ADEONA PHARMACEUTICALS, INC.
Form 10-Q
August 16, 2010

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2010

OR

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

For the transition period from _____ to _____

Commission File Number: 1-12584

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

Nevada (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 x No o

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 o No o

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	Accelerated filer	o
o		
Non-Accelerated filer	Smaller reporting company	x
o		
(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 o No x

As of August 11, 2010, the registrant had 22,837,742 shares of common stock outstanding.

ADEONA PHARMACEUTICALS, INC.

FORM 10-Q
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PART I.—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Adeona Pharmaceuticals, Inc. and Subsidiaries

Consolidated Balance Sheets
(Unaudited)

	June 30, 2010 (Unaudited)	December 31, 2009
Assets		
Current Assets		
Cash	$ 3,270,656	$ 2,715,044
Accounts receivable - net of allowance of $41,628 and $21,481	163,999	30,572
Other	8,176	8,967
Total Current Assets	3,442,831	2,754,583
Property and equipment	816,505	1,051,958
Goodwill	178,229	178,229
Deposits and other assets	90,848	90,848
Total Assets	$ 4,528,413	$ 4,075,618
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 343,256	$ 400,475
Accrued liabilities	199,472	8,163
Current portion of capital lease	17,006	17,006
Total Current Liabilities	559,734	425,644
Long Term Liabilities:		
Accounts payable	122,335	93,000
Capital lease	4,285	12,788
Total Liabilities	686,354	531,432
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 21,726,945 issued and 21,645,463 outstanding and 21,530,834 issued and 21,449,352 outstanding	21,645	21,449
Additional paid-in capital	45,941,235	45,552,918
Deficit accumulated during the development stage	(42,120,821)	(42,013,081)
Subscription Receivable	-	(17,100)

Total Stockholders' Equity		3,842,059		3,544,186
Total Liabilities and Stockholders' Equity	$	4,528,413	$	4,075,618

See accompanying notes to unaudited consolidated financial statements

Adeona Pharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Operations
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Revenues:				
License revenue, net	$ 2,125,000	$ -	$ 2,125,000	$ -
Laboratory revenues, net	69,888	-	129,927	-
Total revenues, net	2,194,888	-	2,254,927	-
Operating Expenses:				
Research and development	562,478	405,645	981,691	901,639
General and administrative	659,127	473,961	1,388,312	1,093,864
Total Operating Expenses	1,221,605	879,606	2,370,003	1,995,503
Income (Loss) from Operations	973,283	(879,606)	(115,076)	(1,995,503)
Other Income (Expense):				
Interest income	148	56	219	2,678
Interest expense	(2,169)	-	(2,169)	-
Other income	8,520	-	9,286	-
Total Other Income (Expense), net	6,499	56	7,336	2,678
Net Income (Loss)	$ 979,782	$ (879,550)	$ (107,740)	$ (1,992,825)
Net Income (Loss) Per Share – Basic	$ 0.05	$ (0.04)	$ (0.00)	$ (0.09)
Weighted average number of common shares outstanding during the period - Basic	21,706,472	21,301,014	21,633,985	21,195,200
Net Income (Loss) Per Share – Dilutive	$ 0.05	$ (0.04)	$ (0.00)	$ (0.09)
Weighted average number of common shares outstanding during the period - Dilutive	21,883,414	21,301,014	23,782.010	21,195,200

See accompanying notes to unaudited consolidated financial statements

Adeona Pharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows
(Unaudited)

	Six months ended June 30, 2010	2009
Cash Flows From Operating Activities:		
Net loss	$ (107,740)	$ (1,992,825)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Recognition of stock-based compensation	236,574	190,243
Stock issued for consulting fees	33,269	55,586
Stock issued as compensation	46,613	-
Stock issued for license fee	-	41,250
Contributed services - related party	-	100,000
Depreciation	180,076	188,226
Provision for uncollectible accounts receivable	20,147	7,785
(Gain) loss on sale of equipment	(3,443)	15,725
Loss on exchange of equipment to settle accounts payable	-	18,674
Changes in operating assets and liabilities:		
Accounts receivable	(153,574)	-
Other receivables	-	(19,960)
Prepaid expenses and other current assets	791	(9,400)
Deposits and other assets	-	(14,000)
Accounts payable	(27,884)	(75,817)
Accrued liabilities	191,309	35,430
Net Cash Provided By (Used In) Operating Activities	416,138	(1,459,083)
Cash Flows From Investing Activities:		
Purchase of property and equipment	(2,070)	-
Proceeds from the sale of equipment	60,890	25,200
Net Cash Provided By Investing Activities	58,820	25,200
Cash Flows From Financing Activities:		
Repayments under capital lease	(8,503)	-
Proceeds from issuance of common stock for stock option exercises	89,157	-
Net Cash Provided By Financing Activities	80,654	-
Net increase (decrease) in cash	555,612	(1,433,883)
Cash at beginning of period	2,715,044	5,856,384
Cash at end of period	$ 3,270,656	$ 4,422,501
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 2,169	$ -

See accompanying notes to unaudited consolidated financial statements

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Adeona Pharmaceuticals, Inc. and Subsidiaries

Notes to Consolidated Financial Statements
(unaudited)

1. Organization

Adeona Pharmaceuticals, Inc. (the "Company" or Adeona"), is a company developing new medicines for serious central nervous system diseases. The Company has five product candidates, four drug candidates and one medical food product candidate in clinical development. Below is a table of Adeona's product candidates, their medical indication(s) and their stage of development.

Program	Medical Indication	Stage of Development
Trimesta (estriol)	Treatment of relapsing remitting multiple sclerosis in women	10-patient, 22-month, single-agent, crossover clinical trial completed, and a 150-patient, 16-center, randomized, double-blind, placebo-controlled clinical trial underway
Effirma (flupirtine)	Treatment of fibromyalgia	Partnered with Meda AB
Zinthionein (zinc cysteine)	Dietary management of Alzheimer's disease and mild cognitive impairment	60-patient, randomized, double-blind, placebo-controlled clinical study underway
dnaJP1 (hsp peptide)	Treatment of rheumatoid arthritis	160-patient, multi-center, randomized, double-blind, placebo-controlled clinical trial completed
ZincMonoCysteine (zinc-monocysteine)	Treatment of dry age-related macular degeneration	80-patient, randomized, double-blind, placebo-controlled clinical trial completed

2. Basis of Presentation

The accompanying unaudited condensed interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and the rules and regulations of the United States Securities and Exchange Commission for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X.

The financial information as of December 31, 2009, is derived from the audited financial statements presented in the Company's Annual Report on Form 10-K for the year ended December 31, 2009. The unaudited condensed interim 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, 2009.

Certain information or footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted, pursuant to the rules and regulations of the Securities and Exchange Commission for interim financial reporting. Accordingly, they do not include all the information and footnotes necessary for a comprehensive presentation of financial position, results of operations, or cash flows. It is management's opinion, however, that all material adjustments (consisting of

normal recurring adjustments) have been made which are necessary for a fair financial statement presentation. The interim results for the period ended June 30, 2010, are not necessarily indicative of results for the full fiscal year.

3. Summary of Significant Accounting Policies

Principles of Consolidation

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

Development Stage

As of June 30, 2010, the Company has emerged from the development stage. According to FASB ASC915-10 a development-stage enterprise is one in which planned principle operations have not commenced or if its operations have commenced, there has been no significant revenue. The Company's primary strategy is to license clinical stage-drug candidates that have already demonstrated a certain level of clinical efficacy and develop them to an inflection point in valuation resulting in a significant development and marketing collaboration. On May 6, 2010, the Company entered into a Sublicense Agreement (the "Meda Agreement") with Meda AB of Sweden ("Meda"). As consideration for such sublicense, the Company received an up-front payment of $2.5 million upon execution of the Meda Agreement. The Company considers the Meda Agreement to be an indication that it has commenced its principal operations and therefore it is not required to report as a development-stage entity.

Use of Estimates

The preparation of consolidated financial statements in conformity with United States generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Such estimates and assumptions impact, among others, the following: the amount allocated to goodwill and other intangible assets, the estimated useful lives for amortizable intangible assets and property, plant and equipment, the fair value of warrants and stock options granted for services or compensation, respectively, estimates of the probability and potential magnitude of contingent liabilities and the valuation allowance for deferred tax assets due to continuing operating losses.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the consolidated financial statements, which management considered in formulating its estimate could change in the near term due to one or more future confirming events. Accordingly, the actual results could differ significantly from our estimates.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are reported at realizable value, net of allowances for doubtful accounts, which is estimated and recorded in the period the related revenue is recorded. The Company has a standardized approach to estimate and review the collectability of its receivables based on a number of factors, including the period they have been outstanding. Historical collection and payer reimbursement experience is an integral part of the estimation process related to allowances for doubtful accounts. In addition, the Company regularly assesses the state of its billing operations in order to identify issues, which may impact the collectability of these receivables or reserve estimates. Revisions to the allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within general and administrative expenses. Receivables deemed uncollectible are charged against the allowance for doubtful accounts at the time such receivables are written-off. Recoveries of receivables previously written-off are recorded as credits to the allowance for doubtful accounts. There were no recoveries during the six months ended June 30, 2010.

Revenue Recognition

The Company records revenue when all of the following have occurred: (1) persuasive evidence of an arrangement exists, (2) the service is completed without further obligation, (3) the sales price to the customer is fixed or determinable, and (4) collectability is reasonably assured. The Company has two streams of revenue, license revenue and laboratory revenue.

License Revenue

On May 6, 2010, the Company entered into a Sublicense Agreement (the “Meda Agreement”) with Meda AB of Sweden (“Meda”). As consideration for the sublicense, the Company received an up-front payment of $2.5 million upon execution of the Meda Agreement. This payment was recorded as license revenue for the three months ended June 30, 2010. Pursuant to the Company’s license agreement with McLean Hospital, the Company paid 15% of the $2.5 million payment ($375,000) to McLean Hospital. The Company is also entitled to additional milestone payments of $5 million upon filing of a New Drug Application with the United States Food and Drug Administration for flupirtine for fibromyalgia and $10 million upon marketing approval. The Meda Agreement also provides that the Company is entitled to receive net royalties of 7% of net sales of flupirtine approved for the treatment of fibromyalgia covered by issued patent claims in the United States and Japan. The Meda Agreement provides that Meda will assume all future development costs for the commercialization of flupirtine for fibromyalgia. Pursuant to the terms of the Company’s agreement with McLean Hospital, the Company is obligated to pay them half of the royalties the Company receives.

Laboratory Revenues

The Company primarily recognizes revenue for services rendered upon completion of the testing process. Billing for services reimbursed by third-party payers, including Medicare and Medicaid, are recorded as revenues, net of allowances for differences between amounts billed and the estimated receipts from such payers.

The Company maintains a sales allowance to compensate for the difference in its billing practices and insurance company reimbursements. In determining this allowance, the Company looks at several factors, the most significant of which is the average difference between the amount charged and the amount reimbursed by insurance carriers over the prior two years, otherwise known as the yearly average adjustment amount. The allowance taken is the averaged yearly average adjustment amount for these prior periods and multiplied by each period’s actual gross sales to determine the actual sales allowance for each period.

The Company generated laboratory revenues from two significant insurance providers for the six months ended June 30, 2010. The Company did not have any revenues in the same period of 2009.

Customer	June 30, 2009	June 30, 2010
A	-	60%
B	-	16%

Risks and Uncertainties

The Company's operations are subject to significant risk and uncertainties including financial, operational, regulatory and other risks, including the potential risk of business failure. The recent global economic crisis has caused a general tightening in the credit markets, lower levels of liquidity, increases in the rates of default and bankruptcy, and extreme volatility in credit, equity and fixed income markets. These conditions not only limit the Company’s access to capital, but also make it difficult for the Company’s customers, the Company’s vendors and the Company to accurately forecast and plan future business activities.

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. As of June 30, 2010, and December 31, 2009, 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 the federally insured limit of $250,000 per depositor, per bank.

Net Income (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. Common equivalent shares, consisting of options and warrants for the purchase of common stock, are not included in the per share calculation where the effect would be anti-dilutive. The Company's share equivalents consist of 2,312,759 stock options and 1,070,472 warrants. The computations of basic and diluted net income (loss) attributable to common share are as follows:

	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Net income (loss)	$ 979,782	$ (879,550)	$ (107,740)	$ (1,992,825)
Basic weighted-average shares	21,706,472	21,301,014	21,633,985	21,195,200
Effect of dilutive securities:				
Stock options	175,527	-	-	-
Warrants	1,415	-	-	-
Dilutive weighted-average shares	21,883,414	21,301,014	21,633,985	21,195,200
Net income (loss) per share:				
Basic	$ 0.05	$ (0.04)	$ (0.00)	$ (0.09)
Dilutive	$ 0.05	$ (0.04)	$ (0.00)	$ (0.09)

Research and Development Costs

The Company expenses research and development costs as incurred. 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.

Fair Value of Financial Instruments

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

Share-Based Payment Arrangements

Generally, all forms of share-based payments, including stock option grants, restricted stock grants and stock appreciation rights are measured at their fair value on the awards' grant date, based on the estimated number of awards that are ultimately expected to vest. Share-based compensation awards issued to non-employees for services rendered are recorded at either the fair value of the services rendered or the fair value of the share-based payment, whichever is more readily determinable. The expense resulting from share-based payments are recorded in cost of goods sold, research and development or general and administrative expenses in the consolidated statement of operations, depending on the nature of the services provided.

Recent Accounting Pronouncements

In January 2010, FASB issued updated guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. This update requires new disclosures on significant transfers of assets and liabilities between Level 1 and Level 2 of the fair value hierarchy (including the reasons for these transfers) and the reasons for any transfers in or out of Level 3. This update also requires a reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition to these new disclosure requirements, this update clarifies certain existing disclosure requirements. For example, this update clarifies that reporting entities are required to provide fair value measurement disclosures for each class of assets and liabilities rather than each major category of assets and liabilities. This update also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. This update will become effective for the interim and annual reporting period beginning January 1, 2010, except for the requirement to provide the Level 3 activity of purchases, sales, issuances, and settlements on a gross basis, which will become effective for the interim and annual reporting period beginning January 1, 2011. The Company will not be required to provide the amended disclosures for any previous periods presented for comparative purposes. Other than requiring additional disclosures, adoption of this update will not have a material effect on the Company's consolidated financial statements.

In April 2010, FASB issued ASU No. 2010-17, Revenue Recognition — Milestone Method (Topic 605): Milestone Method of Revenue Recognition. ASU No. 2010-17 codifies the consensus reached in Emerging Issues Task Force Issue No. 08-9, "Milestone Method of Revenue Recognition." ASU No. 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Consideration that is contingent on achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone is judged to meet certain criteria to be considered substantive. Milestones should be considered substantive in their entirety and may not be bifurcated. An arrangement may contain both substantive and non-substantive milestones, and each milestone should be evaluated individually to determine if it is substantive. ASU No. 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. The Company does not expect the adoption of this ASU to have a material impact on its consolidated results of operations or financial condition.

4. Property and Equipment

Property and Equipment consisted of the following at June 30, 2010, and December 31, 2009.

	June 30, 2010	December 31, 2009
Leasehold improvements	$ 864,429	$ 862,359
Manufacturing equipment	600,625	697,854
Computer and office equipment	234,419	234,419
Laboratory equipment	243,442	243,289
Total	1,942,915	2,037,921
Less accumulated depreciation	(1,126,410)	(985,963)
Property and equipment, net	$ 816,505	$ 1,051,958

During the six months ended June 30, 2010, the Company sold manufacturing equipment, with a net book value of $57,447, for $60,890, resulting in a gain of $3,443.

5. Stockholders' Equity

Common Stock Issuances

During the six months ended June 30, 2010, the Company issued 183,954 shares of common stock, in connection with the exercise of stock options, for proceeds of $72,058. The Company also issued 60,521 shares of common stock for employment service, having a fair value of $46,613 ($0.77 per share) and 33,118 shares of common stock for consulting services, having a fair value of $33,269 ($1.00 per share), based on the quoted closing trading prices.

Stock Incentive Plan

During 2001, Pipex Therapeutics' board of directors and stockholders adopted the 2001 Stock Incentive Plan (the "2001 Stock Plan"). This plan was assumed by Pipex in the October 2006 merger with Sheffield. 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 250,000. All awards pursuant to the 2001 Stock 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, 2010, there were 1,198,670 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. This plan was approved by stockholders on November 2, 2007. 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. 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 250,000.

Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of June 30, 2010, there are 1,114,089 options issued and outstanding under the 2007 Stock Plan.

In the event of an employee's termination, the Company will cease to recognize compensation expense for that employee. 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 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. There were no options issued during the three months ended June 30, 2010. The Black-Scholes assumptions used in the three ended June 30, 2009 and the six months ended June 30, 2010 and 2009 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Exercise Price	-	$0.39 - $0.56	$0.82 - $0.87	$0.39 - $0.56
Expected dividends	-	0%	0%	0%
Expected volatility	-	203.8% - 209%	203% - 204%	203.8% - 209%
Risk free interest rates	-	2.96% - 3.52%	3.59% - 3.63%	2.96% - 3.52%
Expected life options	-	10 years	10 years	10 years
Expected forfeitures	-	0%	0%	0%

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 nine months; and
- one quarter immediate vesting with the remaining over three years.

During the six months ended June 30, 2010, the Company granted 425,000 options to employees and consultants having a fair value of $349,750 based upon the Black-Scholes option pricing model. During the same period of 2009, the Company granted 520,000 options to employees having a fair value of $219,980 based upon the Black-Scholes option pricing model.

A summary of stock option activities as of June 30, 2010, and for the year ended December 31, 2009, is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance – December 31, 2008	2,751,663	$ 1.43		
Granted	979,999	$ 0.50		
Exercised	(104,633)	$ 0.27		
Forfeited or expired	(1,065,697)	$ 1.09		
Balance – December 31, 2009	2,561,332	$ 1.26		
Granted	425,000	$ 0.83		
Forfeited or expired	(489,619)	$ 0.69		
Exercised	(183,954)	$ 0.39		
Balance – June 30, 2010 - outstanding	2,312,759	$ 1.37	6.56 years	$ 761,289

Balance – June 30, 2010 – exercisable	1,851,717	$	1.53	5.85 years	$	591,388

All forfeited and expired options in 2010 relate to employees whose employment has terminated.

The options outstanding and exercisable as of June 30, 2010, are as follows:

	Options Outstanding			Options Exercisable		
Range of Exercise Price	Number outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$ 0.09 - $4.57	2,222,760	3.65 years	$ 1.19	1,763,593	$ 1.31	5.93 years
$ 4.58 - $9.05	89,999	4.26 years	$ 5.93	88,124	$ 5.93	4.20 years
	2,312,759	6.56 years	$ 1.37	1,851,717	$ 1.53	5.85 years

The options outstanding and exercisable as of June 30, 2009, are as follows:

	Options Outstanding			Options Exercisable		
Range of Exercise Price	Number outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$ 0.09 - $4.57	2,283,748	7.24 years	$ 1.18	1,838,744	$ 1.35	6.64 years
$ 4.57 - $9.05	121,770	6.07 years	$ 5.91	102,187	$ 5.91	6.08 years
$ 9.05 - $22.50	3,333	7.53 years	$ 22.50	2,222	$ 22.50	7.53 years
	2,408,851	7.18 years	$ 1.45	1,943,153	$ 1.61	7.18 years

Options of Subsidiary

During 2004 and 2007, CD4 granted 30,000 options. On August 5, 2009, 10,000 of these options expired. As of June 30, 2010, a total of 20,000 options were outstanding and exercisable with an exercise price of $0.20 and a remaining contractual life of 1.87years.

As of June 30, 2010, Epitope has 50,000 options outstanding and 10,000 options exercisable with an exercise price of $0.001 and a remaining contractual life of 8.01 years. 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.

6. Commitments

Employment & Consulting Agreements

On February 6, 2010, James S. Kuo, M.D., M.B.A., was appointed Chairman, Chief Executive Officer and President of Adeona. In connection with his appointment, Dr. Kuo entered into a three-year employment agreement with Adeona (the “Employment Agreement”). Pursuant to the Employment Agreement, Dr. Kuo will be entitled to an annual base salary of $199,000 and will be eligible for discretionary performance and transactional bonus payments. Additionally, Dr. Kuo was granted options 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. Of these options, 100,000

vested immediately upon grant and the remainder will vest pro rata, on a monthly basis, over the following thirty-six months. The fair value of the options totaled $327,680 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 204.5%; risk free interest rate of 3.59% and an expected life of 10 years.

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 has engaged legal counsel to represent the Company in this matter.

7. Subsequent Events

On July 2, 2010, the Company entered into a Common Stock Purchase Agreement (the "Common Stock Purchase Agreement") with Seaside 88, LP, a Florida limited partnership ("Seaside"), relating to the offering and sale (the "Offering") of 1,212,121 shares (the "Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"). The offering price of the Common Stock at the closing was $0.825, which represented a 25% discount from the closing sale price of the Common Stock on June 30, 2010. The Company raised gross proceeds of $1,000,000 at the Closing, before estimated offering expenses of approximately $130,000, which included placement agent fees that have been treated as a direct offering cost. The Offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-166750), which was declared effective by the Securities and Exchange Commission on June 14, 2010. In connection with the Offering, pursuant to a placement agency agreement (the "Placement Agent Agreement") between Enclave Capital LLC ("Enclave") and the Company on July 2, 2010, the Company paid Enclave a cash fee representing 7% or $70,000 of the gross purchase price paid by Seaside for the Shares at the closing. In addition, at the closing, the Company issued to Enclave, or its permitted assigns, a five-year warrant to purchase the number of shares of common stock of the Company equal to 5% of the number of Shares issued to Seaside 88 at such closing, or up to 60,606 shares of Common Stock. Payments to Enclave in cash and warrants are the direct components of direct offering costs. The warrants provide for cashless exercise in the event there is no registration statement covering the underlying warrant shares. The exercise price per share is equal to $1.32. The fair value of these warrants based on the Black-Scholes option-pricing model is approximately $65,000. The announcement of such transaction and accompanying agreements were filed on Form 8-K on July 7, 2010.

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, 2009, 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 this 10-Q and as applicable in Part I, Item 1A of our Annual Report on Form 10K.

Overview

Adeona Pharmaceuticals, Inc., is a company developing new medicines for serious central nervous systems diseases. Our primary strategy is to license clinical-stage drug candidates that have already demonstrated a certain level of clinical efficacy and develop them to a valuation inflection point resulting in a significant development and marketing collaboration. We have five product candidates, four are drug candidates and one is a medical food product candidate in clinical development. Our first product candidate is Trimesta (estriol) for the treatment of relapsing-remitting multiple sclerosis. A randomized, double-blind, placebo-controlled clinical trial is currently underway at 16 centers in the United States. Currently, 97 out of 150 patients have been enrolled. Our second product candidate is Effirma (flupirtine) for the treatment of fibromyalgia syndrome. On May 6, 2010, we entered into a sublicense agreement with Meda AB of Sweden covering all of our patents rights on the use of flupirtine for fibromyalgia. Our third product candidate is Zinthionein ZC (zinc cysteine) for the dietary management of Alzheimer's disease and mild cognitive impairment. A randomized, double-blind, placebo-controlled clinical study is underway at 3 centers in the United States. Currently, 54 out of 60 patients have been enrolled. Our fourth product candidate is dnaJP1 (hsp peptide) for the treatment of rheumatoid arthritis. A 160 patient, multi-center, randomized, double-blind, placebo-controlled clinical trial has been completed. Our fifth product candidate is ZincMonoCysteine (zinc-monocysteine) for the treatment of dry age-related macular degeneration. An 80 patient, randomized, double-blind, placebo-controlled clinical trial has been completed.

Our secondary strategy is to advance our core competency in measuring metabolic serum zinc and copper levels. In furtherance of this strategy, we purchased HartLab, LLC, on July 13, 2009. Recently renamed Adeona Clinical Laboratory, the wholly-owned CLIA-certified clinical testing facility provides a broad array of chemistry and microbiology diagnostic tests in the Greater Chicago area. At Adeona Clinical Laboratory, we developed and offer the CopperProof panel, a series of diagnostic tests for accurately measuring the metabolic serum zinc and copper levels of patients with Alzheimer's disease and mild cognitive impairment. Adeona Clinical Laboratory is a licensed Medicare and Medicaid provider. For the three months ended June 30, 2010, we generated $69,888 of net revenues from clinical testing services.

Our source of liquidity as of June 30, 2010, is cash of $3,270,656. Our projected uses of cash include cash used to fund further clinical development of our drug and medical food candidates, working capital and other general corporate activities. We may also use our cash for the acquisition of businesses, technologies and products that will complement our existing assets.

Effective as of the date of this filing, we emerged from a "Development-Stage Entity" as defined by FASB ASC 915-10. On May 6, 2010, we entered into a sublicense agreement with Meda AB of Sweden. This agreement provides that Meda will assume all future development costs for the commercialization of flupirtine for fibromyalgia. As consideration for such sublicense, we received an up-front payment of $2.5 million and are entitled to milestone payments of $5 million upon filing of a New Drug Application with the United States Food and Drug Administration

of flupirtine for fibromyalgia and $10 million upon marketing approval, plus royalties. We consider the agreement with Meda to be an indication that we have commenced our principal operations and therefore are not required to report as a development-stage entity.

On July 2, 2010, we entered into a Common Stock Purchase Agreement with Seaside 88, LP, a Florida limited partnership, relating to the offering and sale of 1,212,121 shares of common stock, par value $0.001 per share. We raised gross proceeds of $1,000,000, before estimated offering expenses of approximately $130,000, which includes placement agent fees. The Offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-166750), which was declared effective by the Securities and Exchange Commission on June 14, 2010.

We believe that our cash will be sufficient to fund our operations for at least the next 12 months. Therefore, we will need additional capital to continue the development of our other products and programs beyond 12 months. The sale of any equity or debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain financing, we may be required to reduce the scope and timing of the planned clinical and preclinical programs, which could harm our financial condition and operating results.

Therapeutics

Trimesta

Our first product candidate is Trimesta (estriol) for the treatment of relapsing-remitting multiple sclerosis. Estriol is a hormone that is produced by the placenta during pregnancy. Maternal levels of estriol increase in a linear fashion throughout the third trimester of pregnancy until birth, whereupon they abruptly fall to near zero. It has been scientifically documented that pregnant women with certain autoimmune diseases experience a spontaneous reduction of disease symptoms during pregnancy, especially in the third trimester. The PRIMS study (Pregnancy in Multiple Sclerosis), a landmark clinical study published in the New England Journal of Medicine, followed 254 women with multiple sclerosis during 269 pregnancies and for up to one year after delivery. The PRIMS study demonstrated that relapse rates were significantly reduced by 71 percent ($p < 0.001$) through the third trimester of pregnancy from pre-baseline levels and relapse rates then increased by 120 percent ($p < 0.001$) during the first three months post-partum before returning to pre-pregnancy rates. Estriol has been approved and marketed for over 40 years throughout Europe and Asia for the treatment of post-menopausal hot flashes. It has never been approved by the Food and Drug Administration for any indication.

Multiple sclerosis is a progressive neurological disease in which the body loses the ability to transmit messages along central nervous system nerve cells, leading to a loss of muscle control, paralysis, and in some cases, death. According to the National Multiple Sclerosis Society, currently, more than 2.5 million people worldwide (approximately 400,000 patients in the United States), are afflicted with multiple sclerosis. Mainly young adults, ages 20 to 50, and two to three times as many women than men are afflicted. According to the National Multiple Sclerosis Society, approximately 85% of multiple sclerosis patients are initially diagnosed with the relapsing-remitting form, compared to 10-15% with progressive forms. Despite the availability of 7 Food and Drug Administration-approved therapies for the treatment of relapsing-remitting multiple sclerosis, the disease is highly underserved and exacts a heavy economic toll. Multiple sclerosis costs the United States more than $9.5 billion annually in medical care and lost productivity according to the Society for Neuroscience.

An investigator-initiated, 10-patient, 22-month, single-agent, crossover clinical trial was completed in the United States to study the therapeutic effects of 8 mg of oral Trimesta taken daily in nonpregnant female relapsing remitting multiple sclerosis patients. The total volume and number of gadolinium-enhancing lesions was measured by brain magnetic resonance imaging (an established neuroimaging measurement of disease activity in multiple sclerosis) and showed a statistically significant decrease, both in lesion volumes and the number of lesions, during Trimesta treatment compared to baseline and while on drug holiday. During this clinical trial, a statistically significant14-percent improvement from baseline in Paced Auditory Serial Addition Test (PASAT) cognitive testing scores ($p = 0.04$) was also observed in the multiple sclerosis patients at six months of therapy. PASAT is a routine cognitive test performed in patients with a wide variety of neuropsychological disorders such as multiple sclerosis.

A randomized, double-blind, placebo-controlled clinical trial is currently underway at 16 centers in the United States. The purpose of this clinical trial is to study whether 8 mg of oral Trimesta taken daily over a 2 year period would reduce the rate of relapses in a large population of female patients with relapsing remitting multiple sclerosis. Investigators are administering either Trimesta along with glatimer acetate (Copaxone®) injections, a Food and Drug Administration-approved therapy for multiple sclerosis, or a placebo plus glatimer acetate injections to women between the ages of 18 to 50 who have been recently diagnosed with relapsingremitting multiple sclerosis. The primary endpoint is relapse rates at two years with a one year interim analysis using standard clinical measures of multiple sclerosis disability. Currently, 97 out of 150 patients have been enrolled.

The preclinical and clinical development of Trimesta has been primarily financed by a $5 million grant from the National Multiple Sclerosis Society in partnership with the National Multiple Sclerosis Society's Southern California chapter, with support from the National Institutes of Health. In January of 2010, it was announced that an additional

$860,440 in grant funding had been received through the American Recovery and Reinvestment Act allowing the number of clinical sites currently enrolling patients in the clinical study to increase from 7 clinical sites to 16.

Effirma

Our second product candidate is Effirma (flupirtine) for the treatment of fibromyalgia syndrome. Effirma is a selective neuronal potassium channel opener that also has NMDA receptor antagonist properties. Effirma is a non-opioid, non-NSAID, non-steroidal, analgesic. Preclinical data and clinical experience suggest that Effirma should also be effective for neuropathic pain since it acts in the central nervous system via a mechanism of action distinguishable from most marketed analgesics. Effirma is especially attractive because it operates through non-opiate pain pathways, exhibits no known abuse potential, and lacks withdrawal effects. In addition, no tolerance to its antinocioceptive effects has been observed. One common link between neuroprotection, nocioception, and Effirma may be the N-methyl-D-aspartic acid glutamate system, a major receptor subtype for the excitotoxic neurotransmitter, glutamate. Effirma has strong inhibitory actions on N-methyl-D-aspartic acid-mediated neurotransmission. Flupirtine was originally developed by Asta Medica and has been approved in Europe since 1984 for the treatment of pain, although it has never been introduced to the United States market for any indication.

Fibromyalgia is a chronic and debilitating condition characterized by widespread pain and stiffness throughout the body, accompanied by severe fatigue, insomnia and mood symptoms. Fibromyalgia affects an estimated 2-4% of the population worldwide, including an estimated 4 million patients in the United States. There are presently three products approved for this indication in the United States – Lyrica, Cymbalta and Savella. Flupirtine is differentiated from these products in that it employs a unique mode of action. Meda AB of Sweden estimates the United States market for fibromyalgia to be near $1 billion at the time of potential launch of flupirtine.

On May 6, 2010, we entered into a sublicense agreement with Meda that provides that they will assume all future development costs for the commercialization of flupirtine for fibromyalgia. As consideration for such sublicense, we received an up-front payment of $2.5 million and are entitled to milestone payments of $5 million upon filing of a New Drug Application with the United States Food and Drug Administration of flupirtine for fibromyalgia and $10 million upon marketing approval, plus royalties.

Zinthionein

Our third product candidate is Zinthionein (zinc cysteine) for the dietary management of Alzheimer's disease and mild cognitive impairment. Zinthionein is a once-daily, gastroretentive, sustained-release, proprietary, oral tablet formulation of zinc and cysteine. It is being developed as a prescription medical food. All of Zinthionein constituents have GRAS (Generally Regarded as Safe) status. Zinthionein was invented and developed by us to achieve the convenience of once-daily dosing, high bioavailability and to minimize gastrointestinal side effects of oral zinc therapy.

CopperProof-2 is a controlled, randomized, double-blind, placebo-controlled clinical study divided into two parts. Part 1 is a 13-subject, three-arm, single-dose, comparator study in Alzheimer's disease and mild cognitive impairment subjects that compared the tolerability and bioavailability of oral Zinthionein to Galzin®, the only Food and Drug Administration-approved zinc preparation and placebo. Results from Part 1 of the study demonstrated a superior serum zinc bioavailability and a substantially lower incidence of adverse effects in Alzheimer's disease and mild cognitive impairment subjects in favor of Zinthionein compared to Galzin®.

Part 2 of the CopperProof 2 study, underway at 3 centers in the United States, expects to enroll 60 Alzheimer's disease and mild cognitive impairment subjects and randomize them to receive either once-daily oral Zinthionein or matching placebo for six months. Subjects will be assessed at 3 and 6 months for serum parameters of zinc and copper as well as changes in cognitive function using standard clinical tests used in Alzheimer's disease and mild cognitive impairment. Currently, 54 out of 60 patients have been enrolled and we expect completion of this clinical study in the first quarter of 2011.

dnaJP1

Our fourth product candidate is dnaJP1 (hsp peptide) for the treatment of rheumatoid arthritis. dnaJP1 is an epitope-specific immunotherapy for rheumatoid arthritis patients. dnaJP1 is an oral 15-mer heat shock protein-derived peptide that was previously identified as a contributor of T cell-mediated inflammation in rheumatoid arthritis. Immune responses to heat shock protein 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 heat shock protein-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.

Rheumatoid arthritis is an autoimmune disease that afflicts approximately 20 million people worldwide. It is a chronic inflammatory disease that leads to pain, stiffness, swelling and limitation in the motion and function of multiple joints. If left untreated, rheumatoid arthritis can produce serious destruction of joints that frequently leads to permanent disability. Though the joints are the principal body part affected by rheumatoid arthritis, inflammation can develop in other organs as well. The disease currently affects over two million Americans, almost 1% of the population, and is two to three times more prevalent in women than men. Onset can occur at any point in life but is most frequent in the fourth and fifth decades of life, with most patients developing the disease between the ages of 35 and 50. The global market is estimated at over $6.3 billion and disease-modifying antirheumatic drugs, including biologics, accounted for nearly $5 billion of that figure.

In November of 2009, we announced publication of the results of an investigator-initiated, 160-patient clinical trial of dnaJP1 for the treatment of rheumatoid arthritis conducted at 11clinical centers in the United States. The publication, entitled "Epitope-Specific Immunotherapy of Rheumatoid Arthritis: Clinical Responsiveness Occurs With Immune Deviation and Relies on the Expression of a Cluster of Molecules Associated with T Cell Tolerance in a Double-Blind, Placebo-Controlled, Pilot Phase II Trial", can be found in Arthritis & Rheumatism , Vol. 60(11), pages 3207-3216, with related editorial at page A21. The clinical trial sought to test 2 hypotheses 1) whether mucosal induction of immune tolerate to dnaJP1 would lead to a qualitative change from a proinflammatory phenotype to a more tolerogenic functional phenotype and 2) whether immune deviation of responses to an inflammatory epitope might translate into clinical improvement. One hundred sixty patients with active rheumatoid arthritis were randomized to receive oral doses of 25 mg of dnaJP1 or placebo daily for 6 months. This clinical trial was funded by a $5 million grant from the National Institutes of Health and had the following results:

1. dnaJP1 appeared to be safe and well-tolerated;

2. There was a significant reduction in the percentage of T cells producing the proinflammatory cytokine tumor necrosis factor alpha (TNF-alpha) ($p < 0.0007$);

3. The primary efficacy end point (meeting the American College of Rheumatology 20% improvement criteria at least once on day 112, 140, or 168) showed a difference between treatment groups (p = 0.09) that became significant in post hoc analysis using generalized estimating equations (GEE) (p = 0.04).

4. Differences in clinical responses were also found between treatment groups on day 140 and at followup, indicative of a durable response following discontinuation of therapy.

5. Post hoc analysis showed that the combination of dnaJP1 and the commercially available rheumatoid arthritis agent, hydroxychloroquine, was superior to the combination of hydroxychloroquine and placebo, demonstrating potential synergistic effect of dnaJP1 with hydroxychloroquine.

Currently, we are conducting further preclinical activities on dnaJP1 and planning the clinical development strategy.

ZincMonoCysteine

Our fifth product candidate is ZincMonoCysteine (zinc-monocysteine) for the treatment of dry age-related macular degeneration. ZincMonoCysteine is an oral complex of zinc and the amino acid cysteine that we believe may have improved therapeutic properties compared to currently marketed zinc–based nutritional products. ZincMonoCysteine was invented and developed by David A. Newsome, M.D., former Chief of the Retinal Disease Section of the National Eye Institute and our Senior Vice President of Research and Development. Dr. Newsome was the first to pioneer and demonstrate the benefits of oral high dose zinc therapy in dry age-related macular degeneration. Oral high dose zinc containing nutritional products now represent the standard of care for dry age-related macular degeneration affecting over 10 million Americans and have annual sales of approximately $300 million.

ZincMonoCysteine has completed an 80-patient, randomized, double-blind, placebo-controlled clinical trial in dry age-related macular degeneration and demonstrated highly statistically significant improvements in central retinal function. These results were published in a peer-reviewed journal in 2008. We believe that the patent-pending, modified-release oral formulation of ZincMonoCysteine 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. Currently, we are conducting further preclinical activities on ZincMonoCysteine and planning the clinical development strategy.
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Critical Accounting Policies

In December of 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 us. 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.

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 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.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are reported at realizable value, net of allowances for doubtful accounts, which is estimated and recorded in the period the related revenue is recorded. We have a standardized approach to estimate and review the collectability of its receivables based on a number of factors, including the period they have been outstanding. Historical collection and payer reimbursement experience is an integral part of the estimation process related to allowances for doubtful accounts. In addition, we regularly assesses the state of its billing operations in order to identify issues, which may impact the collectability of these receivables or reserve estimates. Revisions to the allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within general and administrative expenses. Receivables deemed uncollectible are charged against the allowance for doubtful accounts at the time such receivables are written-off. Recoveries of receivables previously written-off are recorded as credits to the allowance for doubtful accounts. There were no recoveries during the six months ended June 30, 2010.

Revenue Recognition

We record revenue when all of the following have occurred: (1) persuasive evidence of an arrangement exists, (2) the service is completed without further obligation, (3) the sales price to the customer is fixed or determinable, and (4) collectability is reasonably assured. We have two streams of revenue, license revenue and laboratory revenue.

License Revenue

On May 6, 2010, we entered into a Sublicense Agreement (the "Meda Agreement") with Meda AB of Sweden ("Meda"). As consideration for the sublicense, we received an up-front payment of $2.5 million upon execution of the Meda Agreement. This payment was recorded as license revenue for the three months ended June 30, 2010. Pursuant to our license agreement with McLean Hospital, we paid 15% of the $2.5 million payment ($375,000) to McLean Hospital. We are also entitled to additional milestone payments of $5 million upon filing of a new New Drug Application with the United States Food and Drug Administration for flupirtine for fibromyalgia and $10 million upon marketing approval. The Meda Agreement also provides that we are entitled to receive net royalties of 7% of net sales of flupirtine approved for the treatment of fibromyalgia covered by issued patent claims in the United States and Japan. The Meda Agreement provides that Meda will assume all future development costs for the commercialization of flupirtine for fibromyalgia. Pursuant to the terms of our agreement with McLean Hospital, we are obligated to pay them half of the royalties we receive.

Laboratory Revenue

We primarily recognize revenue for services rendered upon completion of the testing process. Billing for services reimbursed by third-party payers, including Medicare and Medicaid, are recorded as revenues net of allowances for differences between amounts billed and the estimated receipts from such payers.

We maintain a sales allowance to compensate for the difference in its billing practices and insurance company reimbursements. In determining this allowance the company looks at several factors, the most significant of which is the average difference between the amount charged and the amount reimbursed by insurance carriers over the prior two years, otherwise known as the yearly average adjustment amount. The allowance taken is the averaged yearly average adjustment amount for these prior periods and multiplied by each period’s actual gross sales to determine the actual sales allowance for each period.

Results of Operations

Three Months Ended June 30, 2010 and 2009

Revenues, net. Total revenues for the three months ended June 30, 2010 were $2,194,888. Revenues consisted of $2,125,000 from the flupurtine sublicense fee with Meda, which is net of the $375,000 paid to McLean Hospital and $69,888 of laboratory revenues from Adeona Clinical Laboratory. There were no revenues for three months ended June 30, 2009.

Research and Development Expenses. Research and development expenses increased to $562,478 for the three months ended June 30, 2010, from $405,645 for the three months ended June 30, 2009. This increase of 38.7% is primarily the result of increased monthly costs from the acquisition of Adeona Clinical Laboratory in July 2009. Research and development expenses also include a non-cash charge relating to share-based compensation expense of $18,487 for the three months ended June 30, 2010, compared to $63,293 for the three months ended June 30, 2009.

General and Administrative Expenses. General and administrative expenses increased to $659,127 for the three months ended June 30, 2010, from $473,961 for the three months ended June 30, 2009. This increase of 39.1% is

primarily the result of increased legal fees, salary expense and consultant fees. General and administrative expenses also include a non-cash charge relating to share-based compensation expense of $32,460 for the three months ended June 30, 2010, compared to $35,406 for the three months ended June 30, 2009.

Other Income (Expense), net. Other income was $6,499 compared to $56 for the three months ended June 30, 2010 and 2009, respectively. Other income for the three months ended June 30, 2010, included interest income of $148, and $8,520 of other income relating to the sales of miscellaneous non-capital equipment, offset by interest expense of $2,169. Other income for the three months ended June 30, 2009, consisted of $56 in interest income.

Net Profit (Loss). Our net profit was $979,782, or $0.05 per common share for the three months ended June 30, 2010, compared to a net loss of $879,550, or ($0.04) per common share for the three months ended June 30, 2009.

Six Months Ended June 30, 2010 and 2009

Revenues, net. Total revenues for the six months ended June 30, 2010 were $2,254,927. Revenues consisted of $2,125,000 from the flupurtine sublicense fee with Meda, which is net of the $375,000 payment ot McLean Hospital and $129,927 of laboratory revenues from Adeona Clinical Laboratory. There were no revenues for six months ended June 30, 2009.

Research and Development Expenses. Research and development expenses increased to $981,991 for the six months ended June 30, 2010, from $901,639 for the six months ended June 30, 2009. This increase of 8.9% is primarily the result of increased monthly costs from the acquisition of Adeona Clinical Laboratory in July 2009, offset by decreased overhead expenses. Research and development expenses also include a non-cash charge relating to share-based compensation expense of $52,967 for the six months ended June 30, 2010, compared to $119,610 for the six months ended June 30, 2009.

General and Administrative Expenses. General and administrative expenses increased to $1,388,312 for the six months ended June 30, 2010, from $1,093,864 for the six months ended June 30, 2009. This increase of 26.9% is primarily the result of increased salary expense and consultant fees. General and administrative expenses also include a non-cash charge relating to share-based compensation expense of $183,607 for the six months ended June 30, 2010, compared to $70,633 for the six months ended June 30, 2009.

Other Income (Expense), net. Other income was $7,336 compared to $2,678 for the six months ended June 30, 2010 and 2009, respectively. Other income for the six months ended June 30, 2010, included interest income of $219, and $9,286 of other income relating to the sales of miscellaneous non-capital equipment, offset by interest expense of $2,169. Other income for the six months ended June 30, 2009, consisted of $2,678 in interest income.

Net Loss. Our net loss was $107,740, or $0 per common share for the six months ended June 30, 2010, compared to a net loss of $1,992,825, or ($0.09) per common share for the six months ended June 30, 2009.

Liquidity and Capital Resources

We have financed our operations since inception primarily through proceeds from equity financings and various private financings, primarily involving private sales of our common stock and other equity securities, corporate partnering license fee's and to a lesser extent from the proceeds from the sale of our common stock under our registration statement on Form S-3, laboratory testing revenues, miscellaneous equipment sales, which, from inception through June 30, 2010, have totaled approximately $46 million.

Our cash totaled $3,270,656 at June 30, 2010, an increase of $555,612 from December 31, 2009. During the six months ended June 30, 2010, the primary sources of cash were $2,125,000 from the sublicense fee relating to the Meda Agreement, the issuance of common stock from stock option exercises and the proceeds from the sale of equipment. The primary uses of cash during the six months ended June 30, 2010 included working capital requirements and $2,070 in capital equipment additions. Our cash at July 31, 2010 was approximately $3.9 million.

Our continued operations will primarily depend on whether we are able to generate revenues and profits through partnerships, joint ventures or sales of diagnostic clinical laboratory services and/or raising 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 approximately $42.1 million through June 30, 2010. With the exception of this quarter, 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 for at least the next 12 months.

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

- the progress of our research activities;

- the number and scope of our research programs;
- the progress of our pre-clinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to maintain current research and development licensing arrangements 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; and
- profitability of our clinical laboratory diagnostic service business.

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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 4. 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, 2010, 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

None.

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 currently have very minimal product revenues and will need to raise additional capital to operate our business.

With the exception of this quarter, we have experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. To date, other than the licensing fee we received form Meda AB, we have generated very minimal product revenues. As of June 30, 2010, we have expended approximately $31.3 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. If the upfront licensing fee we recently received is not sufficient to sustain our operations, 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 have only recently achieved profitability and may never be able to sustain profitability.

Prior to this quarter, we had a history of losses and we had incurred substantial losses and negative operating cash flow. Even if we succeed in developing and commercializing one or more of our product candidates, we may still incur substantial losses for the foreseeable future and may not sustain profitability. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we do the following:

- continue to undertake pre-clinical development and clinical trials for our product candidates;
- seek regulatory approvals for our product candidates;
- implement additional internal systems and infrastructure;
- lease additional or alternative office facilities; and
- hire additional personnel, including members of our management team.

We may 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 have not yet demonstrated our ability to perform the functions necessary for the successful commercialization of any of our product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

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

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

We have limited experience in commercializing diagnostic testing technologies and therefore we may not be effective in developing and commercializing products.

Many of our technologies, particularly our copper and zinc diagnostic testing technologies, are at an early stage of commercialization. We continue to develop and commercialize new diagnostic products and create new applications for our products through our Adeona Clinical Laboratory subsidiary. We are also researching, developing and pursuing the commercialization of various diagnostic tests for copper and zinc status through Adeona Clinical Laboratory. We have limited or no experience in these applications as well as operating in these markets. You should evaluate us in the context of the uncertainties and complexities affecting an early stage company developing products and applications for the life science industries and experiencing the challenges associated with entering into new markets that are highly competitive. We need to make significant investments to ensure our diagnostic and therapeutic products and applications perform properly and are cost-effective and can be reimbursed by Medicare and other healthcare insurers. There is no assurance that either of these events will occur. Even if we develop products for commercial use, we may not be able to develop products that are accepted in the Alzheimer's disease or other markets that include patients with neurodegenerative diseases.

We may not generate additional revenue from our relationships with our corporate collaborators.

On May 6, 2010 we entered into a sublicense agreement with Meda whereby we may receive milestone payments totaling $17.5 million (including an upfront payment of $2.5 million which has already been received), plus royalties on our flupirtine program. There can be no assurance that Meda will successfully develop flupirtine for fibromyalgia that would allow us to receive such additional $15 million in milestone payments and royalties on sales in connection with such agreement. The successful achievement of the various milestones set forth in the agreement is not within our control and we will be dependent upon Meda for achievement of such milestones.

We may not be able to generate any significant revenue from copper and zinc status tests or any other tests we may develop.

We have committed significant research and development resources to the development of copper and zinc status tests. Although there may be a large potential market for such testing, there is no guarantee that we will successfully generate significant revenues from this or any other tests for any use. We launched through Adeona Clinical Laboratory, our CLIA certified laboratory, a copper and zinc status test panel in November 2009.

However, there is no guarantee that we will be able to successfully market this test panel or other diagnostic tests. If we are not able to successfully market or sell our diagnostic tests we may develop for any reason, we will not generate any revenue from the sale of such tests. Even if we are able to develop diagnostic or other tests for sale in the marketplace, a number of factors could impact our ability to generate any significant revenue from the sale of such tests, including the following:

- reliance on our Adeona Clinical Laboratory operations, which are subject to routine governmental oversight and inspections for continued operation pursuant to CLIA and other regulations;
- our ability to establish and maintain adequate infrastructure to support the commercial launch and sale of our diagnostic tests through our Adeona Clinical Laboratory subsidiary, including establishing adequate laboratory space, information technology infrastructure, sample collection and tracking systems and electronic ordering and reporting systems and other infrastructure and hiring adequate

laboratory and other personnel;
the availability of adequate study samples for validation studies for any diagnostic tests we develop, the success of such validation studies and our ability to publish study results in peer-reviewed journals;
the availability of alternative and competing tests or products and technological innovations or other advances in medicine that cause our technologies to be less competitive;
compliance with federal, state and foreign regulations governing laboratory testing and the sale and marketing of diagnostic or other tests, including copper and zinc; status tests;

the accuracy rates of such tests, including rates of false-negatives and/or false-positives;
concerns regarding the safety effectiveness or clinical utility of our tests;
changes in the regulatory environment affecting health care and health care providers, including changes in laws regulating laboratory testing and/or device manufacturers and any laws regulating diagnostic testing;
the extent and success of our sales and marketing efforts and ability to drive adoption of our diagnostic tests;
coverage and reimbursement levels by government payers and private insurers;
the level of physician and customer adoption of any diagnostic tests we develop;
pricing pressures and changes in third-party payer reimbursement policies;
general changes or developments in the market for Alzheimer's disease diagnostics or diagnostics in general;
ethical and legal issues concerning the appropriate use of the information resulting from Alzheimer's disease diagnostic tests or other tests;
our ability to promote and protect our products and technology; and
intellectual property rights held by others or others infringing our intellectual property rights.

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 until August 20, 2009. 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. Effective February 6, 2010, James S. Kuo, M.D., M.B.A., was appointed our Chairman of the Board, Chief Executive Officer and President and Mr. Lyon resigned from his position as Chief Executive Officer, President and director. 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 only recently acquired our CLIA-certified laboratory and have limited experience operating a diagnostic laboratory. Our ability to successfully develop and commercialize diagnostic tests will depend on our ability to successfully operate our CLIA-certified laboratory and obtain and maintain required regulatory certifications.

In November 2009, we launched a panel of copper and zinc status tests through Adeona Clinical Laboratory, our CLIA-licensed clinical reference laboratory located in Bolingbrook, IL. We acquired Adeona Clinical Laboratory in July 2009. Because there is substantial distance between Adeona Clinical Laboratory and our corporate headquarters in Ann Arbor, Michigan, we may have logistical and operational challenges in effectively managing and operating Adeona Clinical Laboratory. If we are unable to successfully to commercialize our serum based copper and zinc diagnostic test panels through Adeona Clinical Laboratory, we may not be able to achieve significant revenues and profitability with respect to such activities. Our ability to successfully develop and commercialize diagnostic tests will depend on our ability to successfully operate Adeona Clinical Laboratory and obtain and maintain required regulatory approvals.

As a clinical laboratory, Adeona Clinical Laboratory is subject to CLIA regulations, which are designed to ensure the quality and reliability of clinical laboratories by mandating specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. Adeona Clinical Laboratory is also subject to regulation of laboratory operations under state clinical laboratory laws. State clinical laboratory laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. Certain states, including Maryland, New York, Pennsylvania and Rhode Island, each require that you obtain licenses to test specimens from patients residing in those states and additional states may require similar licenses in the future. If we are unable to obtain licenses from these states or there is delay in obtaining such licenses, we will not be able to process any samples from patients located in those states until we have obtained the requisite licenses. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could adversely affect our business and results of operations.

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

We will need FDA approval to commercialize some of our product candidates in the United States 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.

Our diagnostic tests are subject to changes in CLIA, FDA and other regulatory requirements.

We initially plan to develop assays and commercialize our tests in the form of laboratory developed tests (LDTs) through Adeona Clinical Laboratory, our CLIA-certified laboratory. Although LDT testing is currently solely under the purview of CMS and state agencies who provide oversight of the safe and effective use of LDTs, the FDA and the United States Department of Health and Human Services have been reviewing their approach to regulation in the area of LDTs, and the laws and regulations may undergo change in the near future. Although we have no current plans to utilize in our LDT strategy analyte specific reagents (ASRs) or In Vitro Diagnostic Multivariate Index Assay (IVDMIAs), which have been the focus of recent reforms and enforcement actions by the FDA, we cannot predict the extent of the FDA's future regulation and policies with respect to LDTs. Concurrently with our LDT commercialization activities, we may conduct the development, validation, and other activities necessary to file submissions with the FDA seeking approval for selected diagnostic tests. If we are unable to successfully launch any diagnostic tests as LDTs or if we are otherwise required to obtain FDA premarket clearance or approval prior to commercializing any diagnostic tests or maintain Adeona Clinical Laboratory's CLIA-certified laboratory status, our ability to generate revenue from the sale of such tests may be delayed and we may never be able to generate significant revenues from sales of diagnostic products.

If the medical relevance of copper and zinc status is not demonstrated or is not recognized by others, we may have less demand for our products and services and may have less opportunity to enter into diagnostic product development and commercialization collaborations with others.

Some of the products we have developed and additional products that we hope to develop involve new and unproven approaches or involve applications in markets that we are only beginning to explore. They are based on the assumption that information about the roles of copper and zinc in the progression and development of neurodegenerative diseases such as Alzheimer's disease, dementia and mild cognitive impairment may help scientists

and clinicians better understand and treat conditions or complex disease processes. We cannot be certain that this type of information will play a key role in the development of diagnostics or other products in the future, or that any of our findings would be accepted by clinicians, researchers or by any other potential market or industry partner or customer. If we are unable to generate additional valuable information and data about the usefulness of copper and zinc status testing, the demand for our products, applications, and services will be reduced and our business will be harmed.

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 which was recently sublicensed to Meda; 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 University of California San Diego (UCSD) and an exclusive license agreement with Dr. Newsome and Mr. Tate relating to zinc-monocysteine. Each of these agreements requires us or our sublicensee 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 or our sublicensee 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. In addition, in order to maintain this license agreement in effect our agreement with UCSD required our Epitope subsidiary to expend at least $400,000 on the development of oral dnaJP1 for the period comprising July 1, 2009, through June 30, 2010, and to secure access to $2.5 million in funds on or before June 30, 2010, which it did as well as to make other payments. Our license agreement with the University of Michigan relating to tetrathiomolybdate which required that we manufacture cGMP material and support the filing of an investigational new drug application (IND) with the FDA on or before the first half of 2010 in order to maintain this license agreement in effect. We failed to meet those milestones and consequently voluntarily elected to terminate our license with the University of Michigan for terathiomolybdate.

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, Rigel Pharmaceuticals, Incyte Pharmaceuticals, Chelsea Therapeutics International, Aton Pharma, GlaxoSmithKline Pharmaceuticals, Alcon, Shire Pharmaceuticals, Schering-Plough, Organon, Merck & Co., Eli Lilly & Co., Serono, Biogen Idec, Achillion, Active Biotech, Panteri Biosciences, Meda, Merrimack Pharmaceuticals, Merch-Schering, Forest Laboratories, Attenuon, Cypress Biosciences, Genentech, Neurotech, Amgen, Centocor/Johnson and Johnson, UCB Group, Abbott, Wyeth, OM Pharma, Cel-Sci Pharmaceuticals, Novartis, Axcan Pharma, Teva Pharmaceuticals, Intermune, Fibrogen, Active Biotech, CNSBio, Rare Disease Therapeutics, Prana Biotechnology, Merz & Co., AstraZeneca Pharmaceuticals, Chiesi Pharmaceuticals, Alcon, Bausch and Lomb, Targacept, and Johnson & Johnson. Alternative technologies or alternative delivery or dosages of already approved therapies are being developed to treat dry AMD, autoimmune inflammatory, rheumatoid arthritis, psoriasis, fibromyalgia, multiple sclerosis, 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, pirfenidone, 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, ZincMonoCysteine, Zinthionein gastro-retentive sustained release oral high dose zinc preparations, oral dnaJP1, CD4 inhibitors and flupirtine technologies. Should clinicians or regulatory authorities view these therapeutic regiments 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. No assurance can be given that our current clinical trial of once daily Zinthionein for the dietary management of Alzheimer's and mild cognitive impairment will prove to be safe and effective.

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

Since we do not have composition of matter patent claims for flupirtine and estriol, others may obtain approvals for other uses of these products that are not covered by our issued or pending patents. For example, the active ingredients in both Effirma and Trimesta have been approved for marketing in overseas countries for different uses. Other companies, including the original developers or licensees or affiliates may seek to develop Effirma or Trimesta or their respective active ingredient(s) for other uses in the United States 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 estriol in various formulations or delivery systems that might adversely affect our ability or the ability of our sublicensee to develop and market these products in the United States. We are aware that other companies have intellectual property protection using the active ingredients and have conducted clinical trials of flupirtine and estriol for different applications than what we are developing. Many of these companies may have more resources than us. Should a competitor obtain FDA approval for their product for any indication prior to us, we might be precluded under the Waxman-Hatch Act to obtain approval for our product candidates for a period of five years. We cannot provide any assurances that our products will be FDA approved prior to our competitors.

If the FDA approves other products containing our active ingredients to treat indications other than those covered by our issued or pending patent applications, physicians may elect to prescribe a competitor's products to treat the diseases for which we are developing—this is commonly referred to as "off-label" use. While under FDA regulations a competitor is not allowed to promote off-label uses of its product, the FDA does not regulate the practice of medicine and, as a result, cannot direct physicians as to which source it should use for these products they prescribe to their patients. Consequently, we might be limited in our ability to prevent off-label use of a competitor's product to treat the diseases we are developing, even if we have issued patents for that indication. If we are not able to obtain and enforce these patents, a competitor could use our products for a treatment or use not covered by any of our patents. We cannot provide any assurances that a competitor will not obtain FDA approval for a product that contains the same active ingredients as our products.

Our oral Zinthionein product candidate does not contain the patented ingredient zinc-monocysteine and is instead the subject of pending United States and international patent applications in initially filed in January 2006 (see. U.S. Ser. No 11/621,962), which may not provide substantial protection from competitive products until, if and when, such pending patents issue, if at all. As a prescription medical food, no regulatory protection is afforded through FDA regulations to prevent others from marketing similar products. No assurance can be given that our current clinical trial of once daily Zinthionein for the dietary management of Alzheimer's and mild cognitive impairment will achieve superior or sufficient safety and efficacy in order to achievea significant sales. Similarly, the CopperProof Test Panel offered by our Adeona Clinical Labs subsidiary is the subject of pending patent applications that are expected to require a substantial amount of time to issue in order to provide protection from potential competitors.

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

Our competitiveness may be adversely affected if we are unable to protect our proprietary technologies. Other than our CD4 inhibitor, oral dnaJP1 and ZincMonoCysteine program, we do not have composition of matter patents for Trimesta or Effirma, or their respective active ingredients estriol and flupirtine. We rely on issued patent and pending patent applications for use of Trimestato treat multiple sclerosis (issued United States Patent No. 6,936,599) and various other therapeutic indications which have been exclusively licensed to us. We have exclusively licensed issued United States Patent No. 5,773,570, 6,153,200, 6,946,132, 6,989,146, 7,094,597, 7,301,005, including foreign equivalents along with several patent applications which cover dnaJP1, related compositions methods and uses; we have also exclusively licensed an issued patent for the treatment of fibromyalgia with flupirtine, which we have sublicensed to Meda.

Our ZincMonoCysteine product candidate is exclusively licensed from its inventors, David A. Newsome, M.D., and David Tate, Jr. ZincMonoCysteine is the subject of two issued United States patents, 7,164,035 and 6,586,611 and pending United States patent application ser. no. 11/621,380 which covers composition of matter claims. In our annual report on Form 10-KSB for the year ending December 31, 2007 that was filed March 31, 2008 (page 23), we described our receipt in March 2008 (and potential impact on claim 1 of our exclusively licensed issued United States patent 7,164,035) of an English translation of a Russian disclosure, Zegzhda et. al. Chemical Abstracts Vol. 85 Abstract No. 186052 (1976) that was cited by the United States patent examiner during our prosecution of the pending divisional United States patent application Ser. No. 11/621,390. In April 2008, we analyzed the zinc-cysteine complex described by Zegzhda and concluded that such complex describes an insoluble zinc salt and does not describe a non-zinc salt zinc monocyteine complex and therefore believe that such disclosure should not affect the validity of any of our issued United States patent claims relating our zinc-monocysteine composition-of-matter claims. We have filed a response and declaration describing the results of our analysis with the United States Patent and Trademark Office with respect to the Zegzhda reference with respect to United States patent application ser. no. 11/621,380. In an office action dated August 20, 2008, the United States patent examiner did not accept our arguments filed May 23, 2008 in connection with the Zegzhda reference under pending divisional application ser. no. 11/621,390, to which we intend to respond. Public copies of relevant and future communications can be obtained using the electronic PAIR system of the United States Patent and Trademark Office.

Our Zinthionein (gastro-retentive sustained zinc and cysteine tablets) are the subject of United States and international pending patent applications, such as published United States patent application Ser. No. 11/621,962 and corresponding international applications that claim priority to Jan. 10, 2006 as well as additional unpublished patent applications. Such patent applications have not yet been the subject of substantive review by the United States Patent and Trademark Office or corresponding international patent offices. No assurance can be given that such pending patent applications will issue or issue with claims satisfactorily broad enough to prevent others from developing and marketing competing products.

The patent positions of pharmaceutical companies are uncertain and may involve complex legal and factual questions. We may incur significant expense in protecting our intellectual property and defending or assessing claims with respect to intellectual property owned by others. Any patent or other infringement litigation by or against us could cause us to incur significant expense and divert the attention of our management.

We may also rely on the United States Drug Price Competition and Patent Term Restoration Act, commonly known as the “Hatch-Waxman Amendments,” to protect some of our current product candidates, specifically dnaJP1, Trimesta, ZincMonoCysteine, CD4 inhibitor, flupirtine and other future product candidates we may develop. Once a drug containing a new molecule is approved by the FDA, the FDA cannot accept an abbreviated NDA for a generic drug containing that molecule for five years, although the FDA may accept and approve a drug containing the molecule

pursuant to an NDA supported by independent clinical data. Recent amendments have been proposed that would narrow the scope of Hatch-Waxman exclusivity and permit generic drugs to compete with our drug.

We may also rely on the United States Drug Price Competition and Patent Term Restoration Act, commonly known as the “Hatch-Waxman Amendments,” to protect some of our current product candidates, specifically dnaJP1, Trimesta, ZincMonoCysteine, CD4 inhibitor, flupirtine and other future product candidates we may develop. Once a drug containing a new molecule is approved by the FDA, the FDA cannot accept an abbreviated NDA for a generic drug containing that molecule for five years, although the FDA may accept and approve a drug containing the molecule pursuant to an NDA supported by independent clinical data. Recent amendments have been proposed that would narrow the scope of Hatch-Waxman exclusivity and permit generic drugs to compete with our drug.
Others may file patent applications or obtain patents on similar technologies or compounds that compete with our products. We cannot predict how broad the claims in any such patents or applications will be, and whether they will be allowed. Once claims have been issued, we cannot predict how they will be construed or enforced. We may infringe intellectual property rights of others without being aware of it. If another party claims we are infringing their technology, we could have to defend an expensive and time consuming lawsuit, pay a large sum if we are found to be infringing, or be prohibited from selling or licensing our products unless we obtain a license or redesign our product, which may not be possible.

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

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

As of June 30, 2010, we have 10 full-time employees. We have also engaged regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. Our future performance will depend in part on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management.

Certain of our directors, (Jeffrey Kraws, a director and former VP of Business Development, Jeffrey Wolf, a director, Mr. Kanzer, a director and former Chairman and CEO, and Mr. Riley, a director) scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies that might be developing competitive products to ours. Other than corporate opportunities, none of our directors are obligated under any agreement or understanding with us to make any additional products or technologies available to us. Similarly, we can give no assurances, and we do not expect and stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by any of our directors or affiliates in the future would be made available to us other than corporate opportunities.

We can give no assurances that any such other companies will not have interests that are in conflict with our interests.

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

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

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

In order to successfully commercialize our product candidates, we and our sublicensees must be able to manufacture our products in commercial quantities, in compliance with regulatory requirements, at acceptable costs, and in a timely manner. Manufacture of the types of biopharmaceutical products that we propose to develop present various risks. For example, the manufacture of zinc-monocysteine, dnaJP1, and flupirtine is a complex process that can be difficult to scale up for purposes of producing large quantities. This process can also be subject to delays, inefficiencies, and poor or low yields of quality products. Furthermore, zinc-monocysteine has been difficult to scale up at larger quantities. As such, we can give no assurances that we will be able to scale up the manufacturing of zinc-monocysteine. The active ingredient of our dnaJP1 program is a peptide. Traditionally, peptide manufacturing is costly, time consuming, resulting in low yields and poor stability. We cannot give any assurances that we will not encounter this issue when scaling up manufacturing for dnaJP1. We are developing proprietary formulations and specialty packaging solutions to overcome this stability issue, but we can give no assurances that we will be successful in meeting the stability requirements required for approval by regulatory authorities such as the FDA or the requirements that our new proprietary formulations and drug product will demonstrate satisfactory comparability to less stable formulations utilized in prior clinical trials. We may experience delays in demonstrating satisfactory stability requirements and drug product comparability requirements that could delay our planned clinical trials of for any of our products.

For manufacturing and nonclinical information for Trimesta, we have relied upon an agreement with Organon, a division of Schering-Plough for access to clinical, nonclinical, stability and drug supply relating to estriol, the active ingredient in Trimesta, which is currently in a clinical trial for multiple sclerosis. Should Organon terminate our agreement or be unable or unwilling to continue to supply Trimesta to us, this might delay enrollment and

commercialization plans for our Trimesta clinical trial program. Organon has manufactured estriol the active ingredient of Trimesta for the European and Asian market for approximately 40 years but has never been approved in the United States. Organon has recently informed us of their decision to discontinue supply of estriol tablets beyond that required to satisfy the planned future needs of the ongoing clinical trial in relapse remitting multiple sclerosis. Accordingly, prior to initiation of additional clinical studies and/or commercial launch of oral estriol, we may need to identify and execute supply agreement(s) on terms suitable to us with an alternate supplier of estriol tablets.

Our plans to launch oral Zinthionein as a prescription medical food for the dietary management zinc deficiency in Alzheimer's disease and mild cognitive impairment will depend upon the successful cGMP manufacture, quality control and acceptable results of stability studies to be performed for Zinthionein for which we are utilizing and intend to engage third party contract manufacturers and analytic testing services, as well as the successful completion and results of the Part 2 of our CopperProof-2 clinical trial being conducted at three centers in Florida.

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

In addition, any contract manufacturer that we select to manufacture our product candidates might fail to maintain a current "good manufacturing practices" (cGMP) manufacturing facility. During February 2007, we established a manufacturing facility in Ann Arbor, MI and we are currently seeking to sublease some or all of our excess office, laboratory and manufacturing space. In March 2009, our building control systems for clean rooms and associated air handling equipment were removed and sold which might affect our ability to re-achieve cGMP status for our facility.

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

The manufacture of our products is a highly exacting process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We or our materials suppliers may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

If our laboratory facilities are damaged, our business would be seriously harmed.

Our only laboratory facility for copper and zinc testing products and general reference lab services is located in Bolingbrook, IL. Damage to our facilities due to war, fire, natural disaster, power loss, communications failure, terrorism, unauthorized entry, or other events could prevent us from conducting our business for an indefinite period, could result in a loss of important data or cause us to cease development and production of our products. We cannot be certain that our limited insurance to protect against business interruption would be adequate or would continue to be available to us on commercially reasonable terms, or at all.

If the parties we depend on for supplying our drug substance raw materials and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products.

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards and use in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for

our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

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

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

- unforeseen safety issues;
- determination of dosing;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

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

The results of our clinical trials may not support our product candidate claims and the results of preclinical studies and completed clinical trials are not necessarily predictive of future results.

To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our diagnostic product candidates. Favorable results in our early studies or trials may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product-candidate claims. Success in pre-clinical testing and phase II clinical trials does not ensure that later phase II or phase III clinical trials will be successful. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and pre-clinical testing. In particular, the limited results that we have obtained for our diagnostic tests may not predict results from studies in larger numbers of subjects drawn from more diverse populations over a longer period of time. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. Any such failure could cause us or our sublicensee to abandon a product candidate and might delay development of other product candidates. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Any delay in, or termination of, our clinical trials would delay our obtaining FDA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

Physicians and patients may not accept and use our technologies.

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

- the perception of members of the health care community, including physicians, regarding the safety and effectiveness of our drugs;
- the cost-effectiveness of our product relative to competing products;
- availability of reimbursement for our products from government or other healthcare payers; and
- the effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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

We depend on third parties, including researchers and sublicensees, who are not under our control.

Since we have in-licensed some of our product candidates and have sublicensed a product candidate, we depend upon our sublicensee and independent investigators and scientific collaborators, such as universities and medical institutions or private physician scientists, to conduct our pre-clinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs or the timing of their procurement of clinical-trial data or their compliance with applicable regulatory

guidelines. Should any of these scientific inventors/advisors or those of our sublicensee become disabled or die unexpectedly, or should they fail to comply with applicable regulatory guidelines, we or our sublicensee may be forced to scale back or terminate development of that program. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking those programs ourselves. Failing to devote sufficient time and resources to our drug-development programs, or substandard performance and failure to comply with regulatory guidelines, could result in delay of any FDA applications and our commercialization of the drug candidate involved.

These collaborators may also have relationships with other commercial entities, some of which may compete with us. Our collaborators assisting our competitors at our expense could harm our competitive position. For example, we are highly dependent on scientific collaborators for our Trimesta, zinc-monocysteine, CD4 Inhibitor 802-2 and flupirtine development programs. Specifically, all of the clinical trials have been conducted under physician-sponsored investigational new drug applications (INDs), not corporate-sponsored INDs. Generally, we have experienced difficulty in collecting data generated from these physician-sponsored clinical trials for our programs. We cannot provide any assurances that we will not experience any additional delays in the future. For example, the clinical trials for oral TTM have been conducted and completed prior to us licensing this technology from the University of Michigan. Due to various patient privacy regulations and other administrative matters, we had experienced delays and/or an inability to obtain clinical trial data relating to oral TTM. We have also experienced similar difficulties with our zinc-monocysteine and dnaJP1 programs. With respect to our dnaJP1 program, we have recently elected to pursue the filing of a new corporate IND through our Epitope subsidiary, for the further clinical testing of our oral dnaJP1 and to eliminate our reliance on the scientific inventor/IND holder for this program. Unless we are able to negotiate an agreement whereby such inventor/IND holder agrees to allow us to cross-reference the IND held by such inventor/IND holder, our planned corporate IND filing will most likely require us to successfully perform necessary nonclinical studies prior to initiating further human clinical trials. Such additional nonclinical studies may be required even if we successfully conclude an IND cross-reference agreement with such inventor/IND holder. No assurance can be given that we will be able to obtain necessary FDA authorization to initiate clinical pursuant to any proposed corporate IND that may be filed. Our license agreement with University of California for dnaJP1 requires that initiate patient dosing in a phase II clinical trial before the end of 2010 in order to maintain the license in effect. We may not be able to achieve such milestone in and may our license agreement may become subject to termination. Our initial clinical collaborator for oral TTM for Wilson’s disease, has retired from University of Michigan, will no longer participate as a clinical investigator and no longer has an IND for oral TTM. We do not plan to conduct any further clinical studies of oral TTM. Our license agreement with University of Michigan required that we obtain an IND to conduct a clinical trial with oral TTM before July 2010 in order to maintain our license agreement. Since we do not wish to file such an IND for oral TTM, on August 13, 2010 we sent written notice to University of Michigan informing them of same and terminating such license.

We are also highly dependent on government and private grants to fund certain of our clinical trials for our product candidates. For example, Trimesta (estriol) has received a $5 million grant from the Southern California Chapter of the National Multiple Sclerosis Society and the National Institutes of Health which funds a majority of our ongoing 150 patient phase IIb clinical trial in relapsing-remitting multiple sclerosis. If our scientific collaborator is unable to maintain these grants, we might be forced to scale back or terminate the development of this product candidate. We will also need to cross reference our IND with the inventor/IND holder for this program should we elect to file our own corporate IND for our Trimesta (estriol) program.

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

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

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

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

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

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

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

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

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

- developing drugs;

undertaking pre-clinical testing and human clinical trials;
obtaining FDA and other regulatory approvals of drugs;
formulating and manufacturing drugs; and
launching, marketing and selling drugs.

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

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

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

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

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

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

Our products, if approved, may not be commercially viable due to change in health care practice and third party reimbursement limitations

Recent initiatives to reduce the federal deficit and to change health care delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, price controls on pharmaceuticals, and other fundamental changes to the health care delivery system. Any changes of this type could negatively impact the commercial viability of our products, if approved. Our ability to successfully commercialize our product candidates, if they are approved, will depend in part on the extent to which appropriate reimbursement codes and authorized cost reimbursement levels of these products and related treatment are obtained from governmental authorities, private health insurers and other organizations, such as health maintenance organizations. In the absence of national Medicare coverage determination, local contractors that administer the Medicare program may make their own coverage decisions. Any of our product candidates, if approved and when commercially available, may not be included within the then current Medicare coverage determination or the coverage determination of state Medicaid programs, private insurance companies or other health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

We do not currently have product liability or malpractice insurance and may not be able to obtain adequate insurance coverage against product liability claims.

Our business exposes us to potential product liability and other types of claims and our exposure will increase as we prepare to commercialize our copper and zinc status tests. We do not currently have any product liability or malpractice insurance that would cover us against any product liability, or malpractice claims. Any such claim would have to be paid out of our cash reserves, which would have a detrimental effect on our financial condition. Even if it is available, product liability insurance for the pharmaceutical and biotechnology industry generally is expensive. Adequate insurance coverage may not be available at a reasonable cost. We cannot assure you that we can or will be

able to obtain product liability or malpractice insurance policies on commercially acceptable terms, or at all.

RISKS RELATING TO OUR STOCK

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

We expect to seek to raise additional capital in the future to help fund development of our proposed products. If we raise additional capital through the issuance of equity (as we recently did in connection with our sale of securities under our registration statement on Form S-3) or debt securities, the percentage ownership of our current stockholders will be reduced. We may also enter into strategic transactions, issue equity as part of license issue fees to our licensors, compensate consultants or settle outstanding payables using equity that may be dilutive. Our stockholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our common stock. If we cannot raise additional funds, we will have to delay development activities of our products candidates.

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

Currently, our directors, executive officers, and principal stockholders beneficially own a majority of our common stock. As a result, they will be able to exert substantial influence over the election of our board of directors and the vote on issues submitted to our stockholders. As of June 30, 2010, our officers, directors and principal stockholders beneficially owned approximately 8.4 million shares of our common stock, which number excludes shares of common stock issuable upon the exercise of warrants held by our officers, directors and principal stockholders. Because our common stock has from time to time been “thinly traded”, the sale of these shares by our officers, directors and principal stockholders could have an adverse effect on the market for our stock and our share price.

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

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

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

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

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

We cannot assure you that we will be able to maintain the listing standards of the NYSE Amex formerly the American Stock Exchange or NYSE Alternext US. The NYSE Amex requires companies to meet certain continued listing criteria including certain minimum stockholders' equity and equity prices per share as outlined in the Exchange Company Guide. We may not be able to maintain such minimum stockholders' equity or prices per share or may be required to affect a reverse stock split to maintain such minimum prices and/or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSE Amex. If we are delisted from the Exchange then our common stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our common stock could further depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the Exchange could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest

and fewer business development opportunities. In order to remain listed on NYSE Amex, we are required to maintain a minimum stockholders' equity of $4 million and this requirement may increase to $6 million in 2011.

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

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

We have never paid dividends.

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

RISKS RELATED TO OUR INDUSTRY

We are subject to government regulation, compliance with which can be costly and difficult.

In the United States, the formulation, manufacturing, packaging, storing, labeling, promotion, advertising, distribution and sale of our products are subject to regulation by various governmental agencies, including (1) the Food and Drug Administration, or FDA, (2) the Federal Trade Commission, or FTC, (3) the Consumer Product Safety Commission, or CPSC, (4) the United States Department of Agriculture, or USDA. Our proposed activities may also be regulated by various agencies of the states, localities and foreign countries in which our proposed products may be manufactured, distributed and sold. The FDA, in particular, regulates the formulation, manufacture and labeling of over-the-counter, or OTC, drugs, conventional foods, dietary supplements, and cosmetics such as those that we intend to distribute. FDA regulations require us and our suppliers to meet relevant current good manufacturing practice, or cGMP, regulations for the preparation, packing and storage of foods and OTC drugs. As a result of inactivity and the removal and sale of certain equipment, our facility in Ann Arbor, Michigan is no longer currently cGMP compliant.

The United States Dietary Supplement Health and Education Act of 1994, or DSHEA, revised the provisions of the Federal Food, Drug and Cosmetic Act, or FFDCA, concerning the composition and labeling of dietary supplements and, we believe, the revisions are generally favorable to the dietary supplement industry. The legislation created a new statutory class of dietary supplements. This new class includes vitamins, minerals, herbs, amino acids and other dietary substances for human use to supplement the diet, and the legislation grandfathers, with some limitations, dietary ingredients that were on the market before October 15, 1994. A dietary supplement that contains a dietary ingredient that was not on the market before October 15, 1994 will require evidence of a history of use or other evidence of safety establishing that it is reasonably expected to be safe. Manufacturers or marketers of dietary supplements in the United States and certain other jurisdictions that make product performance claims, including structure or function claims, must have substantiation in their possession that the statements are truthful and not misleading. The majority of the products marketed by us in the United States are classified as conventional foods or dietary supplements under the FFDCA. Internationally, the majority of products marketed by us are classified as foods or food supplements.

In January 2000, the FDA issued a regulation that defines the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body pursuant to DSHEA. Under DSHEA, dietary supplement labeling may bear structure or function claims, which are claims that the products affect the structure or function of the body, without prior FDA approval, but with notification to the FDA. They may not bear a claim that they can prevent, treat, cure, mitigate or diagnose disease (a disease claim). The regulation describes how the FDA distinguishes disease claims from structure or function claims. During 2004, the FDA issued guidance, paralleling an earlier guidance from the FTC, defining a manufacturer's obligations to substantiate structure/function claims. The FDA also issued a Structure/Function Claims Small Entity Compliance Guide. In addition, the agency permits companies to use FDA-approved full and qualified health claims for products containing specific ingredients that meet stated requirements.

In order to make disease claims, we may seek to market some our proposed products as medical foods for the dietary management of certain diseases. Medical foods are defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered internally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." Although we believe our products may qualify as medical foods provided we are able to generate, and have published, sufficient clinical data to support such claims. Medical foods are required to be utilized under a medical doctor’s supervision and as such, our distribution channels may be limited and/or complicated.

Should we seek to make disease claims beyond those permitted for medical foods, we may seek to conduct necessary clinical trials to support such claims and file one or more New Drug Applications with respect to such products which would be the subject of the time, expense and uncertainty associated with achieving approval of such NDA by the FDA.

On December 22, 2007, a new law went into effect in the United States mandating the reporting of all serious adverse events occurring within the United States which involve dietary supplements or OTC drugs. We believe that in order to be in compliance with this law we will be required to implement a worldwide procedure governing adverse event identification, investigation and reporting. As a result of our receipt of adverse event reports, we may from time to time elect, or be required, to remove a product from a market, either temporarily or permanently.

Some of the products marketed by us are considered conventional foods and are currently labeled as such. Within the United States, this category of products is subject to the Nutrition, Labeling and Education Act, or NLEA, and regulations promulgated under the NLEA. The NLEA regulates health claims, ingredient labeling and nutrient content claims characterizing the level of a nutrient in the product. The ingredients added to conventional foods must either be generally recognized as safe by experts, or GRAS, or be approved as food additives under FDA regulations. Our zinc-monocysteine complexes are comprised of zinc (a GRAS ingredient) and cysteine (an amino acid that also has GRAS status). While many chelated zinc products are currently on the market and are generally not considered new dietary ingredients, we cannot provide any assurance that zinc-monocysteine will be similarly considered by the FDA.

The FTC, which exercises jurisdiction over the advertising of all of our proposed products, has in the past several years instituted enforcement actions against several dietary supplement companies and against manufacturers of products generally for false and misleading advertising of some of their products. These enforcement actions have often resulted in consent decrees and monetary payments by the companies involved. In addition, the FTC has increased its scrutiny of the use of testimonials, which we also utilize, as well as the role of expert endorsers and product clinical studies. It is unclear whether the FTC will subject our advertisements to increased surveillance to ensure compliance with the principles set forth in its published advertising guidance. The copper industry has supported research studies that conclude that copper has no effect in Alzheimer's disease. In February 2007, the State of California issued its public health goal for copper in drinking water and considered the research studies mentioned above as well as those of our scientific collaborators and concluded that at the present time, the data with respect to copper in drinking water's role in Alzheimer's disease were to be "equivocal" . We cannot provide assurance that the FTC will allow us to publically advertise or promote our products to the American public.

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

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

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

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

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

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

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

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

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

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

We cannot be certain that we will successfully complete phase I, phase II, or phase III testing of our product candidates within any specific time period, if at all. Furthermore, the FDA, an IRB or the IND sponsor may suspend clinical trials at any time on various grounds, including a finding that subjects or patients are exposed to unacceptable health risk. Concurrent with these trials and studies, we also develop chemistry and physical characteristics data and finalize a manufacturing process in accordance with good manufacturing practice (“GMP”) requirements. The manufacturing process must conform to consistency and quality standards, and we must develop methods for testing the quality, purity, and potency of the final products. Appropriate packaging is selected and tested, and chemistry stability studies are conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life. Results of the foregoing are submitted to the FDA as part of a NDA for marketing and commercial shipment approval. The FDA reviews each NDA submitted and may request additional information.

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

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

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

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

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

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

The FDA’s policies may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Increased attention to the containment of health care costs worldwide

could result in new government regulations materially adverse to our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Failure to adhere to the quality control and other regulatory requirements could result in the suspension of such certification necessary to perform clinical testing and generate revenues.

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

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

Clinical laboratories in the United States are subject to regulation under the Clinical Laboratory Improvements Act of 1988 ("CLIA") as well as corresponding state regulations. Failure to adhere to the quality control and other regulatory requirements of CLIA could result in the suspension of such certification necessary to perform clinical testing and generate revenues.

Failure to comply with requirements of the European Union can be costly and time consuming.

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

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

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

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

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

We are subject to pricing controls that may not result in favorable arrangements for our products.

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

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

If we are not able to receive third-party reimbursements we may not be able to sell products at competitive prices.

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

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

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

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

We could be subject to challenges under fraud and abuse laws.

The United States federal Medicare/Medicaid anti-kickback law and similar state laws prohibit remuneration intended to induce physicians or others either to refer patients, or to acquire or arrange for or recommend the acquisition of health care products or services. While the federal law applies only to referrals, products or services receiving federal reimbursement, state laws often apply regardless of whether federal funds are involved. Other federal and state laws prohibit anyone from presenting or causing to be presented false or fraudulent payment claims. Recent federal and state enforcement actions under these statutes have targeted sales and marketing activities of prescription drug manufacturers. As we begin to market our products to health care providers, the relationships we form, such as compensating physicians for speaking or consulting services, providing financial support for continuing medical education or research programs, and assisting customers with third-party reimbursement claims, could be challenged under these laws and lead to civil or criminal penalties, including the exclusion of our products from federally-funded reimbursement. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition. We intend to consult counsel concerning the potential application of these and other laws to our business and to our sales, marketing and other activities to comply with them. Given their broad reach and the increasing attention given them by law enforcement authorities, however, we cannot assure you that some of our activities will not be challenged.

We do not have a guarantee of patent restoration and marketing exclusivity of the ingredients for our drugs even if we are granted FDA approval of our products.

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

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. RESERVED AND REMOVED

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

31.1 Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) *

31.2 Certification of Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) *

32.1 Certification pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 *

*Filed herewith

SIGNATURE

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

ADEONA PHARMACEUTICALS, INC.

By: /s/ James S. Kuo
James S. Kuo, M.D., M.B.A.
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)
Date: August 16, 2010