PIPEX PHARMACEUTICALS, INC.
Form 424B3
February 14, 2007

Filed pursuant to Rule 424(b)(3)
Registration No. 333-139354

PROSPECTUS

30,958,113 shares of common stock

This prospectus relates to the resale or other disposition of up to 30,958,113 shares of our common stock, $0.001 par value per share, by the persons who are, or will become, our shareholders. These persons, together with their transferees, are referred to throughout this prospectus as “selling shareholders.” Of these shares, up to 10,206,037 shares are issuable on the exercise of certain warrants.

All of the shares and warrants described above were previously issued in a merger and a private placement transaction completed prior to the filing of this registration statement.

We are not selling any shares of our common stock in this offering and therefore will not receive any proceeds from this offering. We may receive proceeds on exercise of outstanding warrants for shares of common stock covered by this prospectus if the warrants are exercised for cash. We will bear all costs associated with this registration. The selling shareholders may offer the shares covered by this prospectus at fixed prices, at prevailing market prices at the time of sale, at varying prices or negotiated prices, in negotiated transactions, or in trading markets for our common stock.

Our common stock trades on the OTC Bulletin Board under the symbol “PPXP.” The closing price of our common stock on the OTC Bulletin Board on February 6, 2007, was $5.68 per share.

You should consider carefully the risk factors beginning on page 5 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved these securities or determined that this prospectus is accurate or complete. Any representation to the contrary is a criminal offense.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

The date of this prospectus is February 14, 2007

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PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. It is not complete and may not contain all of the information that is important to you. To understand this offering fully, you should read the entire prospectus carefully. Investors should carefully consider the information set forth under the heading "Risk Factors." In this prospectus, the terms "Pipex Pharmaceuticals," "we," "us," and "our" refer to Pipex Pharmaceuticals, Inc. and its subsidiaries Pipex Therapeutics, Inc., Effective Pharmaceuticals, Inc., Solovax, Inc., CD4 Biosciences, Inc., and Putney Drug Corp.

Our Company

We are 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 New Drug Applications (NDA) with the FDA and potential Marketing Application Authorizations (MAA) with the European Medicines Evaluation Agency (EMEA).

Our lead drug candidate, COPREXA™ (oral tetrathiomolybdate), is a novel, oral, anticopper therapeutic that has completed two pivotal clinical trials in neurologically-presenting Wilson's disease that we believe have demonstrated sufficient safety and efficacy to support the filing of an NDA with the FDA as well as a MAA with the European Medicines Evaluation Agency. In order to expand the therapeutic utility of COPREXA™ beyond the indication of initially-presenting neurological Wilson's disease, our investigators have recently completed an initial 12 month, 16 patient, open label phase II clinical trial for the treatment of refractory idiopathic pulmonary fibrosis (IPF), a progressive fibrotic lung disease associated with high rates of mortality and for which there is no currently approved therapy. IPF is estimated to affect 124,000 patients in the U.S., resulting in approximately 30,000 deaths annually, exceeding the annual number of deaths attributable to breast and prostate cancer.

We are also developing TRIMESTA™ (oral estriol), for the treatment of multiple sclerosis (MS), a life threatening autoimmune disease that affects the central nervous system (CNS). MS is characterized by a progressive loss of motor function, leading to paralysis and death. Estriol has been approved for the treatment of post-menopausal hot flashes in Europe and Asia for approximately 40 years but has never been approved in the U.S. TRIMESTA™ has completed a phase IIa clinical trial in the U.S. for the treatment of MS and demonstrated statistically significant benefits in relapsing-remitting MS patients. We plan to initiate a phase II/III clinical trial using TRIMESTA™ for the treatment of relapsing-remitting MS.

We are also developing a series of small molecule and peptide based inhibitors of the CD4 co-receptor of T-cells, an important pathway for the treatment and prevention of autoimmune diseases. Our lead anti-CD4 molecule, Anti-CD4 802-2, is a cyclic, seven amino acid peptide that has demonstrated efficacy in a number of animal models of autoimmune diseases, including MS, and is currently nearing completion of a dose ranging phase I/II clinical trial for the prevention of graft-versus-host disease.

We have eight employees. Our management team includes experienced senior level professionals with a combined 50 years of experience at leading companies in the pharmaceutical industry, including Pfizer, Pharmacia, and Warner-Lambert.

Our corporate headquarters is located at 3985 Research Park Drive, Ann Arbor MI 48108. Our telephone number is (734) 332-7800 and our website is located at www.pipexpharma.com. The information on our website is not part of this prospectus.

Recent Transactions

On October 31, 2006, our wholly owned subsidiary completed a merger with Pipex Therapeutics, Inc. ("Pipex Therapeutics") whereby Pipex Therapeutics' shareholders were issued 34 million of our shares and we assumed the then outstanding options and warrants of Pipex Therapeutics.

Prior to the merger, Pipex Therapeutics completed a private placement to institutional and accredited investors resulting in approximately $4.5 million in gross proceeds to us.

During November 2006, we completed a separate private placement to institutional and accredited investors resulting in approximately $9.3 million in gross proceeds. As a result of these two placements (the “Placements”) we received approximately $13.9 million in gross proceeds.

In connection with these transactions, we agreed to file, within 45 days of the closing date of the merger, a registration statement registering for resale the shares exchanged by the Registrant and have it declared effective within 150 days of the closing of the merger. The registration statement of which this prospectus forms a part is being filed to fulfill the obligations to the investors of the Placements.

The Offering	
Common stock outstanding	50,979,171 shares as of February 7, 2007.
Common stock that may be offered by selling shareholders	Up to 30,958,113 shares, representing 20,752,076 shares of our common stock that were issued to the selling shareholders and 10,206,037 shares of our common stock underlying warrants that were issued to the selling shareholders.
Total proceeds raised by offering	We will not receive any proceeds from the resale or other disposition of the shares covered by this prospectus by any selling shareholder. We may receive proceeds from the exercise of the warrants whose underlying shares of common stock are covered by this prospectus.
Risk factors	There are significant risks involved in investing in our company. For a discussion of risk factors you should consider before buying our common stock, see “Risk Factors” beginning on page 5.

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 September 30, 2006, we have expended approximately $6 million on a consolidated basis acquiring and developing our current product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Therefore, for the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees, and grants. We will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We are not currently profitable and may never become profitable.

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

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

• seek regulatory approvals for our product candidates;

• implement additional internal systems and infrastructure;

• lease additional or alternative office facilities; and

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

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

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

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

• continuing to undertake pre-clinical development and clinical trials;

• participating in regulatory approval processes;

• formulating and manufacturing products; and

• conducting sales and marketing activities.

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

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

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

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

• delay commercialization of, and our ability to derive product revenues from, our product candidates;

• impose costly procedures on us; and

• diminish any competitive advantages that we may otherwise enjoy.

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

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

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

We currently rely on an exclusive worldwide license agreement with the University of Michigan relating to various uses of COPREXA™ . We also have an exclusive license agreement with the McLean Hospital relating to the use of EFFIRMA™ to treat fibromyalgia syndrome; an exclusive license agreement with Thomas Jefferson University relating to our anti-CD4 inhibitors; an exclusive license agreement with the Regents of the University of California relating to our TRIMESTA™ technology; an exclusive license agreement with the Children's Hospital-Boston relating to our CORRECTA™ technology and an exclusive option agreement to license our T-cell vaccine program from the University of Southern California (USC). Each of these agreements requires us to use our best efforts to commercialize each of the technologies as well as meet certain diligence requirements and timelines in order to keep the license agreement in effect. In the event we are not able to meet our diligence requirements, we may not be able to retain the rights granted under our agreements or renegotiate our arrangement with these institutions on reasonable terms, or at all.

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

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

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

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

We may not succeed in enforcing our orphan drug designations.

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

orphan drug for a rare disease generally receives marketing exclusivity for use of that drug for the designated condition for a period of seven years in the United States and ten years in the European Union.

To be successful in enforcing this designation, our new drug application would need to be the first NDA approved to use COPREXA™ to treat Wilson's disease. While we are not aware of any other companies that have sought orphan drug designation for COPREXA™ or its active ingredient, tetrathiomolybdate, for this indication, other companies may in the future seek it and may obtain FDA marketing approval before we do. In addition, the FDA may permit other companies to market a form of tetrathiomolybdate to treat Wilson's disease patients with neurologic complication if their product demonstrates clinical superiority. This could create a more competitive market for us.

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

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

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

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

Our competitiveness may be adversely affected if we are unable to protect our proprietary technologies. Currently, there are no composition of matter patents for TRIMESTA™, EFFIRMA™, CORRECTA™, COPREXA™ or their respective active ingredients estriol, flupirtine, clotrimazole and tetrathiomolybdate. Additionally, we do not have an issued patent for COPREXA™'s use to treat Wilson's disease, although we do have Orphan Drug Designation for this indication. Orphan Drug

Designation provides protection for seven years of marketing exclusivity for that product in that disease indication in the U.S. We also expect to rely on patent protection from an issued U.S. Patent for the use of COPREXA™ and related compounds to treat inflammatory and fibrotic diseases (U.S. Patent No 6,855,340) and we have received a notice of allowance for the use of COPREXA™ and related compounds to treat Alzheimer's disease. Both of these patents have been exclusively licensed to us. We have also filed various pending patent applications which cover various formulations, packaging, distribution & monitoring methods for COPREXA™. We rely on issued patent and pending patent applications for use of TRIMESTA™ to treat MS (issued U.S. Patent No. 6,936,599) and various other therapeutic indications which have been exclusively licensed to us. We have also exclusively licensed an issued patent for the treatment of fibromyalgia with EFFIRMA™ and have pending patent applications for our uses of CORRECTA™.

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

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

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

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

We also rely on trade secrets and proprietary know-how to develop and maintain our competitive position. Some of our current or former employees, consultants, or scientific advisors, or current or prospective corporate collaborators, may unintentionally or willfully disclose our confidential

information to competitors or use our proprietary technology for their own benefit. Furthermore, enforcing a claim alleging the infringement of our trade secrets would be expensive and difficult to prove, making the outcome uncertain. Our competitors may also independently develop similar knowledge, methods, and know-how or gain access to our proprietary information through some other means.

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

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

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

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

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

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

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

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

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

If we decide to establish a full-scale commercial manufacturing facility, we would require substantial additional funds, we would need to hire and train significant numbers of employees and comply with the extensive regulations applicable to such a facility. We might find that we are unable to develop a cGMP manufacturing facility that is able to manufacture quantities of products required for all clinical trials, as well as commercial-scale manufacturing.

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

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

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

• unforeseen safety issues;

• determination of dosing;

• lack of effectiveness during clinical trials;

• slower than expected rates of patient recruitment;

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

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

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

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

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

Physicians and patients may not accept and use our technologies.

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

• the perception of members of the health care community, including physicians, regarding the safety and effectiveness of our drugs;

• the cost-effectiveness of our product relative to competing products;

• availability of reimbursement for our products from government or other healthcare payers; and

• the effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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

We depend on researchers who are not under our control.

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

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

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

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

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

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

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

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

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

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

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

• developing drugs;

• undertaking pre-clinical testing and human clinical trials;

• obtaining FDA and other regulatory approvals of drugs;

• formulating and manufacturing drugs; and

• launching, marketing and selling drugs.

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

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

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

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

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

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

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

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

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

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

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

RISKS RELATING TO OUR STOCK

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

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

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

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

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

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

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

Our common stock is quoted on the OTCBB (as opposed to NASDAQ or AMEX) and the price of the common stock is below $5.00 per share, we are therefore subject to "penny stock" regulation. The

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

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

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

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

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

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

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

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

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

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

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

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

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

We have never paid dividends.

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

RISKS RELATED TO OUR INDUSTRY

Government Regulation

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

• Preclinical laboratory and animal tests;

• Submission of an IND, prior to commencing human clinical trials;

• Adequate and well-controlled human clinical trials to establish safety and efficacy for intended use;

• Submission to the FDA of a NDA; and

• FDA review and approval of a NDA.

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

Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, and animal studies to assess potential safety and efficacy. Certain preclinical tests must be

conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. In some cases, long-term preclinical studies are conducted concurrently with clinical studies.

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

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

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

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

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

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

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

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

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

Submission of a NDA with clinical data requires payment of a fee (for fiscal year 2004, $573,500). In return, the FDA assigns a goal of ten months for issuing its "complete response," in which the FDA may approve or deny the NDA, or require additional clinical data. Even if these data are submitted, the FDA may ultimately decide the NDA does not satisfy approval criteria. If the FDA approves the NDA, the product becomes available for physicians prescription. Product approval may be withdrawn if regulatory compliance is not maintained or safety problems occur. The FDA may require post-marketing studies, also known as phase IV studies, as a condition of approval, and requires

surveillance programs to monitor approved products that have been commercialized. The agency has the power to require changes in labeling or prohibit further marketing based on the results of post-marketing surveillance.

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

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

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

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

Other Regulatory Requirements

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

We are subject to numerous federal, state and local laws relating to safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with these laws and regulations. The regulatory framework under which we operate will inevitably change in light of

scientific, economic, demographic and policy developments, and such changes may have a material adverse effect on our business.

European Product Approval

Prior regulatory approval for human healthy volunteer studies (phase I studies) is required in member states of the 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.

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

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

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

Pricing Controls

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

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

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

Third-Party Reimbursements

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

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

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

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

Fraud and Abuse Laws

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

counsel concerning the potential application of these and other laws to our business and to our sales, marketing and other activities to comply with them. Given their broad reach and the increasing attention given them by law enforcement authorities, however, we cannot assure you that some of our activities will not be challenged.

Patent Restoration and Marketing Exclusivity

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

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

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

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

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

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

FORWARD-LOOKING STATEMENTS

Most of the matters discussed within this registration statement 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 expressions. These statements are based on our current beliefs, expectation 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 prospectus, 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 prospectus might not occur.

AVAILABLE INFORMATION

In accordance with the Securities Act of 1933, we filed with the SEC a registration statement on Form SB-2 covering the securities in this offering. As permitted by rules and regulations of the SEC, this prospectus does not contain all of the information in the registration statement. For further information regarding both our company and the securities in this offering, we refer you to the registration statement, including all exhibits and schedules, which you may inspect without charge at the public reference facilities of the SEC’s Washington, D.C. office, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies may be obtained upon request and payment of prescribed fees.

We are subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, and in accordance with the Securities Exchange Act of 1934, we file annual, quarterly and special reports, and other information with the SEC. These periodic reports and other information are available for inspection and copying at the regional offices, public reference facilities and website of the SEC referred to above.

USE OF PROCEEDS

We will not receive any proceeds from sale of the shares of common stock covered by this prospectus by the selling shareholders. We may, however, receive proceeds on the exercise of outstanding warrants for shares of common stock covered by this prospectus. We intend to use for general working capital and other corporate purposes any such proceeds we receive. Furthermore, the warrants may expire without having been exercised. Even if some or all of these warrants are exercised, we cannot predict when they will be exercised and when we would receive the proceeds.

MARKET FOR COMMON STOCK AND RELATED SHAREHOLDER MATTERS

Our common stock currently trades on the OTC Bulletin Board under the symbol “PPXP.” The following table states the range of the high and low bid-prices per share of our common stock for each of the calendar quarters during the last two fiscal years, as reported by the National Quotation Bureau Incorporated and the OTC Bulletin Board. These quotations represent inter-dealer prices, without retail mark-up, markdown, or commission, and may not represent actual transactions. The last price of our common stock as reported on the OTC Bulletin Board on February 6, 2007 was $5.68 per share. As of December 14, 2006, there were 350 shareholders of record of our common stock, and approximately 3,200 shareholders held in street name.

	High	Low
YEAR ENDED DECEMBER 31, 2006		
Fourth quarter	$ 5.75	$ 3.00
Third quarter	$ 1.10	$ 1.00
Second quarter	$ 1.60	$ 1.25
First quarter	$ 1.02	$ 0.01
YEAR ENDED DECEMBER 31, 2005		
Fourth quarter	$ 3.00	$ 0.00
Third quarter	$ 2.50	$ 0.03
Second quarter	$ 0.03	$ 0.02
First quarter	$ 0.01	$ 0.00

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.

PLAN OF OPERATION

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

Overview

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

Our company resulted from the October 2006 merger of a newly-created wholly owned subsidiary of Sheffield Pharmaceuticals, Inc. (“Sheffield”), a Delaware corporation incorporated in September 1993, and Pipex Therapeutics, Inc., a Delaware corporation (“Pipex Therapeutics”). In connection with that transaction, a wholly owned subsidiary of Sheffield merged with and into Pipex Therapeutics, with Pipex Therapeutics remaining as the surviving corporation and a wholly-owned subsidiary of Sheffield. On December 11, 2006, Sheffield changed its name to “Pipex Pharmaceuticals, Inc.”. 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, Inc. 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, Inc., unless the context indicates otherwise.

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

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

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

Results of Operations

Nine Months Ended September 30, 2006; Compared to Nine Months Ended September 30, 2005.

General and administrative expenses. For the nine months ended September 30, 2006, general and administrative expense was $409,875 as compared to $88,024 for the nine months ended September 30, 2005. The increase of $321,851 is due primarily to an increase in payroll expenses of approximately $62,645, an increase in rent and utilities expense of approximately $85,692 and increases to professional fees/accounting fees of $103,408, travel expense of approximately $58,270, and depreciation of $22,410. There was also a decrease in internet charges and insurance expenses of $3,730 and $8,464 respectively.

Research and development expenses. For the nine months ended September 30, 2006, research and development expense was $1,277,722 as compared to $589,738 for the nine months ended September 30, 2005. The increase of $687,984 is due primarily to an increase in salaries of $199,044, an increase of $493,461 associated with milestone payments related to advancements in our licensed compounds, and an increase in patent expenses of $70,088. For the nine months ended September 30, 2006 the Company also incurred stock based compensation expense for options issued to employees totaling approximately $124,340, as compared to $99,360 for the nine months ended September 30, 2005.

Other income (expense), net. For the nine months ended September 30, 2006, other expense was $0 as compared to ($1,600) for the nine months ended September 30, 2005.

Interest income. For the nine months ended September 30, 2006, interest income was $1 as compared to $867 for the corresponding period of 2005. This decrease is because the Company no longer maintained an interest bearing cash account in 2006. The increase is attributed to the Company's interest bearing cash account not present in 2006.

Net loss. Net loss for the nine months ended September 30, 2006, was $1,989,288 as compared to $880,061 for the nine months ended September 30, 2005. This increase in net loss is attributable primarily to an increase in research and development expenses of $687,984 and an increase in general and administrative expenses of $321,851.

Merger costs expense. In the nine months ended September 30, 2006 merger cost expense was $12,500 as compared to $0 for the nine months ended September 30, 2005.

Compensation expense. For the nine months ended September 30, 2006 the Company has incurred $289,192 in compensation expenses as compared to $201,566 for the nine months ended September 30, 2005.

Years Ended December 31, 2005 and 2004

General and administrative expenses. For the year ended December 31, 2005, general and administrative expense was $285,701 as compared to $221,612 for the year ended December 31, 2004. The increase of $64,089 is due primarily to increases in payroll expenses of approximately $43,835, professional/accounting fees of $9,847, and travel expenses of approximately $22,000. Rent/utilities and insurance decreased $8,252 and $3,829 respectively.

Research and development expenses. For the year ended December 31, 2005, research and development expense was $946,065 as compared to $349,551 for the year ended December 31, 2004. The increase of $596,514 is due primarily to increases in payroll expenses of $43,836, an increase of $65,902 related to patent expenses, and $469,705 associated with milestone payments related to advancements in our licensed compounds.

Net loss. Net loss for the year ended December 31, 2005, was $1,355,842 as compared to $602,493 for the year ended December 31, 2004. This increase in net loss is attributable primarily to an increase in research and development expenses of $596,514 and an increase in general and administrative expenses of $64,089.

For the year ended December 31, 2005, interest income was $868 as compared to $3 for the corresponding period of 2004.

Merger cost expenses. For the year ended December 31, 2005 merger cost expense was $37,500 as compared to $0 expensed in the year ended December 31, 2004.

Compensation expenses. In the year ended December 31, 2005 the Company incurred compensation expenses of approximately $87,444 as compared with the corresponding period of the year ended December 31, 2004 of $31,333.

Liquidity and Capital Resources

From inception to September 30, 2006, we have incurred an aggregate net loss of $5,713,306, primarily as a result of expenses incurred through a combination of research and development activities of approximately $3,445,236 related to the various technologies under our control and general and administrative expenses of approximately $1,689,980 supporting those activities. From inception to September 30, 2006 we have also incurred $552,928 in compensation expenses and an expense of $50,000 related to merger costs. Interest income since inception was $26,601 and other expenses was $1,733.

We have financed our operations since inception primarily through related party debt financing and equity raising, consisting of common and preferred stock. During the nine months ended September 30, 2006, we had a net decrease in cash and cash equivalents of $692,079. Total cash resources as of

September 30, 2006 were $465,711. During October and November 2006, we consummated private placements of commons stock and warrants to acquire common stock resulting in approximately $13.9 million in gross proceeds.

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.

License and Contractual Agreement Obligations.

Below is a table of our contractual obligations for the years 2006, 2007 and 2008.

	Year			
Agreements	**Total**	**2006**	**2007**	**2008**
License Agreements	$ 350,000	$ 140,000	$ 155,000	$ 55,000
Research and Development Agreements	$ 1,587,163	$ 593,500	$ 593,500	$ 400,163
Employment Agreements	$ 2,645,601	$ 386,735	$ 1,129,433	$ 1,129,433

Current and Future Financing Needs

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 and cash equivalents and net proceeds from this offering will be sufficient to enable us to meet our planned operating needs for at least the next 18 months. Over the next 18 months we expect to spend approximately $5.0 million on clinical development, $1.8 million on general corporate expenses, and $50,000 on facilities rent.

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.

Research and Development Projects

COPREXA™ (oral tetrathiomolybate)

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

COPREXA™ has received clinical development grants from the FDA's Orphan Products group. These grants have covered the predominant cost of pre-clinical efficacy and safety testing, and Phase II and Phase III clinical program. Through September 30, 2006, we have incurred $593,560 of costs related to our development of COPREXA™, of which $150,285 was incurred in fiscal 2005, and $443,276 has been incurred in the first nine months of 2006.

TRIMESTA™ (oral estriol)

During 2007, we plan to initiate a multicenter, placebo controlled 130 patient phase II/III clinical trial using TRIMESTA™ for the treatment of relapsing-remitting Multiple Sclerosis (MS). This phase II/III clinical trial builds upon our encouraging results from our earlier phase IIa clinical trial. The primary purpose of this study will be to evaluate the safety and efficacy of TRIMESTA™ in a larger MS patient population. The preclinical and clinical development of TRIMESTA™ has been primary financed by grants from the NIH and various non-profit foundations. Through September 30, 2006, we have incurred $118,656 of costs related to our development of TRIMESTA™ of which $49,500 was incurred in fiscal 2005, and $69,156 has been incurred in the first nine months of 2006.

Anti-CD4 802-2

During 2007, we plan to complete our phase I/II clinical trial of anti-CD4 802-2 in the prevention of graft-vs-host disease as well as complete our preclinical animal studies of anti-CD4 802-2. The primary purpose of these preclinical studies is to evaluate the molecules potential efficacy in different disease settings. If successful, we may choose to initiate clinical studies in these diseases. The preclinical and clinical development of anti-CD4 802-2 has been primary financed by grants from the NIH and various non-profit foundations. Through September 30, 2006, we have incurred $1,287,408 of costs related to our development of anti-CD4 802-2 of which $57,836, $331,831, $303,332, $295,069, $112,505 was incurred in fiscal 2001, 2002, 2003, 2004 and 2005 respectively and $186,836 has been incurred in the first nine months of 2006.

CORRECTA™ (clotrimazole emema)

During 2007, we plan to complete our inflamatory bowel phase II clinical trial of CORRECTA™ in the treatment of acute refractory pouchitis, a gastrointestinal disease. 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.

If successful, we may choose to initiate a phase III clinical study in this disease. The preclinical and clinical development of CORRECTA™ has been primarily financed by grants from the FDA's orphan drug products group and various non-profit foundations. Through September 30, 2006, we have incurred $156,930 of costs related to our development of CORRECTA of which $103,238 was incurred in fiscal 2005, and $46,692 has been incurred in the first nine months of 2006.

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

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 September 30, 2006, we have incurred $658,740 of costs related to our development of SOLOVAX™ of which $106,842, $157,721, $164,320, $162,848, and $66,858 was incurred in fiscal 2001, 2002, 2003, 2004, and 2005 respectively, and $152 has been incurred in the first nine months of 2006.

We believe we currently have sufficient capital to fund development activities of COPREXA™, TRIMESTA™, anti-CD4 802-2, CORRECTA™ and SOLOVAX™ during 2006 and 2007 and 2008. Since our business does not generate any cash flow, however, we will need to raise additional capital to continue development of the product beyond 2009. We expect to raise such additional capital by either borrowing money or by selling shares of our capital stock. 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 prospectus.

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.

Use of Estimates

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

Research and Development Expense

Research and development expenses are expensed as incurred.

BUSINESS

GENERAL

We are 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).

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

PRODUCT	THERAPEUTIC INDICATION	STAGE OF DEVELOPMENT
COPREXA™ (oral tetrathiomolybdate)	Initially Presenting Neurologic Wilson's Disease	Phase III Clinical Trial (complete) NDA in preparation
COPREXA™ (oral tetrathiomolybdate)	Refactory Idiopathic Pulmonary Fibrosis (IPF)	Phase IIa Clinical Trial (complete)
COPREXA™ (oral tetrathiomolybdate)	Primary Biliary Cirrhosis (PBC)	Phase II Clinical Trial (on-going)
TRIMESTA™ (oral estriol)	Relapsing-Remitting Multiple Sclerosis	Phase IIA Clinical Trial (completed)
Anti-CD4 802-2	Prevention of Severe Graft Vs. Host Disease	Phase I/II Clinical Trial (ongoing)
Anti-CD4 802-2	Autoimmune Diseases	Preclinical studies
CORRECTA™ (clotrimazole enema)	Refractory Acute Pouchitis	Phase II Clinical Trial (ongoing)
EFFIRMA™ (oral flupirtine)	Fibromyalgia	Phase II Clinical Trial (planned)
SOLOVAX™ (MS T-cell vaccine)	Multiple Sclerosis Vaccine	Phase II Clinical Trial (complete)

PRODUCT SUMMARY

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

COPREXA™ (oral tetrathiomolybdate)

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

COPREXA™ for Neurologic Wilson's Disease

COPREXA™ has successfully completed two pivotal clinical trials for the treatment of neurologically-presenting Wilson's disease, a genetic disease characterized by psychiatric and neurologic disorders caused by impaired hepatic copper excretion which results in elevated levels of toxic free copper in the systemic circulation and CNS. Based upon the positive results of these two pivotal clinical trials and communication from the FDA, we intend to submit an NDA with the FDA and an MAA with the EMEA to market COPREXA™ in the U.S. and Europe for the initial indication of

neurologically-presenting Wilson's disease. Wilson's disease is an orphan drug indication. There are approximately 6,000 Wilson's disease patients in the U.S., of which approximately half are diagnosed with neurologic symptoms and half with hepatic symptoms. It is estimated that several hundred of them annually are newly diagnosed, neurologically-presenting patients who are suitable candidates for treatment with COPREXA™. Wilson's disease is an inherited genetic disease in which affected patients have an impaired ability to properly excrete copper via the liver and stool. Due to the rarity of Wilson' s disease and the fact that it is easily mistaken for psychosis, patients typically are not diagnosed until the presentation of neurodegenerative symptoms.

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

Current Therapies for Wilson's Disease

Therapy for Wilson's disease can be divided into two broad categories: (1) initial therapy in acutely ill patients, and (2) maintenance therapy. Initial therapy relates to the first few weeks to months of therapy, during which a newly presenting patient is still suffering from acute copper toxicity. Once the copper levels have been brought down to a subtoxic threshold, maintenance therapy is provided for the remainder of the patient's life to prevent recurrence of copper accumulation and further copper toxicity. However, the currently approved therapies for Wilson's disease offer suboptimal treatment options for newly-diagnosed Wilson's patients and indeed the FDA approved chelators, penicillamine and trientine, may be contraindicated due to the high incidence of irreversible neurologic worsening attributable to the mechanism of these agents.

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

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

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

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

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

In a second double-blind, randomized comparator, pivotal clinical trial, 48 newly diagnosed, neurologically-presenting Wilson's patients were treated with either trientine (Syprine®), a copper chelator having a similar mechanism of action to that of penicillamine and approved for use as second line therapy for Wilson's disease, versus COPREXA™. The primary endpoint of this comparator study was the incidence of neurological worsening between the two groups This comparator trial demonstrated a statistically significant reduction in the incidence of neurologic worsening in favor of COPREXA™(p*l*0.05). Twenty-six percent (26%) of trientine treated patients (6 of 23) experienced neurologic worsening compared to only four percent (4.0%) of COPREXA™ treated patients (1 of 25). Importantly, in addition to the high incidence of irreversible neurologic deterioration associated with trientine, this pivotal comparator trial also suggested that neurologic deterioration during the initial treatment phase with trientine is an important prognostic indicator of death in this patient group.

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

COPREXA™ for Idiopathic Pulmonary Fibrosis (IPF)

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

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

Phase II Clinical Trials of COPREXA in Refractory IPF Patients

Based upon the successful animal experiments described above, a 16-patient, one-year, open-label, phase II clinical trial of COPREXA™ was completed for the treatment of refractory IPF. The prospectively defined primary endpoint of the study was the percentage of patients capable of maintaining clinically stable pulmonary function as determined by forced vital capacity (FVC), an

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

COPREXA™ for Primary Biliary Cirrhosis (PBC)

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

Phase II Clinical Trial of COPREXA™ in Primary Biliary Cirrhosis

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

TRIMESTA™ (oral estriol)

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

TRIMESTA™ for Relapsing-Remitting Multiple Sclerosis (MS)

Current Therapies for Relapsing-Remitting MS.

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

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

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

Decrease in Volume and Number of Myelin Lesions

In relapsing-remitting MS patients treated, the total volume and number of pathogenic gadolinium enhancing myelin lesions (an established neuroimaging measurement of disease activity in MS)

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

Market Opportunities for TRIMESTA™

Multiple Sclerosis

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

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

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

ANTI-CD4 802-2

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

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

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

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

CORRECTA™ (clotrimazole enema)

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

Market Opportunity for CORRECTA™

Pouchitis

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

EFFIRMA™ (oral flupirtine)

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

EFFIRMA™ for FMS

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

INTELLECTUAL PROPERTY

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

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

We have also obtained various regulatory exclusivities, such as “Orphan Drug” designations for two of our product candidates, COPREXA™ and CORRECTA™. 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 COPREXA in the treatment of neurologic Wilson’s disease. We have also obtained orphan drug protection for the use of CORRECTA for the treatment of acute pouchitis. These regulatory exclusivities combined with our patents and patent applications provide for supplemental intellectual property protection for our products against competitors.

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

University of Michigan (UM) Exclusive License Agreement

We have entered into an exclusive worldwide license agreement with the University of Michigan (UM) for all uses of U.S. Patent No. 6,855,340, corresponding international applications, and a related corresponding patent application that relates to various uses of anticopper therapeutics, including COPREXA™, to treat inflammatory and fibrotic diseases. Pursuant to this agreement, we will use our

best efforts to commercialize COPREXA™ for the therapeutic uses embodied in the issued patent and pending patent application; reimburse UM for patent expenses; pay UM royalties equal to 2% of net sales of COPREXA™ for uses covered by the UM patents; issue UM 1,261,492 shares of our common stock; pay UM success-based milestone fees totaling $350,000 (the first of which is due when we file an NDA and the second of which is due when we receive FDA approval for COPREXA™ 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 COPREXA™ to treat other copper mediated diseases. Pursuant to that agreement, we sponsor approximately $450,000 per annum, payable in monthly installments. This agreement can be extended for an additional two-year period.

Consulting Agreement with Dr. George Brewer

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

McLean Hospital Exclusive License Agreement

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

University of Southern California Agreement

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

Children’s Hospital-Boston Agreement

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

Pursuant to this agreement, we paid a $150,000 upfront payment in two installments, as well as annual maintenance fees, milestone payments totaling $3 million that are payable on issuance of U.S. and European patents covering the clotrimazole technology, on initiation of a pivotal phase III clinical trial, on filing of a New Drug Application (NDA), and on approval of an NDA with the FDA and

European Medical Agency, as well as royalties on net sales of the clotrimazole technology covered by the licensed patents. We may be permitted to partially pay milestone payments in the form of equity. We also acquired rights to valuable data generated under an investigational new drug (IND) application filing with the FDA and an orphan drug designation. These data include all preclinical and clinical data know-how relating to the clotrimazole technology. We would also be required to indemnify Children's Hospital and its employees against certain liabilities.

Thomas Jefferson University License Agreement

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

The Regents of University of California License Agreement

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

Asset Purchase Agreement for TRIMESTA™

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

Agreement to Acquire EPI

During December 2005, we acquired 65.47% of Effective Pharmaceuticals, Inc. (EPI) from two of our directors for no additional consideration. During December 2006, we entered into a letter of intent to consummate a merger with EPI in which we will acquire the 34.53% of EPI's outstanding securities that we do not currently own for 2,987,959 shares of our common stock. We consummated this merger on January 5, 2007. Upon the closing of this merger, EPI became our wholly-owned subsidiary.

MANUFACTURING

We utilize contract manufacturing firms to produce the bulk active ingredients for COPREXA™, TRIMESTA™, CORRECTA™, Anti-CD4 802-2, and EFFIRMA™ in accordance with "current good manufacturing processes" (cGMP) guidelines outlined by the FDA.

SALES AND MARKETING

We plan to establish our own in-house neuroscience sales and marketing effort in the United States to market our neurology products, specifically, COPREXA™ and TRIMESTA™. As we expand the use of COPREXA™ and TRIMESTA™ into larger CNS diseases, we will be able to utilize our existing

marketing infrastructure to market these products. We may choose to enter into a co-promotion or licensing agreement for specific territories with biotechnology or pharmaceutical companies to market CORRECTA™, Anti-CD4 802-2, EFFIRMA™, SOLOVAX™, and certain uses of COPREXA™.

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.

DESCRIPTION OF PROPERTY

Our primary offices are located at 3985 Research Park Drive, Ann Arbor, MI 48108. We currently rent approximately 5,500 square feet of office, laboratory and production space on a month-to-month basis for monthly rent of $5,500. Our phone number is (734) 332-7800 and our facsimile number is (734) 332-7878. Our website is located at www.pipexinc.com. We also have additional offices in Miami, Florida, which we share with Accredited Ventures, Inc., an affiliate of our company for which we pay $2,150 on a month to month basis. We are currently considering leasing an additional 3,300 square feet of production space in Ann Arbor, Michigan, and believe our current offices will be adequate for the foreseeable future until a suitable replacement facility is located.

DIRECTORS AND EXECUTIVE OFFICERS

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

Name	Age	Position
Steve H. Kanzer, CPA, Esq.	43	Chairman and Chief Executive Officer
Charles L. Bisgaier, Ph.D.	53	President and Director
Jeffrey J. Kraws	41	Vice President, Business Development and Director
A. Joseph Rudick, M.D.	49	Chief Medical Officer and Director
Nicholas Stergis, M.S.	32	Chief Operating Officer and Director
John S. Althaus, M.S., M.B.A.	52	Vice President, Advanced Technology
Jeff Wolf, Esq.	43	Director

Steve H. Kanzer, CPA, Esq.

Mr. Kanzer, 43, is our co-founder and has served as President since our inception in February 2001 until May 2006. In September 2004, Mr. Kanzer assumed the additional roles of Chairman and Chief Executive Officer and serves on a full-time basis at our corporate headquarters in Ann Arbor, Michigan. Mr. Kanzer has also been a director and officer of our subsidiaries, including Solovax, Inc., Effective Pharmaceuticals, Inc., Putney Drug Corp. and CD4 Biosciences, Inc. Since December 2000, he has served as co-founder and Chairman of Accredited Ventures Inc. and Accredited Equities Inc., a venture capital firm and NASD-member investment bank, respectively, which both specialize in the biotechnology industry. Mr. Kanzer was co-founder, Chairman, President and Chief Executive Officer of Developmental Therapeutics, Inc., a cardiovascular drug development company which was developing an oral thyroid hormone analog, DITPA, for congestive heart failure. Developmental Therapeutics was acquired in October 2003 by Titan Pharmaceuticals, Inc., a publicly traded biopharmaceutical company. Prior to founding Accredited Ventures and Accredited Equities in December 2000, Mr. Kanzer served as Senior Managing Director-Head of Venture Capital at Paramount Capital from 1991 until December 2000. While at Paramount Capital, Mr. Kanzer was involved in the formation and financing of a number of biotechnology companies and held various positions in these companies. From 1995 through 1999, Mr. Kanzer was founding Chairman of the Board of Discovery Laboratories, Inc., a public biotechnology company that has a pending NDA for a

drug called SURFAXIN® which Mr. Kanzer licensed in 1995. From 1997 until 2000, Mr. Kanzer was founding President of PolaRx Biopharmaceuticals, Inc., a biopharmaceutical company that licensed and developed TRISENOX® (arsenic trioxide), a leukemia drug that was approved by the FDA in 2000 and which currently holds the FDA record for fastest drug ever developed from IND filing until NDA approval (30 months). PolaRx was merged with Cell Therapeutics Inc. (NASDAQ:CTIC) in January 2000, and Cephalon acquired the rights to TRISENOX® in 2005 for $165 million. Since 1996, Mr. Kanzer has served as a member of the board of directors of DOR BioPharma, Inc., a public biotechnology company that has a pending NDA for orBec® (oral beclomethasone dipropionate), a drug that Mr. Kanzer licensed in 1997. Mr. Kanzer currently serves as non-executive Vice Chairman of the Board of DOR and also served as Interim President from June 2002 until January 2003. In March 1998, Mr. Kanzer led the privatization of the Institute for Drug Research Kft. (IDR) in Budapest, Hungary, a 400-employee, 26 acre pharmaceutical research and development center. Since 1950, IDR operated as the central pharmaceutical R&D center for the country of Hungary, served the active pharmaceutical ingredients (API) needs of Eastern Europe, and performed original drug discovery research, resulting in the registration of over 80 API products. Mr. Kanzer served as Chief Executive Officer of IDR from March 1998 and led the sale of IDR to IVAX Corporation in October 1999. Mr. Kanzer has also been a co-founder and director of 23 biotechnology companies, including Avigen, Inc., XTLBio, Boston Life Sciences, Inc. and Titan Pharmaceuticals, Inc., all publicly traded companies. Prior to joining Paramount Capital in 1992, Mr. Kanzer was an attorney at the law firm of Skadden, Arps, Slate, Meagher & Flom in New York where he specialized in mergers and acquisitions. Mr. Kanzer received his J.D. from New York University School of Law in 1988 and a B.B.A. in Accounting from Baruch College in 1985, where he was a Baruch Scholar. Mr. Kanzer is active in university-based pharmaceutical technology licensing and has served as Co-Chair of the New York Chapter of the Licensing Executives Society.

Charles L. Bisgaier, Ph.D.

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

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

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

Dr. Bisgaier received a B.A. (1974) in Biology from the State University College at Oneonta, NY, and a M.S. (1977) and Ph.D. (1981) in Biochemistry from George Washington University. Following his doctorate, he studied lipoprotein metabolism within a Specialized Center of Research (SCOR) for

atherosclerosis at Columbia University College of Physicians and Surgeons prior to joining Warner-Lambert/Parke-Davis in 1990.

Jeffrey J. Kraws

Mr. Kraws, 41, is a director of Pipex and our Vice President of Business Development. Mr. Kraws is Chief Executive Officer and co-founder of Crystal Research Associates. Well known and respected on Wall Street, Mr. Kraws has received some of the most prestigious awards in the industry. Among other awards, he was given a "5-Star Rating" in 2001 by Zacks and was ranked the number one analyst among all pharmaceutical analysts for stock performance in 2001 by Starmine.com. Prior to founding Crystal Research Associates, Mr. Kraws served as co-president of The Investor Relations Group (IRG), a firm representing primarily under-followed, small-capitalization companies. Previously, Mr. Kraws served as a managing director of healthcare research for Ryan Beck & Co. and as director of research/senior pharmaceutical analyst and managing director at Gruntal & Co., LLC (prior to its merger with Ryan Beck & Company). Mr. Kraws served as managing director of the healthcare research group and senior pharmaceutical analyst at First Union Securities (formerly EVEREN Securities); as senior U.S. pharmaceutical analyst for the Swedish-Swiss conglomerate Asea Brown Boveri; and as managing director and president of the Brokerage/Investment Banking operation of ABB Aros Securities, Inc. He also served as senior pharmaceutical analyst at 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. Mr. Kraws only devotes a portion of his time to our business.

A. Joseph Rudick, M.D.

Dr. Rudick, 49, was appointed to the board of directors of Pipex during December 2004. Dr. Rudick currently serves as our Chief Medical Officer and is president and chief medical officer of our subsidiary Effective Pharmaceuticals, Inc.

Dr. Rudick was Chief Executive Officer and President of Atlantic Technology Ventures, Inc. (Atlantic), a public drug-development company, as well as a member of 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 Catarex™, as well as a partnership with Indevus Pharmaceuticals, Inc. for development of their novel clinical-stage neuropathic pain compound, now known as IP-571. From 1994 to 2001, Dr. Rudick was a vice president of Paramount Capital, Inc., an investment bank specializing in the biotechnology and biopharmaceutical industries, where he participated in numerous private equity financings.

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

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

Mr. Althaus, 52, currently serves as the Vice President, Advanced Technology for Pipex. Mr. Althaus' professional career spans 30 + years of scientific research and development in academia and industry and business development in industry. His industry experience includes employment in pharmaceutical, biotechnology and medical device businesses. Mr. Althaus was a faculty research associate at the University of Virginia, Department of Anesthesiology, where he investigated the

impact of anesthesia on neurotransmitter mechanisms in peripheral and central nervous systems. While at Pharmacia & Upjohn and the Upjohn Companies, Mr. Althaus became an expert in free-radical-dependent drug therapies in the treatment of neurological diseases and traumatic brain injury. He was a member of the discovery, research and development team that produced the drug Mirapex, a treatment for Parkinson's disease. He was also a member of the discovery, research and development team that produced the drug Freedox, a treatment for brain hemorrhage. Mr. Althaus presented lectures nationally and internationally as the scientific liaison for marketing regarding the promotion of Freedox.

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

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

Nicholas Stergis, M.S.

Mr. Stergis, 32, is our co-founder, Chief Operating Officer and a member of our board of directors. Mr. Stergis is also a co-founder and Interim Chief Operating Officer and director of our subsidiary Effective Pharmaceuticals, Inc. Prior to co-founding Pipex, Mr. Stergis was a co-founder, Chief Operating Officer and director of Developmental Therapeutics, Inc., a cardiovascular drug development company, until its acquisition in October 2003 by Titan Pharmaceuticals, Inc. (AMEX: TTP), a publicly-traded pharmaceutical company.

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

Jeffrey Wolf, Esq.

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

No director is compensated for the performance of duties in that capacity or for his/her attendance at board of director or committee meetings. We reimburse our directors for travel and other out-of-pocket expenses incurred in attending board of director or committee meeting.

Directors' Term of Office

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

Audit Committee and Audit Committee Financial Expert

Our board of directors acts as our audit committee. No member of our board of directors is an "audit committee financial expert," as that term is defined in Item 401(e) of Regulation S-B promulgated under the Securities Act.

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. Accordingly, our board of directors concluded that the benefits of retaining an individual who qualifies as an "audit committee financial expert" would be outweighed by the costs of retaining such a person.

We do not have a nominating committee or compensation committee of the board of directors. Until formal committees are established our board of directors performs some of the functions associated with a nominating committee and a compensation committee, including reviewing all forms of compensation provided to our executive officers, directors, consultants and employees, including stock compensation.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

During January 2001, we sold approximately $1.1 million of Series A Preferred Stock to Accredited Venture Capital, LLC, a company controlled by Steve H. Kanzer, our Chairman and Chief Executive Officer. From 2002 until October 2006, we relied on non-interest bearing bridge loans from Accredited Ventures, Inc. (AVI), a company controlled Steve H. Kanzer, our Chairman and Chief Executive Officer and the managing member of our largest stockholder, Accredited Venture Capital, LLC. During this 5 year period, AVI loaned us $3,363,494 for no additional consideration. In connection with the private placement during October 2006, AVI agreed to convert these loans into units in the offering. As a result of the conversion of these loans, we issued 4,995,634 million shares of common stock and 2,497,817 warrants to purchase common stock. In the merger, all shares of preferred stock were converted into common stock of the Registrant.

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

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

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

We have entered into an agreement with Crystal Research Associates, LLC, a firm in which Mr. Kraws one of our directors and VP of Business Development is the CEO to write an executive information overview. Pursuant to this agreement, we have paid Crystal Research Associates $17,500 and will pay an additional $17,500 upon completion of the report.

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

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

EXECUTIVE COMPENSATION

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

SUMMARY COMPENSATION TABLE

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

(1) The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model. The weighted average assumptions used for the valuation of these option awards are as follows: Expected dividends 0%; Expected volatility 200%; Risk free interest rate ranging from 4.57% - 4.99%; Expected life of options ranging from 3 to 10 years. The assumptions are also disclosed in Note 7 in the Notes to the Consolidated Financial Statements for the Nine Months ended September 30, 2006 included in this prospectus.

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 1,992,756 shares of common stock, of which 332,126 have already vested. The remainder of this option will vest quarterly over a three year period. In the event of a termination without just cause, we will provide Dr. Bisgaier with six months severance, payable over a six month period.

We entered into an employment letter agreement with Jeffrey Kraws, a director and Vice President of Business Development, pursuant to which we will pay him an annual base salary of $75,000 and have granted him an option to purchase 686,320 shares of common stock, at an exercise price of $0.03 per share, with 343,160 vested upon execution of his employment agreement and the remainder vesting annually over three years. As of the date of this filing, we have not paid Mr. Kraws.

Pursuant to an employment letter agreement, our subsidiary EPI agreed to pay Dr. Rudick $175,000 per annum, pay life and disability insurance on behalf of Dr. Rudick and he received an option to purchase 262,500 shares of EPI common stock.

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 commencing at the completion of our private placement financing, and issue him a ten-year option to acquire 813,175 shares of our common stock, vesting annually over a three year period.

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

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

OPTION/SAR GRANTS IN LAST FISCAL YEAR

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

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

The following table discloses information regarding outstanding equity awards as of the end of fiscal 2006 for each of our senior executive officers.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

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

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

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

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

our common stock, (ii) each director and executive officer, and (iii) all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. The principal address of each of the stockholders listed below except as indicated is c/o Pipex Pharmaceuticals, Inc., 3985 Research Park Drive, Ann Arbor, MI 48108. We believe that all persons named in the table have sole voting and investment power with respect to shares beneficially owned by them. All share ownership figures include shares issuable upon exercise of options or warrants exercisable within 60 days of February 6, 2007, which are deemed outstanding and beneficially owned by such person for purposes of computing his or her percentage ownership, but not for purposes of computing the percentage ownership of any other person.

Principal Stockholders Table

Name of Owner	Shares Owned	Percentage of Shares Outstanding
Accredited Venture Capital, LLC (1)	24,900,826	45.59%
Steve H. Kanzer (1)	24,900,826	45.59%
Ridgeback Capital Investment Ltd. (2)	5,569,686	10.54%
Firebird Capital (3)	4,459,648	8.5%
Nicholas Stergis (4)	5,209,747	10.00%
Charles Bisgaier, Ph.D. (5)	778,091	1.60%
Jeffrey J. Kraws (6)	343,160	*
A. Joseph Rudick, M.D. (7)	569,375	1.11%
Jeffrey Wolf, Esq. (8)	32,527	*