss per share for the years ended December 31, 2007 and 2006 and for the period from January 8, 2001 (inception) to December 31, 2007 was computed assuming the recapitalization associated with the reverse acquisition, as such, all share and per share amounts have been retroactively restated. Additionally, the numerator for computing net loss per share was adjusted for preferred stock dividends recorded during the year ended December 31, 2006 and the period from January 8, 2001 (inception) to December 31, 2007, in connection with the acquisition of EPI (See Note 1(D)(4)) as well as and certain provisions relating to the sale of EPI's Series B, convertible preferred stock.

(I) Research and Development Costs

The Company expenses all research and development costs as incurred for which there is no alternative future use. Research and development expenses consist primarily of manufacturing costs, license fees, salaries, stock based compensation and related personnel costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and other expenses relating to the design, development, testing and enhancement of the Company's product candidates, as well as an allocation of overhead expenses incurred by the Company.

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(J) Income Taxes

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

(K) Fair Value of Financial Instruments

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

(L) Stock Based Compensation

All share-based payments to employees since inception have been recorded and expensed in the statements of operations as applicable under SFAS No. 123R "Share-Based Payment".

(M) Reclassifications

Certain amounts in the year 2006 financial statements have been reclassified to conform to the year 2007 presentation. The results of these reclassifications did not materially affect the Company's consolidated financial position, results of operations or cash flows.

(N) Recent Accounting Pronouncements

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

On February 15, 2007, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities — Including an Amendment of FASB Statement No. 115" ("SFAS 159"). This standard permits an entity to measure financial instruments and certain other items at estimated fair value. Most of the provisions of SFAS No. 159 are elective; however, the amendment to FASB No. 115, "Accounting for Certain Investments in Debt and Equity Securities," applies to all entities that own trading and available-for-sale securities. The fair value option created by SFAS 159 permits an entity to measure eligible items at fair value as of specified election dates. The fair value option (a) may generally be applied instrument by instrument, (b) is irrevocable unless a new election date occurs, and (c) must be applied to the entire instrument and not to only a portion of the instrument. SFAS 159 is effective as of the beginning of the first fiscal year that begins after November 15, 2007. Early adoption is permitted as of the beginning of the previous fiscal year provided that the entity (i) makes that choice in the first 120 days of that year, (ii) has not yet issued financial statements for any interim period of such year, and (iii) elects to apply the provisions of FASB 157. Management is currently evaluating the impact of SFAS 159, if any, on the Company's financial statements. The adoption of SFAS No. 159 is not expected

to have a material effect on its financial position, results of operations or cash flows.

In June 2007, the Emerging Issues Task Force (“EITF”) issued EITF No. 07-01, Accounting for Collaborative Arrangements, (“EITF 07-1”). EITF 07-1 provides guidance for companies in the biotechnology or pharmaceutical industries that may enter into agreements with other companies to collaboratively develop, manufacture, and market a drug candidate (Collaboration Agreements) and is effective for fiscal years beginning after December 15, 2007. The Company does not expect that EITF 07-01 will have an effect on its financial condition or results of operations.

In June 2007, the EITF issued EITF No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities, (“EITF 07-3”). EITF 07-3 provides guidance for upfront payments related to goods and services of research and development costs and is effective for fiscal years beginning after December 15, 2007. The Company is currently evaluating the impact of EITF 07-3 on its financial statements.

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In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No 51" (SFAS 160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, changes in a parent's ownership of a noncontrolling interest, calculation and disclosure of the consolidated net income attributable to the parent and the noncontrolling interest, changes in a parent's ownership interest while the parent retains its controlling financial interest and fair value measurement of any retained noncontrolling equity investment. SFAS 160 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The adoption of SFAS No. 160 is not expected to have a material effect on its financial position, results of operations or cash flows.

In December 2007, the FASB issued SFAS 141R, Business Combinations ("SFAS 141R"), which replaces FASB SFAS 141, Business Combinations. This Statement retains the fundamental requirements in SFAS 141 that the acquisition method of accounting be used for all business combinations and for an acquirer to be identified for each business combination. SFAS 141R defines the acquirer as the entity that obtains control of one or more businesses in the business combination and establishes the acquisition date as the date that the acquirer achieves control. SFAS 141R will require an entity to record separately from the business combination the direct costs, where previously these costs were included in the total allocated cost of the acquisition. SFAS 141R will require an entity to recognize the assets acquired, liabilities assumed, and any non-controlling interest in the acquired at the acquisition date, at their fair values as of that date. This compares to the cost allocation method previously required by SFAS No. 141. SFAS 141R will require an entity to recognize as an asset or liability at fair value for certain contingencies, either contractual or non-contractual, if certain criteria are met. Finally, SFAS 141R will require an entity to recognize contingent consideration at the date of acquisition, based on the fair value at that date. This Statement will be effective for business combinations completed on or after the first annual reporting period beginning on or after December 15, 2008. Early adoption of this standard is not permitted and the standards are to be applied prospectively only. Upon adoption of this standard, there would be no impact to the Company's results of operations and financial condition for acquisitions previously completed. The adoption of SFAS No. 141R is not expected to have a material effect on its financial position, results of operations or cash flows.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date and are not expected to have a material impact on the financial statements upon adoption.

Note 3 Property and Equipment

Property and Equipment consisted of the following at December 31,

	2007	2006
Manufacturing equipment	$ 1,054,289	$ 298,990
Leasehold Improvements	850,302	-
Computer and office equipment	227,274	7,760
Laboratory equipment	163,932	23,473
Total	2,295,797	330,223

Less accumulated depreciation	(232,564)	(32,935)
Property and equipment, net	$ 2,063,233	$ 297,288

Note 4 Notes Payable

During 2007, the Company borrowed $1,100,000 and repaid $200,000. These notes were secured by all assets of the Company as well as the stock certificates of the subsidiaries; the notes bore interest at 9.25% (prime plus 2%) and were due March 30, 2010. These borrowings represented a 100% concentration of debt at December 31, 2007. On March 6, 2008, all of the outstanding principal and accrued interest totaling $834,443 was repaid. As a result, all of the debt was classified as a current liability at December 31, 2007. (See Note 9)

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Loans Payable – Related Party

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

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

On October 31, 2006, the non-interest bearing loans payable to the Company's founder, Chairman and Chief Executive Officer, which amounted to $3,274,728, were converted into 1,665,211 shares of common stock and 832,606 warrants to purchase common stock.

Note 5 Stockholders' Equity

(A) Preferred Stock Issuances

1. For the Year Ended December 31, 2001

On January 8, 2001, EPI issued 3,000,000 shares of Series A Convertible Preferred Stock to the Founder serving as the CEO and Chairman of the Board of EPI in exchange for $250,000 ($0.08 per share). On January 5, 2007, pursuant to the acquisition of EPI, these shares were cancelled and retired.

On January 15, 2001, Pipex Therapeutics issued 5,421,554 shares of Series A Convertible Preferred Stock to a founder serving as CEO and Chairman of the Board of Pipex in exchange for $300,000 ($0.055 per share). On October 31, 2006, pursuant to the reverse acquisition with Sheffield, these shares were cancelled and retired.

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

On February 7, 2001, CD4 issued 1,000,000 shares of Series A Convertible Preferred Stock, to an affiliate of a founder serving as the CEO and Chairman of the Board of CD4 in exchange for $300,000 ($0.30 per share).

2. For the Year Ended December 31, 2005

On March 10, 2005, EPI's board of directors and stockholders voted to authorize the designation of a Series B Convertible Preferred Stock. From March through June 2005, EPI issued 1,902,500 shares of Series B Convertible Preferred Stock, at $1 per share, for proceeds of $1,902,500. In connection with this offering, EPI paid $152,200 of offering costs that were charged against additional paid in capital. The Company also granted 171,225 warrants as compensation in connection with this equity raise.

On January 5, 2007, pursuant to the acquisition of EPI, the shares of Series B Convertible Preferred Stock were converted into 765,087 shares of Pipex common stock and the warrants were converted into 68,858 warrants of Pipex. (See Note 1(E)(4))

(B) Series A Convertible Preferred Stock

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

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

1. Dividends

Each share of Series A Convertible Preferred Stock is entitled to receive dividends in an amount equal to dividends declared and paid with respect to that number of shares of common stock into which one share of Series A Convertible Preferred Stock is then convertible. For the period from January 8, 2001 (inception) to December 31, 2007, neither the Company, nor any of its majority owned subsidiaries has declared any Series A Convertible Preferred Stock dividends.

2. Liquidation Preference

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

3. Conversion

Each share of Series A Convertible Preferred Stock is immediately convertible on a one for one basis at the option of the holder. The conversion ratio is determined by dividing the original issue price of the Series A Convertible Preferred Stock by the conversion price for the Series A, convertible preferred stock in effect on the date the certificate is surrendered for conversion. The conversion price will initially be the original issue price, which is subject to future adjustment. At December 31, 2007, the conversion ratio is 1.00.

4. Voting Rights

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

5. Beneficial Conversion Feature and Derivative Liability

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

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

(C) Series B Convertible Preferred Stock

Pipex Therapeutics has authorized Series B Convertible Preferred Stock. At December 31, 2007, Pipex Therapeutics has not issued any of its Series B Convertible Preferred Stock. Pipex Therapeutics has not yet designated their Series B Convertible Preferred Stock as it pertains to dividends, liquidation preference, conversion, voting rights, and other rights and preferences.

(D) Common Stock Issuances of Issuer

In December 2007, the Company issued 5,102 shares of common stock having a fair value of $25,000 ($4.90 per share) based on the quoted closing trading price for a milestone payment.

In September and December of 2007, the Company issued an aggregate 2,920 shares of common stock having a fair value of $20,000 ($6.85 per share) based on the quoted closing trading price for license fees.

During 2007, the Company issued 3,401,972 shares of common stock in connection with the exercise of warrants for net proceeds of $6,972,809 ($2.22 per share).

During October and November of 2006, the Company completed private placements of its stock, which resulted in the issuance of 6,900,931 shares of common stock and 3,451,524 warrants. The net proceeds from the private placements were $12,765,945, which included cash paid as direct offering costs of $1,160,418.

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On October 31, 2006, the loans payable to the Company's founder, President and CEO were converted into 1,665,211 shares of common stock and 832,606 warrants. There were no gain or loss on this transaction since it was with a related party.

During October 2006, the Company converted all of its 5,421,554 shares of Series A, convertible preferred stock in exchange for equivalent common shares. The fair value of the exchange was based upon par value with a net effect of $0 to the statement of equity.

During October 2006, the Company issued 422,314 shares of common stock to an unrelated third party in connection with the terms of a license agreement. The fair value was $388,691 based upon the recent cash offering price at that time and was charged to research and development expense.

(E) Common Stock Issuances of Subsidiaries

During the period from January 8, 2001 (inception) to December 31, 2007, the Company's majority owned subsidiaries; CD4, Solovax and EPI issued 419,000, 419,000 and 825,000 shares of common stock, respectively, for $1,663. Of the 825,000 shares of common stock issued by EPI, 75,000 were converted into 30,161 common shares of Pipex and the remaining 750,000 shares were cancelled and retired for no additional consideration in the acquisition of EPI on January 5, 2007.

(F) Stock Option Plan

On March 20, 2007, the Company's Board of Directors approved the Company's 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 2,500,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. The exercise price of stock options under the plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of December 31, 2007, there are 808,011 options issued and outstanding under the 2007 Stock Plan. This plan was approved by stockholders on November 2, 2007.

During 2001, Pipex Therapeutics' Board and stockholders adopted the 2001 Stock Incentive Plan (the "2001 Stock Plan"). This plan was assumed by Pipex in the merger, in October 2006. As of the date of the merger, there were 1,489,353 options issued and outstanding. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period shall not exceed 1,250,000. All awards pursuant to the Plan shall terminate upon the termination of the grantee's employment for any reason. Awards include options, restricted shares, stock appreciation rights, performance shares and cash-based awards (the "Awards"). The Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined in the Plan. The Plan provides for a Committee of the Board to

grant awards and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the awards, including acceleration of the vesting of an award at any time. As of December 31, 2007, there are 1,489,353 options issued and outstanding under the 2001 Stock Plan.

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

The Company has followed fair value accounting and the related provisions of SFAS No. 123R for all share based payment awards since inception. The fair value of each option or warrant granted is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes assumptions used in the years ended December 31, 2007 and 2006 are as follows:

	Year Ended December 31,	
	2007	2006
Exercise price	$0.09 - $22.50	$0.03 - $4.00
Expected dividends	0%	0%
Expected volatility	103.29% - 200.94%	93.09% - 200%
Risk fee interest rate	3.83% - 5.16%	4.43% - 4.99%
Expected life of option	5-10 years	3-10 years
Expected forfeitures	0%	0%

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All option grants are expensed in the appropriate period based upon each awards vesting terms, in each case with an offsetting credit to additional paid in capital. The stock-based compensation expense recorded by the Company for the years ended December 31, 2007 and 2006 and the period from January 8, 2001 (inception) to December 31, 2007 with respect to awards under the Plan is as follows:

	Year Ended December 31,		Inception to
	2007	2006	December 31, 2007
Research and development:			
employees	$ 1,226,687	$ 226,909	$ 1,465,871
non-employees	145,783	—	240,523
General and administrative:			
employees	858,148	183,730	1,054,153
non-employees	527,488	411,310	938,798
	$ 2,758,106	$ 821,949	$ 3,699,345

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

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A summary of stock option activity for the years ended December 31, 2007 and 2006 is as follows:

	Number of Shares	Weighted Average Exercise Price
Balance at December 31, 2005	254,795	$ 0.09
Granted	1,364,060	$ 2.19
Exercised	—	$ —
Forfeited	(5,000)	$ 0.90
Balance at December 31, 2006	1,613,855	$ 1.45
Granted	700,176	$ 5.97
Exercised	—	$ —
Forfeited	(16,667)	$ 15.75
Balance at December 31, 2007	2,297,364	$ 2.72

The options outstanding and exercisable at December 31, 2007 are as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.09 - $0.99	588,728	5.72 Years	$ 0.11	517,170	$ 0.10
$1.00 - $1.99	664,252	8.42 Years	$ 1.83	332,126	$ 1.83
$2.00 - $2.99	370,560	8.86 Years	$ 2.07	280,207	$ 2.08
$3.00 - $3.99	74,158	9.19 Years	$ 3.87	64,158	$ 3.87
$4.00 - $4.57	40,000	6.30 Years	$ 4.35	-	-
$4.58 - $9.05	497,999	9.26 Years	$ 5.84	102,833	$ 5.89
$9.05 -$13.54	41,667	9.01 Years	$12.00	8,334	$12.00
$13.54 -$18.02	16,667	9.07 Years	$16.20	-	-
$18.02 - $22.50	3,333	9.03 Years	$22.50	-	-
	2,297,364	7.99 Years	$ 2.72	1,304,828	$1.68

Of the 700,176 options granted in 2007, 120,111 were granted to related parties of which all are fully vested.

(G) Stock Warrants

During October and November 2007, the Company issued 3,274,566 shares of common stock in connection with the exercise of common stock warrants, pursuant to a warrant call for $2.22/share. The warrant call had occurred due to the terms by which the Company sold its common stock and warrants in private placement offerings. The net proceeds from the warrant call were $6,972,809, which included cash paid as direct offering costs of $579,569.

During May through August 2007, the Company issued 127,406 shares of common stock in exchange for common stock warrants for $2.22/share. The net proceeds totaled $282,841.

In connection with this warrant call, the Company entered into a warrant solicitation agreement with Noble International Investments, Inc. (“Noble”). As compensation for Noble’s services, the Company paid Noble a cash fee of $579,569 which totals 8% of the gross proceeds from the Holder’s exercise of warrants. In addition, the Company issued Noble 327,456 common stock warrants. The warrants have a term of five years, will contain customary anti-dilution provisions, piggyback registration rights, and will be exercisable at a purchase price of $6.36 per share. The Company may, at its option, call the warrants if the average daily trading price of the Company’s common stock exceeds, for at least 20 of 30 consecutive trading days, a price per share that is equal to or greater than 250% of the warrant’s exercise price of $6.36 per share, and there is an effective registration statement registering the shares of the Company’s common stock underlying the warrant. Noble will have the right at any time during the five-year term of the warrants to exercise the warrants at its option on a “cashless” basis, only if the Company fails to maintain an effective registration statement registering the shares of the Company’s common stock underlying the warrants. Since these warrants were granted as compensation in connection with an equity raise, the Company has treated these warrants as a direct offering cost. The result of the warrant grant has a $0 net effect to equity. These warrants are fully vested and non-forfeitable.

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On February 15, 2007, the Company executed an agreement with a third party to provide certain consulting services. Pursuant to the terms of the agreement, the Company will issue warrants to purchase 100,000 shares of common stock upon the achievement of various milestones as well as over the life of the contract. The warrants have an exercise price of $3.75. The fair value of the warrants totals $374,760 and was determined by using the Black-Scholes model with the following assumptions: expected dividend yield of 0%; expected volatility of 187.22%; risk-free interest rate of 4.68% and an expected life of five years. As of December 31, 2007, 41,667 warrants have been issued for which the Company has recognized stock based consulting expense for $156,148.

On January 5, 2007, the Company issued warrants to purchase 68,858 shares of common stock as part of the acquisition of EPI. (See Note (1)(D)(4))

In October and November 2006, the Company issued warrants to purchase 3,451,524 shares of common stock as part of the private placement offering. The warrants have an exercise price of $2.22 and each warrant has a life of 5 years.

In addition, as part of the private placements, the Company issued warrants to purchase 958,277 shares of common stock to the placement agent, which is a company that is controlled by the Company's Chairman and CEO. The warrants have an exercise price of $2.22. Since these warrants were granted as compensation in connection with an equity raise, the Company has treated these warrants as a direct offering cost. The result of the transaction has a $0 net effect to equity. The warrants are fully vested and non-forfeitable.

On October 31, 2006, the loans payable to the Company's founder, President and CEO were converted into 1,665,211 shares of common stock and 832,606 warrants to purchase common stock. The warrants have an exercise price of $2.22 and a life of 5 years. (See Note 4)

A summary of warrant activity for the years ended December 31, 2007 and 2006 is as follows:

	Number of Shares
Balance as December 31, 2005	—
Granted	5,242,407
Exercised	—
Forfeited	—
Balance as December 31, 2006	5,242,407
Granted	437,981
Exercised	(3,401,972)
Forfeited	—
Balance as December 31, 2007	2,278,416

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All outstanding warrants are fully vested and exercisable.

Warrants Outstanding and Exercisable

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life
$ 2.22	588,728	6.37 Years
$ 3.30	68,858	7.42 Years
$ 3.75	41,667	8.13 Years
$ 6.36	327,456	4.86 Years
	2,278,416	6.07 Years

(H) Options and Warrants of Subsidiaries

CD4 has 30,000 options outstanding and exercisable, with an exercise price of $0.20 and a remaining weighted average remaining contractual life of 2.98 years as of December 31, 2007.

Note 6 Commitments

(A) License Agreements

Since inception, the Company has entered into various option and license agreements for the use of patents and their corresponding applications. These agreements have been entered into with various educational institutions and hospitals. These agreements contain payment schedules or stated amounts due for (a) option and license fees, (b) expense reimbursements, and (c) achievement of success milestones. All expenses related to these agreements have been recorded as research and development.

In connection with these agreements, the Company may be obligated to make milestone payments up to an amount of $8,425,000. Some of these payments may be fulfilled through the issuance of the Company's common stock, at the Company's option. As of December 31, 2007, the Company has achieved one milestone which the Company fulfilled by issuing common stock having a fair value of $25,000. See Note (5(D)). The Company can give no assurances that any other milestones will be achieved. In addition to the milestone payments, the Company may be obligated to make royalty payments on future sales pursuant to the agreements. The schedule below does not include the value of these commitments.

(B) Research Agreement

In September 2005, the Company entered into a three-year sponsored research agreement with a University. Pursuant to that agreement, the Company sponsors approximately $460,000 per year, payable in monthly installments. This agreement can be extended for an additional two-year period.

(C) Consulting Agreements

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

On February 15, 2007, the Company executed an agreement with a third party to provide certain services. Pursuant to the terms of the agreement, the Company will pay $9,000 per month for a period of twelve months and grant 100,000 stock warrants with a cashless exercise provision. These warrants vest upon various milestones as well as over the life of the contract.

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(D) Employment Agreements

In January 2005, the Company entered into a four-year employment agreement with the Company's Chairman and Chief Executive Officer. Pursuant to this agreement, Pipex will pay an annual base salary of $297,000, an annual bonus equal to 30% of base salary and a ten-year option to acquire 271,058 shares of common stock at the completion of the Company's private placement that occurred on October 31, 2006. As of December 31, 2007, 180,705 options have vested, with the remainder vesting on October 31, 2008.

The fair value of the options totaled $544,827 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 200%, risk free interest rate of 4.61% and an expected life of 10 years. On July 20, 2007, the Board of Directors approved an amended and restated employment agreement with the Chief Executive Officer. The amended employment agreement provides that the Chief Executive Officer is to be paid a base salary of $195,000 per year plus a guaranteed bonus of $100,000. The Chief Executive Officer may also be entitled to discretionary transactional bonuses. In addition, the amended agreement provides that the Chief Executive Officer has waived the receipt of any salary and bonus payable under the original agreement, which amounts to $275,645, for no additional consideration. This amount was treated as a capital contribution to the Company in September 2007.

The Company entered into an employment agreement with its President on May 24, 2006. Pursuant to this agreement, Pipex will pay an annual base salary of $295,000 and a guaranteed bonus of one-third of base salary. Pipex has also granted a ten-year option to purchase 664,252 shares of common stock, of which 332,126 have vested as of December 31, 2007. The remainder of these options will vest quarterly over a three-year period. In the event of a termination, the Company will provide six-month severance, payable over a six-month period. On March 5, 2008, the Company's President has agreed to work for no cash compensation until May 17, 2008 at which time his compensation will be at the discretion of the compensation committee. The President will be eligible to receive a contingent bonus in the event that the Company is acquired or the stock price retraces or exceeds to the level of the share price on January 28th 2008. Additionally, the President agreed to eliminate severance provisions of his agreement.

On October 10, 2007, the Company entered into a three-year employment agreement with its Chief Scientific Officer. The Company paid the Chief Scientific Officer a $7,500 signing bonus and a base salary of $205,000 per year. The agreement also provides that the Chief Scientific Officer is eligible for cash and non-cash bonuses at the end of each of the Company's fiscal years during the term of the agreement at the discretion of the Company's compensation committee as well as additional commission-based cash and stock bonuses during each fiscal year based on significant revenue-generating, out-licensing and merger and acquisition transactions initiated and completed by the Chief Scientific Officer, again at the discretion of the compensation committee. Pursuant to the agreement, the Company granted a ten-year option to purchase 150,000 shares of the Company's common stock of which none have vested as of December 31, 2007. The options will vest quarterly over a three-year period. This agreement was terminated on March 7, 2008. (See Note 9)

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(E) Operating Lease

During 2007, the Company entered into a non-cancelable operating lease for 17,675 square feet of office, laboratory and production space. This lease expires on February 28, 2011.

The following schedule shows committed amounts due for the lease agreement as of December 31, 2007:

2008:	$141,375
2009:	145,733
2010:	150,152
2011:	25,148
Total:	$ 462,408

During the years ended December 31, 2007 and 2006 and for the period from January 8, 2001 (inception) to December 31, 2007, the Company recognized rent expense of $202,361, $54,813 and $590,829, respectively.

The following schedule shows committed amounts due for license agreements, patent cost reimbursements, sponsored research agreements and consulting fees as of December 31, 2007:

2008:	$ 621,824
2009:	128,332
2010:	130,000
2011:	132,500
2012:	132,500
Each Year Thereafter:	167,500
Total:	$1,312,656

Note 7 Income Taxes

There was no income tax expense for the years ended December 31, 2007 and 2006 due to the Company's net losses.

The Company's tax expense differs from the "expected" tax expense for the years ended December 31, 2007 and 2006, (computed by applying the Federal Corporate tax rate of 34% to loss before taxes and 5.5% for State Corporate taxes, the blended rate used was 37.63%), as follows:

	2007	2006
Computed "expected" tax expense (benefit) - Federal	$ (3,178,439)	$ (1,317,039)
	(544,084)	(225,450)

Computed “expected” tax expense (benefit) - State		
Meals and Entertainment	3,097	-
Non-deductible stock and stock based compensation	1,054,809	455,564
Contributed services – related party	103,725	-
Change in valuation allowance	2,560,892	1,542,489
	$ -	$ -

During the year ended December 31, 2006, the Company inadvertently recorded non-deductible stock based compensation and consulting as a temporary tax difference and thus increased the computed deferred tax asset. However, the Company has reassessed its original position and determined that these payments should have been recorded as non-deductible permanent differences. The above schedule has treated the change retroactively by showing the correct presentation of permanent and temporary differences, as they should have been reflected for both December 31, 2007 and 2006. Since this was a management estimate affecting a fully reserved deferred tax asset, no additional changes for financial reporting are required.

The effects of temporary differences that gave rise to significant portions of deferred tax assets at December 31, 2007 and 2006 are as follows:

Deferred tax assets:	2007	2006
Net operating loss carryforward	$ (5,009,698)	$ (2,448,806)
Total gross deferred tax assets	(5,009,698)	(2,448,806)
Less valuation allowance	5,009,698	2,448,806
Net deferred tax assets	$ -	$ -

At December 31, 2007, the Company has a net operating loss carry-forward of $13,313,043 available to offset future taxable income expiring through 2027. Utilization of these net operating losses may be limited due to potential ownership changes under Section 382 of the Internal Revenue Code.

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The valuation allowance at December 31, 2006 was $2,448,806. The net change in valuation allowance during the year ended December 31, 2007 was an increase of $2,560,892. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on consideration of these items, Management has determined that enough uncertainty exists relative to the realization of the deferred income tax asset balances to warrant the application of a full valuation allowance as of December 31, 2007.

Note 8 Related Party Transactions

During January 2001, Pipex sold approximately $1.1 million of Series A Preferred Stock to a company controlled by our Chairman and Chief Executive Officer. From 2002 until October 2006, we relied on non-interest bearing bridge loans from a company controlled by our Chairman and Chief Executive Officer. During this 5-year period, the Chairman loaned us $3,274,728 for no additional consideration. In connection with the private placement during October 2006, the Chairman agreed to convert these loans into units in the offering. As a result of the conversion of these loans, we issued 1,665,211 shares of common stock and 832,606 warrants to purchase common stock.

In connection with private placements in October and November 2006, Pipex engaged a company that is controlled by its Chairman and Chief Executive Officer as our placement agent. At the closing of the private placement during October and November 2006, Pipex paid the placement agent the sum of $1,033,800 as commissions for its services. The placement agent also received a warrant to purchase 958,277 shares of common stock. (See Note 5 (G)) Two of our directors and officers are representatives of the placement agent.

As part of the October 2006 private placement, the Company sold 99,104 shares of its common stock and 49,552 warrants to purchase common stock for total proceeds of $200,000 to entities controlled by our President. As part of the same private placement, Pipex sold 49,552 shares of its common stock and 24,776 warrants to purchase common stock for total proceeds of $100,000 to a related family member of our Chairman and CEO. The terms on which their purchases were made were identical to the terms in which the other investors in these offerings purchased shares.

Note 9 Subsequent Event

Corporate Restructuring

On March 11, 2008, the Company announced that it has implemented cost reduction measures in order to substantially reduce operating expenses given the delay in refilling its New Drug Application for oral tetrathiomolybdate (oral TTM) for the treatment of initially presenting neurologic Wilson’s disease. As part of the corporate restructuring, the Company eliminated 14 positions in the areas of manufacturing, analytical, quality control, quality assurance, clinical, regulatory, diagnostic product development, principally relating to the development of oral TTM and diagnostics division. The Company also eliminated the position of Chief Scientific Officer (“CSO”), as part of the cost cutting measures.

In addition, the Company's President has agreed to work for no cash compensation until May 17, 2008, at which time his compensation will be at the discretion of the compensation committee. The President will be eligible to receive a contingent bonus in the event that the Company is acquired or the stock price retraces or exceeds to the level of the share price on January 28, 2008. Additionally, the President agreed to eliminate severance provisions of his agreement. For the period February 16, 2008 to May 17, 2008, the Company will record contributed services from a related party totaling $73,750.

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

There have been no disagreements on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure with our independent auditors for the period ended December 31, 2007.

ITEM 8A. CONTROLS AND PROCEDURES

Pursuant to Rule 13a-15(b) under the Securities Exchange Act of 1934 ("Exchange Act"), the Company carried out an evaluation, with the participation of the Company's management, including the Company's Chief Executive Officer ("CEO"), of the effectiveness of the Company's disclosure controls and procedures (as defined under Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, the Company's CEO concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Company's CEO, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Controls Over Financial Reporting

Internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of consolidated financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. There has been no change in the Company's internal control over financial reporting during the year ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company's management, including the Company's CEO, does not expect that the Company's disclosure controls and procedures or the Company's internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of the controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting. Based on this evaluation, management concluded that the company's internal control over financial reporting was effective as of December 31, 2007.

The Company is not an "accelerated filer" for the 2007 fiscal year because it is qualified as a "small business issuer". Hence, under current law, the internal controls certification and attestation requirements of Section 404 of the Sarbanes-Oxley act will not apply to the Company.

ITEM 8B. OTHER INFORMATION

Not applicable.

PART III

ITEM 9. DIRECTORS AND EXECUTIVE OFFICERS

Below is certain information regarding our directors and executive officers.

Name	Age	Position
Steve H. Kanzer, CPA, Esq.	44	Chairman and Chief Executive Officer
Charles L. Bisgaier, Ph.D.	54	President and Director
Jeffrey J. Kraws	43	Director
A. Joseph Rudick, M.D.	51	Director
Nicholas Stergis, M.S.	33	Vice Chairman of the Board and Director
Jeff Wolf, Esq.	44	Director
Daniel J. Dorman	45	Director
James S. Kuo, M.D., M.B.A.	43	Director

STEVE H. KANZER, CPA, Esq. Mr. Kanzer is our co-founder and served as our President from our inception in February 2001 until May 2006. In September 2004, Mr. Kanzer assumed the additional roles of Chairman and Chief Executive Officer and serves on a full-time basis at our corporate headquarters in Ann Arbor, Michigan. Mr. Kanzer has also been a director and officer of our subsidiaries, including Solovax, Inc., Effective Pharmaceuticals, Inc., Putney Drug Corp. and CD4 Biosciences, Inc. Since December 2000, he has served as co-founder and Chairman of Accredited Ventures Inc. and Accredited Equities Inc., a venture capital firm and FINRA-member investment bank, respectively, which both specialize in the biotechnology industry. Mr. Kanzer was co-founder, Chairman, President and Chief Executive Officer of Developmental Therapeutics, Inc., a cardiovascular drug development company which was developing an oral thyroid hormone analog, DITPA, for congestive heart failure. Developmental Therapeutics was acquired in October 2003 by Titan Pharmaceuticals, Inc., a publicly traded biopharmaceutical company. Prior to founding Accredited Ventures and Accredited Equities in December 2000, Mr. Kanzer served as Senior Managing Director-Head of Venture Capital at Paramount Capital from 1991 until December 2000. While at Paramount Capital, Mr. Kanzer was involved in the formation and financing of a number of biotechnology companies and held various positions in these companies. From 1995 through 1999, Mr. Kanzer was founding Chairman of the Board of Discovery Laboratories, Inc., a public biotechnology company that has a pending NDA for a drug called SURFAXIN ® which Mr. Kanzer licensed in 1995. From 1997 until 2000, Mr. Kanzer was founding President of PolaRx Biopharmaceuticals, Inc., a biopharmaceutical company that licensed and developed TRISENOX ® (arsenic trioxide), a leukemia drug that was approved by the FDA in 2000 and which currently holds the FDA record for fastest drug ever developed from IND filing until NDA approval (30 months). PolaRx was merged with Cell Therapeutics Inc. (NASDAQ:CTIC) in January 2000, and Cephalon acquired the rights to TRISENOX ® in 2005 for $165 million. 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, a publicly traded 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.

CHARLES L. BISGAIER, Ph.D. Dr. Bisgaier 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, until its acquisition by Pfizer. 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-2 16 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 75 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 also served as the Editor-in-Chief of Current Medicinal Chemistry Immunology, Endocrine and Metabolic Agents. Dr. Bisgaier serves as a board member of the Michigan Society of Medical Research.

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 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 Nationsbanc Montgomery Securities, BT Alex Brown & Sons, and Buckingham Research. Mr. Kraws also has industry experience, having been responsible for competitive analysis within the treasury group at Bristol-Myers-Squibb Company. He holds an MBA from Cornell University and a B.S. degree from State University of New York-Buffalo. During 2006 through February 2007, Mr. Kraws served as our Vice President of Business Development, on a part-time basis.

A. JOSEPH RUDICK, M.D. Dr. Rudick has been a director since 2004. Dr. Rudick was previously president and chief medical officer of our subsidiary Effective Pharmaceuticals, Inc. Dr. Rudick was our Chief Medical Officer until November 1, 2007. 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 it 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 Opthalmalogics, 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 CatarexTM , as well as a partnership with Indevus Pharmaceuticals, Inc. for development of their novel clinical-stage neuropathic pain compound, now known as IP-57 1. 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 was also a registered representative of Accredited Equities, Inc., a company controlled by Mr. Kanzer.

NICHOLAS STERGIS, M.S. Mr. Stergis is our co-founder, and Vice Chairman of our board of directors. Mr. Stergis previously served as our Chief Operating Officer from our founding during 2001 until March 2007. Prior to co-founding Pipex, Mr. Stergis was a co-founder, Chief Operating Officer and director of Developmental Therapeutics, Inc., a cardiovascular drug development company, until its acquisition in October 2003 by Titan Pharmaceuticals, Inc. (AMEX: TTP), a publicly-traded pharmaceutical company. Mr. Stergis was also a founder of Encode Pharmaceuticals, Inc., a drug development company until its acquisition by Raptor Pharmaceuticals, Inc., a publicly traded company. Mr. Stergis is also a co-founder and Managing Director of Accredited Ventures Inc., a venture capital firm specializing in the biotechnology and pharmaceutical industries. Mr. Stergis is also Managing Director of Accredited Equities, Inc., a FINRA 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 and MAA approval. He was also instrumental in CTD's divestiture of important botulinum toxin intellectual property to Allergan, Inc. (NYSE:AGN), a publicly traded specialty pharmaceutical companies. Prior to joining CTD, Mr. Stergis was a Technology Associate at Paramount Capital, a New York based private equity, venture capital, investment banking and asset management group specializing in the biotechnology and pharmaceutical industries. There, he participated in the startup, acquisition and financing of various biotechnology companies, including CTD. Mr. Stergis received his M.S. in Biology from New York University as well as a B.S. in Biology from the University at Albany, State University of New York. Mr. Stergis is also a director and interim officer of several privately held biopharmaceutical companies such as General Fiber, Inc. which are engaged in the in-licensing of biopharmaceutical candidates. As such, Mr. Stergis devotes a portion of his time to the business of the company.

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

DANIEL J. DORMAN Mr. Dorman is the President of D. J. Dorman & Co., Inc. and its predecessor companies since 1989. D. J. Dorman & Co., Inc. originates, structures, acquires and manages investments in private equity and buyout opportunities on behalf of several entities. Mr. Dorman is also Chairman and CEO of Dorman Industries, LLC which is a privately owned multi-industry holding company. Mr. Dorman has also been the Chief Executive Officer of Sandston Corporation, a public company, since April 2004. Additionally, Mr. Dorman is a director of Kux Manufacturing Company, Inc., an architectural engineering and manufacturing company; Chairman of Kroll International, LLC, a wholesaler of law enforcement, homeland defense and public safety equipment; Chairman of Versatile Processing Group, Inc., a holding company for various non-ferrous metal processing and utility service companies serving the industrial and electric utility industries and a director of an international private equity fund, AFA Private Equity Fund I. Mr. Dorman is a graduate of Ferris State University where he holds a Bachelor in Business Administration.

JAMES S. KUO, M.D., M.B.A. Dr. Kuo is the Chairman and Chief Executive Officer of Duska Therapeutics, Inc., a public biopharmaceutical company. From 2003 to 2006, he served as founder, Chairman and Chief Executive Officer of BioMicro Systems, Inc. a private venture-backed, microfluidics company. Prior to that time, Dr. Kuo was a founder, President and Chief Executive Officer of Discovery Laboratories, Inc. where he raised over $22 million in initial private funding and was instrumental in the company going public. Dr. Kuo was also a founder and board member of Monarch Labs, LLC, a private medical device company. Dr. Kuo is the former Managing Director of Venture Analysis for Healthcare Ventures, LLC, which managed $378 million in venture funds. He has also been a senior licensing and business development executive at Pfizer, Inc., where he was directly responsible for cardiovascular licensing and development. After studying molecular biology and receiving his B.A. at Haverford College, Dr. Kuo simultaneously received his M.D. from the University of Pennsylvania School of Medicine and his M.B.A. from the Wharton School of Business.

Directors' Term of Office

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

Audit Committee and Audit Committee Financial Expert

The Audit Committee is comprised of Jeff Wolf and Dr. James Kuo. The Audit Committee is responsible for recommending the Company's independent public accounting firm and reviewing management's actions in matters relating to audit functions. The Committee reviews with the Company's independent public accountants the scope and results of its audit engagement and the Company's system of internal controls and procedures. The Committee also reviews the effectiveness of procedures intended to prevent violations of laws. The Committee also reviews, prior to publication, our reports on Form 10-KSB and Form 1 0-QSB. Our board has determined that all audit committee members are independent under applicable SEC regulations. Our board of directors has determined that Dr. Kuo qualifies as an "audit committee financial expert" as that term is used in Section 407 of the Sarbanes-Oxley Act of 2002.

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

Our Compensation Committee consists of Daniel Dorman and Jeff Wolf. Our Nominating Committee consists of Jeff Wolf and Dr. James Kuo. These committees perform several functions, including reviewing all forms of compensation provided to our executive officers, directors, consultants and employees, including stock compensation, and recommending appointments to the board and appointment of executive officers.

ITEM 10. EXECUTIVE COMPENSATION

The following table discloses information for the fiscal year ended December 31, 2007 regarding the total compensation we paid to our principal executive officer and three other most highly compensated executive officers who were serving as executive officers on December 31, 2007, and our former Chief Medical Officer who would have been among our most highly compensated executive officers if he had been serving as an executive officer on December 31, 2007.

Name and Pricipal Position	Salary ($)	Bonus ($)	Option Awards (1)	All Other Annual Compensation	Total
Steve H. Kanzer, CPA, Esq. Chairman & Chief Executive Officer	$ 87,750	$ 45,205	$ -	$ -	$ 132,955
Charles Bisgaier, Ph.D. President	$ 295,000	$ 100,000	$ -	$ -	$ 395,000
John Althaus Vice President, Advanced Technology	$ 100,000	$ 15,000	$ 87,750	$ -	$ 202,750
Margaret McShane Vice Presient, Clinical Development	$ 96,169	$ 15,655	$ 708,755	$ -	$ 820,579
A. Joseph Rudick, M.D. Former Chief Medical Officer	$ 85,833	$ -	$ -	$ -	$ 85,833

(1) The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model. The weighted average assumptions used for the valuation of these option awards are as follows: Expected dividends 0%; Expected volatility 100.24% - 200.33%; Risk free interest rate ranging from 4.31% - 4.76%; Expected life of options 10 years.

The following table contains information relating to grants of stock options made during the fiscal year ended December 31, 2007, to our senior executive officers. No stock options were exercised by our senior executive officers during the last fiscal year.

Option/SAR Grants in Last Fiscal Year

Name and Principal Position	Number of securities underlying options/SARs granted (#)	Percent of total options/SARs granted to employees in fiscal year	Exercise Price ($/Sh)	Expiration date
Steve H. Kanzer, CPA, Esq. Chairman & Chief Executive Officer	-	-	-	-

Charles Bisgaier, Ph.D. President	-	-	-	-
John Althaus Vice President, Advanced Technology	15,000	2.14%	$ 5.85	11/1/2017
Margaret McShane	16,667	2.38%	$ 16.20	1/21/2017
Vice Presient, Clinical Development	75,000	10.71%	$ 5.85	11/1/2017
A. Joseph Rudick, M.D. Former Chief Medical Officer	22,621	3.23%	$ 0.09	9/13/2014

The following table discloses information regarding outstanding equity awards as of December 31, 2007 for each of our senior executive officers.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

Name and Principal Position	Number of securities underlying unexercised options/exercisable	Number of securities underlying unexercised options/unexercisable	Option exercise price	Option expiration date
Steve H. Kanzer, CPA, Esq.	180,705	90,353	$ 2.01	10/30/2016
Chairman & Chief Executive Officer				
Charles Bisgaier, Ph.D.	387,480	276,772	$ 1.83	5/30/2016
President				
John Althaus	36,141	18,071	$ 0.18	2/5/2016
Vice President, Advanced Technology	4,688	10,312	$ 5.85	11/1/2017
Margaret McShane	5,555	11,112	$ 16.20	1/21/2017
Vice Presient, Clinical Development	23,437	51,563	$ 5.85	11/1/2017
A. Joseph Rudick, M.D.	27,106	-	$ 0.09	5/31/2015
Former Chief Medical Officer	22,621	-	$ 0.09	9/13/2014

Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2007 regarding the compensation of our directors who are not also named executive officers.

Name	Fees earned or paid in cash	Option awards (1)	Other compensation	Total
Daniel Dorman	$ 9,000	$ 145,498	$ -	$ 154,498
Jeffrey Kraws	$ 4,000	$ 48,748	$ 17,500	$ 70,248
James Kuo	$ 8,000	$ 145,498	$ -	$ 153,498
Jeffrey Wolf	$ 10,000	$ 103,539	$ -	$ 113,539

(1) The amounts in the “Option awards” column reflect the dollar amounts recognized as compensation expense for the financial statement reporting purposes for stock options for the fiscal year ended December 31, 2007 in accordance with SFAS 123(R). The fair value of the options was determined using the Black-Scholes model with

the following assumptions: expected dividend yield of 0%, expected volatility of 195 - 200%, risk free interest rate of 4.31 – 4.68% and an expected life of 10 years.

During the first quarter of 2007, director compensation for independent members was approved at $2,000 per board meeting that they attend in person, $1,000 per telephonic board meeting and $500 per committee meeting. In addition, we also grant independent members of our board of directors upon appointment to our board 25,000 stock options to purchase 25,000 shares of our common stock at an exercise price equal to the fair market value of our common stock on the date of grant, and an additional 8,333 stock options each year. We also reimburse our directors for travel and other out-of-pocket expenses incurred in attending board of director and committee meetings.

Equity Compensation Plan Information

The following table states certain information with respect to our equity compensation plans as of December 31, 2007:

Plan category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans
2001 Stock Incentive Plan	1,489,353	$ 1.22	0
2007 Stock Incentive Plan	808,011	$ 5.50	1,691,989
Total	2,297,364	$ 2.72	1,691,989

Employment Agreements

On October 10, 2007, the Company we entered into a three-year employment agreement with our Chief Scientific Officer. We paid the Chief Scientific Officer a $7,500 signing bonus and a base salary of $205,000 per year. The agreement also provides that the Chief Scientific Officer is eligible for cash and non-cash bonuses at the end of each of the Company's fiscal years during the term of the agreement at the discretion of the Company's compensation committee as well as additional commission-based cash and stock bonuses during each fiscal year based on significant revenue-generating, out-licensing and merger and acquisition transactions initiated and completed by the Chief Scientific Officer, again at the discretion of the compensation committee. Pursuant to the agreement, we granted a ten-year option to purchase 150,000 shares of our common stock of which none have vested as of December 31, 2007. The options will vest quarterly over a three-year period. This agreement was terminated on March 7, 2008.

We entered into an employment agreement with Dr. Charles L. Bisgaier on May 24, 2006. Pursuant to this agreement, we will pay Dr. Bisgaier an annual base salary of $295,000 and a guaranteed bonus of one-third of his base salary. We also granted Dr. Bisgaier a ten year option to purchase 664,252 shares of our common stock, of which 387,480 have already vested. The remainder of this option will vest quarterly over a three year period. In the event of a termination without just cause, we will provide Dr. Bisgaier with six month severance, payable over a six month period. On March 5, 2008, the Company's President has agreed to work for no cash compensation until May 17, 2008 at which time his compensation will be at the discretion of the compensation committee. The President will be eligible to receive a contingent bonus in the event that the Company is acquired or the stock price retraces or exceeds to the level of the share price on January 28th 2008. Additionally, the President agreed to eliminate severance provisions of his agreement.

During January 2006, we entered into an employment letter agreement with our director Jeffrey Kraws to serve as Vice President of Business Development, pursuant to which we will pay him an annual base salary of $75,000 following the closing of a financing and have granted him an option to purchase 228,773 shares of common stock, at an exercise price of $0.09 per share, with 114,387 vested upon execution of his employment agreement and the remainder vesting annually over three years. During March 2007, we entered into an amended agreement with Mr.

Kraws whereby he forgo any cash compensation and continued as a director in exchange for 38,129 options vesting.

Pursuant to an employment letter agreement, our subsidiary EPI paid Dr. Rudick $175,000 per annum, pay life and disability insurance on behalf of Dr. Rudick and he received an option to purchase 262,500 shares of EPI common stock. Following the acquisition of EPI, Dr. Rudick agreed to reduce his annual base salary to $95,000 per annum, forgo any life or disability reimbursement from us and agree to cancel an unvested option to purchase 294,071 shares of our common stock. As a result of the acquisition of EPI, Dr. Rudick's vested stock options converted into options to purchase 27,106 of Pipex common stock at an exercise price of $0.09 per share which expire on September 13, 2014. His shares of EPI common stock converted to 30,161 shares of Pipex common stock and his EPI warrants converted into 42,845 warrants to purchase Pipex common stock at an exercise price of $3.30 per share with an expiration date of May 30, 2015. During March 2007, Dr. Rudick was appointed as President and Chief Medical Officer of Pipex Neurosciences Inc., a majority owned subsidiary in which Dr. Rudick has received five percent equity ownership. As of November 1, 2007, Dr. Rudick is no longer employed by the Company.

In January 2005, we entered into a four year employment agreement with Steve H. Kanzer to serve as our Chairman and Chief Executive Officer. We agreed to pay him an annual base salary of $297,000, an annual bonus equal to 30% of his base salary and issue him a ten-year option to acquire 271,0585 shares of our common stock, vesting annually over a three year period commencing at the completion of our private placement financing. On July 20, 2007 the Board of Directors approved an amended and restated employment agreement with the Chief Executive Officer. The amended employment agreement provides that the Chief Executive Officer is to be paid a base salary of $195,000 per year plus a guaranteed bonus of $100,000. The Chief Executive Officer may also be entitled to discretionary transactional bonuses. In addition, the amended agreement provides that the Chief Executive Officer has waived the receipt of any salary and bonus payable under the original agreement for no additional consideration. This waiver constituted a capital contribution of $275,645 to the Company.

During November 2005, we entered into an employment agreement as amended with John Althaus, MS, the Vice President of Advanced Technology. We currently pay Mr. Althaus $100,000 per year and we issued him 54,212 options to acquire our common stock.

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

The following table sets forth certain information regarding beneficial ownership of our common stock and warrants to purchase shares of our common stock as of March 24, 2008 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 of our directors and executive officers, and (iii) all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. The principal address of each of the stockholders listed below except as indicated is c/o Pipex Pharmaceuticals, Inc., 3930 Varsity Drive, Ann Arbor, MI 48108. We believe that all persons named in the table have sole voting and investment power with respect to shares beneficially owned by them. All share ownership figures include shares issuable upon exercise of options or warrants exercisable within 60 days of March 24, 2008, 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.

All references to the number of shares and per share amounts have been retroactively restated to reflect a 3 for 1 reverse stock split, of all the outstanding common stock, stock options and stock warrants of the Company, which was effective on April 25, 2007.

Principal Stockholders Table

Name of Owner	Shares Owned	Percentage of Shares Outstanding
Accredited Venture Capital, LLC	8,300,006(1)	38.27%
Steve H. Kanzer	8,805,957(2)	40.27%
Ridgeback Capital Investment Ltd.	1,856,565(3)	9.07%
Firebird Capital	1,486,550(4)	7.26%
Nicholas Stergis	1,709,361(5)	8.21%
Charles Bisgaier, Ph.D.	546,136(6)	2.61%
Jeffrey J. Kraws	218,042(7)	1.05%
A. Joseph Rudick, M.D.	189,792(8)	*
Jeffrey Wolf, Esq.	33,333(9)	*
Daniel J. Dorman	794,525(10)	3.87%
James S. Kuo	33,333(11)	*
All officers and directors as a group (8 persons)	12,330,479	57.26%

* represents less than 1% of our common stock

(1) Consists of 7,086,380 shares held in the name of Accredited Venture Capital, LLC and 1,213,626 shares issuable upon presently exercisable warrants held in the name of Accredited Venture Capital, LLC.

(2) Consists of the 7,086,380 shares of common stock and 1,213,626 warrants, registered in the name of Accredited Venture Capital, LLC, and 325,246 common shares, and 180,705 shares issuable upon stock options presently exercisable or exercisable within 60 days held directly in Mr. Kanzer’s name. Does not include 90,353 shares issuable

upon stock options held directly in Mr. Kanzer's name that are not presently exercisable. Pharmainvestors, LLC is the managing member of Accredited Venture Capital, LLC, and Mr. Kanzer is the managing member of Pharmainvestors, LLC. As such, Mr. Kanzer may be considered to have control over the voting and disposition of the shares registered in the name of Accredited Venture Capital, LLC. Mr. Kanzer disclaims beneficial ownership of those shares, except to the extent of his pecuniary interest.

(3) Consists of 1,856,565 of shares of common stock. Ridgeback Capital Investment Ltd.'s address is 430 Park Avenue, 12th Floor, New York, New York 10022.

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

(5) Consists of 1,355,292 shares of common stock, and warrants to purchase 346,418 and 7,651 shares of common stock, issued to Mr. Stergis. Mr. Stergis's business address is 9100 South Dadeland Blvd., Suite 1809, Miami, Florida 33156.

(6) Consists of 387,480 shares issuable stock options presently exercisable or exercisable within 60 days, 59,552 shares of common stock and 24,776 warrants to purchase common stock issued to Bisgaier Family LLC, a company of which Dr. Bisgaier is the managing member; 49,552 shares of common stock and 24,776 warrants to purchase common stock issued to two trusts for which Dr. Bisgaier has control of. Excludes 276,772 unvested options to purchase common stock that is vesting over three years.

(7) Assumes the exercise of a vested option to purchase 218,042 shares of our common stock presently exercisable or exercisable within 60 days. Excludes an unvested option to purchase 19,064 shares of common stock which will vest on January 26, 2009. Mr. Kraws's business address is 800 Third Avenue, 17th Fl., New York, NY 10022.

(8) Consists of 57,267 shares of common stock, an option to purchase 22,621 shares of common stock and a warrant to purchase 109,904 shares of common stock. Dr. Rudick's business address is 150 Broadway, Suite 1800, New York, NY 10128.

(9) Assumes the exercise of an option to purchase 33,333 shares of our common stock. Mr. Wolf's business address is c/o Seed-One Ventures, LLC, 1205 Lincoln Road, Suite 216, Miami Beach, Florida 33139.

(10) Consists of 18,566 shares of common stock registered in the name of Red Metal Capital, LLC, of which Mr. Dorman is the Managing Member, 742,626 shares of common stock registered in the name of AFA Private Equity Fund I, of which Mr. Dorman is a partner, and 33,333 options to purchase common stock held directly by Mr. Dorman. Mr. Dorman's business address is 40950 Woodward Avenue, Suite 304, Bloomfield Hills, Michigan, 48304.

(11) Consists of 33,333 options to purchase common stock. Mr. Kuo's business address is 470 Nautilus St, Suite 300, La Jolla, California, 92037.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

All references to the number of shares and per share amounts have been retroactively restated to reflect a 3 for 1 reverse stock split, of all the outstanding common stock, stock options and stock warrants of the Company, which was effective on April 25, 2007.

During January 2001, we sold approximately $1.1 million of Series A Preferred Stock to Accredited Venture Capital, LLC, a company controlled by Steve H. Kanzer, our Chairman and Chief Executive Officer. From 2002 until October 2006, we relied on non-interest bearing bridge loans from Accredited Ventures, Inc. (AVI), a company controlled Steve H. Kanzer, our Chairman and Chief Executive Officer and the managing member of our largest stockholder, Accredited Venture Capital, LLC. During this 5 year period, AVI loaned us $3,363,494 for no additional consideration. In connection with the private placement during October 2006, AVI agreed to convert these loans into units in the offering. As a result of the conversion of these loans, we issued 1,665,211 shares of common stock and 832,606 warrants to purchase common stock. In the merger, all shares of preferred stock were converted into common stock of the Registrant.

In connection with a private placement in October and November 2006, we engaged Accredited Equities Inc. (AEI), a company controlled by Steve H. Kanzer, our Chairman and Chief Executive Officer as our placement agent. At the closing of our private placement during October and November 2006, we paid AEI the sum of approximately $639,844 as commissions for its services and the selected dealer was paid a cash fee of $327,950. AEI also received a non-accountable expense allowance of $75,000 and a warrant to purchase 958,277 shares of common stock. Dr. Joseph Rudick, our director, is a registered representative of AEI. Mr. Nicholas Stergis, our co-founder and Vice Chairman, is the managing director of AEI and AVI.

As part of the October 2006 private placement, Pipex sold 99,104 shares of its common stock and 49,552 warrants to purchase common stock for total proceeds of $200,000 to entities controlled by Dr. Charles Bisgaier, our President. As part of the same private placement, Pipex sold 49,552 shares of its common stock and 24,776 warrants to purchase common stock for total proceeds of $100,000 to the father of our Chairman and CEO. The terms on which their purchases were made were identical to the terms in which the other investors in these offerings purchased shares.

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

On January 5, 2007, we acquired the remaining 34.53% interest in our subsidiary EPI in exchange for 795,248 shares of our common stock and assumed a total of 34,685 options to purchase our common stock and 68,858 warrants to purchase our common stock. In connection therewith, Messrs. Kanzer and Stergis each exchanged their existing EPI warrants for 7,651 warrants to purchase our common stock, and Dr. Rudick exchanged EPI common stock for 30,161

shares of our common stock and exchanged his existing EPI options for 27,106 options to purchase our common stock, all of which is vested, and exchanged his EPI warrants for 42,845 warrants to purchase our common stock.

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

We have employment agreements with Dr. Bisgaier and Mr. Kanzer, each a director and an executive officer of the company. See “Employment Agreements” section of this filing for further descriptive information on employment compensation.

ITEM 13. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Berman & Company, P.A., our independent registered public accounting firm, billed to us $68,000 and $127,000 for the 2007 and 2006 fiscal years, respectively, for audit fees. Audit fees consist of fees related to professional services rendered in connection with the audit of our consolidated financial statements, the reviews of the interim financial statements included in our quarterly reports on Form 10-QSB and other professional services provided in connection with statutory and regulatory filings or engagements.

PART IV

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

(a) Financial Statements

1. These financial statements are set forth in Item 8.

2. No financial statement schedules are required.

(b) Reports on Form 8-K

A report on Form 8-K was filed on March 18, 2008 under Item 8.01 Other Events.

A report on Form 8-K was filed on March 10, 2008 under Item 5.02 Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers; Compensatory Arrangement of Certain Officer.

A report on Form 8-K was filed on February 29, 2008 under Item 8.01 Other Events.

A report on Form 8-K was filed on January 29, 2008 under Item 8.01 Other Events.

(c) Exhibits

3.1 Certificate of Incorporation (1)

3.2 By-Laws (1)

4.1 Form of Warrant Certificate (2)

4.2 2001 Stock Incentive Plan (3)

4.3 2007 Stock Incentive Plan (3)

5.1 Opinion of Lehman & Eilen LLP Re: Legality of Shares (4)

10.1 Employment Agreement with Charles L. Bisgaier (5)

10.2 Consulting Agreement with George J. Brewer (5)

10.3 License Agreement with the Regents of the University of Michigan (5)

10.4 Research Agreement with the Regents of the University of Michigan (5)

10.5 Option and License Agreement between University of Southern California and Autoimmune Vaccines, Inc. (5)

10.6 First Amendment to Option and License Agreement between University of Southern California and Solovax, Inc. (formerly Autoimmune Vaccines, Inc.) (5)

10.7 License Agreement between Children's Medical Center Corporation and Effective Pharmaceuticals, Inc. (5)

10.8 License Agreement between Thomas Jefferson University and Quantas Biopharmaceuticals, Inc. (5)

10.9 First Amendment to License Agreement between Thomas Jefferson University and CD4 Biosciences, Inc. (5)

10.10 Private Stock Purchase Agreement with Michael Manion (5)

10.11 Lock-up Agreement with Michael Manion (5)

10.12 Lock-up Agreement with Accredited Venture Capital, LLC (5)

10.13 Lock-up Agreement with Nicholas Stergis (5)

10.14 Lock-up Agreement with Joseph Rudick (5)

10.15 Lock-up Agreement with Jeffrey Kraws (5)

10.16 Lock-up Agreement with Jeffrey Wolf (5)

10.17 Lock-up Agreement with Charles Bisgaier (5)

10.18 Unit Purchase Agreement (2)

10.19 First Amendment to License Agreement between Children's Medical Center Corporation and Effective Pharmaceuticals, Inc. (6)

10.20 License Agreement between Maine Medical Center and Pipex Pharmaceuticals, Inc. (7)

31.1 Certification pursuant to Rule 13a-14(a)/15d-14(a) (8)

32.1 Certification pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 (8)

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

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

(3) Incorporated by reference to the Registrant’s Form S-8 filed on January 18, 2008.

(4) Previously filed.

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

(6) Incorporated by reference to the Registrant’s Form 10QSB filed on August 14, 2007.

(7) Incorporated by reference to the Registrant’s Form 10QSB filed on November 14, 2007.

(8) Filed herewith.

SIGNATURES

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

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PIPEX PHARMACEUTICALS, INC
By: /s/ Nicholas Stergis
Nicholas Stergis
Chief Executive Officer
(Principal Executive Officer and
Principal Financial Officer)
Date: August 29, 2008

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

Date: August 29, 2008	By: /s/ Nicholas Stergis Nicholas Stergis Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)
Date: August 29, 2008	By: /s/ Steve H. Kanzer Steve H. Kanzer Chairman
Date: August 29, 2008	By: /s/ Jeffrey J. Kraws Jeffrey J. Kraws Director
Date: August 29, 2008	By: /s/ Jeffrey Wolf Jeffrey Wolf Director
Date: August 29, 2008	By: /s/ James S. Kuo James S. Kuo Director

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