PIPEX PHARMACEUTICALS, INC.
Form 10-Q
May 15, 2008

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2008

OR

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

Commission File Number: 333-139354

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

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

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

Indicate by check mark 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 ý No o

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. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o	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 o No ý

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

As of May 1, 2008, the registrant had 20,541,272 shares of common stock outstanding.

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

PIPEX PHARMACEUTICALS, INC.

FORM 10-Q
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PART I.—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

Consolidated Balance Sheets

Assets	March 31, 2008 (Unaudited)	December 31, 2007 (Audited)
Current Assets		
Cash	$ 8,761,523	$ 11,492,802
Prepaid expenses	83,962	63,636
Total Current Assets	8,845,485	11,556,438
Property and Equipment, net of accumulated depreciation of $334,414 and $232,564	1,982,781	2,063,233
Deposits and other assets	13,184	13,381
Total Assets	$ 10,841,450	$ 13,633,052
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,007,071	$ 728,119
Accrued liabilities	310,461	59,409
Note payable	-	900,000
Total Current Liabilities	1,317,532	1,687,528
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized,		
none issued and outstanding	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized,		
20,484,361 and 20,433,467 shares issued and outstanding	20,484	20,433
Additional paid-in capital	43,669,519	43,001,609
Deficit accumulated during the development stage	(34,166,085)	(31,076,518)
Total Stockholders' Equity	9,523,918	11,945,524
Total Liabilities and Stockholders' Equity	$ 10,841,450	$ 13,633,052

See accompanying notes to unaudited consolidated financial statements

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

Consolidated Statements of Operations
(Unaudited)

	For the three months ended March 31,		For the period from January 8, 2001 (inception) to March 31,
	2008	2007	2008
Operating Expenses:			
Research and development	2,124,620	1,417,123	13,285,415
General and administrative	1,002,582	1,503,881	7,847,793
Total Operating Expenses	3,127,202	2,921,004	21,133,208
Loss from Operations	(3,127,202)	(2,921,004)	(21,133,208)
Other Income (Expense):			
Interest income	51,577	71,469	394,966
Interest expense	(13,831)	-	(66,760)
Total Other Income, net	37,746	71,469	328,206
Net Loss	$ (3,089,456)	$ (2,849,535)	$ (20,805,002)
Less: Preferred stock dividend - subsidiary	-	-	(951,250)
Less: Merger dividend	-	(12,409,722)	(12,409,722)
Net Loss Applicable to Common Shareholders	$ (3,089,456)	$ (15,259,257)	$ (34,165,974)
Net Loss Per Share - Basic and Diluted	$ (0.15)	$ (0.90)	$ (7.23)
Weighted average number of shares outstanding during the period - basic and diluted	20,454,980	16,979,038	4,726,838

See accompanying notes to unaudited consolidated financial statements

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

Consolidated Statements of Cash Flows
(Unaudited)

	For the three months ended March 31,		For the Period from January 8, 2001 (Inception) to March 31,
	2008	2007	2008
Cash Flows From Operating Activities:			
Net loss	$ (3,089,456)	$ (2,849,535)	$ (20,805,002)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	380,644	596,047	2,317,290
Stock-based consulting	226,145	316,360	1,387,132
Stock issued as compensation	21,858	-	21,858
Stock issued as compensation in acquisition of subsidiary	-	601,612	601,712
Contributed services - related party	36,875	-	312,520
Stock issued for license fee	-	-	408,691
Stock issued for milestone payment	-	-	25,000
Depreciation	101,850	9,562	334,414
Changes in operating assets and liabilities:			
Prepaid expenses and other	(20,240)	(470)	(83,876)
Deposits and other assets	-	(301,225)	(13,381)
Accounts payable	278,952	(138,177)	1,007,071
Accrued liabilities	251,052	(48,799)	313,479
Net Cash Used In Operating Activities	(1,812,320)	(1,814,625)	(14,173,092)
Cash Flows From Investing Activities:			
Purchases of property and equipment	(21,398)	(36,317)	(2,032,805)
Cash paid to acquire shell in reverse merger	-	-	(665,000)
Net Cash Used In Investing Activities	(21,398)	(36,317)	(2,697,805)
Cash Flows From Financing Activities:			
Proceeds from loans payable - related party	-	600,000	3,210,338
Repayments of loans payable - related party	-	-	(220,000)
Proceeds from note payable	-	-	1,100,000
Repayments of note payable	(900,000)	-	(1,100,000)
Proceeds from issuance of preferred and common stock	2,439	-	1,153,029
Proceeds from sale of common stock and warrants in private placements	-	-	13,926,362
Proceeds from sale of common stock in connection with warrants exercise	-	-	7,552,378
Cash paid as direct offering costs in private placements and warrant call	-	-	(1,739,987)

Proceeds from issuance of Series B, convertible preferred stock - subsidiary	-	-	1,902,500
Direct offering costs in connection with issuance of series B, convertible preferred stock - subsidiary	-	-	(152,200)
Net Cash Provided By (Used In) Financing Activities	(897,561)	600,000	25,632,420
Net increase (decrease) in cash	(2,731,279)	(1,250,942)	8,761,523
Cash and cash equivalents at beginning of period	11,492,802	12,192,426	-
Cash and cash equivalents at end of period	$ 8,761,523	$ 10,941,484	$ 8,761,523
Supplemental disclosures of cash flow information:			
Cash paid for interest	$ 13,831	$ -	$ 66,760
Cash paid for taxes	$ -	$ -	$ -
Supplemental disclosure of non-cash investing and financing activities:			
Exchange of EPI preferred stock into Pipex common stock in acquisition	$ -	$ 12,409,722	$ 12,409,722
Pipex acquired equipment in exchange for a loan with a related party	$ -	$ -	$ 284,390
EPI declared a 10% and 30% in-kind dividend on its Series B, convertible preferred stock.	$ -	$ -	$ 951,250
The Company issued shares and warrants in connection with the conversion of certain related party debt.	$ -	$ -	$ 3,274,728
Conversion of accrued liabilities to contributed capital - former related party	$ -	$ -	$ 3,017

See accompanying notes to unaudited consolidated financial statements

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

Notes to Consolidated Financial Statements
(Unaudited)

Note 1 Organization and Nature of Operations and Basis of Presentation

(A) Description of the Business

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

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

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

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

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

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

(C) Reverse Stock Split

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

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

(D) Reverse Acquisition and Recapitalization

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

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

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

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

1. EPI's Acquisition of CD4

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

2. Pipex Therapeutic's Acquisition of Solovax

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

3. Pipex Therapeutic's Acquisition of EPI/CD4

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

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

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

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

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

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

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

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

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

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

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

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

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

Note 2 Summary of Significant Accounting Policies

(A) Principles of Consolidation

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

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Notes to Consolidated Financial Statements
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(B) Development Stage

The Company's consolidated financial statements are presented as statements of a development stage enterprise. For the period from inception (January 8, 2001) to date, the Company has been a development stage enterprise, and accordingly, the Company's operations have been directed primarily toward the acquisition and creation of intellectual properties and certain research and development activities to improve current technological concepts. As the Company is devoting its efforts to research and development, there have been no sales, license fees or royalties earned. Additionally, the Company continually seeks sources of debt or equity based funding to further its intended research and development activities. The Company has experienced net losses since its inception, and had an accumulated deficit of $34,166,085 at March 31, 2008.

(C) Use of Estimates

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

Significant estimates during 2008 and 2007 include depreciable lives of property, valuation of warrants and stock options granted for services or compensation pursuant to EITF No. 96-18 and SFAS No. 123R, respectively, estimates of the probability and potential magnitude of contingent liabilities and the valuation allowance for deferred tax assets due to continuing operating losses.

(D) Cash

The Company minimizes its credit risk associated with cash by periodically evaluating the credit quality of its primary financial institution. The balance at times may exceed federally insured limits. At March 31, 2008, the balance exceeded the federally insured limit by $8,298,789.

(E) Property and Equipment

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

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

(F) Long Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered impaired, the impairment to

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be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. There were no impairment charges taken during the three month periods ended March 31, 2008 and March 31, 2007 and for the period from January 8, 2001 (inception) to March 31, 2008.

(G) Derivative Liabilities

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

(H) Net Loss per Share

Basic earnings (loss) per share is computed by dividing the net income (loss) less preferred dividends for the period by the weighted average number of common shares outstanding. Diluted earnings per share is computed by dividing net income (loss) less preferred dividends by the weighted average number of common shares outstanding including the effect of share equivalents. Since the Company reported a net loss for the three month periods ended March 31, 2008 and March 31, 2007 and for the period from January 8, 2001 (inception) to March 31, 2008, respectively, all common stock equivalents would be anti-dilutive; as such there is no separate computation for diluted earnings per share.

The Company’s net loss per share for the three months ended March 31, 2008 and 2007 and for the period from January 8, 2001 (inception) to March 31, 2008 was computed assuming the recapitalization associated with the reverse acquisition, as such, all share and per share amounts have been retroactively restated. Additionally, the numerator for computing net loss per share was adjusted for preferred stock dividends recorded during the three months ended March 31, 2007 and the period from January 8, 2001 (inception) to March 31, 2008, in connection with the acquisition of EPI (See Note 1(E)(4)) as well as and certain provisions relating to the sale of EPI’s Series B, convertible preferred stock.

(I) Research and Development Costs

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

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(J) Fair Value of Financial Instruments

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

(K) Stock Based Compensation

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

(L) Reclassifications

Certain amounts in the year 2007 financial statements have been reclassified to conform to the year 2008 presentation. The results of these reclassifications did not materially affect the Company's consolidated financial position, results of operations or cash flows.

(M) Recent Accounting Pronouncements

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

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

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

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

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

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

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In March 2008, the FASB issued SFAS No. 161 "Disclosures about Derivative Instruments and Hedging Activities—An Amendment of FASB Statement No. 133." ("SFAS 161"). SFAS 161 establishes the disclosure requirements for derivative instruments and for hedging activities with the intent to provide financial statement users with an enhanced understanding of the entity's use of derivative instruments, the accounting of derivative instruments and related hedged items under Statement 133 and its related interpretations, and the effects of these instruments on the entity's financial position, financial performance, and cash flows. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2008. The Company does not expect its adoption of SFAS 161 to have a material impact on its financial position, results of operations or cash flows.

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

Note 3 Notes Payable

During 2007, the Company borrowed $1,100,000 and repaid $200,000 under notes payable. These notes were secured by all assets of the Company as well as the stock certificates of the subsidiaries; the notes bore interest at 9.25% (prime plus 2%) and were due March 30, 2010. On March 6, 2008, all of the outstanding principal and accrued interest was repaid.

Note 4 Stockholders' Equity and Non-Controlling Interest

(A) Preferred Stock Issuances

1. For the Year Ended December 31, 2001

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

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

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

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

2. For the Year Ended December 31, 2005

On March 10, 2005, EPI's board of directors and stockholders voted to authorize the designation of a Series B Convertible Preferred Stock. From March through June 2005, EPI issued 1,902,500 shares of Series B Convertible

Preferred Stock, at $1 per share, for proceeds of $1,902,500. In connection with this offering, EPI paid $152,200 of offering costs that were charged against additional paid in capital. The Company also granted 171,225 warrants as compensation in connection with this equity raise.

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

(B) Common Stock Issuances of Issuer

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

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

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

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

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

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

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

In January 2008, the Company issued 27,106 shares of common stock in connection with the exercise of stock options for net proceeds of $2,439. The related exercise price was $0.09 per share.

In March 2008, the Company issued 23,788 shares of common stock having a fair value of $21,861 ($0.92 per share) based on the quoted closing trading prices for payment of salaries to employees.

(C) Common Stock Issuances of Subsidiaries

During the period from January 8, 2001 (inception) to March 31, 2008, the Company's majority owned subsidiaries; CD4, Solovax and EPI issued 419,000, 419,000 and 825,000 shares of common stock, respectively, for $1,663. Of the 825,000 shares of common stock issued by EPI, 75,000 were converted into 30,161 common shares of Pipex and the remaining 750,000 shares were cancelled and retired for no additional consideration in the acquisition of EPI on January 5, 2007.

(D) Stock Incentive Plan

During 2001, Pipex Therapeutics' Board and stockholders adopted the 2001 Stock Incentive Plan (the "2001 Stock Plan"). This plan was assumed by Pipex in the merger, in October 2006. As of the date of the merger, there were 1,489,353 options issued and outstanding. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period shall not exceed 1,250,000. All awards pursuant to the Plan shall terminate upon the termination of the grantee's employment for any reason. Awards include options, restricted shares, stock appreciation rights, performance shares and cash-based awards (the "Awards"). The Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined in the Plan. The Plan provides for a Committee of the Board to grant awards and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the awards, including acceleration of the vesting of an award at any time. As of March 31, 2008, there are 1,462,247 options issued and outstanding under the 2001 Stock Plan.

On March 20, 2007, the Company's Board of Directors approved the Company's 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 2,500,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. The exercise price of stock options under the plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of March 31, 2008, there are 718,569 options issued and outstanding under the 2007 Stock Plan. This plan was approved by stockholders on November 2, 2007.

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

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The Company has followed fair value accounting and the related provisions of SFAS No. 123R for all share based payment awards since inception. The fair value of each option or warrant granted is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes assumptions used in the three months ended March 31, 2008 and 2007 are as follows:

	Three Months Ended March 31,	
	2008	2007
Exercise price	$1.22 - $5.10	$0.09 - $22.50
Expected dividends	0%	0%
Expected volatility	201.11% - 221.66%	103.29% - 200%
Risk fee interest rate	3.52% - 3.86%	4.18 – 4.90%
Expected life of option	10 years	7 - 10 years

All option grants are expensed in the appropriate period based upon vesting terms, in each case with an offsetting credit to additional paid in capital. The stock-based compensation expense recorded by the Company for the three months ended March 31, 2008 and 2007 and the period from inception to March 31, 2008 with respect to stock option awards is as follows:

	Three Months Ended March 31,		Inception to March 31,
	2008	2007	2008
Research and development:			
employees	$ 306,025	$ 212,307	$ 1,771,896
non-employees	194,892	—	$ 435,415
General and administrative:			
employees	$ 74,619	$ 185,725	$ 1,128,772
non-employees	—	217,424	$ 938,798
	$ 575,536	$ 615,456	$ 4,274,881

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

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A summary of stock option activity for Pipex for the three months ended March 31, 2008 (unaudited) and for the year ended December 31, 2007 is as follows:

	Number of Shares		Weighted Average Exercise Price
Balance at December 31, 2006	1,613,855	$	1.45
Granted	700,176	$	6.21
Exercised	—	$	—
Forfeited	(16,667)	$	15.75
Balance at December 31, 2007	2,297,364	$	2.72
Granted	230,667	$	2.17
Exercised	(27,106)	$	0.09
Forfeited	(320,109)	$	6.42
Balance at March 31, 2008 (unaudited)	2,180,816	$	2.15

The weighted average remaining contractual term and the aggregate intrinsic value for options outstanding at March 31, 2008 were 7.73 years and $4,697,672 respectively. Of the total options granted, 1,610,155 are fully vested, exercisable and non-forfeitable and have a weighted average exercise price of $1.90.

Of the total 2,180,816 options outstanding, 1,295,036 options are held by related parties of which 908,847 are fully vested, exercisable and non-forfeitable.

(E) Stock Warrants

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

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

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

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

On February 15, 2007, the Company executed an agreement with a third party to provide certain consulting services. Pursuant to the terms of the agreement, the Company will issue warrants to purchase 100,000 shares of common stock upon the achievement of various milestones as well as over the life of the contract. The warrants have an exercise price of $3.75. The fair value of the warrants totals $374,760 and was determined by using the Black-Scholes model with the following assumptions: expected dividend yield of 0%; expected volatility of 187.22%; risk-free interest rate of 4.68% and an expected life of five years. As of March 31, 2008, 50,000 warrants have been issued for which the Company has recognized stock based consulting expense for $187,500.

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

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

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

A summary of warrant activity for Pipex for the three months ended March 31, 2008 (unaudited) and for the year ended December 31, 2007 is as follows:

	Number of Shares	Weighted Average Exercise Price
Balance as December 31, 2006	5,242,402	$2.22
Granted	437,981	$5.63
Exercised	(3,401,972)	$2.22
Forfeited	—	
Balance at December 31, 2007	2,278,416	$2.22
Granted	8,333	$3.75
Exercised	—	
Forfeited	—	
Balance as March 31, 2008 (unaudited)	2,286,749	$2.88

All outstanding warrants are fully vested and exercisable.

	Warrants Outstanding and Exercisable	
Range of Exercise	Number Outstanding	Weighted Average

Price			Remaining Contractual Life
$	2.22	1,840,435	4.57 Years
$	3.30	68,858	7.17 Years
$	3.75	50,000	7.88 Years
$	6.36	327,456	4.61 Years
		2,286,749	5.99 Years

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(F) Options of Subsidiary

CD4 has 30,000 options outstanding and exercisable, with an exercise price of $0.20 and a remaining contractual life of 2.74 years as of March 31, 2008.

(G) Non-Controlling Interest

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

Note 5 Commitments

(A) License Agreements

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

In connection with these agreements, the Company may be obligated to make milestone payments up to an amount of $8,075,000. Some of these payments may be fulfilled through the issuance of the Company's common stock, at the Company's option. As of March 31, 2008, the Company has achieved one milestone which the Company fulfilled by issuing common stock having a fair value of $25,000. See Note (4(B)). The Company can give no assurances that any other milestones will be achieved. In addition to the milestone payments, the Company may be obligated to make royalty payments on future sales pursuant to the agreements.

(B) Research Agreement

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

(C) Consulting Agreement

In August 2005, Pipex entered into an agreement with an individual to provide consulting services for the Company's research and development. The consultant was paid $25,000 upon the execution of the agreement. The consultant will receive annual consulting fees of $120,000 for each of the next three years. The consultant also received 216,847 options having a fair value $59,960 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 200%, risk free interest rate of 1.81% and an expected life of 10 years. On March 24, 2008, the Company granted the individual an additional 21,667 options having a fair value of $$437.667 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%; expected volatility of 221%, risk free interest rate of 3.56% and an expected life of 10

years.

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

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(D) Employment Agreements

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

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

The Company entered into an employment agreement with its President on May 24, 2006. Pursuant to this agreement, Pipex will pay an annual base salary of $295,000 and a guaranteed bonus of one-third of base salary. Pipex has also granted a ten-year option to purchase 664,252 shares of common stock, of which 332,126 have vested as of December 31, 2007. The remainder of these options will vest quarterly over a three-year period. In the event of a termination, the Company will provide six-month severance, payable over a six-month period. On March 5, 2008, the Company's President has agreed to work for no cash compensation until May 17, 2008 at which time his compensation will be at the discretion of the compensation committee. The President will be eligible to receive a contingent bonus in the event that the Company is acquired or the stock price retraces or exceeds to the level of the share price on January 28th 2008. Additionally, the President agreed to eliminate severance provisions of his agreement. The Company has recorded contributed services from a related party totaling $36,874 during the first quarter of 2008.

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

Note 6 Corporate Restructuring

On March 11, 2008, the Company announced that it has implemented cost reduction measures in order to substantially reduce operating expenses given the delay in refilling its New Drug Application for oral tetrathiomolybdate (oral

TTM) for the treatment of initially presenting neurologic Wilson's disease. As part of the corporate restructuring, the Company eliminated 14 positions in the areas of manufacturing, analytical, quality control, quality assurance, clinical, regulatory, diagnostic product development, principally relating to the development of oral TTM and diagnostics division.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL INFORMATION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with the attached unaudited consolidated financial statements and notes thereto, and with our audited consolidated financial statements and notes thereto for the fiscal year ended December 31, 2007, found in our Annual Report on Form 10-KSB. 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 II, 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

Three Months Ended March 31, 2008 and 2007.

Research and Development Expenses. For the three months ended March 31, 2008, research and development expense was $2,124,620 as compared to $1,417,123 for the three months ended March 31, 2007. The increase of $707,497 is due primarily to an increase of approximately $568,000 associated with payments related to further the development of our licensed clinical drug candidates, an increase in salaries and payroll taxes of approximately $211,000, and is offset by a decrease in stock based compensation charges of approximately $231,000.

General and Administrative Expenses. For the three months ended March 31, 2008, general and administrative expense was $1,002,582 as compared to $1,503,881 for the three months ended March 31, 2007. The decrease of $501,299 is due primarily to a decrease in stock based compensation charge of approximately $676,000, offset by an increase in salaries and payroll taxes of approximately $228,000.

Other Income (Expense), net. For the three months ended March 31, 2008, other income-net was $37,746 compared to $71,469 for the three months ended March 31, 2007. For the three months ended March 31, 2008, interest income was $51,577 as compared to $71,469 for the three months ended March 31, 2007. Interest income was lower for the period in 2008 as compared to the same period in 2007, due to lower interest rates and lower levels of cash in interest bearing accounts. For the three months ended March 31, 2008, interest expense was $13,831 as compared to $0 for the three months ended March 31, 2007. Interest expense for the period in 2008 relates to interest paid on the notes payable which were repaid in March 2008.

Net Loss. Net loss for the three months ended March 31, 2008, was $3,089,456 as compared to $2,849,535 for the three months ended March 31, 2007. This increase in net loss is attributable primarily to an increase in research and development expenses of $707,497 and offset by the decrease in general and administrative expenses of $501,229 as discussed above.

Net Loss Applicable to Common Shareholders. The net loss applicable to common shareholders for the three months ended March 31, 2007 includes a non-cash charge of $12,409,722 related to the acquisition of Effective Pharmaceuticals, Inc (“EPI”). The total of the non-cash charge 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 three months ended March 31, 2007 and for the period from January 8, 2001 (inception) to March 31, 2008.

Liquidity and Capital Resources

During the three months ended March 31, 2008, we had a net decrease in cash of $2,731,279. Total cash resources as of March 31, 2008 was $8,761,523. During the three months ended March 31, 2008 and 2007, net cash used in operating activities was $1,812,320 and $1,814,625 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 three months ended March 31, 2008 and 2007 was $21,398 and $36,317, respectively. The net cash used in investing activities for the three months ended March 31, 2008 resulted from the acquisition of property and equipment. The net cash used in investing activities for the three months ended March 31, 2007 resulted from $36,317 for the purchase of property and equipment.

Net cash used in financing activities was $897,561 for the three months ended March 31, 2008 compared to $600,000 of net cash provided by financing activities for the three months ended March 31, 2007. The net cash used in financing activities for the three months ended March 31, 2008 resulted from $900,000 for the repayment on notes payable, less proceeds of $2,439 from the issuance of common stock. The net cash proceeds from financing activities for the three months ended March 31, 2007 resulted from proceeds from a note payable in the amount of $600,000.

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

Current and Future Financing Needs

We have incurred an accumulated deficit of $34,166,085 through March 31, 2008. We have incurred negative cash flow from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts. Based on our current plans, we believe that our cash will be sufficient to enable us to meet our planned operating needs at least for the next 12 months.

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

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our pre-clinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

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

Product Candidates

TRIMESTATM (oral estriol)

In June 2007, a two year seven U.S. center, placebo controlled 150 patient phase II/III clinical trial using TRIMESTATM for the treatment of relapsing-remitting Multiple Sclerosis (MS) was initiated under a $5 million grant from the Southern California Chapter of the National Multiple Sclerosis Society and NIH. This phase II/III clinical trial builds upon our encouraging results from an earlier phase IIa clinical trial. The primary purpose of this study is to evaluate the safety and efficacy of TRIMESTATM in a larger MS patient population with a one year blinded interim analysis. The preclinical and clinical development of TRIMESTATM has been primary financed by grants from the NIH and various non-profit foundations. Through March 31, 2008, we have incurred approximately $544,000 of costs related to our development of TRIMESTATM of which approximately $49,500, $185,500 and $194,000 was incurred in fiscal years 2005, 2006 and 2007, respectively, and approximately $115,000 was incurred during the first three months of 2008.

Z-monocys (oral zinc-monocysteine)

We plan to initially develop Z-monocys as an oral treatment for dry age-related macular degeneration (“dry AMD”). Z-monocys has completed a six month double blind randomized placebo controlled trial in 80 dry AMD patients with statistically significant improvements in visual acuity, contrast sensitivity and photorecovery times. A manuscript describing these results has been submitted to a leading peer-reviewed ophthalmic journal. On May 1, 2008, we were notified that this manuscript has been accepted for publication. Through March 31, 2008, we have incurred approximately $224,000 of costs related to our development of Z-monocys of which $154,000 was incurred during 2007 and $70,000 was incurred in 2008.

EFFIRMATM (oral flupirtine)

A scientific collaborator of ours has filed and received an IND with the FDA to conduct a phase II clinical trial with EFFIRMA in fibromyalgia patients. We plan to fund this double-blind placebo controlled phase II clinical study which is designed to enroll up to 90 patients with fibromyalgia. Through March 31, 2008, we have incurred approximately $99,000 of costs related to our development of EFFIRMATM, of which $85,000 was incurred during 2007 and $14,000 was incurred during the first three months of 2008.

FreeboundTM (metals diagnostic device)

We are developing a proprietary diagnostic device, FreeboundTM capable of measuring levels of free and bound metals in biological samples. Altered metal dyshomeostasis, in a particular copper, is associated with major disease indications, such as Alzheimer’s disease. In the first quarter of 2008 we entered into a preliminary supply agreement with a cGMP medical device manufacturer supplier and have initiated limited testing of these newly supplied disposable assay components. Based upon limited testing conducted by us during 2008 with these new disposable assay components, we believe that FreeBound may be capable of measuring free copper levels in whole blood (i.e. finger stick) as opposed to being limited to serum samples which require pre-assay separation and preparation. A potential whole blood assay opens the possibility that FreeBound can become an immediate point-of-care diagnostic and greatly expands its market potential. We intend to reinitiate 510(k) testing once we have finalized and selected final design parameters and consistent manufacturing processes of our FreeBound disposable assay components.

Oral TTM (oral tetrathiomolybate)

Through March 31, 2008, we have incurred approximately $3,500,000 of costs related to our development of oral TTM, of which approximately $150,000, $1,061,000 and $1,676,000 was incurred in fiscal years 2005, 2006 and

2007, respectively, and approximately $613,000 was incurred for the three months ended March 31, 2008.

We continue to make progress with evaluating the chemistry, manufacturing and controls issues (CMC) relating to identity, strength and purity of oral TTM which would be necessary to first resolve and which we believe is a necessary first step in the potential further development of Oral TTM. We may continue to explore therapeutic indications of oral TTM outside of Wilson's Disease and/or through potential corporate acquirors, strategic partnerships, granting agencies and through collaborative arrangements.

Anti-CD4 802-2

Through March 31, 2008, we have incurred $1,443,000 of costs related to our development of anti-CD4 802-2 of which $58,000, $332,000, $303,000, $295,000, $113,000, $161,000 and $121,000 was incurred in fiscal years 2001, 2002, 2003, 2004, 2005, 2006 and 2007 respectively and approximately $60,000 has been incurred in 2008.

CORRECTATM (clotrimazole emema)

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

SolovaxTM (multivalent T-cell vaccine for MS)

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

If successful, we may choose to initiate a phase IIb clinical study in this disease. The preclinical and clinical development of SOLOVAX has been primarily financed by grants from the NIH and various non-profit foundations totaling $5.5 million. Through March 31, 2008, we have incurred approximately $707,000 of costs related to our development of SOLOVAX of which $107,000, $158,000, $164,000, $163,000, $67,000, $21,000 and $8,000 was incurred in fiscal 2001, 2002, 2003, 2004, 2005, 2006 and 2007, respectively, and $19,000 has been incurred during 2008.

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

Additional Licenses

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

ITEM 3. CONTROLS AND PROCEDURES

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

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during our fiscal quarter ended March 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Not applicable.

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 March 31, 2008, we have expended approximately $19.0 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 TRIMESTA technology; an exclusive license agreement with the Children's Hospital-Boston relating to our CORRECTA technology; an exclusive license agreement to license our T-cell vaccine program from the University of Southern California (USC) and an exclusive license agreement with Drs. Newsome and Tate relating to our Z-monocys program. 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.

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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., Active Biotech, CNSBio, Pty., Rare Disease Therapeutics, Inc., Prana Biotechnology, Inc., Merz & Co., AstraZeneca Pharmaceuticals, Inc., Chiesi Pharmaceuticals, Inc., Alcon, Inc., Bausch and Lomb, Inc., Targacept, Inc., and Johnson & Johnson, Inc. Alternative technologies or alternative delivery or dosages of already approved therapies are being developed to treat dry AMD, autoimmune inflammatory, Fibromyalgia, MS, fibrotic, Huntington's, Alzheimer's and Wilson's diseases, several of which may be approved or are in early and advanced clinical trials, such as zinc based combinations, FTY-720, Laquinimod, pirfenidone, milnacipram, Lyrica, anti-depressant combinations, 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 TRIMESTA, zinc-monocysteine, anti-CD4 inhibitors, EFFIRMA, CORRECTA and oral TTM technologies. Should clinicians or regulatory authorities view these therapeutic regiments as or more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, 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, and TRIMESTA, others may obtain approvals for other uses of these products. For example, the active ingredients in both EFFIRMA and TRIMESTA 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 or TRIMESTA 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 EFFIRMA or TRIMESTA 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 TRIMESTA, EFFIRMA, CORRECTA, 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 TRIMESTA to treat MS (issued U.S. Patent No. 6,936,599) and various other therapeutic indications which have been exclusively licensed to us. We have also exclusively licensed an issued patent for the treatment of fibromyalgia with EFFIRMATM and have pending patent applications for our uses of CORRECTA.

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 our annual Form 10-KSB for the year ending December 31, 2007 filed March 31, 2008 (page 23), we described our receipt in March 2008 (and potential impact on claim 1 of our exclusively licensed issued U.S. patent 7,164,035) of an English translation of a Russian disclosure, Zegzhda et. al. Chemical Abstracts Vol. 85 Abstract No. 186052 (1976) that was cited by the U.S. patent examiner during our prosecution of the pending divisional U.S. patent application Ser. No. 11/621,390. In April 2008, we analyzed the zinc-cysteine complex described by Zegzhda and concluded that such complex describes an insoluable zinc salt and does not describe a non-zinc salt zinc monocyteine complex and therefore believe that such disclosure should not affect the validity of any of our issued U.S. patent claims relating our zinc-monocysteine composition-of-matter claims. We intend to file in the near future a response and declaration describing the results of our analysis with the U.S. Patent and Trademark Office with respect to the Zegzhda reference

with respect to U.S. patent application ser. no. 11/621,380.

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 CORRECTA 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 CORRECTA. To be successful in enforcing this designation, our NDA would need to be the first NDA approved to use oral TTM and CORRECTA for that indication. While we are not aware of any other companies that have sought orphan drug designation for oral TTM and CORRECTA for any indication, other companies may in the future seek it and may obtain FDA marketing approval before we do.

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

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

In July 2007 our exclusively licensed European patent covering our multivalent T-cell vaccine, Solvax, 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 development 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 TRIMESTA, SOLOVAX, CORRECTA, anti-CD4 802-2, EFFIRMA 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. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In March 2008, we issued a total of 23,788 shares of our common stock to 4 of our employees for services rendered. This offering and sale of shares 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. 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 for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

31.1 Certification pursuant to Rule 13a-14(a)/15d-14(a)
32.1 Certification pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002.

SIGNATURE

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

PIPEX PHARMACEUTICALS, INC.
By: /s/ Steve H. Kanzer
Steve H. Kanzer
Chairman & Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)
Date: May 15, 2008