

ADEONA PHARMACEUTICALS, INC.

Form 10-Q

August 14, 2009

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2009

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 1-12584

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

Delaware  
(State or other jurisdiction of incorporation or  
organization)

13-3808303

(IRS Employer Identification Number)

3930 Varsity Drive  
Ann Arbor, MI  
(Address of principal executive offices)

48108  
(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:  
Common Stock, \$0.001 par value per share

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

(Title of Class)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated file, a non-accelerated file, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-Accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>

(Do not check if a smaller reporting company)

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

As of August 1, 2009, the registrant had 21,457,640 shares of common stock outstanding.

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## PART I.—FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

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

## Consolidated Balance Sheets

Assets	June 30, 2009 (Unaudited)	December 31, 2008 (Audited)
<b>Current Assets</b>		
Cash	\$ 4,422,501	\$ 5,856,384
Other receivables	67,594	55,419
Prepaid expenses	24,509	15,109
<b>Total Current Assets</b>	<b>4,514,604</b>	<b>5,926,912</b>
Property and Equipment, net of accumulated depreciation of \$765,552 and \$591,876	1,192,657	1,446,407
Deposits and other assets	25,989	11,989
<b>Total Assets</b>	<b>\$ 5,733,250</b>	<b>\$ 7,385,308</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 370,819	\$ 574,896
Accrued liabilities	81,250	45,820
<b>Total Current Liabilities</b>	<b>452,069</b>	<b>620,716</b>
<b>Long Term Liabilities:</b>		
Accounts payable	122,335	-
<b>Total Liabilities</b>	<b>574,404</b>	<b>620,716</b>
<b>Stockholders' Equity</b>		
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, 21,353,428 and 20,882,839 shares issued and outstanding	21,354	20,883
Additional paid-in capital	45,411,993	45,025,385
Deficit accumulated during the development stage	(40,274,501)	(38,281,676)
<b>Total Stockholders' Equity</b>	<b>5,158,846</b>	<b>6,764,592</b>

Total Liabilities and Stockholders' Equity	\$	5,733,250	\$	7,385,308
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See accompanying notes to unaudited consolidated financial statements

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

Consolidated Statements of Operations  
(Unaudited)

	For the three months ended June 30, 2009	2008	For the six months ended June 30, 2009	2008	For the Period from January 8, 2001 (Inception) to June 30, 2009
Operating Expenses:					
Research and development	405,645	1,168,363	901,639	3,292,983	16,706,000
General and administrative	473,961	633,588	1,093,864	1,636,170	10,615,060
Total Operating Expenses	879,606	1,801,951	1,995,503	4,929,153	27,321,070
Loss from Operations	(879,606)	(1,801,951)	(1,995,503)	(4,929,153)	(27,321,072)
Other Income (Expense):					
Interest income	56	30,238	2,678	81,815	474,300
Interest expense	-	-	-	(13,831)	(66,760)
Total Other Income (Expense), net	56	30,238	2,678	67,984	407,540
Net Loss	\$ (879,550)	\$ (1,771,713)	\$ (1,992,825)	\$ (4,861,169)	\$ (26,913,529)
Less: Preferred stock dividend - subsidiary	-	-	-	-	(951,250)
Less: Merger dividend	-	-	-	-	(12,409,722)

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Net Loss Applicable to Common Shareholders	\$	\$	(1,771,713)	\$	\$	(4,861,169)	\$
	(879,550)			(1,992,825)			(40,274,501)
Net Loss Per Share - Basic and Diluted	\$	\$	(0.09)	\$	\$	(0.24)	\$
	(0.04)			(0.09)			(5.66)
Weighted average number of shares outstanding during the period - basic and diluted	21,301,014	20,590,592	21,195,200	20,522,574	7,110,444		

See accompanying notes to unaudited consolidated financial statements

## Adeona Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Company)

Consolidated Statements of Cash Flows  
(Unaudited)

	For the six months ended June 30,		For the period from January 8, 2001 (Inception) to June 30, 2009
	2009	2008	
<b>Cash Flows From Operating Activities:</b>			
Net loss	\$ (1,992,825)	\$ (4,861,169)	\$ (26,913,529)
Adjustments to reconcile net loss to net cash			
used in operating activities:			
Recognition of stock-based consulting	42,144	323,097	1,569,814
Recognition of stock-based compensation	148,099	870,314	3,309,720
Stock issued as compensation	-	55,385	55,385
Stock issued as compensation in acquisition of subsidiary	-	-	601,712
Stock issued for consulting fees	55,586	11,110	159,628
Stock issued for milestone payment	-	50,000	75,000
Stock issued for license fee	41,250	125,000	594,941
Contributed services - related party	100,000	73,750	449,395
Depreciation	188,226	204,383	825,413
Provision for uncollectible receivable	7,785	-	7,785
Loss on exchange of equipment to settle accounts payable	18,674	-	19,031
Loss on sale of equipment	15,725	-	15,725
Changes in operating assets and liabilities:			
(Increase) Decrease in:			
Prepaid expenses and other current assets	(29,360)	(3,514)	(91,203)
Deposits and other assets	(14,000)	1,392	(25,989)
(Increase) Decrease in:			
Accounts payable	(75,817)	(91,155)	591,374
Accrued liabilities	35,430	119,825	84,268
<b>Net Cash Used In Operating Activities</b>	<b>(1,459,083)</b>	<b>(3,121,582)</b>	<b>(18,671,530)</b>
<b>Cash Flows From Investing Activities:</b>			
Purchases of property and equipment	-	(21,398)	(2,032,805)
Proceeds from the sale of equipment	25,200	-	157,465
Cash paid to acquire shell in reverse acquisition	-	-	(665,000)
<b>Net Cash Provided By (Used In) Investing Activities</b>	<b>25,200</b>	<b>(21,398)</b>	<b>(2,540,340)</b>



<b>Cash Flows From Financing Activities:</b>				
Proceeds from loans payable - related party	-			3,210,338
Repayments of loans payable - related party	-			(220,000)
Proceeds from notes payable	-	-		1,100,000
Repayments of notes payable	-	(900,000)		(1,100,000)
Proceeds from issuance of common stock for stock option exercises	-	-		4,390
Proceeds from issuance of preferred and common stock	-	3,415		1,150,590
Proceeds from sale of common stock and warrants in private placements	-	-		13,926,362
Proceeds from sale of common stock in connection with warrant 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	-	(896,585)		25,634,371
Net increase (decrease) in cash	(1,433,883)	(4,039,565)		4,422,501
Cash at beginning of period	5,856,384	11,492,802		-
Cash at end of period	\$ 4,422,501	\$ 7,453,237	\$	4,422,501
<b>Supplemental disclosures of cash flow information:</b>				
Cash paid for interest	\$ -	\$ 13,831	\$	66,760
Cash paid for taxes	\$ -	\$ -	\$	-
<b>Supplemental disclosure of non-cash investing and financing activities:</b>				
Loss on exchange of equipment to settle accounts payable	\$ 5,925	\$ -	\$	98,219
Sale of equipment in exchange for other receivables	\$ -	\$ -	\$	8,685
Exchange of EPI preferred stock into Pipex common stock in acquisition	\$ -	\$ -	\$	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

Adeona 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

Adeona Pharmaceuticals, Inc. (“Adeona”) is a company dedicated to the awareness, diagnosis, prevention and treatment of subclinical zinc deficiency and chronic copper toxicity in the mature population. Adeona believes that such conditions may contribute to the progression of debilitating degenerative diseases, including, Dry Age-Related Macular Degeneration (Dry AMD), Alzheimer’s disease (AD) and mild cognitive impairment (MCI) in susceptible persons. Adeona is also developing a number of late-stage clinical drug candidates for the treatment of rheumatoid arthritis and multiple sclerosis.

(B) Corporate Name Change

On October 16, 2008, the Company completed a corporate name change to Adeona Pharmaceuticals, Inc. from Pipex Pharmaceuticals, Inc.

(C) Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly they do not include all of the information and footnotes necessary for a fair presentation of financial condition, results of operations and cash flows in conformity with generally accepted accounting principles. In the opinion of management of Adeona, the interim consolidated financial statements included herewith contain all adjustments (consisting of normal recurring accruals and adjustments) necessary for their fair presentation.

The unaudited interim consolidated financial statements should be read in conjunction with the Company’s Annual Report on Form 10-K, which contains the audited financial statements and notes thereto, together with the Management’s Discussion and Analysis, for the year ended December 31, 2008. The interim results for the period ended June 30, 2009 are not necessarily indicative of results for the full fiscal year.

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

The Company has seven subsidiaries, Pipex Therapeutics, Inc. (“Pipex Therapeutics”), Effective Pharmaceuticals, Inc. (“EPI”), Solovax, Inc. (“Solovax”), CD4 Biosciences, Inc. (“CD4”), Epitope Pharmaceuticals, Inc. (“Epitope”), Healthmine Inc. (“Healthmine”) and Putney Drug Corp. (“Putney”) which were previously under common control. As of June 30, 2009, EPI, Healthmine and Putney are wholly owned and Pipex Therapeutics, Solovax, CD4 and Epitope are majority owned. The combinations of these entities prior to 2006 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 Adeona, 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, except for EPI, which was incorporated on December 12, 2000, Epitope which was incorporated in January of 2002, Putney which was incorporated in November of 2006 and Healthmine which was incorporated in December 2007. All of the subsidiaries were incorporated under the laws of the State of Delaware.

For financial accounting purposes, the Company's date of 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.

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

Notes to Consolidated Financial Statements  
(Unaudited)

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.

(E) Reverse Stock Split

In January 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 Adeona. The reverse split was effective on April 25, 2007 following shareholder approval. All share and per share amounts have been retroactively restated to reflect this reverse stock split.

(F) 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 because Sheffield did not have any operations at the time of the merger, and therefore 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' outstanding options and warrants, but did not assume the options and warrants outstanding within any of Pipex Therapeutics' 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.

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 this Note 1(F).



Adeona Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Company)

Notes to Consolidated Financial Statements

(Unaudited)

(G) 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 Therapeutics' 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 Therapeutics' 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, each of these transactions described in Notes 1(G)(1), 1(G)(2) and 1(G)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. Adeona'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 Adeona, Effective Acquisition Corp. In the transaction, Adeona 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 Adeona 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 part of the exchange with Adeona. 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.



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

Notes to Consolidated Financial Statements  
(Unaudited)

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.

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 period from January 8, 2001 (inception) to June 30, 2009.

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, Adeona 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

All significant inter-company accounts and transactions have been eliminated in consolidation.

(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 \$40,274,501 at June 30, 2009.

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

Notes to Consolidated Financial Statements  
(Unaudited)

(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 2009 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 and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. At June 30, 2009 and December 31, 2008, respectively, the Company had no cash equivalents.

The Company minimizes 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 June 30, 2009 and December 31, 2008, the balance exceeded the federally insured limit by \$0 and \$5,653,635, respectively. During 2009, the Company moved its cash into a non-interest bearing account which has unlimited insurance protection through December 31, 2009.

(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

On April 3, 2009, the Company sold manufacturing equipment with a net book value of \$40,925, for \$25,200, resulting in a loss of \$15,725.

On March 17, 2009, the Company transferred manufacturing equipment with a net book value of \$24,599 to settle accounts payable of \$5,925, resulting in a loss of \$18,674.

On October 14, 2008, the Company sold manufacturing equipment with a net book value of \$154,787, for \$140,000, resulting in a loss of \$14,787.

On September 19, 2008, the Company transferred certain manufacturing equipment with a net book value of \$77,710 and \$30,000 in cash to settle accounts payable of \$122,140. This transaction resulted in a gain on the sale of \$14,430.

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

Notes to Consolidated Financial Statements  
(Unaudited)

(F) Long Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. There were no impairment charges taken during the three and six month periods ended June 30, 2009 and 2008 and for the period from January 8, 2001 (inception) to June 30, 2009.

(G) Derivative Liabilities

In connection with the reverse acquisition, all outstanding convertible preferred stock of Adeona 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 Note 1(G)(4)), all issued and outstanding shares of Series A and B, convertible preferred stock were cancelled and retired. Consequentially there is 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 (loss) 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. The Company's share equivalents consist of 2,488,851 stock options and 1,070,472 warrants. Since the Company reported a net loss for the three and six month periods ended June 30, 2009 and 2008 and for the period from January 8, 2001 (inception) to June 30, 2009, 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 and six month periods ended June 30, 2009 and 2008 and for the period from January 8, 2001 (inception) to June 30, 2009 was computed assuming the effect of 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 period from January 8, 2001 (inception) to June 30, 2009, in connection with the acquisition of EPI (See Note 1(G)(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.

(J) Fair Value of Financial Instruments

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

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(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) Non-Employee Stock Based Compensation

All stock-based compensation awards issued to non-employees for services have been recorded at either the fair value of the services rendered or the instruments issued in exchange for such services, whichever is more readily determinable, using the measurement date guidelines enumerated in Emerging Issues Task Force Issue EITF No. 96-18, "Accounting for Deficit Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" ("EITF 96-18").

(M) Recent Accounting Pronouncements

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.

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.





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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.

In April 2008, the FASB issued FASB Staff Position (“FSP”) SFAS No. 142-3, “Determination of the Useful Life of Intangible Assets”. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, “Goodwill and Other Intangible Assets” (“SFAS 142”). The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R, and other GAAP. This FSP 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 Company does not expect the adoption of SFAS FSP 142-3, to have a material impact on its financial position, results of operations or cash flows.

In May 2008, the FASB issued FSP Accounting Principles Board (“APB”) 14-1 “Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)” (“FSP APB 14-1”). FSP APB 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability (debt) and equity (conversion option) components of the instrument in a manner that reflects the issuer’s non-convertible debt borrowing rate. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 on a retroactive basis. The Company does not expect the adoption of FSP APB 14-1, to have a material impact on its financial position, results of operations or cash flows.

In October 2008, the FASB issued FSP FAS 157-3, “Determining the Fair Value of a Financial Asset When the Market For That Asset Is Not Active” (“FSP FAS 157-3”), with an immediate effective date, including prior periods for which financial statements have not been issued. FSP FAS 157-3 amends FAS 157 to clarify the application of fair value in inactive markets and allows for the use of management’s internal assumptions about future cash flows with appropriately risk-adjusted discount rates when relevant observable market data does not exist. The objective of FAS 157 has not changed and continues to be the determination of the price that would be received in an orderly transaction that is not a forced liquidation or distressed sale at the measurement date. The adoption of FSP FAS 157-3 is not expected to have a material effect on the Company’s financial position, results of operations or cash flows.

In April 2009, the FASB issued FSP SFAS 157-4, “Determining Whether a Market Is Not Active and a Transaction Is Not Distressed,” which further clarifies the principles established by SFAS No. 157. The guidance is effective for the periods ending after June 15, 2009 with early adoption permitted for the periods ending after March 15, 2009. The adoption of FSP FAS 157-4 is not expected to have a material effect on the Company’s financial position, results of operations, or cash flows.

In May 2009, the FASB issued SFAS No. 165 “Subsequent Events” (“SFAS 165”). SFAS 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS 165 sets forth: (i) the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements; (ii) the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements; and (iii) the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. SFAS 165 is effective for interim or annual financial periods ending after June 15, 2009. The Company is evaluating the impact the adoption of SFAS 165 will have on its financial statements.

In June 2009, the FASB issued SFAS No. 166 “Accounting for Transfers of Financial Assets—an amendment of FASB Statement No. 140” (“SFAS 166”). SFAS 166 improves the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial statements about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor’s continuing involvement, if any, in transferred financial assets. SFAS 166 is effective as of the beginning of each reporting entity’s first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period and for interim and annual reporting periods thereafter. The Company is evaluating the impact the adoption of SFAS 166 will have on its financial statements.

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In June 2009, the FASB issued SFAS No. 167 “Amendments to FASB Interpretation No. 46(R)” (“SFAS 167”). SFAS 167 improves financial reporting by enterprises involved with variable interest entities and to address (1) the effects on certain provisions of FASB Interpretation No. 46 (revised December 2003), “Consolidation of Variable Interest Entities”, as a result of the elimination of the qualifying special-purpose entity concept in SFAS 166 and (2) constituent concerns about the application of certain key provisions of Interpretation 46(R), including those in which the accounting and disclosures under the Interpretation do not always provide timely and useful information about an enterprise’s involvement in a variable interest entity. SFAS 167 is effective as of the beginning of each reporting entity’s first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. The Company is evaluating the impact the adoption of SFAS 167 will have on its financial statements.

In June 2009, the FASB issued SFAS No. 168 “The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles—a replacement of FASB Statement No. 162”. The FASB Accounting Standards Codification (“Codification”) will be the single source of authoritative nongovernmental U.S. generally accepted accounting principles. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. SFAS 168 is effective for interim and annual periods ending after September 15, 2009. All existing accounting standards are superseded as described in SFAS 168. All other accounting literature not included in the Codification is nonauthoritative. The Codification is not expected to have a significant impact on the Company’s financial statements.

Other accounting standards 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.

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### 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 of Pipex Therapeutics, EPI, Solovax and CD4; the notes bore interest of prime plus 2% and were due March 30, 2010. As of March 6, 2008, all of the outstanding principal and accrued interest has been repaid.

### Note 4 Stockholders' Equity and Non-Controlling Interest

#### (A) Preferred Stock Issuances

##### 1. 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 Adeona common stock and the warrants were converted into 68,858 warrants of Adeona. (See Note 1(E)(4))

##### 2. 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 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 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 in exchange for \$300,000 (\$0.30 per share).

#### (B) Common Stock Issuances of Issuer

For the Six Months Ended June 30, 2009

During the first half of 2009, the Company issued 212,775 shares of common stock for consulting fees having a fair value of \$55,586 (\$0.26 per share) based on the quoted closing trading price.

During the first quarter of 2009, the Company issued an aggregate 257,813 shares of common stock for license fees having a fair value of \$41,250 (\$0.16 per share) based on the quoted closing trading price.

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For the Year Ended 2008

In 2008, the Company issued 61,392 shares of common stock having a fair value of \$55,385 (\$0.90 per share) based on the quoted closing trading prices for payment of salaries to employees.

In 2008, the Company issued 172,157 shares of common stock having a fair value of \$104,042 (\$0.60 per share) based on the quoted closing trading prices for consulting fees.

In 2008, the Company issued 39,370 shares of common stock having a fair value of \$50,000 (\$1.27 per share) based on the quoted closing trading price for a milestone payment.

In 2008, the Company issued an aggregate 138,505 shares of common stock having a fair value of \$145,000 (\$1.05 per share) based on the quoted closing trading prices for license fees.

In 2008, the Company issued 37,948 shares of common stock in connection with the exercise of stock options for net proceeds of \$4,390. The related exercise prices were \$0.09 and \$0.18 per share.

For the Year Ended 2007

In 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.

In 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.

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).

For the Year Ended 2006

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

During 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 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.

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(C) Common Stock Issuances of Subsidiaries

During the period from January 8, 2001 (inception) to September 30, 2008, the Company's majority owned subsidiaries; CD4, Solovax, EPI and Epitope issued 419,000, 419,000, 825,000 and 125,000 shares of common stock, respectively, for an aggregate \$1,788. Of the 825,000 shares of common stock issued by EPI, 75,000 were converted into 30,161 common shares of Adeona 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 under the 2001 plan. 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 under the 2001 plan 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 2001 Stock 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 2001 Stock 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 June 30, 2009, there are 1,229,987 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 2007 Stock 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. This plan was approved by stockholders on November 2, 2007. As of June 30, 2009, there are 1,178,864 options issued and outstanding under the 2007 Stock Plan.

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

The Company has applied 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 and six months ended June 30, 2009 and 2008 are as follows:

Three Months Ended June 30,

Six Months Ended June 30,



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	2009	2008	2009	2008
Exercise price	\$0.38 - \$0.56	\$0.81	\$0.38 - \$0.56	\$0.81 - \$5.10
Expected dividends	0%	0%	0%	0%
Expected volatility	203.8% - 209%	225%	203.8% - 209%	201.11% - 225%
Risk free interest rate	2.96% - 3.52%	4.02%	2.96% - 3.52%	3.52% - 4.02%
Expected life of option	10 years	10 years	10 years	10 years

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Pursuant to FAS 123R, the Company records stock based compensation based upon the stated vested provisions in the related agreements, with recognition of expense recorded on the straight line basis over the term of the related agreement. 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. All option grants are expensed in the appropriate period based upon each award 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 and six months ended June 30, 2009 and 2008 and the period from January 8, 2001 (inception) to June 30, 2009 with respect to awards under the Plan and awards issued under warrants is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,		Inception to June 30, 2009
	2009	2008	2009	2008	
Research and development:					
employees	\$ 42,221	\$360,265	\$ 77,467	\$666,290	\$2,366,955
non-employees	21,072	96,952	42,143	292,247	582,307
General and administrative:					
employees	35,405	129,405	70,633	204,024	1,526,331
non-employees	-	-	-	30,851	970,890
<b>Total</b>	<b>\$ 98,698</b>	<b>\$586,622</b>	<b>\$190,243</b>	<b>\$1,193,412</b>	<b>\$5,446,483</b>

A summary of stock option activity for Adeona for the six months ended June 30, 2009 (unaudited) and for the year ended December 31, 2008 is as follows:

	Number of Shares	Weighted Average Exercise Price
Balance at December 31, 2007	2,297,364	\$ 2.72
Granted	1,180,666	\$ 1.00
Exercised	(37,948)	\$ 0.12
Forfeited	(688,419)	\$ 5.07
Balance at December 31, 2008	2,751,663	\$ 1.43
Granted	520,000	\$ 0.42
Exercised	-	\$ -
Forfeited	(862,812)	\$ 0.76

Balance at June 30, 2009 (unaudited)	2,408,851	\$	1.45
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The weighted average remaining contractual term for options outstanding at June 30, 2009 was 7.18 years. At June 30, 2009, the Company had 950,780 stock options outstanding and exercisable that had an exercise price less than the market price on that date for an aggregate intrinsic value of \$180,349.

Of the total options granted, 1,943,153 are fully vested, exercisable and non-forfeitable and have a weighted average exercise price of \$1.61. The weighted average remaining contractual term for options that are exercisable was 6.61 years.

Of the total 2,408,851 options outstanding, 1,188,162 options are held by related parties of which 750,176 are fully vested, exercisable and non-forfeitable.

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(E) Stock Warrants

On November 18, 2008, the Company issued warrants to purchase 5,000 shares of common stock pursuant to a settlement agreement. The warrants have an exercise price of \$0.41. The fair value of the warrants totals \$1,265 and was determined by using the Black-Scholes model with the following assumptions: expected dividend yield of 0%; expected volatility of 179.13%; risk-free interest rate of 1.15% and an expected life of two and one-half years.

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 per 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.

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.

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.

On February 15, 2007, the Company executed an agreement with a third party to provide certain consulting services. Pursuant to the terms of the agreement, the Company will issue warrants to purchase 100,000 shares of common stock upon the achievement of various milestones as well as over the life of the contract. The warrants have an exercise price of \$3.75. The fair value of the warrants totals \$374,760 and was determined by using the Black-Scholes model with the following assumptions: expected dividend yield of 0%; expected volatility of 187.22%; risk-free interest rate of 4.68% and an expected life of five years. As of December 31, 2008, 50,000 warrants have been issued for which the Company has recognized stock based consulting expense for \$187,380.

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)(G)(4))

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

In addition, as part of the private placements, the Company issued warrants to purchase 958,277 shares of common stock to the placement agent, that is a company that is controlled by the Company's Chairman with the majority of these warrants being reissued to the Company's former 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 14, 2009, 381,020 of these warrants representing all of the warrants held by an affiliate of the Company's Chairman were cancelled.

On October 31, 2006, the loans payable to the Company's founder, and Chairman were converted into 1,665,211 shares of common stock and 832,606 warrants to purchase common stock. The warrants had an exercise price of \$2.22 and a life of 5 years. The warrants were forfeited on January 14, 2009.

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A summary of warrant activity for Adeona for the six months ended June 30, 2009 (unaudited) and for the year ended December 31, 2008 is as follows:

	Number of Shares
Balance as December 31, 2007	2,278,416
Granted	13,333
Exercised	—
Forfeited	—
Balance at December 31, 2008	2,291,749
Granted	—
Exercised	—
Forfeited	(1,221,277)
Balance as June 30, 2009 (unaudited)	1,070,472

All outstanding warrants are fully vested and exercisable.

Warrants Outstanding and Exercisable

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life
\$ 0.41	5,000	1.88 Years
\$ 2.22	626,809	3.57 Years
\$ 3.30	61,207	5.92 Years
\$ 3.75	50,000	6.63 Years
\$ 6.36	327,456	3.36 Years
	1,070,472	4.60 Years

(F) Options of Subsidiary

CD4 has 30,000 options outstanding and exercisable which were granted during 2004 and 2007, with an exercise price of \$0.20 and a remaining contractual life of 1.49 years as of June 30, 2009.

Epitope has 50,000 options outstanding and none exercisable, with an exercise price of \$.001 and a remaining contractual life of 9.01 years as of June 30, 2009. These options were granted during 2008, vest annually over 5 years and have a fair value of \$50 which 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 2.47% and an expected life of 10

years.

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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 future milestone payments up to an amount of \$15,675,000. 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, 2009, the Company has achieved two milestones which the Company fulfilled by issuing common stock having a fair value of \$75,000. 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 sponsored approximately \$460,000 per year, payable in monthly installments. This agreement can be extended for an additional two-year period. The Company can terminate the agreement by giving 90 days prior written notice. On March 20, 2008, the Company provided the University with written notice of termination of the agreement. On March 24, 2009 the Company entered into a repayment plan with the University to pay the outstanding amount owed under the original agreement in the amount of \$197,335. The Company will pay \$5,000 per month until the payable is paid in full.

(C) Employment Agreements

In January 2005, the Company entered into a four-year employment agreement with Steve H. Kanzer, the Company's then Chairman and Chief Executive Officer. Pursuant to that agreement, Mr. Kanzer was entitled to receive an annual base salary of \$297,000 and annual bonuses equal to 30% of his base salary, plus 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. However, Mr. Kanzer did not take any of the salary or bonuses he was entitled to under this agreement, but did exercise his stock options, which had vested on or before December 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 for Mr. Kanzer. The amended employment agreement provided that he be paid a base salary of \$195,000 per year plus a guaranteed bonus of \$100,000 (of which he took only \$45,000 in January 2008). The agreement also called for discretionary transactional bonuses. In addition and for no additional consideration, Mr. Kanzer formally waived the receipt of any



unpaid salary and bonuses payable under the original agreement, which amounted to \$275,645. This amount was treated as a capital contribution to the Company in September 2007.

On July 1, 2008, Mr. Kanzer resigned his position as Chief Executive Officer, but remained as Chairman of the Board.

Also on July 1, 2008, the Company's Board of Directors appointed Nicholas Stergis (the then Vice Chairman of the Board and former Chief Operating Officer of the Company's Effective Pharmaceuticals subsidiary) as Chief Executive Officer and approved his compensation package, which increased Mr. Stergis's annual cash compensation from \$150,000 per annum to \$195,000 per annum salary, and included a six month severance clause. Mr. Stergis was also eligible for a bonus at the discretion of the Board of Directors. The Company also granted him a ten year option to purchase 800,000 shares of the Company's common stock, exercisable at \$0.72 per share, with one-quarter of the options vesting immediately, and the remainder vesting quarterly in equal increments over three years. The fair value of the options totaled \$576,000 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 225.79%, risk free interest rate of 3.95% and an expected life of 10 years.

Adeona Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Company)

Notes to Consolidated Financial Statements

(Unaudited)

Effective March 29, 2009, Mr. Stergis resigned his position as the Company's Chief Executive Officer, but remains a director of the Company and is being paid severance of \$97,500 over six months, ending September 2009. Per the terms of the agreement, 500,000 unvested stock options were cancelled on March 29, 2009 and 300,000 vested options that were unexercised cancelled on June 28, 2009.

On January 6, 2009, Mr. Kanzer (Chairman of the Board) entered into an amended agreement with the Company which extends his employment agreement through January 9, 2010 with an annual salary of \$1. Also, Mr. Kanzer agreed to forego the \$100,000 guaranteed bonus otherwise due to him on January 1, 2009. The amount of \$100,000 was recorded as a capital contribution during the first quarter of 2009. Mr. Kanzer reimburses the Company for the Company's cost of Mr. Kanzer's health insurance. On March 29, 2009, Mr. Kanzer assumed the duties of the Chief Executive Officer and President until the appointment of Max Lyon, the Company's current Chief Executive Officer and President.

On April 9, 2009, the Company's wholly owned subsidiary Healthmine, entered into an employment agreement with its President, David Newsome. The Company paid a \$10,000 signing bonus and will pay a base salary of \$120,000 per year. The agreement also provided that the President was 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. The Company has also granted a ten year option to purchase 120,000 shares of the Company's common stock, exercisable at \$0.56 per share, with 20,000 of the options vesting immediately, and the remainder vesting quarterly in equal increments over three years. The fair value of the options totaled \$67,200 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 209.00%, risk free interest rate of 2.96% and an expected life of 10 years.

On June 26, 2009, the Company entered into an employment agreement with Max Lyons to become the Company's new Chief Executive Officer. Pursuant with the employment agreement the Chief Executive Officer will receive a base salary of \$190,000 per year and will be eligible for discretionary performance and transactional bonus payments. If the Employment Agreement is terminated for certain events such as the death or disability, a material breach by the Company of the terms of the Employment Agreement or termination without "Just Cause", the Company has agreed to either continue Mr. Lyon's salary for three months or issue freely tradable shares of the Company stock with a value equal to three months of his salary. Additionally, the Company has granted a ten year option to purchase 400,000 shares of the Company's common stock with an exercise price equal to the Company's per share market price on the date of issue; 100,000 of the options vest immediately with the remainder vesting pro rata, on a monthly basis, over the following three years. The fair value of the options totaled \$152,000 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 203.8%; risk free interest rate of 3.52% and an expected life of 10 years.

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

Notes to Consolidated Financial Statements  
(Unaudited)

(D) Litigation

On January 13, 2009, EPI was served with legal action from an individual regarding payment of past consulting services and associated expenses from 2005. The Company believes the lawsuit is without merit. The Company has engaged legal counsel to respond to this matter.

Note 6 Stock Repurchase Program

On April 3, 2009, the Company's Board of Directors approved a Stock Repurchase Program authorizing the Company to repurchase, from time-to-time of up to \$1 million of its common stock, up to a maximum of four (4) million shares at prices of up to \$5.00 per share. The Stock Repurchase Program is intended to remain in effect until December 31, 2009. As of June 30, 2009, the Company has not repurchased any stock.

Note 7 Subsequent Event

The Company has evaluated for subsequent events between the balance sheet date of June 30, 2009 and August 14, 2009, the date the financial statements were issued.

On May 30, 2009 the Company entered into a limited liability company purchase agreement to acquire all of the outstanding membership interests in Hartlab LLC ("Hartlab"), an Illinois limited liability company and CLIA-certified clinical laboratory. By an Amendment dated June 30, 2009, the Company and the owner of Hartlab agreed to extend the closing date of the transaction from June 30, 2009 to July 10, 2009. On July 8, 2009, the Company entered into a second amendment to the limited liability purchase agreement and consummated the acquisition contemplated by the Purchase Agreement as amended.

The Company acquired Hartlab to be able to develop and commercialize diagnostic test panels for the detection of zinc and copper abnormalities in the mature population.

The Company paid \$201,141 in cash and issued 50,000 unregistered shares of the Company's common stock in exchange for all of the issued and outstanding membership interests of HartLab. The Company paid \$14,000 of the cash purchase price upon signing of the Purchase Agreement in May, 2009 and the remainder of \$187,141 was paid at closing. In addition, Adeona agreed to guarantee and seek to release the seller from the seller's personal guarantee of the remaining balance of two outstanding clinical equipment leases of HartLab totaling \$78,859. The Company has placed this amount in escrow which will be returned within 60 days provided the seller is released from his personal guarantee, or in the alternative, after 60 days will be paid to the lessors to pay off such equipment leases. Additionally, the Company entered into a consulting agreement with the seller for a period of up to twelve months for a monthly consulting fee of \$4,000.



## 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, 2008, found in our Annual Report on Form 10K. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward looking statements by using words such as "anticipate," "believe," "intends," or similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10K.

### Overview

Since our inception during January 2001, our efforts and resources have been focused primarily on acquiring and developing our pharmaceutical products, raising capital and recruiting personnel. We are a development stage company and have had no product sales to date. Our major sources of working capital have been proceeds from equity financings from affiliates of our Chairman 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") and on October 16, 2008 the Company changed its name to Adeona Pharmaceuticals, Inc. ("Adeona"). 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.

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 as amortized in the period of recognition. 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 June 30, 2009 and March 31, 2009

The net loss for the quarter ended June 30, 2009 was \$879,550 or \$0.04 per share compared to a net loss of \$1,113,275 or \$0.05 per share for the previous quarter ended March 31, 2009, a reduction of 21%. The net loss for the quarter ended June 30, 2009 excluding depreciation, stock based compensation, and stock-based consulting and contributed services was \$659,299 compared to \$758,221 for the previous quarter ended March 31, 2009, a reduction of 13%. The net loss for the quarter ended June 30, 2009 included a one-time cash expense of \$75,000 related to the cancelled acquisition of Colwell Clinical Laboratories.

#### Three Months Ended June 30, 2009 and 2008.

**Research and Development Expenses.** For the three months ended June 30, 2009, research and development expense was \$405,645 as compared to \$1,168,363 for the three months ended June 30, 2008. The decrease of \$762,718 is due primarily to a decrease of approximately \$394,000 in stock based compensation charges, a decrease of approximately \$226,000 associated with payments related the development of our licensed clinical drug candidates, a decrease in salaries and related taxes of approximately \$102,000 and a decrease in allocated overhead expenses of approximately \$41,000.

**General and Administrative Expenses.** For the three months ended June 30, 2009, general and administrative expense was \$473,961 as compared to \$633,588 for the three months ended June 30, 2008. The decrease of \$159,627 is due primarily to a decrease in salaries and payroll taxes of approximately \$160,000 and a decrease in stock based compensation charge of approximately \$94,000, offset by an increase in allocated overhead of approximately \$36,000.

**Other Income (Expense), net.** For the three months ended June 30, 2009, other income was \$56 compared to other income of \$30,238 for the three months ended June 30, 2008. For the three months ended June 30, 2009, interest income was \$56 as compared to \$30,238 for the three months ended June 30, 2008. Interest income was lower for the period in 2009 as compared to the same period in 2008 due to lower interest rates and lower levels of cash in interest bearing accounts.

**Net Loss.** Net loss for the three months ended June 30, 2009, was \$879,550 as compared to \$1,771,713 for the three months ended June 30, 2008. This decrease in net loss of \$892,163 is attributable primarily to a decrease in research and development expense of \$762,718, a decrease in general and administrative expenses of \$159,627 and an increase

in other income of \$30,182 as discussed above.

Six Months Ended June 30, 2009 and 2008.

**Research and Development Expenses.** For the six months ended June 30, 2009, research and development expense was \$901,639 as compared to \$3,292,983 for the six months ended June 30, 2008. The decrease of \$2,391,344 is due primarily to a decrease of approximately \$1,067,000 associated with payments related to the development of our licensed clinical drug candidates, a decrease of approximately 839,000 in stock based compensation charges, a decrease in salaries and related taxes of approximately \$398,000 and a decrease in allocated overhead expenses of approximately \$87,000.

**General and Administrative Expenses.** For the six months ended June 30, 2009, general and administrative expense was \$1,093,864 as compared to \$1,636,170 for the six months ended June 30, 2008. The decrease of \$542,306 is due primarily to a decrease in salaries and payroll taxes of approximately \$260,000, a decrease in stock based compensation charge of approximately \$164,000, a decrease in allocated overhead of approximately \$60,000 and a decrease in professional fees of approximately \$52,000.

**Other Income (Expense), net.** For the six months ended June 30, 2009, other income was \$2,678 compared to other income-net of \$67,984 for the six months ended June 30, 2008. For the six months ended June 30, 2009, interest income was \$2,678 as compared to \$81,815 for the six months ended June 30, 2008. Interest income was lower for the period in 2009 as compared to the same period in 2008 due to lower interest rates and lower levels of cash in interest bearing accounts. For the six months ended June 30, 2009, interest expense was \$0 as compared to \$13,831 for the six months ended June 30, 2008. 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 six months ended June 30, 2009, was \$1,992,825 as compared to \$4,861,169 for the six months ended June 30, 2008. This decrease in net loss of \$2,868,344 is attributable primarily to a decrease in research and development expense of \$2,391,344, a decrease in general and administrative expenses of \$542,306 and an increase in other income-net of \$65,306 as discussed above.

#### Liquidity and Capital Resources

At June 30, 2009, Adeona had cash of approximately \$4.42 million and working capital of approximately \$4.06 million. Excluding the one-time cash expenditure of \$75,000 related to the cancelled acquisition of Colwell Clinical Laboratories, Adeona's net decrease in working capital, or "burn rate", for the quarter ended June 30, 2009 was \$572,373 which compares to Adeona's burn rate of \$596,288 for the previous quarter ended March 31, 2009. Adeona currently believes that it has sufficient working capital to fund operations for the next 16 months. As a result of Adeona's acquisition on July 9, 2009 of Hartlab LLC, a Chicago-area CLIA-certified clinical reference laboratory, Adeona has begun generating revenues in the current quarter and plans to launch a suite of assays intended to diagnose and quantify potential copper toxicity and other metal-implicated neurodegenerative conditions.

During the six months ended June 30, 2009, we had a net decrease in cash of \$1,433,883. Total cash resources as of June 30, 2009 was \$4,422,501. During the six months ended June 30, 2009 and 2008, net cash used in operating activities was \$1,459,083 and \$3,121,582 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 provided by investing activities was \$25,200 for the six months ended June 30, 2009 compared to \$21,398 net cash used in investing activities for the six months ended June 30, 2008. The net cash provided by investing activities for the six months ended June 30, 2009 resulted from the proceeds from the sale of equipment in the amount of \$25,200. The net cash used in investing activities for the six months ended June 30, 2008 resulted from the purchase of property and equipment in the amount of \$21,398.

Net cash used in financing activities was \$0 for the six months ended June 30, 2009 compared to \$896,585 of net cash used in financing activities for the six months ended June 30, 2008. The net cash used in financing activities for the six months ended June 30, 2008 resulted from \$900,000 for the repayment on notes payable, less proceeds of \$3,415 from the issuance of preferred and common stock.

Our continued operations will depend on whether we are able to generate revenues and profits through our planned introduction of diagnostic clinical laboratory services and zinc-based products or raise additional funds through various potential sources, such as license fees from a potential corporate partner, 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 \$40,274,501 through June 30, 2009. 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 16 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;
- our potential stock repurchases under our Stock Repurchase Program, and
- the success, timing, and profitability of our planned clinical laboratory services and zinc-based product launches.

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

### Copper and Zinc Metabolism Clinical Diagnostic Products and Services

During the first quarter of 2009, we analyzed patient samples from an IRB-approved, prospective, observational, blinded clinical trial that we sponsored and conducted during 2007 and 2008. Such study enrolled 90 subjects, 30 with Alzheimer's disease (AD), 30 with Parkinson's disease (PD) and 30 age-matched normal subjects. The purpose of the study was to evaluate serum markers of copper status and compare these results across the three groups of patients. The results of such study indicate highly statistically significant differences in serum markers of copper status between AD and normal subjects. We believe that the differences observed suggest that Alzheimer's patients have impaired metabolic functioning that decreases their protection from chronic copper toxicity, which may contribute to the progression of their disease. The results from this study also appear to indicate a subclinical zinc deficiency in AD subjects. We announced these results in the first half of July at the 2009 International Conference on Alzheimer's Disease (ICAD) in Vienna, Austria and intend to launch a panel of copper and zinc metabolism clinical diagnostics based upon our findings through our Hartlab LLC subsidiary. There are an estimated 5.8 million, 1.5 million and 15 million persons in the U.S. with Alzheimer's disease, Parkinson's disease and mild cognitive impairment (MCI), respectively, that may benefit from our planned panel of clinical diagnostic products and services.

On July 8, 2009 we consummated the acquisition of Hartlab LLC ("Hartlab"), an Illinois limited liability company and CLIA-certified clinical laboratory through which we intend to launch and market our intended panel of copper and zinc metabolism clinical diagnostic products and services.

Through June 30, 2009, we incurred approximately \$41,000 associated with our copper and zinc metabolism clinical diagnostics products and services.

### Products for Subclinical Zinc Deficiency and Chronic Copper Toxicity

Our leading product candidate brands, Zinthionein™ and EyeDaily™ with Zinthionein™, are expected to be products that contain proprietary ingredients (such as, zinc monocyteine complex), proprietary combinations of ingredients, proprietary modified-release zinc-containing formulations and proprietary product packaging. We believe that our technologies and expertise may provide physicians and aging patients with the most timely, convenient, well-tolerated, "best-in-class" product solutions we consider to be an under-recognized, potential multi-billion dollar market to address for the prevention and treatment of degenerative conditions that we believe involve subclinical zinc deficiency and/or chronic copper toxicity.

Zinc-monocyteine is a complex of zinc and the amino acid cysteine that we believe may have improved properties compared to currently marketed zinc-based products. Zinc-monocyteine was invented and developed by David A. Newsome, M.D., President of the Company's subsidiary Healthmine and former Chief of the Retinal Disease Section of the National Eye Institute (NEI). Dr. Newsome was the first to pioneer and demonstrate the benefits of oral high dose zinc therapy in Dry Age-Related Macular Degeneration ("Dry AMD"). Oral high dose zinc containing products now represent the standard of care for Dry AMD affecting over 10 million Americans and have annual sales of approximately \$300 million. Zinc monocyteine has completed an 80-patient, randomized, double-masked, placebo controlled clinical trial in dry AMD and demonstrated highly statistically significant improvements in central retinal function the results of which were published in a peer-reviewed journal in 2008. In addition, we believe that our patent pending modified-release formulations of zinc-monocyteine and other zinc moieties may offer the significant advantages of convenient once-a-day dosing and improved gastrointestinal tolerability compared to currently-marketed oral high dose zinc-containing products.

Our sales and marketing plans include promoting prevention through public awareness, physician and patient education including current research, the research and development, through our Hartlab subsidiary, of potential proprietary diagnostic products to aid in the identification of individuals who may be at increased risk as well as the commercialization of our proprietary zinc-based products intended for the treatment and/or nutritional support of conditions characterized by subclinical zinc deficiency and chronic copper toxicity. Through our Healthmine subsidiary, we launched copperproof.com, a website intended to increase public awareness aimed at the prevention of chronic copper toxicity. Our EyeDaily™ brand of oral zinc-based therapies is expected to utilize patent-pending product packaging that incorporates an eye-self test to improve compliance and convenience of patients with Dry AMD.

Through June 30, 2009, we have incurred approximately \$476,000 of costs related to our development of Zinthionein of which \$154,000 was incurred during 2007, \$256,000 which was incurred in 2008 and \$66,000 which was incurred during the first half of 2009.

#### Oral dnaJP1

In June 2008, we in-licensed Oral dnaJP1, an oral, candidate for the treatment of rheumatoid arthritis (RA) which has completed a 160 patient, multi-center, double-blind, randomized, placebo-controlled Phase II clinical trial for the treatment of RA. Rheumatoid arthritis is an autoimmune disease which affects approximately 20 million people worldwide. Oral dnaJP1 is an epitope specific immunotherapy for RA patients. Oral dnaJP1 is a heat shock protein (hsp)-derived peptide which was previously identified as a contributor of T cell mediated inflammation in RA. Immune responses to hsp are often found at sites of inflammation and have an initially amplifying effect that needs to be down regulated to prevent tissue damage. The mechanisms for this regulation involve T cells with regulatory function that are specific for hsp-derived antigens. This regulatory function is one of the key components of a "molecular dimmer" whose physiologic function is to modulate inflammation independently from its trigger. This function is impaired in autoimmunity and could be restored for therapeutic purposes. Through June 30, 2009, we have incurred approximately \$361,000 of costs related to our development of Oral dnaJP1 of which \$219,000 has been incurred in 2008 and \$142,000 was incurred during the first half of 2009. We are seeking potential U.S. and international corporate partners for the manufacturing, testing and further development of oral dnaJP1.

#### TRIMESTA™ (oral estriol)

In June 2007, a two year seven U.S. center, placebo controlled 150 patient phase IIb clinical trial using TRIMESTA™ 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 IIb clinical trial builds upon our encouraging results from an earlier phase IIa clinical trial. The primary purpose of this study is to evaluate the safety and efficacy of TRIMESTA™ in a larger MS patient population with a one year blinded interim analysis. The preclinical and clinical development of TRIMESTA™ has been primarily financed by grants from the NIH and various non-profit foundations. Through June 30, 2009, we have incurred approximately \$741,000 of costs related to our development of TRIMESTA™ of which approximately \$49,500, \$185,500, 194,000 and \$256,000 was incurred in fiscal years 2005, 2006, 2007 and 2008 respectively, and approximately \$56,000 was incurred in 2009. During 2009, this clinical trial was expanded to include 16 total clinical trial sites.

#### Oral flupirtine

A scientific collaborator of ours has filed and received an IND with the FDA to conduct a phase II clinical trial with flupirtine in fibromyalgia patients. Our scientific collaborator also received institutional review board (IRB) approval to conduct this study. Through June 30, 2009, we have incurred approximately \$112,000 of costs related to our development of flupirtine, of which \$85,000 was incurred during 2007 and \$27,000 was incurred during 2008 and \$0 during 2009. During 2008, we obtained an option to license issued and pending patent applications relating to flupirtine's use in the treatment of ophthalmic indications. We are seeking potential U.S. and international corporate partners for the further development of flupirtine for various indications.

#### Oral TTM (oral tetrathiomolybdate)

Through June 30, 2009, we have incurred approximately \$3,624,000 of costs related to our development of oral TTM, of which approximately \$150,000, \$1,061,000, \$1,676,000 and \$725,000 was incurred in fiscal years 2005, 2006, 2007 and 2008, respectively, and approximately \$12,000 was incurred during 2009.

We are seeking potential U.S. and international corporate partners for the further development of Oral TTM for Wilson's Disease, Alzheimer's disease, Parkinson's disease and Huntington's Disease.

#### Anti-CD4 802-2

Through June 30, 2009, we have incurred \$1,532,000 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, \$121,000 and \$82,000 was incurred in fiscal years 2001, 2002, 2003, 2004, 2005, 2006, 2007 and 2008 respectively and approximately \$67,000 has been incurred in 2009. We are seeking potential U.S. and international corporate partners for the further development of anti-CD4 802-2 for various indications.

Additional Licenses

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

None.

ITEM 4T. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure 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.

(b) 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 June 30, 2009 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

On January 13, 2009, a subsidiary of the Company was served with legal action from an individual regarding payment of past consulting services and associated expenses from 2005. The Company believes the lawsuit is without merit. The Company has engaged legal counsel to respond to this matter.

### 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 our business and 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 June 30, 2009, we have expended approximately \$24.3 million on a consolidated basis acquiring and developing our current product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Therefore, for the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees, and grants. We will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We are not currently profitable and may never become profitable.

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

- continue to undertake pre-clinical development and clinical trials for our product candidates;
- incur sales and marketing expenses associated with our proposed diagnostic products and services;
- 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 Hartlab LLC subsidiary, 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.

We have experienced several management changes.

We have had significant changes in management in the past two years. Effective July 1, 2008, Charles L. Bisgaier resigned as our President and Corporate Secretary and as a director of our Company. Also effective on July 1, 2008, Steve H. Kanzer resigned as our Chief Executive Officer (although he did remain as our Chairman of the Board). Effective July 1, 2008, Nicholas Stergis was appointed our Chief Executive Officer; however effective March 29, 2009, Mr. Stergis resigned his position, but remained a director of the Company. The Board then appointed Steve H. Kanzer as our interim Chief Executive Officer and President. Effective June 26, 2009, Max Lyon was appointed our Chief Executive Officer and President, while Mr. Kanzer remained as Chairman of the Board of the Company. Changes in key positions in our Company, as well as additions of new personnel and departures of existing personnel, can be disruptive, might lead to additional departures of existing personnel and could have a material adverse effect on our business, operating results, financial results and internal controls over financial reporting.

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

We will need FDA approval to commercialize our product candidates in the U.S. and approvals from equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval for any of our product candidates, we must submit to the FDA 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 licensing agreements with third party patent holders/licensors for our products. We have an exclusive license agreement with the McLean Hospital relating to the use of flupirtine to treat fibromyalgia syndrome; an exclusive license agreement with Thomas Jefferson University relating to our CD4 inhibitor program; an exclusive license agreement with the Regents of the University of California relating to our TRIMESTA™ technology; an exclusive license to our oral immunotherapeutic tolerance program, named dnaJP1 from UCSD and an exclusive license agreement with Dr. Newsome and Mr. Tate relating to our Zinthionein 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.

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 and autoimmune diseases include: Pfizer, Inc., Rigil Pharmaceuticals, Incyte Pharmaceuticals, Chelsea Therapeutics International, Inc., Aton Pharma, GlaxoSmithKline Pharmaceuticals, Alcon, Inc., Shire Pharmaceuticals, Plc., Schering-Plough, Organon NV, Merck & Co., Eli Lilly & Co., Serono, SA, Biogen Idec, Inc.,

Achillion, Ltd., Active Biotech, Inc., Panteri Biosciences, Meda, Merrimack Pharmaceuticals, Inc., Merck-Schering AG, Forest Laboratories, Inc., Attenuon, LLC, Cypress Biosciences, Inc., Genentech, Neurotech, Amgen, Inc., Centocor/Johnson and Johnson, UCB Group, Abbott, Wyeth, OM Pharma, Cel-Sci Pharmaceuticals, 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, rheumatoid arthritis, psoriasis, Fibromyalgia, MS, 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, Syk inhibitors, Jak inhibitors, connective tissue growth factors (CTGF), FTY-720, Laquinimod, pifrenidone, milnacipram, Lyrica, anti-depressant combinations, Rituxan, Enbrel, Cimzia, Humira, Remicade, 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, Zinthonin, dnaJP1, CD4 inhibitors and flupirtine technologies. Should clinicians or regulatory authorities view these therapeutic regimens as 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.

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

Since we do not have composition of matter patent claims for, flupirtine and TRIMESTA, others may obtain approvals for other uses of these products which are not covered by our issued or pending patents. For example, the active ingredients in both flupirtine and TRIMESTA have been approved for marketing in overseas countries for different uses. Other companies, including the original developers or licensees or affiliates may seek to develop flupirtine or TRIMESTA or their respective active ingredient(s) for other 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 flupirtine or TRIMESTA in various formulations or delivery systems that might adversely affect our ability to develop and market these products in the US. We are aware that other companies have intellectual property protection using the active ingredients and have conducted clinical trials of flupirtine, and TRIMESTA