COMMERCIAL NATIONAL FINANCIAL CORP /PA
Form 10-K
March 29, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
ACT OF 1934
For the fiscal year ended December 31, 2010

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

Commission file number 0-18676

COMMERCIAL NATIONAL FINANCIAL CORPORATION
(Exact name of registrant as specified in its charter)

PENNSYLVANIA	25-1623213
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
900 LIGONIER STREET, LATROBE, PA	15650
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (724) 539-3501

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

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

Common Stock, $2 Par Value
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act. Yes [ ] No [X]

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes[ ] No [ ]

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.
Large Accelerated Filer [ ] Accelerated Filer [ ] Non-accelerated Filer [ ] Smaller reporting company [X]

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

The aggregate market value of registrant's outstanding voting common stock held by non-affiliates on June 30, 2010, the last business day of the registrant's most recently completed second fiscal quarter, was $37,375,044.

Number of shares of common stock outstanding at March 1, 2011 2,860,953

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement relating to its 2011 annual meeting of shareholders to be held May 17, 2011 are incorporated by reference into Part III of this Form 10-K. In addition, portions of the registrant's Annual Report to Shareholders for the fiscal year ended December 31, 2010 are incorporated by reference into Part II of this Form 10-K.

Commercial National Financial Corporation

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PART I

Item 1. BUSINESS

The Commercial National Financial Corporation (the "Corporation") is a Pennsylvania corporation and is registered as a bank holding company under the Bank Holding Company Act of 1956 as amended. Through its subsidiary the Corporation is engaged in banking and trust operations.

The Corporation is owner of 100% of the outstanding shares of common stock of Commercial Bank & Trust of PA (the "Bank"). The Bank has been providing banking services since 1934. At the present time, two (2) banking offices are in operation in Latrobe, Pennsylvania, two (2) in Unity Township, Pennsylvania, two (2) in Hempfield Township, Pennsylvania and one (1) each in Ligonier, West Newton, Greensburg and North Huntington, Pennsylvania. All of these offices are within the boundaries of Westmoreland County, Pennsylvania. In addition, the building that houses the Bank's downtown Latrobe banking office is the location of the Corporation's and the Bank's executive and administrative offices. The institution's operations center is located at the Latrobe Plaza in Latrobe.

Each of the banking offices is equipped with a 24 hour a day automatic teller machine (ATM). Bank ATM units are also located on the campus of Saint Vincent College in Unity Township, the terminal of the Arnold Palmer Regional Airport, at the Latrobe Area Hospital, an in-store machine in the Norvelt Open Pantry and Latrobe 30 Shop-N- Save. A separate freestanding drive-up teller staffed banking facility is attached to the Lincoln Road office in Latrobe. This facility also provides ATM service.

The Bank offers the full range of banking services normally associated with a general commercial banking business. Services include extending credit, providing deposit services, marketing non-deposit investments and offering financial counseling. The ATM system described above is a part of the Cirrus, Honor, Plus and Star networks, which provides the Bank's customers access to an extensive regional and national network. The Bank also has implemented a comprehensive electronic Online Banking system. By using a personal computer with internet access, customers can access their Commercial Bank accounts, perform common banking tasks and pay bills 24 hours a day, seven days a week, 365 days a year.

The Corporation purchased Ridge Properties Inc. in 2008, Ridge Properties' only asset is Commercial National Financial Corporation stock. The Corporation currently has one inactive subsidiary, Commercial National Investment Corp. There are no current plans for this subsidiary.

Competition

All aspects of the Corporation's business are highly competitive. The Corporation competes for deposits, loans and banking services with major financial institutions, several national and state banks, thrift institutions, credit unions, mortgage brokers, finance companies, insurance companies, investment companies and mutual funds.

Customers are generally influenced by convenience of location, quality of service, price of services and availability of products. The Corporation believes that it effectively competes with other financial service providers within its market area.

Supervision and Regulation

Introduction

The Corporation and the Bank are subject to extensive regulation by federal and state agencies. The primary focus of these regulations is for the protection of depositors, federal deposit insurance funds and the banking system, not for the protection of security holders. Set forth below is a brief description of certain laws which relate to the regulation of the Corporation and its subsidiaries. The description is not meant to be complete and is qualified by reference to applicable laws and regulations.

Holding Company. The Corporation, as a bank holding company is subject to regulation by the Federal Reserve Board (FRB), the Securities and Exchange Commission, and the Federal Deposit Insurance Corporation (FDIC). The nature of the supervision extends to such areas as safety and soundness, truth-in-lending, truth-in-savings, rate restrictions, consumer protection, community reinvestment lending, permissible loan and securities activities, merger and acquisition limitations, reserve requirements, dividend payments, required disclosures and regulations concerning activities by corporate officers and directors. No regulatory restrictions or actions are currently pending against the Corporation.

Subsidiary Bank The Bank is subject to regulation and examination primarily by the FDIC and Pennsylvania Department of Banking (the "Department").

Capital Requirements

Banks are required to be in compliance with the FRB's risk-based capital standards. These standards require that (1) at least 50% of total capital must be "Tier 1 capital". This consists primarily of common and certain other "core" equity capital; (2) assets and off-balance sheet items must be weighted according to risk; (3) the total capital to risk-weighted asset ratio must be at least 8%; and (4) a minimum 4% leverage ratio of Tier 1 capital to average assets must be maintained. The Department requires state chartered banks to maintain a 6% leverage capital and 10% risk based capital, defined substantially the same as the federal regulations. The Bank is subject to almost identical capital requirements adopted by the FDIC.

Effects of Governmental Policies

In addition to regulatory requirements, the Corporation and its subsidiary Bank are affected by the national economy and the influence on that economy exerted by governmental bodies through monetary and fiscal policies and their efforts to implement such policies. In particular, the impact of the open market operations on interest rates, the establishment of reserve requirements and the setting of the discount rate will continue to affect business volumes and earnings. The exact nature or the full extent of this impact is almost impossible to predict; however, management continues to monitor these activities on a regular basis and seeks to modify its policies and procedures accordingly.

Employees

As of December 31, 2010, the Corporation employed 92 fulltime and 16 parttime employees. Approximately 57 employees are represented by the United Auto Workers, Local 1799. In 2008, the Corporation and bargaining unit employees entered into a five-year labor agreement effective February 2009 through February 2014.

Executive Officers of the Corporation

The following table shows the names and ages of the current executive officers and the present and previous positions held by them for at least the past five years.

Name	Age	Present and Previous Positions
Gregg E. Hunter	52	Vice chairman, president and chief executive officer (February 2004 - present), Vice chairman and chief financial officer (December 1995 to January 2004)
Thomas D. Watters, CPA	49	Executive vice president and chief financial officer (July 2005- present), Chief Auditor (January 1998-July 2005)
Wendy S. Schmucker	42	Secretary/treasurer and senior vice president, division manager corporate administration (February 2004 – present) Secretary/treasurer and vice president, manager corporate administration (November 1997 to January 2004)
Susan R. Skoloda	36	Vice president, corporate controls and community relations officer (March 2004 to present); assistant vice president (April 2001 to February 2004); assistant secretary/treasurer (April 1998 to present)
Keith M. Visconti	53	Executive vice president, group manager, sales and service (January 2008 to present), senior vice president, division manager, commercial banking (December 2002 to January 2008)
Kelly R. Moreman	41	Executive vice president, division manager, risk management & support (August 2009 to present); senior vice president, division manager, risk management & support (February 2005 to August 2009); vice president, manager, risk management (January 2003 to January 2005)

Item 1A. RISK FACTORS

Not Applicable

Item 1B. UNRESOLVED STAFF COMMENTS

None

Item 2. PROPERTIES

All of the Corporation's facilities are owned with the exception of the Lincoln Road banking office and adjacent drive-up facility, the Norwin Hills banking office and the West Point banking office. All of the properties are used in their entirety for banking purposes. In each case, the properties have been maintained in good repair, are well suited for their present use and appear to be adequate for the immediate needs of the Corporation and its subsidiary. See Item 1, Business, in this form 10-K for a description of the location of each of the Corporation's banking offices.

Item 3. LEGAL PROCEEDINGS

The Corporation, in the normal course of business, is subject to various legal proceedings. Management does not expect the outcome of these proceedings to have a material adverse impact on the Corporation's financial condition or results of operations.

Item 4. (REMOVED AND RESERVED)

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of March 3, 2011 there were 420 shareholders of record of the Corporation's common stock. The number of shareholders of record and those shareholders listed by each registered clearing agent is approximately 849. Commercial National Financial Corporation common stock is traded on The Nasdaq National Market under the trading symbol “CNAF” with an additional descriptive listing of “CmclNat.” The high and low closing sale prices and dividends per share of our common stocks for the four quarters of 2010 and 2009 are summarized in the following table:

	High	Low	Cash Dividend Per Share
2010			
First Quarter	$ 18.30	$ 16.00	$ .22
Second Quarter	17.75	16.29	.22
Third Quarter	16.98	16.00	.22
Fourth Quarter	19.48	16.07	.22
2009			
First Quarter	$ 16.65	$ 13.25	$ .22
Second Quarter	19.70	12.75	.22
Third Quarter	18.70	14.44	.22
Fourth Quarter	19.71	16.60	.22

We have historically paid quarterly dividends on our common stock and currently intend to continue to do so in the foreseeable future. Our ability to pay dividends depends on a number of factors, however, including restrictions on the ability of the Corporation to pay dividends under federal laws and regulations, and as a result there can be no assurance that dividends will be paid in the future.

In 2000, the Board of Directors authorized the repurchase of up to 360,000 shares of the Corporation’s common stock from time to time when warranted by market conditions. There have been 245,174 shares purchased under this authorization through December 31, 2010.

The Corporation did not purchase any shares of treasury stock during the quarter ended December 31, 2010, see table below.

ISSUER PURCHASES OF EQUITY SECURITIES

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans	(d) Maximum Number of Shares that May Yet Be Purchased Under the Plans
October 1-October 31	0	0	0	114,826
November 1 –	0	0	0	114,826

November 30				
December 1-December 31	0	0	0	114,826
Total	0	0	0	

Item 6. SELECTED FINANCIAL DATA

Not Applicable

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Information appearing in the Annual Report in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” is incorporated herein by reference. See the applicable portion of the Annual Report attached hereto as an exhibit.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Information appearing in the Corporation’s Annual Report to shareholders for 2010 in the section titled “Interest Sensitivity and Market Risk” as part of the Corporation’s Management Discussion and Analysis of Financial Condition and Results of Operations is incorporated herein by reference. See the applicable portion of the Annual Report attached hereto as an exhibit.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Corporation’s consolidated financial statements, the notes thereto and the report of the independent registered public accounting firm appearing in the Corporation’s Annual Report to shareholders are incorporated herein by reference. See the applicable portion of the Annual Report attached hereto as an exhibit.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

The Corporation has had no disagreements with its independent accountants.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Corporation maintains a system of disclosure controls and procedures that is designed to ensure that information required to be disclosed by the Corporation in this Form 10-K, and in other reports required to be filed under the Securities Exchange Act of 1934 (Exchange Act), is recorded, processed, summarized and reported within the time periods specified in the rules and forms for such filings. Management of the Corporation, under the direction of the Corporation's Chief Executive Officer and Chief Financial Officer, reviewed and performed an evaluation of the effectiveness of the Corporation's disclosure controls and procedures (as defined in Rules 13a-15a(e) and 15d-15(e) under the Exchange Act) as of December 31, 2010. Based on that review and evaluation, the Chief Executive Officer and Chief Financial Officer, along with other key management of the Corporation, have determined that the disclosure controls and procedures were and are effective as designed to ensure that material information relating to the Corporation and its consolidated subsidiaries required to be disclosed by the Corporation by the Exchange Act, was recorded, processed, summarized and reported within the applicable time periods.

Changes in Internal Controls

There have been no significant changes in our internal controls or in other factors that could significantly affect our internal controls during the quarter ended December 31, 2010.

Management's Report on internal Control over Financial Reporting.

The Corporation is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. Under the supervision and with the participation of management, including the principal executive officer and principal financial officer, the Corporation's management have conducted an evaluation of the effectiveness of the Corporation's internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation under the framework in Internal Control-Integrated Framework, management have concluded that the internal control over financial reporting was effective as of December 31, 2010.

This annual report does not include an attestation report of the company's registered public accounting firm regarding internal control over financial reporting. Because the Corporation is a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act, managem,ent's report is not required to be subject to attestation by the company's registered public accountant.

Because of its inherent limitations, internal control over the financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Item 9B. OTHER INFORMATION

None

PART III

Item 10.DIRECTORS, EXECUTIVE OFFICERS OF THE REGISTRANT AND CORPORATE GOVERANCE

Information concerning (i) directors, appearing under the captions “Election of Directors” and “Corporate Governance” in the Corporation’s Proxy Statement, related to the Annual Meeting of Shareholders to be held May 17, 2011 (the “Proxy Statement”) (ii) information concerning executive officers, appearing under the caption “Executive Officers of the Registrant” in Part I of this Form 10-K, and (iii) information contained under the section “Section 16(a) Beneficial Ownership Reporting Compliance”, in the Proxy Statement, are incorporated herein by reference to this Item 10.

The Corporation has adopted a Code of Ethics for Senior Financial Officers which is applicable to the Corporation’s principal executive officer and principal financial officer. A copy of such Code of Ethics has been filed as an exhibit to this Form 10-K.

Item 11. EXECUTIVE COMPENSATION

The information contained in the Corporation’s Proxy Statement under the following sections is hereby incorporated into this Item 11: (i) “Summary Compensation Table,” (ii) “Compensation ” (iii) “Compensation of Directors,” and “Director Compensation Table.”

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information contained in the sections titled "Beneficial Ownership of Common Stock" and "Beneficial Ownership by Officers, Directors and Nominees" in the Proxy Statement is incorporated herein by reference to this Item 12.

Equity Compensation Plan Information

None

Item 13.CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information contained in the section titled “Corporate Governance”, as well as information contained in “Related Party Transactions” as part of the “Compensation” in the Proxy Statement is incorporated herein by reference to this Item 13.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

University of Michigan (UM) Exclusive License Agreement

We have entered into an exclusive worldwide license agreement with the University of Michigan (UM) for all uses of U.S. Patent No. 6,855,340, corresponding international applications, and a related corresponding patent application that relates to various uses of anti-copper therapeutics, including oral TTM, to treat inflammatory and fibrotic diseases. Pursuant to this agreement, we will use our best efforts to commercialize oral TTM for the therapeutic uses embodied in the issued patent and pending patent application; reimburse UM for patent expenses; pay UM royalties equal to 2% of net sales of oral TTM for uses covered by the UM patents; issue UM 422,314 shares of our common stock; pay UM success-based milestone fees totaling $350,000 (the first of which is due when we file an NDA and the second of which is due when we receive FDA approval for oral TTM in an indication covered by the UM patents), and indemnify UM against certain liabilities.

Collaborative Research and Development Agreement with UM

During September 2005, we entered into a three-year sponsored research agreement with UM relating to expanding the therapeutic utility of oral TTM to treat other copper mediated diseases. Pursuant to that agreement, we sponsor approximately $450,000 per annum, payable in monthly installments. This agreement can be extended for an additional two-year period. This agreement initially expires August 30, 2008. As part of our corporate restructuring during March 2008, we provided notice of termination of this agreement.

Consulting Agreement with Dr. George Brewer

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

McLean Hospital Exclusive License Agreement

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

University of Southern California Agreement

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

Children’s Hospital-Boston Agreement

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

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

Thomas Jefferson University License Agreement

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

The Regents of University of California License Agreement

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

Oregon Health & Sciences License Agreement

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

Maine Medical Institute License Agreement

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

Manufacturing

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

Sales and Marketing

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

ITEM 1A. RISK FACTORS

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

RISKS RELATING TO OUR BUSINESS

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

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

We are not currently profitable and may never become profitable.

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

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

- seek regulatory approvals for our product candidates;

- implement additional internal systems and infrastructure;

- lease additional or alternative office facilities; and

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

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

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

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

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

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

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

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

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

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

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

studies.

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

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

Satisfying the FDA's regulatory requirements typically takes many years, depending on the type, complexity, and novelty of the product candidate, and requires substantial resources for research development, and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies.

The approval process may also be delayed by changes in government regulation, future legislation or administrative action, or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may do the following:

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

- impose costly procedures on us; and

- diminish any competitive advantages that we may otherwise enjoy.

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

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

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

In addition to our own patent applications, we also currently rely on an exclusive worldwide license agreement with the University of Michigan relating to various uses of oral TTM. We also have an exclusive license agreement with the McLean Hospital relating to the use of EFFIRMATM to treat fibromyalgia syndrome; an exclusive license agreement with Thomas Jefferson University relating to our anti-CD4 inhibitors; an exclusive license agreement with the Regents of the University of California relating to our TRIMESTATM technology; an exclusive license agreement with the Children's Hospital-Boston relating to our CORRECTATM technology and an exclusive license agreement to license our T-cell vaccine program from the University of Southern California (USC). Each of these agreements requires us to use our best efforts to commercialize each of the technologies as well as meet certain diligence requirements and timelines in order to keep the license agreement in effect. In the event we are not able to meet our

diligence requirements, we may not be able to retain the rights granted under our agreements or renegotiate our arrangement with these institutions on reasonable terms, or at all.

Furthermore, we currently have very limited product development capabilities, and limited marketing or sales capabilities. For us to research, develop, and test our product candidates, we would need to contract with outside researchers, in most cases those parties that did the original research and from whom we have licensed the technologies.

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

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

Companies that currently sell or are developing both generic and proprietary pharmaceutical compounds to treat central-nervous-system, inflammatory, autoimmune and fibrotic diseases include: Pfizer, Inc., Aton Pharma, GlaxoSmithKline Pharmaceuticals, Shire Pharmaceuticals, Plc., Merck & Co., Eli Lilly & Co., Serono, SA, Biogen Idec, Inc., Achillion, Ltd., Active Biotech, Inc., Panteri Biosciences, Meda, Merrimack Pharmaceuticals, Inc., Schering AG, Forest Laboratories, Inc., Attenuon, LLC, Cypress Biosciences, Inc., Novartis, Axcan Pharma, Inc., Teva Pharmaceuticals, Inc., Intermune, Inc. Fibrogen, Inc., Rare Disease Therapeutics, Inc., Prana Biotechnology, Inc., Merz & Co., AstraZeneca Pharmaceuticals, Inc., Chiesi Pharmaceuticals, Inc., Targacept, Inc., and Johnson & Johnson, Inc. Alternative technologies or alternative delivery or dosages of already approved therapies are being developed to treat autoimmune inflammatory, Fibromyalgia, MS, fibrotic, Alzheimer's and Wilson's diseases, several of which may be approved or are in early and advanced clinical trials, such as pirfenidone, milnacipram, Lyrica, Cymbalta, Effexor, Actimmune and other interferon preparations. Unlike us, many of our competitors have significant financial and human resources. In addition, academic research centers may develop technologies that compete with our CORRECTATM, TRIMESTA TM, zincmonocysteine, anti-CD4 inhibitors, EFFIRMATM and oral TTM technologies. We are aware that other companies are developing competitive anti-copper therapies that are in various stages of clinical trials or have been approved by regulatory authorities. For example, trientine, d–-pennicillamine and zinc based therapies, all FDA approved anti-copper agents have been or are being tested in various treatment regiments for the treatment of Wilson's disease. Should clinicians or regulatory authorities view these therapeutic regiments as or more effective than oral TTM in the treatment of neurologic Wilson's disease, this might delay or prevent us from obtaining regulatory approval for oral TTM, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid and private insurers.

We may not succeed in enforcing our orphan drug designations.

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

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

their product demonstrates clinical superiority. This could create a more competitive market for us.

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

A competitor could develop our products in a similar format, but for a different indication. For example, other companies could manufacture and develop oral TTM and its active ingredient, tetrathiomolybdate, and secure approvals for different indications. We are aware that a potential competitor has an exclusive license from the University of Michigan (UM) to an issued U.S. patent that relates to the use of tetrathiomolybdate to treat angiogenic diseases (the "Angiogenic Patent") and is currently in phase I and phase II clinical trials for the treatment of various forms of cancer. To our knowledge, this competitor and UM have filed additional patent applications claiming various analog structures and formulations of tetrathiomolybdate to treat various diseases. Further, we cannot predict whether our competitor might obtain approval in the U.S. or Europe to market tetrathiomolybdate for cancer or another indication ahead of us. We also cannot predict whether, if issued, any patent corresponding to the Angiogenic Patent may prevent us from conducting our business or result in lengthy and costly litigation or the need for a license. Furthermore, if we need to obtain a license to these or other patents in order to conduct our business, we may find that it is not available to us on commercially reasonable terms, or is not available to us at all.

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

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

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

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

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

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

We also expect to rely on regulatory exclusivities, such as the Orphan Drug Designation with the FDA and EMEA ("Orphan Drug") to protect oral TTM, CORRECTATM and our other future products for certain therapeutic indications. Orphan Drug protection provides for seven years of marketing exclusivity for that disease indication in the U.S. and ten years of marketing exclusivity for that disease indication in Europe. We have received an Orphan Drug Designation for the use of CORRECTATM to treat pouchitis as well as an Orphan Drug Designation for the use

of oral TTM to treat neurologically presenting Wilson's disease and are in the process of filing similar designations in Europe. Orphan Drug Designation is an important element of our competitive strategy for oral TTM and CORRECTATM. To be successful in enforcing this designation, our NDA would need to be the first NDA approved to use oral TTM and CORRECTATM for that indication. While we are not aware of any other companies that have sought orphan drug designation for oral TTM and CORRECTATM for any indication, other companies may in the future seek it and may obtain FDA marketing approval before we do.

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

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

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

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

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

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

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

Certain of our officers, directors, (including Mr. Stergis, our Vice Chairman of the Board and former Chief Operating Officer, Dr. Rudick, a director and former Chief Medical Officer, Jeffrey Kraws, a director and former VP of Business Development, Jeffrey Wolf, a director, and Dr. Kuo, a director) scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies which might be developing competitive products to ours. None of our directors or officers is obligated under any agreement or understanding with us to make any additional products or technologies available to us. Similarly, we can give no assurances, and we do not expect and stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by any of our directors or affiliates in the future would be made available to us.

We can expect this to also be the case with personnel that we engage in the future. We can give no assurances that any such other companies will not have interests that are in conflict with our interests.

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

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

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

In order to successfully commercialize our product candidates, we must be able to manufacture our products in commercial quantities, in compliance with regulatory requirements, at acceptable costs, and in a timely manner. Manufacture of the types of biopharmaceutical products that we propose to develop present various risks. For example, manufacture of the active ingredient in oral TTM is a complex process that can be difficult to scale up for purposes of producing large quantities. This process can also be subject to delays, inefficiencies, and poor or low yields of quality products. Furthermore, the active ingredient of oral TTM is known to be subject to a loss of potency as a result of prolonged exposure to moisture and other normal atmospheric conditions. We are developing proprietary formulations and specialty packaging solutions to overcome this stability issue, but we can give no assurances that we will be successful in meeting the stability requirements required for approval by regulatory authorities such as the FDA or the requirements that our new proprietary formulations and drug product will demonstrate satisfactory comparability to less stable formulations utilized in prior clinical trials. We may experience delays in demonstrating satisfactory stability requirements and drug product comparability requirements that could delay acceptance or approval of our planned NDA for oral TTM.

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

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

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

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

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

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

- unforeseen safety issues;

- determination of dosing;

- lack of effectiveness during clinical trials;

- slower than expected rates of patient recruitment;

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

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

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

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

Even if our clinical trials are completed as planned, we cannot be certain that the results will support our product-candidate claims. Success in pre-clinical testing and phase II clinical trials does not ensure that later phase II or phase III clinical trials will be successful. We cannot be sure that the results of later clinical trials would replicate

the results of prior clinical trials and pre-clinical testing. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. Any such failure could cause us to abandon a product candidate and might delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay our obtaining FDA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

Physicians and patients may not accept and use our technologies.

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

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

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

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

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

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

We depend on researchers who are not under our control.

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

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

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

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

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

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

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

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

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

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

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

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

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

• developing drugs;

• undertaking pre-clinical testing and human clinical trials;

• obtaining FDA and other regulatory approvals of drugs;

• formulating and manufacturing drugs; and

• launching, marketing and selling drugs.

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

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

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

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

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

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

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

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

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

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

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

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

RISKS RELATING TO OUR STOCK

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

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

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

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

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

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

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

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

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

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

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

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

We have never paid dividends.

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

RISKS RELATED TO OUR INDUSTRY

Government Regulation

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

- Preclinical laboratory and animal tests;
- Submission of an IND, prior to commencing human clinical trials;
- Adequate and well-controlled human clinical trials to establish safety and efficacy for intended use;
- Submission to the FDA of a NDA; and
- FDA review and approval of a NDA.

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

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

We will submit the preclinical test results, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we begin human clinical trials. The IND automatically becomes effective 30 days after filing, unless the FDA raises questions about conduct of the trials outlined in the IND and

imposes a clinical hold, in which case, the IND sponsor and FDA must resolve the matters before clinical trials can begin. It is possible that our submission may not result in FDA authorization to commence clinical trials.

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

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

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

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

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

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

Concurrent with these trials and studies, we also develop chemistry and physical characteristics data and finalize a manufacturing process in accordance with good manufacturing practice ("GMP") requirements. The manufacturing process must conform to consistency and quality standards, and we must develop methods for testing the quality, purity, and potency of the final products. Appropriate packaging is selected and tested, and chemistry stability studies are conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life. Results of the foregoing are submitted to the FDA as part of a NDA for marketing and commercial shipment approval. The FDA reviews each NDA submitted and may request additional information.

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

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

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

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

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

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

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

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

Other Regulatory Requirements

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

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

European Product Approval

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

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

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

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

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

Pricing Controls

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

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

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

Third-Party Reimbursements

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

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

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

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

Fraud and Abuse Laws

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

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

Patent Restoration and Marketing Exclusivity

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

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

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

ITEM 2. PROPERTIES

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

ITEM 3. LEGAL PROCEEDINGS

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

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

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

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

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

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

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

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

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

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

PART II

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

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

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

Dividend Policy

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

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

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

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

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

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

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

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

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

Overview

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

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

Critical Accounting Policies

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

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

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

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

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

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

Results of Operations

Year Ended December 31, 2007 and 2006.

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

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

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

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

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

Liquidity and Capital Resources

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

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

Net cash proceeds from financing activities were $7,872,809 and $14,111,288 for the years ended December 31, 2007 and 2006, respectively. The net cash proceeds from financing activities for the year ended December 31, 2007 resulted from $7,552,378 for proceeds from the exercise of warrants, less $579,569 paid as direct offering costs. In addition, the Company raised $1,100,000 in proceeds from notes payable under term loans, less $200,000 of repayments under these loans. The net cash proceeds from financing activities for the year ended December 31, 2006 resulted from proceeds from the sale of common stock an