

ADEONA PHARMACEUTICALS, INC.  
Form 10-Q  
November 16, 2009

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2009

OR

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

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

Commission File Number: 1-12584

ADEONA PHARMACEUTICALS,  
INC.

(Name of small business issuer in its  
charter)

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  No

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

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

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

(Do not check if a smaller reporting company)

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

As of November 12, 2009, the registrant had 21,477,336 shares of common stock outstanding.

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## ADEONA PHARMACEUTICALS, INC.

FORM 10-Q  
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## PART I.—FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

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

## Consolidated Balance Sheets

| Assets   | September<br>30, 2009<br>(Unaudited) | December<br>31, 2008<br>(Audited) |
|--|--------------------------------------|-----------------------------------|
| Current Assets   |                                      |                                   |
| Cash   | \$3,532,469                          | \$5,856,384                       |
| Accounts receivable -net   | 98,205                               | -                                 |
| Other receivables  | 300                                  | 55,419                            |
| Prepaid expenses   | 27,275                               | 15,109                            |
| Total Current Assets   | 3,658,249                            | 5,926,912                         |
| Property and equipment, net of accumulated depreciation of \$888,208 and 591,876   | 1,147,862                            | 1,446,407                         |
| Goodwill   | 178,229                              | -                                 |
| Deposits and other assets  | 90,848                               | 11,989                            |
| Total Assets   | \$5,075,188                          | \$7,385,308                       |
| Liabilities and Stockholders' Equity   |                                      |                                   |
| Current Liabilities:   |                                      |                                   |
| Accounts payable   | \$255,856                            | \$574,896                         |
| Accrued liabilities  | 1,050                                | 45,820                            |
| Current portion of long term liabilities   | 17,006                               | -                                 |
| Total Current Liabilities  | 273,912                              | 620,716                           |
| Long Term Liabilities:   |                                      |                                   |
| Accounts payable   | 175,160                              | -                                 |
| Total Liabilities  | 449,072                              | 620,716                           |
| Stockholders' Equity   |                                      |                                   |
| Preferred stock, \$0.001 par value; 10,000,000 shares authorized,<br>none issued and outstanding                           | -                                    | -                                 |
| Common stock, \$0.001 par value; 100,000,000 shares authorized,<br>21,477,336 and 20,882,839 shares issued and outstanding | 21,477                               | 20,883                            |
| Additional paid-in capital   | 45,503,923                           | 45,025,385                        |
| Deficit accumulated during the development stage   | (40,899,284)                         | (38,281,676)                      |
| Total Stockholders' Equity   | 4,626,116                            | 6,764,592                         |
| Total Liabilities and Stockholders' Equity   | \$5,075,188                          | \$7,385,308                       |

See accompanying notes to unaudited consolidated financial statements

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

Consolidated Statements of Operations  
(Unaudited)

|  | For the three months ended<br>September 30, |                | For the nine months ended<br>September 30, |                | For the<br>Period<br>from January<br>8, 2001<br>(Inception) to<br>September<br>30, 2009 |
|--|---|----------------|--|----------------|---|
|  | 2009  | 2008           | 2009                                       | 2008           |   |
| Net Revenues:                                    | \$51,085                                    | \$-            | \$51,085                                   | \$-            | \$51,085  |
| Operating Expenses:                              |   |                |  |                |   |
| Research and development                         | 325,662                                     | 863,272        | 1,219,135                                  | 4,156,255      | 17,023,500  |
| General and administrative                       | 351,646                                     | 606,685        | 1,410,200                                  | 2,242,855      | 10,931,047  |
| Total Operating Expenses                         | 677,308                                     | 1,469,957      | 2,629,335                                  | 6,399,110      | 27,954,547  |
| Loss from Operations                             | (626,223 )                                  | (1,469,957 )   | (2,578,250 )                               | (6,399,110 )   | (27,903,462 )   |
| Other Income (Expense):                          |   |                |  |                |   |
| Interest income                                  | 148   | 26,688         | 2,826                                      | 108,503        | 474,451   |
| Gain (loss) in sale of equipment                 | -   | 14,430         | (42,184 )                                  | 14,430         | (41,827 )   |
| Interest expense                                 | -   | -              | -  | (13,831 )      | (66,760 )   |
| Total Other Income, net                          | 148   | 41,118         | (39,358 )                                  | 109,102        | 365,864   |
| Net Loss   | \$(626,075 )                                | \$(1,428,839 ) | (2,617,608 )                               | \$(6,290,008 ) | \$(27,537,598 )   |
| Less: Preferred stock dividend -<br>subsidiary   | -   | -              | -  | -              | (951,250 )  |
| Less: Merger dividend                            | -   | -              | -  | -              | (12,409,722 )   |
| Net Loss Applicable to Common<br>Shareholders    | \$(626,075 )                                | \$(1,428,839 ) | (2,617,608 )                               | \$(6,290,008 ) | \$(40,898,570 )   |
| Net Loss Per Share - Basic and Diluted           | \$(0.03 )                                   | \$(0.07 )      | \$(0.12 )                                  | \$(0.31 )      | \$(5.44 )   |
| Weighted average number of shares<br>outstanding |   |                |  |                |   |
| during the period - basic and diluted            | 21,437,701                                  | 20,715,966     | 21,276,912                                 | 20,587,746     | 7,524,006   |

See accompanying notes to unaudited consolidated financial statements

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

Consolidated Statements of Cash Flows  
(Unaudited)

|   | For the nine months<br>September 30, |               | For the<br>period<br>from January<br>8, 2001<br>(Inception) to<br>September<br>30, 2009 |
|---|--------------------------------------|---------------|---|
|   | 2009                                 | 2008          |   |
| <b>Cash Flows From Operating Activities:</b>                                |                                      |               |   |
| Net loss  | \$(2,617,608)                        | \$(6,290,008) | \$(27,537,598)  |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                      |               |   |
| Recognition of stock-based consulting                                       | 63,215                               | 344,169       | 1,590,885   |
| Recognition of stock-based compensation                                     | 181,325                              | 1,110,771     | 3,342,946   |
| Stock issued as compensation  | -                                    | 55,385        | 55,385  |
| Stock issued as compensation in acquisition of subsidiary                   | -                                    | -             | 601,712   |
| Stock issued for consulting fees  | 64,586                               | 90,042        | 168,628   |
| Stock issued for milestone payment  | -                                    | 50,000        | 75,000  |
| Stock issued for license fee  | 41,250                               | 145,000       | 594,941   |
| Contributed services - related party  | 100,000                              | 73,750        | 449,395   |
| Depreciation  | 272,485                              | 307,466       | 909,672   |
| Provision for uncollectible accounts receivable                             | 7,785                                | -             | 7,785   |
| Loss on exchange of equipment to settle accounts payable                    | 18,674                               | -             | 19,031  |
| Loss on sale of equipment   | 15,725                               | (14,430)      | 15,725  |
| <b>Changes in operating assets and liabilities:</b>                         |                                      |               |   |
| Accounts receivable   | (18,548)                             | -             | (18,548)  |
| Prepaid expenses and other current assets                                   | 35,168                               | 4,436         | (26,675)  |
| Deposits and other assets   | (78,859)                             | 1,392         | (90,848)  |
| Accounts payable  | (364,033)                            | (135,177)     | 302,443   |
| Current portion of Long Term Liabilities                                    | 17,006                               | -             | 17,006  |
| Accrued liabilities   | (44,770)                             | 116,979       | 4,068   |
| Long Term Payables  | 143,243                              | -             | 143,243   |
| Net Cash Used In Operating Activities                                       | (2,163,356)                          | (4,140,225)   | (19,375,804)  |

## Cash Flows From Investing Activities:

|   |            |           |              |
|---|------------|-----------|--------------|
| Purchases of property and equipment               | -          | (21,398 ) | (2,032,805 ) |
| Proceeds from the sale of equipment               | 25,200     | -         | 157,465      |
| Cash paid to acquire shell in reverse acquisition | -          | -         | (665,000 )   |
| Cash paid to acquire Hart Lab                     | (201,141 ) | -         | (201,141 )   |
| Cash received from Acquisition of Hart Lab        | 5,624      | -         | 5,624        |
| Net Cash Used In Investing Activities             | (170,317 ) | (21,398 ) | (2,735,857 ) |

## Cash Flows From Financing Activities:

|   |       |            |              |
|---|-------|------------|--------------|
| Proceeds from loans payable - related party   | -     | -          | 3,210,338    |
| Repayments of loans payable - related party   | -     | -          | (220,000 )   |
| Proceeds from notes payable   | -     | -          | 1,100,000    |
| Repayments of notes payable   | -     | (900,000 ) | (1,100,000 ) |
| Proceeds from issuance of common stock for stock option exercises                                       | 9,758 | 4,428      | 14,149       |
| Proceeds from issuance of preferred and common stock  | -     | -          | 1,150,590    |
| Proceeds from sale of common stock and warrants in private placements                                   | -     | -          | 13,926,362   |
| Proceeds from sale of common stock in connection with warrant exercise                                  | -     | -          | 7,552,378    |
| Cash paid as direct offering costs in private placements and warrant call                               | -     | -          | (1,739,987 ) |
| Proceeds from issuance of Series B, convertible preferred stock - subsidiary                            | -     | -          | 1,902,500    |
| Direct offering costs in connection with issuance of series B, convertible preferred stock - subsidiary | -     | -          | (152,200 )   |
| Net Cash Provided By (Used In) Financing Activities   | 9,758 | (895,572 ) | 25,644,130   |

## Net increase (decrease) in cash and cash equivalents

|             |              |           |
|-------------|--------------|-----------|
| (2,323,915) | (5,057,195 ) | 3,532,469 |
|-------------|--------------|-----------|

## Cash and cash equivalents at beginning of period

|           |            |   |
|-----------|------------|---|
| 5,856,384 | 11,492,802 | - |
|-----------|------------|---|

## Cash and cash equivalents at end of period

|             |             |             |
|-------------|-------------|-------------|
| \$3,532,469 | \$6,435,607 | \$3,532,469 |
|-------------|-------------|-------------|

## Supplemental disclosures of cash flow information:

|                        |     |          |          |
|------------------------|-----|----------|----------|
| Cash paid for interest | \$- | \$13,831 | \$66,760 |
| Cash paid for taxes    | \$- | \$-      | \$-      |



## Supplemental disclosure of non-cash investing and financing activities:

|   |         |     |              |
|---|---------|-----|--------------|
| Loss on exchange of equipment to settle accounts payable  | \$5,925 | \$- | \$98,219     |
| Sale of equipment in exchange for other receivables   | \$-     | \$- | \$8,685      |
| Exchange of EPI preferred stock into Pipex common stock in acquisition                                  | \$-     | \$- | \$12,409,722 |
| Pipex acquired equipment in exchange for a loan with a related party                                    | \$-     | \$- | \$284,390    |
| EPI declared a 10% and 30% in-kind dividend on its Series B, convertible preferred stock.               | \$-     | \$- | \$951,250    |
| The Company issued shares and warrants in connection with the conversion of certain related party debt. | \$-     | \$- | \$3,274,728  |
| Conversion of accrued liabilities to contributed capital - former related party                         | \$-     | \$- | \$3,017      |

See accompanying notes to unaudited consolidated financial statements

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

Notes to Consolidated Financial Statements  
(Unaudited)

Note 1 Organization and Nature of Operations and Basis of Presentation

(A) Description of the Business

Adeona Pharmaceuticals, Inc. a Nevada corporation (“Adeona” or the “Company”) is dedicated to the awareness, diagnosis, prevention and treatment of subclinical zinc deficiency and chronic copper toxicity in the mature population. Adeona believes that such conditions may contribute to the progression of debilitating degenerative diseases, including, Dry Age-Related Macular Degeneration (Dry AMD), Alzheimer's disease (AD) and mild cognitive impairment (MCI) in susceptible persons. The Company has launched its Copper-Proof™ Test Panel to allow physicians, via the company’s HartLab subsidiary, to determine the copper and zinc status of their patients with these diseases and is also preparing to commercialize an advanced, oral, gastro-retentive, sustained release zinc therapy for this patient population which the Company currently plans to initially launch in the first quarter of 2010. Adeona also has a number of late-stage clinical drug candidates for the treatment of rheumatoid arthritis, such as oral dnaJP1, and oral estriol (Trimesta™) for women with relapse-remitting multiple sclerosis.

(B) Corporate Name Change and Nevada Reincorporation

On October 16, 2008, the Company completed a corporate name change to Adeona Pharmaceuticals, Inc. from Pipex Pharmaceuticals, Inc. On October 15, 2009, the Company reincorporated to Nevada from Delaware pursuant to the discretionary reincorporation plan approved by stockholders at the Company’s 2008 Annual Meeting of Stockholders held in June 2008. The reincorporation was effected by the merger of Adeona Pharmaceuticals, Inc., a Delaware corporation (“Adeona Delaware”), with and into a newly created, wholly-owned Nevada subsidiary corporation.

In the reincorporation, each outstanding share of common stock of the Delaware corporation was automatically converted into one share of common stock of the Company as a Nevada corporation and all options and other rights to acquire Adeona Delaware common stock outstanding immediately prior to the reincorporation were automatically converted into options and rights to acquire the same number of shares of common stock of the Company as a Nevada corporation. Shareholders are not required to exchange their existing stock certificates of Adeona Delaware, which now represent the same number of shares of common stock of the Company as a Nevada corporation. Outstanding shares of the Company’s common stock retain the same CUSIP number as the corresponding shares of Adeona Delaware prior to the reincorporation, and the Company’s common stock continues to be listed on the NYSE Amex stock exchange (formerly known as the American Stock Exchange and the NYSE Alternext US exchange) under the same symbol, “AEN”. The reincorporation did not result in any material changes in our business, offices, assets, liabilities, obligations or net worth, or our directors, officers or employees, and Adeona Delaware ceased to exist as a separate legal entity. We continue to maintain our principal executive offices at 3930 Varsity Drive, Ann Arbor, Michigan 48106.

As a result of the reincorporation and by operation of Rule 12g-3(a) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), the Company, as a Nevada corporation, is the successor issuer to Adeona Delaware and has succeeded to the attributes of Adeona Delaware as the registrant. The common stock of the Company, as a Nevada corporation, is deemed to be registered under Section 12(b) of the Exchange Act, and the Company is subject to the informational requirements of the Exchange Act, and the rules and regulations promulgated thereunder.

(C) Basis of Presentation

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

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

(D) Corporate Structure and Non-Controlling Interest

The Company has eight active subsidiaries, Pipex Therapeutics, Inc. ("Pipex Therapeutics"), Hart Lab, LLC ("HartLab"), Effective Pharmaceuticals, Inc. ("EPI"), Solovax, Inc. ("Solovax"), CD4 Biosciences, Inc. ("CD4"), Epitope Pharmaceuticals, Inc. ("Epitope"), Healthmine, Inc. ("Healthmine") and Putney Drug Corp. ("Putney") which were previously under common control. As of September 30, 2009, EPI, HartLab, Healthmine and Putney are wholly owned and Pipex Therapeutics, Solovax, CD4 and Epitope are majority owned. The combinations of these entities prior to 2006 were accounted for in a manner similar to a pooling of interests.

For financial reporting purposes, the outstanding common stock of the Company is that of Adeona a Nevada corporation as well as that of its predecessor corporation prior to October 15, 2009, a Delaware corporation. All statements of operations, stockholders' equity (deficit) and cash flows for each of the entities are presented as consolidated since January 8, 2001 (inception) due to the existence of common control since that date. All subsidiaries were formed under the laws of the State of Delaware on January 8, 2001, except for EPI, which was incorporated in Delaware on December 12, 2000, Epitope which was incorporated in Delaware in January of 2002, Putney which was incorporated in Delaware in November of 2006, Healthmine which was formed in Delaware in December 2007 and HartLab which was incorporated in Illinois as a limited liability company on August 8, 2005 and whose income is included in the Company's consolidated financial statements as of its acquisition date of July 10, 2009.

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

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

Notes to Consolidated Financial Statements  
(Unaudited)

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

(E) Reverse Stock Split

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

(F) Reverse Acquisition and Recapitalization

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

Since the transaction is considered a reverse acquisition and recapitalization, pro-forma financial statements are not required.

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

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



Adeona Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Company)

Notes to Consolidated Financial Statements

(Unaudited)

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

1. EPI's Acquisition of CD4

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

2. Pipex Therapeutics' Acquisition of Solovax

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

3. Pipex Therapeutics' Acquisition of EPI/CD4

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

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

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

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

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

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

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

Adeona Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Company)

Notes to Consolidated Financial Statements

(Unaudited)

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

The Company has determined that the fair value of the consideration transferred to the holders of EPI Series B, convertible preferred stock over the carrying amount of the preferred stock represents a return to the preferred stockholders. The difference is \$12,409,722, which is included as a component of paid in-kind dividends. This amount is included as an additional reduction in net loss applicable to common shareholders for purposes of computing loss per share in the accompanying financial statements for the period from January 8, 2001 (inception) to September 30, 2009.

As part of the acquisition of EPI, the Company granted an aggregate 68,858 warrants and 34,685 options for the outstanding warrants and options held by the EPI warrant and option holders. These new warrants and options will continue to vest according to their original terms. The Company treated the exchange as a modification of an award of equity instruments. As such, incremental compensation cost was measured as the excess of the fair value of the replacement award over the fair value of the cancelled award at the cancellation date. In substance, Adeona repurchased the EPI instruments by issuing a new instrument of greater value.

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

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

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

## Note 2 Summary of Significant Accounting Policies

### (A) Principles of Consolidation

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

### (B) Development Stage

The Company's consolidated financial statements are presented as statements of a development stage enterprise. For the period from inception (January 8, 2001) to date, the Company has been a development stage enterprise, and accordingly, the Company's operations have been directed primarily toward the acquisition and creation of intellectual



properties and certain research and development activities to improve current technological concepts. As the Company is devoting its efforts to research and development, there have been no sales, license fees or royalties earned other than the sales by the Company's HartLab subsidiary. Additionally, the Company continually seeks sources of debt or equity based funding to further its intended research and development activities. The Company has experienced net losses since its inception, and had an accumulated deficit of \$40,899,284 at September 30, 2009.

Adeona Pharmaceuticals, Inc. and Subsidiaries

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(C) Use of Estimates

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

Significant estimates during 2009 include depreciable lives of property, valuation of warrants and stock options granted for services or compensation, respectively, estimates of the probability and potential magnitude of contingent liabilities and the valuation allowance for deferred tax assets due to continuing operating losses.

(D) 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 nine months ended September 30, 2009.

(E) 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 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.

(F) Risks and Uncertainties

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 our access to capital, but also make it difficult for our customers, our vendors and us to accurately forecast and plan future business activities.

(G) Cash and Cash Equivalents

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

The Company minimizes credit risk associated with cash by periodically evaluating the credit quality of its primary financial institution. The balance at times may exceed federally insured limits. At September 30, 2009 and December 31, 2008, the balance exceeded the federally insured limit by \$0 and \$5,639,249, respectively. During 2009, the Company moved its cash into a non-interest bearing account which has unlimited insurance protection through December 31, 2009.

(H) Property and Equipment

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

| Description                         | Estimated Useful Life                            |
|-------------------------------------|--|
| Office equipment and furniture      | 5 years  |
| Laboratory equipment                | 7-10 years                                       |
| Manufacturing equipment             | 10 years   |
| Leasehold improvements and fixtures | Lesser of estimated useful life or life of lease |

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

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

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

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

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(I) Long Lived Assets

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

(J) Goodwill

Goodwill is tested for impairment at the reporting unit level (operating segment or one level below an operating segment) on an annual basis and between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying value. These events or circumstances could include a significant change in the business climate, legal factors, operating performance indicators, competition or sale or disposition of a significant portion of a reporting unit. Application of the goodwill impairment test requires judgment, including the identification of reporting units, assignment of assets and liabilities to reporting units, assignment of goodwill to reporting units, and determination of the fair value of each reporting unit. The fair value of each reporting unit is estimated using a discounted cash flow methodology. This requires significant judgments including estimation of future cash flows, which is dependent on internal forecasts, estimation of the long-term rate of growth for our business, the useful life over which cash flows will occur, and determination of our weighted average cost of capital. Changes in these estimates and assumptions could materially affect the determination of fair value and/or goodwill impairment for each reporting unit.

We will continue to evaluate goodwill for impairment, at least annually. During the nine months ended September 30, 2009, we did not identify any indication of goodwill impairment.

(K) Derivative Liabilities

In connection with the reverse acquisition, all outstanding convertible preferred stock of Adeona was cancelled and retired. The Company's majority owned subsidiaries also contain issued convertible preferred stock; however, none of these instruments currently contains any provisions that require the recording of a derivative liability. In connection with the acquisition of EPI on January 5, 2007 (See Note 1(G)(4)), all issued and outstanding shares of Series A and B, convertible preferred stock were cancelled and retired. Consequentially there is no potential derivative liabilities will exist pertaining to these instruments.

(L) Net Loss per Share

Basic earnings (loss) per share is computed by dividing the net income (loss) less preferred dividends for the period by the weighted average number of common shares outstanding. Diluted earnings (loss) per share is computed by dividing net income (loss) less preferred dividends by the weighted average number of common shares outstanding including the effect of share equivalents. The Company's share equivalents consist of 2,392,451 stock options and 1,070,472 warrants. Since the Company reported a net loss for the three and nine month periods ended September 30, 2009 and 2008 and for the period from January 8, 2001 (inception) to September 30, 2009, respectively, all common stock equivalents would be anti-dilutive; as such there is no separate computation for diluted earnings per share.

The Company's net loss per share for the three and nine month periods ended September 30, 2009 and 2008 and for the period from January 8, 2001 (inception) to September 30, 2009 was computed assuming the effect of the recapitalization associated with the reverse acquisition, as such, all share and per share amounts have been retroactively restated. Additionally, the numerator for computing net loss per share was adjusted for preferred stock dividends recorded during the period from January 8, 2001 (inception) to September 30, 2009, in connection with the acquisition of EPI (See Note 1(G)(4)) as well as and certain provisions relating to the sale of EPI's Series B, convertible preferred stock.

#### (M) Research and Development Costs

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

#### (N) Fair Value of Financial Instruments

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

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(O) Stock Based Compensation

All share-based payments to employees since inception have been recorded and expensed in the statements of operations.

(P) Non-Employee Stock Based Compensation

All stock-based compensation awards issued to non-employees for services have been recorded at either the fair value of the services rendered or the instruments issued in exchange for such services, whichever is more readily determinable.

(Q) Recent Accounting Pronouncements

Effective July 1, 2009, the Company adopted The “FASB Accounting Standards Codification” and the Hierarchy of Generally Accepted Accounting Principles (ASC 105). This standard establishes only two levels of U.S. generally accepted accounting principles (“GAAP”), authoritative and non-authoritative. The FASB Accounting Standards Codification (the “Codification”) became the source of authoritative, nongovernmental GAAP, except for rules and interpretive releases of the SEC, which are sources of authoritative GAAP for SEC registrants. All other non-grandfathered, non-SEC accounting literature not included in the Codification became non-authoritative. The Company began using the new guidelines and numbering system prescribed by the Codification when referring to GAAP in the third quarter of fiscal 2009. As the Codification was not intended to change or alter existing GAAP, it did not have a material impact on the Company’s financial statements.

Effective June 30, 2009, the Company adopted three accounting standard updates which were intended to provide additional application guidance and enhanced disclosures regarding fair value measurements and impairments of securities. They also provide additional guidelines for estimating fair value in accordance with fair value accounting. The first update, as codified in ASC 820-10-65, provides additional guidelines for estimating fair value in accordance with fair value accounting. The second accounting update, as codified in ASC 320-10-65, changes accounting requirements for other-than-temporary-impairment (OTTI) for debt securities by replacing the current requirement that a holder have the positive intent and ability to hold an impaired security to recovery in order to conclude an impairment was temporary with a requirement that an entity conclude it does not intend to sell an impaired security and it will not be required to sell the security before the recovery of its amortized cost basis. The third accounting update, as codified in ASC 825-10-65, increases the frequency of fair value disclosures. These updates were effective for fiscal years and interim periods ended after June 15, 2009. The adoption of these accounting updates did not have a material impact on the Company’s financial statements.

Effective June 30, 2009, the Company adopted a new accounting standard for subsequent events, as codified in ASC 855-10. The update modifies the names of the two types of subsequent events either as recognized subsequent events (previously referred to in practice as Type I subsequent events) or non-recognized subsequent events (previously referred to in practice as Type II subsequent events). In addition, the standard modifies the definition of subsequent events to refer to events or transactions that occur after the balance sheet date, but before the financial statements are issued (for public entities) or available to be issued (for nonpublic entities). It also requires the disclosure of the date through which subsequent events have been evaluated. The update did not result in significant changes in the practice

of subsequent event disclosures, and therefore the adoption did not have a material impact on the Company's financial statements.

Effective January 1, 2009, the Company adopted an accounting standard update regarding the determination of the useful life of intangible assets. As codified in ASC 350-30-35, this update amends the factors considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under intangibles accounting. It also requires a consistent approach between the useful life of a recognized intangible asset under prior business combination accounting and the period of expected cash flows used to measure the fair value of an asset under the new business combinations accounting (as currently codified under ASC 850). The update also requires enhanced disclosures when an intangible asset's expected future cash flows are affected by an entity's intent and/or ability to renew or extend the arrangement. The adoption did not have a material impact on the Company's financial statements.

In February 2008, the FASB issued an accounting standard update that delayed the effective date of fair value measurements accounting for all non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until the beginning of the first quarter of fiscal 2009. These include goodwill and other non-amortizable intangible assets. The Company adopted this accounting standard update effective January 1, 2009. The adoption of this update to non-financial assets and liabilities, as codified in ASC 820-10, did not have a material impact on the Company's financial statements.

Effective January 1, 2009, the Company adopted a new accounting standard update regarding business combinations. As codified under ASC 805, this update requires an entity to recognize the assets acquired, liabilities assumed, contractual contingencies, and contingent consideration at their fair value on the acquisition date. It further requires that acquisition-related costs be recognized separately from the acquisition and expensed as incurred; that restructuring costs generally be expensed in periods subsequent to the acquisition date; and that changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period be recognized as a component of provision for taxes. The adoption did not have a material impact on the Company's financial statements.



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In September 2009, the FASB issued Update No. 2009-13, “Multiple-Deliverable Revenue Arrangements—a consensus of the FASB Emerging Issues Task Force” (ASU 2009-13). It updates the existing multiple-element revenue arrangements guidance currently included under ASC 605-25, which originated primarily from the guidance in EITF Issue No. 00-21, “Revenue Arrangements with Multiple Deliverables” (EITF 00-21). The revised guidance primarily provides two significant changes: 1) eliminates the need for objective and reliable evidence of the fair value for the undelivered element in order for a delivered item to be treated as a separate unit of accounting, and 2) eliminates the residual method to allocate the arrangement consideration. In addition, the guidance also expands the disclosure requirements for revenue recognition. ASU 2009-13 will be effective for the first annual reporting period beginning on or after June 15, 2010, with early adoption permitted provided that the revised guidance is retroactively applied to the beginning of the year of adoption. The Company is currently assessing the future impact of this new accounting update to its financial statements.

Effective July 1, 2009, the Company adopted the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 105-10, Generally Accepted Accounting Principles – Overall (“ASC 105-10”). ASC 105-10 establishes the FASB Accounting Standards Codification (the “Codification”) as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with U.S. GAAP. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative U.S. GAAP for SEC registrants. All guidance contained in the Codification carries an equal level of authority. The Codification superseded all existing non-SEC accounting and reporting standards. All other non-grandfathered, non-SEC accounting literature not included in the Codification is non-authoritative. The FASB will not issue new standards in the form of Statements, FASB Staff Positions or Emerging Issues Task Force Abstracts. Instead, it will issue Accounting Standards Updates (“ASUs”). The FASB will not consider ASUs as authoritative in their own right. ASUs will serve only to update the Codification, provide background information about the guidance and provide the bases for conclusions on the change(s) in the Codification. References made to FASB guidance throughout this document have been updated for the Codification.

Effective July 1, 2009, the Company adopted FASB ASU No. 2009-05, Fair Value Measurements and Disclosures (Topic 820) (“ASU 2009-05”). ASU 2009-05 provided amendments to ASC 820-10, Fair Value Measurements and Disclosures – Overall, for the fair value measurement of liabilities. ASU 2009-05 provides clarification that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using certain techniques. ASU 2009-05 also clarifies that when estimating the fair value of a liability, a reporting entity is not required to include a separate input or adjustment to other inputs relating to the existence of a restriction that prevents the transfer of a liability. ASU 2009-05 also clarifies that both a quoted price in an active market for the identical liability at the measurement date and the quoted price for the identical liability when traded as an asset in an active market when no adjustments to the quoted price of the asset are required are Level 1 fair value measurements. Adoption of ASU 2009-05 did not have a material impact on the Company’s results of operations or financial condition.



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### Note 3 Notes Payable

During 2007, the Company borrowed \$1,100,000 and repaid \$200,000 under notes payable. These notes were secured by all assets of the Company as well as the stock of Pipex Therapeutics, EPI, Solovax and CD4; the notes bore interest of prime plus 2% and were due March 30, 2010. As of March 6, 2008, all of the outstanding principal and accrued interest has been repaid.

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

#### (A) Preferred Stock Issuances

##### 1. For the Year Ended December 31, 2005

On March 10, 2005, EPI's board of directors and stockholders voted to authorize the designation of a Series B Convertible Preferred Stock. From March through June 2005, EPI issued 1,902,500 shares of Series B Convertible Preferred Stock, at \$1 per share, for proceeds of \$1,902,500. In connection with this offering, EPI paid \$152,200 of offering costs that were charged against additional paid in capital. The Company also granted 171,225 warrants as compensation in connection with this equity raise.

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

##### 2. For the Year Ended December 31, 2001

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

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

On January 31, 2001, Solovax issued 1,000,000 shares of Series A Convertible Preferred Stock to the Founder of Solovax in exchange for \$300,000 (\$0.30 per share).

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

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

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For the Nine Months Ended September 30, 2009

During the nine months ended September 30, 2009, the Company issued 54,212 shares of common stock in connection with the exercise of stock options for net proceeds of \$9,758. The related exercise price was \$0.18 per share.

During the nine months ended September 30, 2009, the Company issued 232,472 shares of common stock for consulting fees having a fair value of \$64,586 (\$0.28 per share) based on the quoted closing trading price.

During the nine months ended September,30, 2009, the Company issued an aggregate 257,813 shares of common stock for license fees having a fair value of \$41,250 (\$0.16 per share) based on the quoted closing trading price.

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For the Year Ended 2008

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

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

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

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

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

For the Year Ended 2007

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

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

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

For the Year Ended 2006

During 2006, the loans payable to Steve Kanzer the Company's co-founder, and current Chairman were converted into 1,665,211 shares of common stock and 832,606 warrants. There were no gain or loss on this transaction since it was with a related party.

During 2006, the Company completed private placements of its stock, which resulted in the issuance of 6,900,931 shares of common stock and 3,451,524 warrants. The net proceeds from the private placements were \$12,765,945, which included cash paid as direct offering costs of \$1,160,418. As part of the October 2006 private placement, the Company sold 99,104 shares of its common stock and 49,552 warrants to purchase common stock for total proceeds of \$200,000 to entities controlled by its then President Charles Bisgaier. As part of the same private placement, Adeona sold 49,552 shares of its common stock and 24,776 warrants to purchase common stock for total proceeds of \$100,000 to a related family member of the Company's current Chairman. The terms on which their purchases were made were identical to the terms in which the other investors in these offerings purchased shares.

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

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

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(C) Common Stock Issuances of Subsidiaries

During the period from January 8, 2001 (inception) to September 30, 2008, the Company's majority owned subsidiaries; CD4, Solovax, EPI and Epitope issued 419,000, 419,000, 825,000 and 125,000 shares of common stock, respectively, for an aggregate \$1,788. Of the 825,000 shares of common stock issued by EPI, 75,000 were converted into 30,161 common shares of Adeona and the remaining 750,000 shares were cancelled and retired for no additional consideration in the acquisition of EPI on January 5, 2007. In 2005 and prior to our acquisition, HartLab issued limited liability interests to its founder and subsequently received capital contributions for no additional consideration. On July 10, 2009 the Company acquired all of the outstanding limited liability interests of Hart Lab from its founder. See Note 7 below.

(D) Stock Incentive Plan

During 2001, Pipex Therapeutics' Board and stockholders adopted the 2001 Stock Incentive Plan (the "2001 Stock Plan"). This plan was assumed by Pipex in the merger, in October 2006. As of the date of the merger, there were 1,489,353 options issued and outstanding under the 2001 plan. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2001 plan shall not exceed 1,250,000. All awards pursuant to the Plan shall terminate upon the termination of the grantee's employment for any reason. Awards include options, restricted shares, stock appreciation rights, performance shares and cash-based awards (the "Awards"). The 2001 Stock Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined in the plan. The 2001 Stock Plan provides for a Committee of the Board to grant awards and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the awards, including acceleration of the vesting of an award at any time. As of September 30, 2009, there are 1,175,775 options issued and outstanding under the 2001 Stock Plan.

On March 20, 2007, the Company's Board of Directors approved the Company's 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 2,500,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. The exercise price of stock options under the 2007 Stock Plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. This plan was approved by stockholders on November 2, 2007. As of September 30, 2009, there are 1,216,676 options issued and outstanding under the 2007 Stock Plan.

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

The Company has applied fair value accounting for all share based payment awards since inception. The fair value of each option or warrant granted is estimated on the date of grant using the Black-Scholes option-pricing model. The

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Black-Scholes assumptions used in the three and nine months ended September 30, 2009 and 2008 are as follows:

|                         | Three Months Ended September 30, |          | Nine months Ended September 30, |                 |
|-------------------------|----------------------------------|----------|---------------------------------|-----------------|
|                         | 2009                             | 2008     | 2009                            | 2008            |
| Exercise price          | \$0.37 - \$0.80                  | \$0.81   | \$0.37 - \$0.80                 | \$0.81 - \$5.10 |
| Expected dividends      | 0%                               | 0%       | 0%                              | 0%              |
| Expected volatility     | 198% - 209%                      | 225%     | 198% - 209%                     | 201.11% - 225%  |
| Risk free interest rate | 1.56% - 3.52%                    | 4.02%    | 1.56% - 3.52%                   | 3.52% - 4.02%   |
| Expected life of option | 10 years                         | 10 years | 10 years                        | 10 years        |



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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. All option grants are expensed in the appropriate period based upon each award vesting terms, in each case with an offsetting credit to additional paid in capital. The stock-based compensation expense recorded by the Company for the three and nine months ended September 30, 2009 and 2008 and the period from January 8, 2001 (inception) to September 30, 2009 with respect to awards under the Plan and awards issued under warrants is as follows:

|                             | Three Months Ended<br>September 30, |                  | Nine months Ended<br>September 30, |                    | Inception to<br>September<br>30, |
|-----------------------------|-------------------------------------|------------------|------------------------------------|--------------------|----------------------------------|
|                             | 2009                                | 2008             | 2009                               | 2008               | 2009                             |
| Research and development:   |                                     |                  |                                    |                    |                                  |
| employees                   | \$12,349                            | \$102,556        | \$89,816                           | \$768,846          | \$2,379,304                      |
| non-employees               | 21,072                              | 21,071           | 63,216                             | 313,319            | 603,379                          |
| General and administrative: |                                     |                  |                                    |                    |                                  |
| employees                   | 20,875                              | 137,902          | 91,508                             | 341,926            | 1,547,207                        |
| non-employees               | -                                   | -                | -                                  | 30,850             | 970,890                          |
| <b>Total</b>                | <b>\$54,396</b>                     | <b>\$261,529</b> | <b>\$243,540</b>                   | <b>\$1,454,941</b> | <b>\$5,500,780</b>               |

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

|                              | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price |
|------------------------------|---------------------|--|
| Balance at December 31, 2007 | 2,297,364           | \$ 2.72                                  |
| Granted                      | 1,180,666           | \$ 1.00                                  |
| Exercised                    | (37,948)            | \$ 0.12                                  |
| Forfeited                    | (688,419)           | \$ 5.07                                  |
| Balance at December 31, 2008 | 2,751,663           | \$ 1.43                                  |
| Granted                      | 585,000             | \$ 0.44                                  |
| Exercised                    | 54,212              | \$ 0.18                                  |
| Forfeited                    | (890,000)           | \$ 0.81                                  |

|   |           |    |      |
|---|-----------|----|------|
| Balance at September 30, 2009 (unaudited) | 2,392,451 | \$ | 1.45 |
|---|-----------|----|------|

The weighted average remaining contractual term for options outstanding at September 30, 2009 was 7.01 years. At September 30, 2009, the Company had 1,126,567 and 696,775 stock options outstanding and exercisable that had an exercise price less than the market price on that date for an aggregate intrinsic value of \$547,845 and \$400,595, respectively.

Of the total options granted, 1,905,508 are fully vested, exercisable and non-forfeitable and have a weighted average exercise price of \$1.62. The weighted average remaining contractual term for options that are exercisable was 6.39 years.

Of the total 2,392,451 options outstanding, 1,118,162 options are held by related parties of which 787,572 are fully vested, exercisable and non-forfeitable.

Adeona Pharmaceuticals, Inc. and Subsidiaries

(A Development Stage Company)

Notes to Consolidated Financial Statements

(Unaudited)

(E) Stock Warrants

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

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

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

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

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

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

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

In addition, as part of the private placements, the Company issued warrants to purchase 958,277 shares of common stock to the placement agent, that is a company that is controlled by the Company's Chairman with the majority of these warrants being reissued to the Company's former CEO. The warrants have an exercise price of \$2.22. Since these warrants were granted as compensation in connection with an equity raise, the Company has treated these warrants as a direct offering cost. The result of the transaction has a \$0 net effect to equity. The warrants are fully vested and non-forfeitable. On January 14, 2009, 381,020 of these warrants representing all of the warrants held by an affiliate of the Company's Chairman were cancelled.

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

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

Notes to Consolidated Financial Statements  
(Unaudited)

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

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

All outstanding warrants are fully vested and exercisable.

Warrants Outstanding and Exercisable

| Range of<br>Exercise<br>Price | Number<br>Outstanding | Weighted<br>Average<br>Remaining<br>Contractual<br>Life |
|-------------------------------|-----------------------|---|
| \$ 0.41                       | 5,000                 | 1.63 Years  |
| \$ 2.22                       | 626,809               | 3.32 Years  |
| \$ 3.30                       | 61,207                | 5.67 Years  |
| \$ 3.75                       | 50,000                | 6.38 Years  |
| \$ 6.36                       | 327,456               | 3.11 Years  |
|                               | 1,070,472             | 4.34 Years  |

(F) Options of Subsidiary

CD4 had 30,000 options outstanding and exercisable which were granted during 2004 and 2007. On August 5, 2009, 10,000 of these options expired. As of September 30, 2009 a total of 20,000 options were outstanding and exercisable with an exercise price of \$0.20 and a remaining contractual life of 2.62 years.

Epitope has 50,000 options outstanding and 10,000 options exercisable, with an exercise price of \$0.001 and a remaining contractual life of 8.75 years as of September 30, 2009. These options were granted during 2008, vest annually over 5 years and have a fair value of \$50 which was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%; expected volatility of 200%, risk free interest rate of 2.47% and an expected life of 10 years.

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

Notes to Consolidated Financial Statements  
(Unaudited)

Note 5 Commitments

(A) License Agreements

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

(B) Research Agreement

In September 2005, the Company entered into a three-year sponsored research agreement with the University of Michigan. Pursuant to that agreement, the Company sponsored approximately \$460,000 per year, payable in monthly installments. This agreement can be extended for an additional two-year period. The Company can terminate the agreement by giving 90 days prior written notice. On March 20, 2008, the Company provided the University with written notice of termination of the agreement. On March 24, 2009 the Company entered into a repayment plan with the University to pay the outstanding amount owed under the original agreement in the amount of \$197,335. The Company will pay \$5,000 per month until the payable is paid in full.

(C) Employment Agreements

In January 2005, the Company entered into a four-year employment agreement with Steve H. Kanzer, the Company's then Chairman and Chief Executive Officer. Pursuant to that agreement, Mr. Kanzer was entitled to receive an annual base salary of \$297,000 and annual bonuses equal to 30% of his base salary, plus a ten-year option to acquire 271,058 shares of common stock at the completion of the Company's private placement that occurred on October 31, 2006. However, Mr. Kanzer did not take any of the salary or bonuses he was entitled to under this agreement, but did exercise his stock options, which had vested on or before December 31, 2008. The fair value of the options totaled \$544,827 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 200%, risk free interest rate of 4.61% and an expected life of 10 years.

On July 20, 2007, the Board of Directors approved an amended and restated employment agreement for Mr. Kanzer. The amended employment agreement provided that he be paid a base salary of \$195,000 per year plus a guaranteed bonus of \$100,000 (of which he took only \$45,000 in January 2008). The agreement also called for discretionary transactional bonuses. In addition and for no additional consideration, Mr. Kanzer formally waived the receipt of any unpaid salary and bonuses payable under the original agreement, which amounted to \$275,645. This amount was treated as a capital contribution to the Company in September 2007.

On July 1, 2008, Mr. Kanzer resigned his position as Chief Executive Officer, but continues to serve as the Company's Chairman on a full time basis.

Also on July 1, 2008, the Company's Board of Directors appointed Nicholas Stergis (the then Vice Chairman of the Board and former Chief Operating Officer of the Company's Effective Pharmaceuticals subsidiary) as Chief Executive

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

Effective March 29, 2009, Mr. Stergis resigned his position as the Company's Chief Executive Officer, and was paid severance of \$97,500 over six months, ending September 2009. Per the terms of the agreement, 500,000 unvested stock options were cancelled on March 29, 2009 and 300,000 vested options that were unexercised cancelled on June 28, 2009. On August 20, 2009 Mr. Stergis resigned from the Company's Board of Directors.

On January 6, 2009, Mr. Kanzer (our current Chairman) entered into an amended agreement with the Company which extended his employment agreement through January 9, 2010 with an annual salary of \$1. Also, Mr. Kanzer agreed to forego the \$100,000 guaranteed bonus otherwise due to him on January 1, 2009. The amount of \$100,000 was recorded as a capital contribution during the first quarter of 2009. Mr. Kanzer reimburses the Company for the Company's cost of Mr. Kanzer's health insurance. On March 29, 2009, Mr. Kanzer assumed the duties of the Chief Executive Officer and President until the appointment of Max Lyon, the Company's current Chief Executive Officer and President on June 26, 2009.

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

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



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

Notes to Consolidated Financial Statements  
(Unaudited)

(D) Litigation

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

Note 6 Stock Repurchase Program

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

Note 7 Acquisition of Hart Lab, LLC

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

The Company acquired HartLab to be able to development and commercialize its diagnostic test panel for the detection of zinc and copper deficiencies in the mature population. The Company paid \$201,141 in cash and issued 50,000 unregistered shares of the Company's common stock, having a fair value of \$19,000 (\$0.36/share), based upon the quoted closing trading price in exchange for all of the issued and outstanding membership interests of HartLab. The Company paid \$14,000 of the cash purchase price upon signing of the Purchase Agreement in May, 2009 and the remainder of \$187,141 was paid at closing. In addition, Adeona agreed to guarantee and seek to release the seller from the seller's personal guarantee of the remaining balance of two outstanding clinical equipment leases of HartLab totaling \$78,859. As of September 30, 2009 this amount remains in escrow, however all personal guarantee's of the seller have been removed and the company expects to have this money returned in the near term.

The estimated purchase price for HartLab, as presented below, represents preliminary fair value estimates at the date of acquisition. Goodwill includes a preliminary estimate for the value of certain customer accounts. As applicable, these intangibles will be identified and valued for purposes of presenting intangible assets outside of the presentation for goodwill.

Consideration transferred at fair value:

|                     |           |
|---------------------|-----------|
| Cash                | \$201,141 |
| Common stock        | 19,000    |
| Total consideration | 220,141   |

Net assets acquired:

|                           |           |
|---------------------------|-----------|
| Current assets            | 124,746   |
| Current liabilities       | 82,834    |
| Total net assets acquired | 41,912    |
| Goodwill – at fair value  | \$178,229 |

The following unaudited interim condensed consolidated pro forma information gives effect to the acquisition of HartLab as if the transaction had occurred on January 1, 2008. The following pro-forma information is presented for illustration purposes only and is not necessarily indicative of the results that would have been attained had the acquisition been completed on January 1, 2008, nor are they indicative of results that may occur in any future periods:

|   | For the<br>Nine Months<br>Ended<br>September 30,<br>2009 | For the Three<br>Months<br>Ended<br>September 30,<br>2008 | For the Nine<br>Months<br>Ended<br>September 30,<br>2008 |
|---|--|---|--|
| Revenues  | \$ 144,634   | \$ 25,411   | \$ 98,139  |
| Net Loss  | (2,517,753)  | (1,433,657)   | (6,303,233)  |
| Basic and Diluted Loss from Continuing Operations per<br>Common Share |  |   |  |
|   | \$ (0.12)  | \$ (0.07)   | \$ (0.31)  |
| Weighted Average Shares Outstanding - Basic and Diluted               | 21,248,718   | 20,266,243  | 20,587,746   |

Included in the above table, is the following for HartLab, for the period July 10, 2009 to September 30, 2009:

|          |            |
|----------|------------|
| Revenues | \$50,893   |
| Net Loss | \$(55,779) |

#### Note 8 Subsequent Event

The Company has evaluated for subsequent events between the balance sheet date of September 30, 2009 and November 16, 2009, the date the financial statements were issued.

On October 15, 2009, the Company reincorporated from Delaware to Nevada pursuant to the discretionary reincorporation plan approved by stockholders at the Company's 2008 Annual Meeting of Stockholders in June 2008.

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

The following discussion should be read in conjunction with the attached unaudited consolidated financial statements and notes thereto, and with our audited consolidated financial statements and notes thereto for the fiscal year ended December 31, 2008, found in our Annual Report on Form 10K. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward looking statements by using words such as "anticipate," "believe," "intends," or similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in this 10-Q and as applicable in Part I, Item 1A of our Annual Report on Form 10K.

### Overview

Since our inception in January 2001, our efforts and resources have been focused primarily on acquiring and developing our pharmaceutical products, raising capital and recruiting personnel. We are a development stage company and have had no product sales to date. Our major sources of working capital have been proceeds from equity financings from affiliates of our Chairman and various private financings, primarily involving private sales of our common stock and other equity securities.

Our company's current corporate structure resulted from the October 2006 merger of a newly-created wholly owned subsidiary of Sheffield Pharmaceuticals, Inc. ("Sheffield"), a Delaware corporation incorporated in September 1993, and Pipex Therapeutics, Inc., a Delaware corporation ("Pipex Therapeutics"). In connection with that transaction, a wholly owned subsidiary of Sheffield merged with and into Pipex Therapeutics, with Pipex Therapeutics remaining as the surviving corporation and a wholly-owned subsidiary of Sheffield. On December 11, 2006, Sheffield changed its name to Pipex Pharmaceuticals, Inc. ("Pipex") and on October 16, 2008 the Company changed its name to Adeona Pharmaceuticals, Inc. ("Adeona"). In exchange for their shares of capital stock in Pipex Therapeutics, the former stockholders of Pipex Therapeutics received shares of capital stock of Sheffield representing approximately 98 percent of the outstanding equity of Sheffield on a primary diluted basis after giving effect to the transaction, with Sheffield assuming Pipex's outstanding options and warrants. In addition, the board of directors of Sheffield was reconstituted shortly following the effective time of the transaction such that the directors of Sheffield were replaced by our current directors, all of whom were previously directors of Pipex Therapeutics. Further, upon the effective time of the merger, the business of Sheffield was abandoned and the business plan of Pipex Therapeutics was adopted. The transaction was therefore accounted for as a reverse acquisition with Pipex Therapeutics as the acquiring party and Sheffield as the acquired party. Accordingly, when we refer to our business and financial information relating to periods prior to the merger, we are referring to the business and financial information of Pipex Therapeutics, unless the context indicates otherwise.

On October 15, 2009 we reincorporated in Nevada from Delaware pursuant to the discretionary reincorporation plan approved by our stockholder's at the Company's annual meeting of stockholders held in June 2008. The reincorporation was effected by the merger of Adeona Pharmaceuticals, Inc., a Delaware corporation ("Adeona Delaware"), with and into a newly created, wholly-owned Nevada subsidiary corporation.

In the reincorporation, each outstanding share of common stock of the Delaware corporation was automatically converted into one share of common stock of the Company as a Nevada corporation and all options and other rights to acquire Adeona Delaware common stock outstanding immediately prior to the reincorporation were automatically converted into options and rights to acquire the same number of shares of common stock of the Company as a Nevada corporation. Shareholders are not required to exchange their existing stock certificates of Adeona Delaware, which now represent the same number of shares of common stock of the Company as a Nevada corporation. Outstanding

shares of the Company's common stock retain the same CUSIP number as the corresponding shares of Adeona Delaware prior to the reincorporation, and the Company's common stock continues to be listed on the NYSEAmex stock exchange (formerly known as the American Stock Exchange and the NYSE Alternext US exchange) under the same symbol, "AEN". The reincorporation did not result in any material changes in our business, offices, assets, liabilities, obligations or net worth, or our directors, officers or employees, and Adeona Delaware ceased to exist as a separate legal entity. We continue to maintain our principal executive offices at 3930 Varsity Drive, Ann Arbor, Michigan 48106.

As a result of the reincorporation and by operation of Rule 12g-3(a) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Company, as a Nevada corporation, is the successor issuer to Adeona Delaware and has succeeded to the attributes of Adeona Delaware as the registrant. The common stock of the Company, as a Nevada corporation, is deemed to be registered under Section 12(b) of the Exchange Act, and the Company is subject to the informational requirements of the Exchange Act, and the rules and regulations promulgated thereunder.

## Recent Developments

### Acquisition of HartLab

On July 10, 2009 the Company acquired 100% of the membership interest in Hart Lab, LLC, an Illinois LLC, to development and commercializes its diagnostic test panel for the detection of zinc and copper deficiencies in the mature population. The Company paid \$201,141 in cash and issued 50,000 unregistered shares of the Company's common stock valued at \$19,000 in exchange for all of the issued and outstanding membership interests of HartLab. The Company paid \$14,000 of the cash purchase price upon signing of the Purchase Agreement in May, 2009 and the remainder of \$187,141 was paid at closing. Additionally, the Company entered into a consulting agreement with the seller for a period of up to twelve months for a monthly consulting fee of \$4,000.

## Critical Accounting Policies

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

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

Our results include non-cash compensation expense as a result of the issuance of stock and stock option grants. Compensation expense for options granted to employees represents the fair value of the award at the date of grant as amortized in the period of recognition. All share-based payments to employees since inception have been recorded and expensed in the statements of operations.

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

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

#### 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 nine months ended September 30, 2009.

#### 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 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.

#### Goodwill

Goodwill is tested for impairment at the reporting unit level (operating segment or one level below an operating segment) on an annual basis and between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying value. These events or circumstances could include a significant change in the business climate, legal factors, operating performance indicators, competition or sale or disposition of a significant portion of a reporting unit. Application of the goodwill impairment test requires judgment, including the identification of reporting units, assignment of assets and liabilities to reporting units, assignment of goodwill to reporting units, and determination of the fair value of each reporting unit. The fair value of each reporting unit is estimated using a discounted cash flow methodology. This requires significant judgments including estimation of future cash flows, which is dependent on internal forecasts, estimation of the long-term growth rate for our business, the useful life over which cash flows will occur, and determination of our weighted average cost of capital. Changes in these estimates and assumptions could materially affect the determination of fair value and/or goodwill impairment charge for each reporting unit.

We will continue to evaluate goodwill for impairment, at least annually. During the nine months ended September 30, 2009, we did not identify any indication of goodwill impairment.

## Results of Operations

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

**Research and Development Expenses.** For the three months ended September 30, 2009, research and development expense was \$325,662 as compared to \$863,272 for the three months ended September 30, 2008. The decrease of \$537,610 is due primarily to a substantial decrease in stock based compensation charges, a decrease associated with payments related the development of our licensed clinical drug candidates, a decrease in salaries and related taxes and a decrease in allocated overhead expenses.

**General and Administrative Expenses.** For the three months ended September 30, 2009, general and administrative expense was \$351,646 as compared to \$606,685 for the three months ended September 30, 2008. The decrease of \$255,039 is due primarily to a decrease in salaries and payroll taxes and a decrease in stock based compensation charge offset by higher general and administrative expenses associated with the cost of services and marketing activities associated with our acquisition of CLIA-certified HartLab on July 10, 2009.

**Other Income (Expense), net.** For the three months ended September 30, 2009, interest income was \$148 as compared to \$41,118 for the three months ended September 30, 2008. Interest income was lower for the period in 2009 as compared to the same period in 2008 due to lower interest rates and lower levels of cash kept in interest bearing accounts to ensure FDIC insurance coverage.

**Net Loss.** Net loss for the three months ended September 30, 2009, was \$626,075 as compared to \$1,428,839 for the three months ended June 30, 2008. This decrease in net loss of \$802,764 is attributable primarily to a decrease in research and development expense of 537,610, a decrease in general and administrative expenses of 255,039 and an increase in other income (loss) net of \$41,118 as discussed above.

### Nine months Ended September 30, 2009 and 2008.

**Research and Development Expenses.** For the nine months ended September 30, 2009, research and development expense was \$1,219,135 as compared to \$4,156,255 for the nine months ended September 30, 2008. The decrease of \$2,937,120 is due primarily to a substantial decrease associated with payments related to the development of our licensed clinical drug candidates, a decrease in stock based compensation charges, a decrease in salaries and related taxes and a decrease in allocated overhead expenses.

**General and Administrative Expenses.** For the nine months ended September 30, 2009, general and administrative expense was \$1,410,200 as compared to \$2,242,855 for the nine months ended September 30, 2008. The decrease of \$832,417 is due primarily to a decrease in salaries and payroll taxes, a decrease in stock based compensation charge, a decrease in allocated overhead and a decrease in professional fees all brought about by corporate restructuring, offset by higher general and administrative expenses associated with the cost of services and marketing activities associated with our acquisition of HartLab on July 10, 2009.

**Other Income (Expense), net.** For the nine months ended September 30, 2009, other expense was \$39,358 compared to other income-net of \$109,102 for the nine months ended September 30, 2008. For the nine months ended September 30, 2009, interest income was \$2,826 as compared to \$108,503 for the nine months ended June 30, 2008. Interest income was lower for the period in 2009 as compared to the same period in 2008 due to lower interest rates and lower levels of cash in interest bearing accounts.

**Net Loss.** Net loss for the nine months ended September 30, 2009, was \$2,617,608 as compared to \$6,290,008 for the nine months ended September 30, 2008. This decrease in net loss of \$3,672,400 is attributable primarily to a decrease



in research and development expense of \$2,937,120, a decrease in general and administrative expenses of \$832,417 and an increase in other income (loss)-net of \$148,460 as discussed above.

#### Liquidity and Capital Resources

During the nine months ended September 30, 2009, we had a net decrease in cash of \$2,323,915. Total cash resources as of September 30, 2009 was \$3,532,469. During the nine months ended September 30, 2009 and 2008, net cash used in operating activities was \$2,163,356 and \$4,140,225 respectively. This cash was used to fund our operations for the periods, adjusted for non-cash expenses and changes in operating assets and liabilities.

Net cash used in investing activities was \$170,317 for the nine months ended September 30, 2009 compared to \$21,398 for the nine months ended September 30, 2008. The net cash used in investing activities for the nine months ended September 30, 2009 were used in our acquisition of HartLab, offset by \$25,200 received from the sale of equipment. The net cash used in investing activities for the nine months ended September 30, 2008 resulted from the purchase of property and equipment in the amount of \$21,398.

Net cash provided by financing activities was \$9,758 for the nine months ended September 30, 2009 compared to \$895,572 of net cash used in financing activities for the nine months ended September 30, 2008. The net proceeds gained in financing activities for the nine months ended September 30, 2009 was from the issuance common stock in exchange for stock options exercised. The net cash used in financing activities for the nine months ended September 30, 2008 resulted from \$900,000 for the repayment on notes payable, less proceeds of \$4,428 from the issuance of common stock.

Our continued operations will depend on whether we are able to generate revenues and profits through our sales of diagnostic clinical laboratory services and zinc-based products or raise additional funds through various potential sources, such as license fees from a potential corporate partner, equity and debt financing. Such additional funds may not become available on acceptable terms and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term. We will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs.

### Current and Future Financing Needs

We have incurred an accumulated deficit of \$40,899,285 through September 30, 2009. We have incurred negative cash flow from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts. Based on our current plans, we believe that our cash will be sufficient to enable us to meet our planned operating needs at least for the next 12 months.

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

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our pre-clinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals;
- our potential stock repurchases under our Stock Repurchase Program, and
- the success, timing, and profitability of our copper/zinc clinical laboratory diagnostic services and zinc-based product launches.

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

## Product Candidates

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

During the first quarter of 2009, we analyzed patient samples from an IRB-approved, prospective, observational, blinded clinical trial that we sponsored and conducted during 2007 and 2008. Such study enrolled 90 subjects, 30 with Alzheimer's disease (AD), 30 with Parkinson's disease (PD) and 30 age-matched normal subjects. The purpose of the study was to evaluate serum markers of copper status and compare these results across the three groups of patients. The results of such study indicate highly statistically significant differences in serum markers of copper status between AD and normal subjects. We believe that the differences observed suggest that Alzheimer's patients have impaired metabolic functioning that decreases their protection from chronic copper toxicity, which may contribute to the progression of their disease. The results from this study also appear to indicate a subclinical zinc deficiency in AD subjects. On July 16, 2009 we announced the presentation of our findings from this study at the 2009 International Conference on Alzheimer's disease (ICAD). There is an estimated 5.8 million, 1.5 million and 15 million persons in the U.S. with Alzheimer's disease, Parkinson's disease and mild cognitive impairment (MCI), respectively, that may benefit from our planned panel of clinical diagnostic products and services.

On July 10, 2009 we acquired Hart Lab, LLC, an Illinois limited liability company and CLIA-certified clinical laboratory through which we intend to launch and market our intended panel of copper and zinc metabolism clinical diagnostic products and services.

On September 8, 2009 we announced the creation of our initial sales and marketing team to launch the CopperProof™ Test Panel to neurologists, gerontologists and other physicians that care for Alzheimer's disease and cognitive impairment patients. . On November 9, 2009, we announced that we had initiated the U.S. launch of our HartLab subsidiary's high precision diagnostic test panel for the comprehensive evaluation of zinc and copper status in patients with Alzheimer's disease (AD) and mild cognitive impairment (MCI). The CopperProof™ test panel provides a comprehensive analysis at the metabolic serum copper and zinc status of AD and MCI patients, which status has been shown to be impaired in this patient population. Defects in copper metabolism and high free copper levels are increasingly being recognized as significant factors in the progression of neurodegenerative diseases, including AD and MCI. This panel will allow physicians to determine the copper and zinc metabolic status of these patients as an aid in their continued treatment program.

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

Our leading therapeutic product candidate brands, Zinthionein™ and EyeDaily™ with Zinthionein™, are expected to be products that contain proprietary ingredients (such as, zinc monocyteine complex), proprietary combinations of ingredients, proprietary modified-release zinc-containing formulations, such as Zinthionein™ ZC GS-150 (containing 150mg elemental zinc and the amino acid cysteine) and proprietary product packaging. We believe that our technologies and expertise may provide physicians and aging patients with the most timely, convenient, well tolerated, "best-in-class" product solutions we consider to be an under-recognized, potential multi-billion dollar market to address for the prevention and treatment of degenerative conditions that we believe involve subclinical zinc deficiency and/or chronic copper toxicity.

Zinc-monocyteine is a complex of zinc and the amino acid cysteine that we believe may have improved properties compared to currently marketed zinc-based products. Zinc-monocyteine was invented and developed by David A. Newsome, M.D., President of the Company's subsidiary Healthmine and former Chief of the Retinal Disease Section of the National Eye Institute (NEI). Dr. Newsome was the first to pioneer and demonstrate the benefits of oral high dose zinc therapy in Dry Age-Related Macular Degeneration ("Dry AMD"). Oral high dose zinc containing products now represent the standard of care for Dry AMD affecting over 10 million Americans and have annual sales of

approximately \$300 million. Zinc monocyteine has completed an 80-patient, randomized, double-masked, placebo controlled clinical trial in dry AMD and demonstrated highly statistically significant improvements in central retinal function the results of which were published in a peer-reviewed journal in 2008. In addition, we believe that our patent pending modified-release formulations of zinc-monocyteine and other zinc moieties may offer the significant advantages of convenient once-a-day dosing and improved gastrointestinal tolerability compared to currently-marketed oral high dose zinc-containing products. During the third quarter of 2009 we made continued progress in the manufacture and scale up of zinc-monocyteine to support the further nonclinical testing and cGMP manufacturing required to support our planned Generally Regarded as Safe affirmation process, which we consider to be among one of several prerequisites prior to the potential product launch of products containing zinc-monocyteine as an active ingredient and second generation product potentially replacing the active ingredients in Zinthionein™ ZC GS-150, namely zinc and the amino acid cysteine.

Our sales and marketing plans include direct sales to physicians through a specialty sales force, promoting the understanding of chronic copper toxicity and zinc deficiency and patient education regarding the potential risks of chronic free copper exposure, and Through our Hart Lab CLIA-certified clinical reference laboratory, we are commercializing serum based diagnostic tests to assist physicians in identifying patients with zinc deficiency and patients at increased risk chronic copper toxicity due to impaired serum copper binding. Through our specialty sales force, we currently intend to launch Zinthionein™ ZC GS-150, our patent pending proposed once-daily gastro-retentive sustained release oral zinc preparation containing 150mg elemental zinc and the amino acid cysteine in the first quarter of 2010 as a prescription medical food for the dietary management of patients having conditions characterized by zinc deficiency and chronic copper toxicity, such as, Alzheimer's disease and mild cognitive impairment (MCI). Through our Healthmine subsidiary, we launched copperproof.com, a website intended to increase public awareness aimed at the prevention of chronic copper toxicity. Our EyeDaily™ brand of oral zinc-based therapies is expected to utilize patent-pending product packaging that incorporates an eye-self test to improve compliance and convenience of patients with Dry AMD.

On November, 2, 2009 we announced that we received Institutional Review Board (IRB) approval to initiate a 60 patient, randomized, double-blind, placebo-controlled clinical trial of our patent pending Zinthionein™ ZC-GS150 in an Alzheimer's disease (AD) and mild cognitive impairment (MCI) patient group. The clinical trial, titled "CopperProof 2," will test the effects of Zinthionein™ ZC-GS150, a novel gastro-retentive, sustained release zinc/cysteine combination tablet on the amelioration of sub-clinical zinc deficiency, and elevated percentage serum free copper, associated with Alzheimer's Disease and Mild Cognitive Impairment (MCI). Zinthionein™ ZC-GS150 is our patent pending, first generation modified release formulation of high dose zinc and other GRAS ingredients that does not include zinc-monocyteine, that we believe is capable of delivering 150mg of elemental zinc in a convenient once-a-day dose with superior gastrointestinal tolerability compared currently marketed zinc preparations required to be taken two to three times a day and that are associated with nausea in up 90% of patients and gastric irritation in 30% of patients. The first part of the CopperProof-2 study will compare the tolerability and bioavailability of Zinthionein™ ZC-GS150 to a currently marketed high dose zinc preparation and is expected to yield results within the next several months. The second part of the CopperProof-2 study will compare once-daily Zinthionein™ ZC-GS150 versus placebo for six months in a double-blind, randomized fashion in 60 patients with Alzheimer's disease and Mild Cognitive Impairment to determine whether dietary management of such diseases with Zinthionein™ ZC-GS150 will demonstrate improvements in cognition (ADAS-Cog and Mini Mental State Exam scores) compared to placebo as well as improvement in serum parameters of copper/zinc dysfunction. Assuming successful results of Part 1 of the CopperProof-2 study, we currently plan to launch once-daily Zinthionein™ ZC-GS150 in the first quarter of 2010 for the dietary management of zinc deficiency in AD and MCI patients.

Through September 30, 2009, we have incurred approximately \$515,000 of costs related to our development of Zinthionein of zinc-monocyteine, our modified release oral zinc candidates, such as Zinthionein™ ZC GS-150, which \$154,000 was incurred during 2007, \$256,000 which was incurred in 2008 and \$105,000 which was incurred during the first half of 2009.



### Oral dnaJP1

In June 2008, we in-licensed Oral dnaJP1, an oral, candidate for the treatment of rheumatoid arthritis (RA) which has completed a 160 patient, multi-center, double-blind, randomized, placebo-controlled Phase II clinical trial for the treatment of RA. Rheumatoid arthritis is an autoimmune disease which affects approximately 20 million people worldwide. Oral dnaJP1 is an epitope specific immunotherapy for RA patients. Oral dnaJP1 is a heat shock protein (hsp)-derived peptide which was previously identified as a contributor of T cell mediated inflammation in RA. Immune responses to hsp are often found at sites of inflammation and have an initially amplifying effect that needs to be down regulated to prevent tissue damage. The mechanisms for this regulation involve T cells with regulatory function that are specific for hsp-derived antigens. This regulatory function is one of the key components of a "molecular dimmer" whose physiologic function is to modulate inflammation independently from its trigger. This function is impaired in autoimmunity and could be restored for therapeutic purposes. Through September 30, 2009, we have incurred approximately \$392,000 of costs related to our development of oral dnaJP1 all of which \$219,000 has been incurred in 2008 and \$173,000 was incurred during the first half of 2009. On November 13, 2009 we announced the publication of results of the 160 patient, multi-center, double-blind, randomized, placebo-controlled Phase II clinical trial for the treatment of RA. 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 the current issue of *Arthritis & Rheumatism*, Vol. 60(11), pages 3207-3216, with related editorial at page A21. We are currently engaged in the cGMP manufacture and scale up of the dnaJP1 active ingredient and other nonclinical activities necessary to support the potential filing and approval of our own corporate investigational drug application (IND) for the further clinical testing of oral dnaJP1. We are also actively seeking potential U.S. and international corporate partners to assist in the further manufacturing, testing and clinical development of oral dnaJP1; however, there can be no assurances that we will in fact find such partners.

### TRIMESTA™ (oral estriol)

In June 2007, a two year seven U.S. center, placebo controlled 150 patient phase IIb clinical trial using TRIMESTA™ for the treatment of relapsing-remitting Multiple Sclerosis (MS) was initiated under a \$5 million grant from the Southern California Chapter of the National Multiple Sclerosis Society and NIH. This phase IIb clinical trial builds upon our encouraging results from an earlier phase IIa clinical trial. The primary purpose of this study is to evaluate the safety and efficacy of TRIMESTA™ in a larger MS patient population with a one year blinded interim analysis. The preclinical and clinical development of TRIMESTA™ has been primary financed by grants from the NIH and various non-profit foundations. Through September 30, 2009, we have incurred approximately \$747,000 of costs related to our development of TRIMESTA™ of which approximately \$49,500, \$185,500, 194,000 and \$256,000 was incurred in fiscal years 2005, 2006, 2007 and 2008 respectively, and approximately \$62,000 was incurred in 2009. During 2009, this clinical trial was expanded to include 16 total clinical trial sites and currently approximately 60 of 150 patients have been enrolled in this Phase IIb study and the rate of enrollment has been positively impacted through the activation of the additional nine (9) new clinical sites..

### Oral flupirtine

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

Oral TTM (oral tetrathiomolybdate)

Through September 30, 2009, we have incurred approximately \$3,639,000 of costs related to our development of oral TTM, of which approximately \$150,000, \$1,061,000, \$1,676,000 and \$725,000 was incurred in fiscal years 2005, 2006, 2007 and 2008, respectively, and approximately \$27,000 was incurred during 2009.

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

Anti-CD4 802-2

Through September 30, 2009, we have incurred \$1,532,000 of costs related to our development of anti-CD4 802-2 of which \$58,000, \$332,000, \$303,000, \$295,000, \$113,000, \$161,000, \$121,000 and \$82,000 was incurred in fiscal years 2001, 2002, 2003, 2004, 2005, 2006, 2007 and 2008 respectively and approximately \$67,000 has been incurred in 2009. We are seeking potential U.S. and international corporate partners for the further development of anti-CD4 802-2 for various indications.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

None.

ITEM 4T. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures

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

(b) Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during our fiscal quarter ended September 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



## PART II—OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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

### ITEM 1A. RISK FACTORS

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

#### RISKS RELATING TO OUR BUSINESS

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

We are a development stage company that has experienced significant losses since inception and has a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. To date, we have generated no product revenues. As of September 30, 2009, we have expended approximately \$24.3 million on a consolidated basis acquiring and developing our current product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Therefore, for the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees, and grants. We will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We are not currently profitable and may never become profitable.

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

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



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

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

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

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

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

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. Changes in key positions in our Company, as well as additions of new personnel and departures of existing personnel, can be disruptive, might lead to additional departures of existing personnel and could have a material adverse effect on our business, operating results, financial results and internal controls over financial reporting.

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

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

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

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

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

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

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

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

In addition to our own patent applications, we also currently rely on licensing agreements with third party patent holders/licensors for our products. We have an exclusive license agreement with the McLean Hospital relating to the use of flupirtine to treat fibromyalgia syndrome; an exclusive license agreement with Thomas Jefferson University relating to our CD4 inhibitor program; an exclusive license agreement with the Regents of the University of California relating to our TRIMESTA™ technology; an exclusive license to our oral immunotherapeutic tolerance program, named dnaJP1 from 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 to use our best efforts to commercialize each of the technologies as well as meet certain diligence requirements and timelines in order to keep the license agreement in effect. In the event we are not able to meet our diligence requirements, we may not be able to retain the rights granted under our agreements or renegotiate our arrangement with these institutions on reasonable terms, or at all. In addition, our agreement with UCSD requires 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 secure access to \$2.5 million in funds on or before June 30, 2010 in order to maintain this license agreement in effect. Our license agreement with the University of Michigan relating to tetrathiomolybdate requires 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. If we fail to meet these milestones we could lose such licenses.

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

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

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

Companies that currently sell or are developing both generic and proprietary pharmaceutical compounds to treat central-nervous-system and autoimmune diseases include: Pfizer, Inc., Rigil Pharmaceuticals, Incyte Pharmaceuticals, Chelsea Therapeutics International, Inc., Aton Pharma, GlaxoSmithKline Pharmaceuticals, Alcon, Inc., Shire Pharmaceuticals, Plc., Schering-Plough, Organon NV, Merck & Co., Eli Lilly & Co., Serono, SA, Biogen Idec, Inc., Achillion, Ltd., Active Biotech, Inc., Panteri Biosciences, Meda, Merrimack Pharmaceuticals, Inc., Merck-Schering AG, Forest Laboratories, Inc., Attenuon, LLC, Cypress Biosciences, Inc., Genentech, Neurotech, Amgen, Inc., Centocor/Johnson and Johnson, UCB Group, Abbott, Wyeth, OM Pharma, Cel-Sci Pharmaceuticals, Novartis, Axcan Pharma, Inc., Teva Pharmaceuticals, Inc., Intermune, Inc. Fibrogen, Inc., Active Biotech, CNSBio, Pty., Rare Disease Therapeutics, Inc., Prana Biotechnology, Inc., Merz & Co., AstraZeneca Pharmaceuticals, Inc., Chiesi Pharmaceuticals, Inc., Alcon, Inc., Bausch and Lomb, Inc., Targacept, Inc., and Johnson & Johnson, Inc. Alternative technologies or alternative delivery or dosages of already approved therapies are being developed to treat dry AMD, autoimmune inflammatory, rheumatoid arthritis, psoriasis, Fibromyalgia, MS, Huntington's, Alzheimer's and Wilson's diseases, several of which may be approved or are in early and advanced clinical trials, such as zinc based combinations, Syk inhibitors, Jak inhibitors, connective tissue growth factors (CTGF), FTY-720, Laquinimod, pifenedone, 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, zinc-monocysteine, Zinthionein™ ZC GS-150 gastro-retentive sustained release oral high dose zinc preparations, oral dnaJP1, CD4 inhibitors and flupirtine technologies. Should clinicians or regulatory authorities view these therapeutic regimens as more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid and private insurers.

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

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

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

If the FDA approves other 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™ ZC GS-150 product candidate that we plan to launch in the first quarter of 2010 does not contain the patented ingredient zinc-monocysteine and is instead the subject of pending U.S. and international patent applications in initially filed in January 2006, 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. Similarly, the CopperProof™ Test Panel offered by our HartLab 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 Zinthionein program, we do not have composition of matter patents for TRIMESTA, flupirtine, oral TTM or their respective active ingredients estriol, flupirtine, and ammonium tetrathiomolybdate. We also expect to rely on patent protection from an issued U.S. Patent for the use of oral TTM and related compounds to treat Alzheimer's disease (U.S. Patent No 7,416,741). These patents have been exclusively licensed to us. We have also filed various pending patent applications which cover various formulations, packaging, distribution & monitoring methods for oral TTM. We rely on issued patent and pending patent applications for use of TRIMESTA to treat MS (issued U.S. Patent No. 6,936,599) and various other therapeutic indications which have been exclusively licensed to us. We have exclusively licensed issued U.S. 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.

Our zinc-monocysteine product candidate is exclusively licensed from its inventors, David A. Newsome, M.D. and David Tate, Jr. zinc-monocysteine is the subject of two issued U.S. patents, 7,164,035 and 6,586,611 and pending U.S. patent application ser. no. 11/621,380 which cover 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 U.S. patent 7,164,035) of an English translation of a Russian disclosure, Zegzhda et. al. Chemical Abstracts Vol. 85 Abstract No. 186052 (1976) that was cited by the U.S. patent examiner during our



prosecution of the pending divisional U.S. patent application Ser. No. 11/621,390. In April 2008, we analyzed the zinc-cysteine complex described by Zegzhda and concluded that such complex describes an insoluble zinc salt and does not describe a non-zinc salt zinc monocysteine complex and therefore believe that such disclosure should not affect the validity of any of our issued U.S. patent claims relating our zinc-monocysteine composition-of-matter claims. We have filed a response and declaration describing the results of our analysis with the U.S. Patent and Trademark Office with respect to the Zegzhda reference with respect to U.S. patent application ser. no. 11/621,380. In an office action dated August 20, 2008, the U.S. 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 U.S. Patent and Trademark Office.

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

We may also rely on the United States Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Amendments," to protect some of our current product candidates, specifically oral TTM, dnaJP1, TRIMESTA, zinc-monocystine, 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 November 13, 2009, 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.

Effective March 29, 2009, Nicholas Stergis resigned as our Chief Executive Officer. Mr. Stergis remains a director of the Company. Steve H. Kanzer was appointed our President and Chief Executive Officer. Effective June 26, 2009, Steve H. Kanzer resigned as our President and Chief Executive Officer upon the appointment of Max Lyon as

President and Chief Executive Officer.

Certain of our directors, (Jeffrey Kraws, a director and former VP of Business Development, Jeffrey Wolf, a director, Nicholas Stergis, a director, and Dr. Kuo, a director) scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies which might be developing competitive products to ours. 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.

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

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

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

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

In order to successfully commercialize our product candidates, we must be able to manufacture our products in commercial quantities, in compliance with regulatory requirements, at acceptable costs, and in a timely manner. Manufacture of the types of biopharmaceutical products that we propose to develop present various risks. For example, manufacture of zinc-monocysteine, dnaJP1, flupirtine, and TTM is a complex process that can be difficult to scale up for purposes of producing large quantities. This process can also be subject to delays, inefficiencies, and poor or low yields of quality products. Furthermore, 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. Oral TTM is also known to be subject to a loss of potency as a result of prolonged exposure to moisture and other normal atmospheric conditions. 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 issues 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 rely 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 phase IIb clinical trial for MS. 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 US.

Our plans to launch oral Zinthionein<sup>TM</sup> ZC GS-150 as prescription medical food for the dietary management zinc deficiency in Alzheimer's disease and Mild Cognitive Impairment (MCI) will depend upon the successful cGMP manufacture, quality control and acceptable results of stability studies to be performed for Zinthionein<sup>TM</sup> ZC GS-150 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 first part of our CopperProof-2 clinical trial to be conducted at Clearwater, 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 cleanrooms 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 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.

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

Physicians and patients may not accept and use our technologies.

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

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

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

We depend on researchers who are not under our control.

Since we have in-licensed some of our product candidates, we depend upon 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 become disabled or die unexpectedly, or should they fail to comply with applicable regulatory guidelines, we 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 dnaJP1, 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 or physician sponsored INDs 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 have 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 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. Should we or a future sublicensee elect to seek to conduct additional clinical trials of oral TTM, we or such sublicensee as the case may be would be expected to be required to file a new IND with the FDA for oral TTM and gain FDA approval for such IND prior to initiating any clinical studies and would be subject to the risks and potential delays associated with obtaining such approval. Any delay or inability to obtain any data, and any such regulatory issues, might result our inability to advance our products through the regulatory process or obtain pharmaceutical partners for them.

We are also highly dependent on government and private grants to fund certain of our clinical trials for our product candidates. For example, TRIMESTA (oral estriol) has received a \$5 million grant from the Southern California Chapter of the National Multiple Sclerosis Society and the National Institutes of Health (NIH) 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 reach an IND cross reference agreement with the inventor/IND holder for this program should we elect to file our own corporate IND for our TRIMESTA (oral estriol) program.

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

We currently only have limited sales, marketing, or distribution capabilities as our sales force is currently only comprised of three full-time sales representatives. 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 U.S. Patent and Trademark Office to determine priority of invention. We, or our licensors, may also need to participate in interference proceedings involving our issued patents and pending applications of another entity.

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

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

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

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

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

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

#### RISKS RELATING TO OUR STOCK

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

We expect to seek to raise additional capital in the future to help fund development of our proposed products. If we raise additional capital through the issuance of equity or debt securities, the percentage ownership of our current stockholders will be reduced. We may also enter into strategic transactions, issue equity as part of license issue fees to our licensors, compensate consultants 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. In January 2009, we registered for sale under the Securities Act of 1933, as amended, 8,816,918 shares of our outstanding common stock held by our officers, directors and principal stockholders and 1,148,753 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. During 2009, in order to remain listed on NYSE Amex, we are required to maintain a minimum stockholders' equity of \$4 million and this requirement will likely increase to \$6 million in 2010.

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

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

We have never paid dividends.

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

## RISKS RELATED TO OUR INDUSTRY

### Government Regulation

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. On June 25, 2007, the FDA published its final rule regulating cGMPs for dietary supplements. The final rule became effective August 24, 2007 and small companies with less than 20 employees, such as us, have until June 2010 to achieve compliance. 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 U.S. Dietary Supplement Health and Education Act of 1994, or DSHEA, revised the provisions of the Federal Food, Drug and Cosmetic Act, or FDCA, 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 a guidance, paralleling an earlier guidance from the FTC, defining a manufacturers 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 enterally 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 (for fiscal year 2008, \$1,178,500). In return, the FDA assigns a goal of ten months for issuing its “complete response,” in which the FDA may approve or deny the NDA, or require additional clinical data. Even if these data are submitted, the FDA may ultimately decide the NDA does not satisfy approval criteria. If the FDA approves the NDA, the product becomes available for physicians prescription. Product approval may be withdrawn if regulatory compliance is not maintained or safety problems occur. The FDA may require post-marketing studies, also known as phase IV studies, as a condition of approval, and requires surveillance programs to monitor approved products that have been commercialized. The agency has the power to require changes in labeling or prohibit further marketing based on the results of post-marketing surveillance.

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

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

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

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

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

#### Other Regulatory Requirements

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

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

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.

#### European Product Approval

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

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

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

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

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

#### Pricing Controls

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

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

#### Third-Party Reimbursements

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

In the U.S., consumer willingness to choose a self-administered outpatient prescription drug over a different drug or other form of treatment often depends on the manufacturer's success in placing the product on a health plan formulary or drug list, which results in lower out-of-pocket costs. Favorable formulary placement typically requires the product to be less expensive than what the health plan determines to be therapeutically equivalent products, and often requires manufacturers to offer rebates. Federal law also requires manufacturers to pay rebates to state Medicaid programs in order to have their products reimbursed by Medicaid. Medicare, which covers most Americans over age 65 and the disabled, has adopted a new insurance regime that will offer eligible 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.

## Fraud and Abuse Laws

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

## Patent Restoration and Marketing Exclusivity

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

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

We have limited experience.

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 HartLab subsidiary. We are also researching, developing and pursuing the commercialization of various diagnostic tests for copper and zinc status through HartLab. 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 be able to generate any 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 is 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 only recently launched through HartLab, 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 launch this test panel or other diagnostic tests on the anticipated timelines or at all. We have no experience in performing, selling or marketing diagnostic test panel or any other 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 HartLab 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 HartLab 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 or 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 payors and private insurers;

- the level of physician and customer adoption of any diagnostic tests we develop;

- pricing pressures and changes in third-party payor 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 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.

We have recently developed and launched initial copper and zinc status tests through Hart Lab, our CLIA-licensed clinical reference laboratory located in Bolingbrook, IL. We only recently acquired Hart Lab in July 2009 and as a result have little experience operating a CLIA-licensed laboratory. Because there is substantial distance between Hart Lab and our corporate headquarters in Ann Arbor, Michigan, we may have logistical and operational challenges in effectively managing and operating Hart Lab. If we are unable to successfully commercialize our serum based copper and zinc diagnostic test panels through Hart Lab, 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 Hart Lab and obtain and maintain required regulatory approvals.

HartLab as a clinical laboratory is subject to CLIA, which is 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. HartLab 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.

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 HartLab, 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 U.S. 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 HartLab'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.

The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current diagnostic product candidates may not have favorable results in later studies or trials.

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. Our

product candidates may fail to demonstrate positive results in clinical trials despite having progressed through earlier-stage trials. 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. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a product development program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization.

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.

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

Our only laboratory facility for copper and zinc testing products 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.

We do not currently have product liability or malpractice insurance.

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. 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.

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

During the first nine months of 2009, the Company issued a total of 232,472 shares of our common stock to 3 consultants for services rendered. These offerings and sales of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuances did not involve a public offering. The offerings were not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the offering. This offering was done with no general solicitation or advertising by the Registrant. Based on an analysis of the above factors, the Registrant has met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

In February 2009, we issued a total of 257,813 shares of our common stock to a university for license fees. These offerings and sales of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuances did not involve a public offering. The offerings were not a public offering as defined in Section 4(2) because the offer and sale was made to an insubstantial number of persons and because of the manner of the offering. The offerings were done with no general solicitation or advertising by the Registrant. Based on an analysis of the above factors, the Registrant has met the requirements to qualify for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

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

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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/ Max Lyon

Max Lyon

President and Chief Executive Officer

(Principal Executive Officer and Principal Financial Officer)

Date: November 16, 2009