

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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:

(Title of Class)

Common Stock, \$0.001 par value per share

Name of each exchange on which registered

NYSE AMEX

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

None

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

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

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

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

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

Indicate by 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   
Non-accelerated filer   
(Do not check if a smaller  
reporting company)

Accelerated filer   
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

The aggregate market value of the issuer's common stock held by non-affiliates of the registrant as of March 28, 2010, was approximately \$20,701,549 based on \$1.56, the price at which the registrant's common stock was last sold on that date.

As of March 28, 2010, the issuer had 21,671,446 shares of common stock outstanding.

Documents incorporated by reference: None.

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**ADEONA PHARMACEUTICALS, INC.**

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## PART I.

### Forward-Looking Statements

Most of the matters discussed within this report include forward-looking statements on our current expectations and projections about future events. In some cases you can identify forward-looking statements by terminology such as “may,” “should,” “potential,” “continue,” “expects,” “anticipates,” “intends,” “plans,” “believes,” “estimates,” and similar expressions. These statements are based on our current beliefs, expectations, and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and generally beyond our control, that could cause actual results to differ materially from those expressed, projected or implied in or by the forward-looking statements. Such risks and uncertainties include the risks noted under “Item 1A Risk Factors.” We do not undertake any obligation to update any forward-looking statements.

### ITEM 1. BUSINESS

#### GENERAL

Adeona Pharmaceuticals, Inc., a Nevada corporation, (“Adeona” or the “Company”) is a pharmaceutical company developing new medicines for serious central nervous systems diseases. Adeona’s primary strategy is to in-license clinical-stage drug candidates that have already demonstrated a certain level of clinical efficacy and develop them further to either commercialization or a development collaboration. Trimesta (estriol) is an investigational oral drug for the treatment of relapsingremitting multiple sclerosis. A 150-patient, 16-center, randomized, double-blind, placebo-controlled clinical trial is currently underway. Zinthionein™ ZC (zinc cysteine) is an oral, gastro-retentive, sustained-release medical food candidate being developed for the dietary management of Alzheimer’s disease and mild cognitive impairment. In December of 2009, Adeona initiated a 60-patient clinical study. Effirma (flupirtine) is a novel centrally-acting investigational oral drug for the treatment of fibromyalgia syndrome. It is ready for a 90-patient proof-of-concept clinical trial. dnaJP1 (hsp peptide) is an investigational oral drug for the treatment of rheumatoid arthritis. It has completed a 160-patient, multi-center, randomized, double-blind, placebo-controlled clinical trial. CD4 Inhibitor 802-2 (cyclic heptapeptide) is an investigational drug for the prevention of severe graft-versus-host disease. A 23-patient clinical trial has been completed.

Below is a table of Adeona’s product candidates, their medical indication(s) and their stage of development:

<b>Product Candidate</b>	<b>Medical Indication</b>	<b>Stage of Development</b>
Trimesta (estriol)	Treatment of relapsingremitting multiple sclerosis in women	10-patient, 22-month, single-agent, crossover clinical trial completed and a 150-patient, 16-center, randomized, double-blind, placebo-controlled clinical trial underway
Zinthionein™ ZC (zinc cysteine)	Dietary management of Alzheimer’s disease and mild cognitive impairment	60-patient, randomized, double-blind, placebo-controlled clinical study underway
Effirma (flupirtine)	Treatment of fibromyalgia	IND and IRB approved for 90-patient clinical trial
dnaJP1 (hsp peptide)	Treatment of rheumatoid arthritis	160-patient, multi-center, randomized, double-blind, placebo-controlled clinical trial completed
CD4 Inhibitor 802-2 (cyclic heptapeptide)	Prevention of severe graft-versus-host disease	23-patient clinical trial completed

Through our HartLab clinical reference laboratory, serum-based diagnostic tests are being commercialized including the CopperProof™ Panel to assist physicians in identifying patients with zinc deficiency and patients at increased risk of chronic copper toxicity due to impaired serum copper binding.

In addition, we are seeking United States, European and Asian corporate partners for the further development of the investigational oral tetrathiomolybdate drug for treating Alzheimer's disease, Parkinson's disease and Huntington's disease.

## **Product Candidates**

### ***Trimesta***

Trimesta (estriol) is an investigational oral drug for the treatment of relapsing-remitting multiple sclerosis. Estriol has been approved and marketed for over 40 years throughout Europe and Asia for the treatment of post-menopausal hot flashes. It has never been approved by the Food and Drug Administration for any indication. Estriol is a hormone that is produced by the placenta during pregnancy. Maternal levels of estriol increase in a linear fashion throughout the third trimester of pregnancy until birth, whereupon they abruptly fall to near zero.

It has been scientifically documented that pregnant women with certain autoimmune diseases experience a spontaneous reduction of disease symptoms during pregnancy, especially in the third trimester. The list of autoimmune diseases that have been seen to improve during pregnancy includes multiple sclerosis, rheumatoid arthritis, thyroiditis, uveitis, juvenile rheumatoid arthritis, ankylosing spondylitis with peripheral arthritis, and psoriatic arthritis. It has further been scientifically documented that these same pregnant women have high rates of disease relapse post-partum, particularly in the immediate three-month post-partum period.

The PRIMS study (Pregnancy in Multiple Sclerosis), a landmark clinical study published in the *New England Journal of Medicine*, followed 254 women with multiple sclerosis during 269 pregnancies and for up to one year after delivery. The PRIMS study demonstrated that relapse rates were significantly reduced by 71 percent ( $p < 0.001$ ) through the third trimester of pregnancy from pre-baseline levels and relapse rates then increased by 120 percent ( $p < 0.001$ ) during the first three months post-partum before returning to pre-pregnancy rates.

The inventor of Trimesta has conducted scientific research on the role that estriol plays in creating immunologic privilege to the fetus in order to prevent its rejection by the mother. She believes that estriol's immunomodulatory and anti-inflammatory properties may explain the remissions seen in certain Th1-mediated autoimmune diseases during pregnancy. Based upon these insights, this scientist has conducted clinical trials of Trimesta in female patients with relapsing-remitting multiple sclerosis.

### **Clinical Trial Results of Trimesta- in RelapsingRemitting Multiple Sclerosis Patients**

An investigator-initiated, 10-patient, 22-month, single-agent, crossover clinical trial was completed in the United States to study the therapeutic effects of 8 mg of Trimesta daily in nonpregnant female relapsing-remitting multiple sclerosis patients. The total volume and number of gadolinium -enhancing lesions was measured by monthly brain magnetic resonance imaging (an established neuroimaging measurement of disease activity in multiple sclerosis) over a six-month pre-treatment period to establish a baseline measurement. Over the next three months of treatment with Trimesta, the median total enhancing lesion volumes decreased by 79% ( $p = 0.02$ ) and the number of lesions decreased by 82% ( $p = 0.09$ ). They remained decreased during the next 3 months of treatment, with lesion volumes decreased by 82% ( $p = 0.01$ ), and numbers decreased by 82% ( $p = 0.02$ ). Following a six-month drug holiday during which the patients were not on any drug therapies, median lesion volumes and numbers returned to near baseline pretreatment levels, Trimesta therapy was reinitiated during a four-month retreatment phase of this clinical trial. The relapsing-remitting multiple sclerosis patients again demonstrated a decrease in enhancing lesion volumes of 88% ( $p = 0.008$ ) and a decrease in the number of lesions by 48% ( $p = 0.04$ ) compared with original baseline scores.

During this clinical trial, a 14-percent improvement in Paced Auditory Serial Addition Test (PASAT) cognitive testing scores ( $p = 0.04$ ) was also observed in the multiple sclerosis patients at six months of therapy. PASAT is a routine cognitive test performed in patients with a wide variety of neuropsychological disorders such as multiple sclerosis. The PASAT scores were expressed as a mean percent change from baseline and were significantly improved in the relapsing-remitting group. The study investigators concluded that a larger, placebo-controlled clinical

trial of Trimesta is warranted in women with relapsing remitting multiple sclerosis. In addition, they added that this novel treatment strategy of using Trimesta in multiple sclerosis has relevance to other autoimmune diseases that also improve during pregnancy.

#### Clinical Trial Currently Underway of Trimesta in Relapsing-Remitting Multiple Sclerosis Patients

In March of 2007, an investigator-initiated, randomized, double-blind, placebo-controlled, 150-patient clinical trial was started at 7 clinical centers in the United States. The purpose of this clinical trial is to study whether 8 mg of Trimesta daily over a 2 year period would reduce the rate of relapses in a large population of female patients with relapsing remitting multiple sclerosis. Investigators are administering either Trimesta along with glatimer acetate (Copaxone®) injections, a Food and Drug Administration-approved therapy for multiple sclerosis, or a placebo plus glatimer acetate injections to women between the ages of 18 to 50 who have been recently diagnosed with relapsingremitting multiple sclerosis. The primary endpoint is relapse rates at two years with a one year interim analysis using standard clinical measures of multiple sclerosis disability. Secondary endpoints of magnetic resonance imaging measurements of brain lesion and effects on cognition will also be studied. In January of 2010, it was announced that an additional \$860,440 in grant funding had been received allowing the number of clinical sites enrolling patients to increase to 16 clinical sites. Currently, over 75 of 150 patients have been enrolled in this clinical study.

#### Trimesta Grant Funding

The preclinical and clinical development of Trimesta has been primarily financed by a \$5 million grant from the National Multiple Sclerosis Society in partnership with the National Multiple Sclerosis Society's Southern California chapter, with support from the National Institutes of Health. In January of 2010, it was announced that an additional \$860,440 in grant funding had been received through the American Recovery and Reinvestment Act allowing the number of clinical sites currently enrolling patients in the clinical study to increase from 7 clinical sites to 16. The rate of enrollment in the clinical trial has been positively impacted through the addition of the 9 new clinical sites.

#### Current Therapies for Relapsing-Remitting Multiple Sclerosis.

There are currently 7 Food and Drug Administration-approved therapies for the treatment of relapsing-remitting multiple sclerosis: Betaseron®, Rebif®, Avonex®, Novantrone®, Copaxone®, Tysabri® and Ampyra™. These therapies provide only a modest benefit for patients with relapsing-remitting multiple sclerosis and therefore serve to only delay progression of the disease. All of these drugs except Ampyra™ require frequent (daily, weekly & monthly) injections (or infusions) on an ongoing basis and are associated with unpleasant side effects (such as flu-like symptoms), high rates of non-compliance among users, and eventual loss of efficacy due to the appearance of resistance in approximately 30% of patients.

#### Multiple Sclerosis Market Opportunity for Trimesta

Multiple sclerosis is a progressive neurological disease in which the body loses the ability to transmit messages along central nervous system nerve cells, leading to a loss of muscle control, paralysis, and, in some cases, death. According to the National Multiple Sclerosis Society, currently, more than 2.5 million people worldwide (approximately 400,000 patients in the United States), mainly young adults aged 20-50, are afflicted with multiple sclerosis and two to three times as many women are affected than men. Relapsingremitting multiple sclerosis is the most common disease course at the time of diagnosis according to the National Multiple Sclerosis Society. Approximately, 85% of people with multiple sclerosis are initially diagnosed with the relapsingremitting form, compared to 10-15% with progressive forms.

Multiple sclerosis exacts a heavy economic toll on the United States health care system. The disease costs the United States more than \$9.5 billion annually in medical care and lost productivity according to the Society for Neuroscience. The average annual cost of multiple sclerosis is approximately \$44,000 to \$95,625 per person. These figures include lost wages and healthcare costs (care giving, hospital and physician costs, pharmaceutical therapy and nursing home care). The cost of treating patients with later-stage progressive forms of multiple sclerosis is approximately \$65,000 per year per person.

#### **Zinc-based Medical Food Candidates**

##### Zinthionein™ ZC

Zinthionein™ ZC (zinc cysteine) is an oral, gastro-retentive, sustained-release medical food candidate being developed for the dietary management of Alzheimer's disease and mild cognitive impairment. Adeona believes it may be capable of delivering up to 150 mg of elemental zinc in a convenient once-a-day dose with superior gastrointestinal tolerability compared to currently marketed zinc preparations that must be taken two to three times a day and are associated with nausea in up to 90% of patients and gastric irritation in up to 30% of patients.

In December of 2009, Adeona initiated a 60-patient, randomized, double-blind, placebo-controlled clinical study of Zinthionein™ ZC. The clinical study, CopperProof -2, will test the effects of Zinthionein™ ZC on the amelioration of sub-clinical zinc deficiency and elevated serum free copper percentage that can be associated with Alzheimer's disease and mild cognitive impairment. The first part of the CopperProof -2 study will compare the tolerability and bioavailability of Zinthionein™ ZC to a currently marketed high dose zinc preparation. The second part of the CopperProof -2 study will compare once-daily Zinthionein™ ZC versus placebo for 6 months in a randomized, double-blind, placebo-controlled study in patients with Alzheimer's disease and mild cognitive impairment. The primary endpoint is whether dietary management of such diseases with Zinthionein™ ZC 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.

#### Zinc-monocysteine

Zinc-monocysteine is a complex of zinc and the amino acid cysteine that Adeona believes may have improved properties compared to currently marketed zinc-based medical food products. Zinc-monocysteine was invented and developed by David A. Newsome, M.D., former Chief of the Retinal Disease Section of the National Eye Institute. Dr. Newsome was the first to pioneer and demonstrate the benefits of oral high dose zinc therapy in dry age-related macular degeneration. Oral high dose zinc containing products now represent the standard of care for dry age-related macular degeneration affecting over 10 million Americans and have annual sales of approximately \$300 million.

Zinc-monocysteine has completed an 80-patient, randomized, double-masked, placebo-controlled clinical trial in dry age-related macular degeneration and demonstrated highly statistically significant improvements in central retinal function. These results were published in a peer-reviewed journal in 2008. Adeona believes that the patent-pending, modified-release formulations of zinc-monocysteine 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, Adeona did further manufacturing and scale up of zinc-monocysteine to support the further nonclinical testing and cGMP manufacturing required to support a planned Generally Regarded as Safe affirmation process.

#### *Effirma*

Effirma (flupirtine) is a novel centrally-acting investigational oral drug for the treatment of fibromyalgia syndrome. Fibromyalgia is a common, centrally-mediated pain disorder characterized by chronic diffuse pain and other symptoms. Flupirtine was originally developed by Asta Medica and has been approved in Europe since 1984 for the treatment of pain, although it has never been introduced to the United States market for any indication. Adeona is also seeking to develop Effirma, a non-opiate, non-addictive oral therapy, for certain ophthalmic indications. During 2008, Adeona obtained an option to license issued and pending patent applications relating to flupirtine's use in the treatment of these ophthalmic indications.

Preclinical data and clinical experience suggests that Effirma should also be effective for neuropathic pain since it acts in the central nervous system via a mechanism of action distinguishable from most marketed analgesics. Effirma is especially attractive because it operates through non-opiate pain pathways, exhibits no known abuse potential, and lacks withdrawal effects. In addition, no tolerance to its antinociceptive effects has been observed. One common link between neuroprotection, nociception, and Effirma may be the N-methyl-D-aspartic acid glutamate system, a major receptor subtype for the excitotoxic neurotransmitter, glutamate. Effirma has strong inhibitory actions on N-methyl-D-aspartic acid-mediated neurotransmission.

#### Effirma Clinical Trial Status

Adeona's scientific collaborator has demonstrated preliminary evidence of clinical efficacy in a small number of patients treated with Effirma whom were suffering from fibromyalgia that was refractive to other analgesics and therapies. Effirma was well tolerated by patients with no untoward side effects. In addition, substantial improvement in signs and symptoms was demonstrated in this difficult-to-treat fibromyalgia

patient population. Adeona's scientific collaborator filed an investigator-initiated Investigational New Drug with the Food and Drug Administration to test Effirma in a clinical trial of 90 fibromyalgia patients. During 2008, this proposed clinical trial and Investigational New Drug was approved by the Food and Drug Administration. Additionally, this protocol has been approved by an institutional review board.

### Market Opportunity for Effirma

Fibromyalgia is an arthritis-related condition that is characterized by generalized muscular pain and fatigue. Fibromyalgia is a common, centrally-mediated debilitating pain disorder characterized by widespread pain and stiffness throughout the body, accompanied by severe fatigue, insomnia and mood symptoms. It is estimated to affect between two and four percent of the world's population and, after osteoarthritis, is the most commonly diagnosed disorder in rheumatology clinics. Adeona estimates that there are approximately 6 million Americans with fibromyalgia. During 2007, Lyrica®, which is marketed by Pfizer for fibromyalgia and other medical indications, recorded \$1.8 billion in sales and \$1.2 billion during its first year on the market.

### *dnaJP1*

dnaJP1 (hsp peptide) is an investigational oral drug for the treatment of rheumatoid arthritis. It has completed a 160-patient, multi-center, randomized, double-blind, placebo-controlled clinical trial for the treatment of rheumatoid arthritis. dnaJP1 is an epitope-specific immunotherapy for rheumatoid arthritis patients. It is a 15-mer heat shock protein-derived peptide that was previously identified as a contributor of T cell-mediated inflammation in rheumatoid arthritis. Immune responses to heat shock protein are often found at sites of inflammation and have an initially amplifying effect that needs to be down regulated to prevent tissue damage. The mechanisms for this regulation involve T cells with regulatory function that are specific for heat shock protein-derived antigens. This regulatory function is one of the key components of a "molecular dimmer" whose physiologic function is to modulate inflammation independently from its trigger. This function is impaired in autoimmunity and could be restored for therapeutic purposes.

dnaJP1 contains the five amino acid cassette present on most of the HLA (human leukocyte antigen) class II alleles associated with rheumatoid arthritis. In preclinical work, the most relevant epitope was mapped and showed its contribution to pro-inflammatory T cell responses *in vitro* in patients with active rheumatoid arthritis. These data led to the hypothesis that the sequences shared between immunologically relevant self and foreign proteins (HLA and heat shock protein) would affect thymic selection and peripheral activation of potentially pathogenic T cells at different stages. The mechanistic hypothesis is that mucosal tolerization to dnaJP1 could determine immune tolerization primarily of T cells and secondarily of antigen presenting cells. The effects of immune tolerance are initially peptide-specific but affect secondarily non-epitope specific pathways.

Computer-aided, rational drug design techniques of dnaJP1 resulted in a short synthetic peptide derived from a heat shock protein dnaJ. Heat shock proteins and dnaJ are upregulated during cellular stress, including inflammation and autoimmune diseases. Heat shock protein responses have been found in several other autoimmune diseases other than rheumatoid arthritis, including juvenile idiopathic arthritis, multiple sclerosis, and inflammatory bowel disease. The mechanism of action of dnaJP1 relies on selectively inducing an immune shift of a T-cell function from inflammatory to regulatory, thus inhibiting disease-related inflammation and inducing a tolerogenic immunologic response.

Adeona is currently engaged in the cGMP manufacture and scale up of the dnaJP1 active drug substance and other nonclinical activities necessary to support the potential filing and approval of a corporate investigational new drug application for the further clinical testing of dnaJP1. The Company is seeking potential United States, European and Asian corporate partners to assist in the further manufacturing, testing and clinical development of dnaJP1.

### Clinical Trial Results of dnaJP1 in Rheumatoid Arthritis Patients

In November of 2009, Adeona announced publication of the results of an investigator-initiated, 160-patient clinical trial of dnaJP1 for the treatment of rheumatoid arthritis conducted at 11 clinical centers in the United States. The publication, entitled "Epitope-Specific Immunotherapy of Rheumatoid Arthritis: Clinical Responsiveness Occurs With Immune Deviation and Relies on the Expression of a Cluster of Molecules Associated with T Cell Tolerance in a Double-Blind, Placebo-Controlled, Pilot Phase II Trial", can be found in *Arthritis & Rheumatism*, Vol. 60(11), pages 3207-3216, with related editorial at page A21. This clinical trial was funded by a \$5 million grant from the National Institutes of Health. It sought to test 2 hypotheses 1) whether mucosal induction of immune tolerance to dnaJP1 would lead to a



qualitative change from a proinflammatory phenotype to a more tolerogenic functional phenotype and 2) whether immune deviation of responses to an inflammatory epitope might translate into clinical improvement. One hundred sixty patients with active rheumatoid arthritis were randomized to receive oral doses of 25 mg of dnaJP1 or placebo daily for 6 months.

Results of the published study showed the following:

1. dnaJP1 appeared to be safe and well-tolerated;
2. There was a significant reduction in the percentage of T cells producing the proinflammatory cytokine tumor necrosis factor alpha (TNF-alpha) ( $p < 0.0007$ );
3. The primary efficacy end point (meeting the American College of Rheumatology 20% improvement criteria at least once on day 112, 140, or 168) showed a difference between treatment groups ( $p = 0.09$ ) that became significant in post hoc analysis using generalized estimating equations (GEE) ( $p = 0.04$ ).
4. Differences in clinical responses were also found between treatment groups on day 140 and at followup, indicative of a durable response following discontinuation of therapy.
5. Post hoc analysis showed that the combination of dnaJP1 and the commercially available rheumatoid arthritis agent, hydroxychloroquine, was superior to the combination of hydroxychloroquine and placebo, demonstrating potential synergistic effect of dnaJP1 with hydroxychloroquine.

Consistent with the disease modifying process of active immune tolerization, there was a progressive separation between treatment and placebo groups for both ACR20 and ACR50 endpoints after day 112. ACR20 is a composite endpoint developed by the American College of Rheumatology and generally accepted as an FDA-approved scoring criteria. dnaJP1 treated patients achieved a 40.7% ACR20 response at follow up versus 21.5% of placebo-treated patients (CMH test  $p = 0.007$ , GEE  $p < 0.001$ ). The proportion of dnaJP1-treated patients who achieved an ACR20 response at Days 112, 140, 168, and follow up was significantly higher than that of placebo-treated patients (CMH  $p = 0.03$ ; GEE  $p = 0.0005$ ). A statistically significant difference was also seen for the AUC when more strict ACR50 criteria were applied (GEE  $p = 0.02$ ). The primary endpoint (AUC 112-140-168) found more patients succeeding on dnaJP1 ( $p = 0.09$  by CMH and  $p = 0.04$  by adjusted GEE). GEE analysis was employed to correct for intercenter variability and this was possible as randomization occurred per center. Patients in this study were permitted to be on currently available standard background therapies, including hydroxychloroquine, corticosteroids, sulfasalazine, analgesics, and non-steroidal anti-inflammatory drugs, but not on disease modifying agents or biologics.

From an immunologic standpoint, dnaJP1 also demonstrated an 80% reduction in the *in vitro* production of TNF-alpha by T cells ( $p < 0.007$ ), a hallmark cytokine of inflammation. Additionally, oral dnaJP1 treated patients demonstrated an increase in tolerogenic cytokines and immune response genes, including IL-10 and FoxP3 production. The study investigators concluded that tolerization to dnaJP1 leads to immune deviation and a trend toward clinical efficacy.

In combination with low dose etanercept (Enbrel®), an animal equivalent of dnaJP1 has also demonstrated a significant reduction of mean arthritis scores achieved on day 23 ( $p = 0.0004$ ) as compared to placebo in preclinical animal models. Additionally, oral dnaJP1 and single low dose etanercept combination therapy led to a significant improvement of the histological score in the joints ( $p = 0.014$  versus untreated). Lastly, combination therapy of etanercept and oral dnaJP1 led to an antigen-specific increase of tolerogenic cytokines, including IL-10 and IL-4 production and up regulation of CTLA-4 expression.

#### Market Opportunity for dnaJP1

Rheumatoid arthritis is an autoimmune disease that affects approximately 20 million people worldwide. It is a chronic inflammatory disease that leads to pain, stiffness, swelling and limitation in the motion and function of multiple joints. If left untreated, rheumatoid arthritis can produce serious destruction of joints that frequently leads to permanent disability. Though the joints are the principal body part affected by rheumatoid arthritis, inflammation can develop in other organs as well. The disease currently affects over two million Americans, almost 1% of the population, and is two to three times more prevalent in women than men. Onset can occur at any point in life but is most frequent in the

fourth and fifth decades of life, with most patients developing the disease between the ages of 35 and 50. Over 20 million people suffer from rheumatoid arthritis worldwide and the global market is estimated at over \$6.3 billion. Disease-modifying antirheumatic drugs, including biologics, accounted for nearly \$5 billion of that figure.

### ***CD4 Inhibitor 802-2***

CD4 Inhibitor 802-2 (cyclic heptapeptide) is an investigational drug for the prevention of severe graft-versus-host disease. The molecule is based on a series of small molecule and peptide-based inhibitors of the T-cell CD4 co-receptor. The CD4 co-receptor is central to a number of autoimmune disorders such as multiple sclerosis. Adeona's CD4 Inhibitor molecules are designed to selectively block the dimerization and oligomerization of adjacent CD4 receptors via the D1 domains of such receptors. CD4 dimerization is believed to be necessary for the proper formation of the immunological synapse between antigen present cells and T-cells, which results in the achievement of the critical threshold signaling required for CD4 T-Cell activation.

By selectively blocking critical threshold signaling, CD4 Inhibitor molecules display the important advantage of causing apoptosis (via activation-induced cell death) and/or anergy of CD4 T-cells. Adeona's CD4 Inhibitor molecules are selective for otherwise active CD4 T-cells and demonstrate the ability to modify the course of CD4-mediated diseases through the selective deletion of pathogenic memory T-cells, thereby inducing immune tolerance. As opposed to monoclonal antibody approaches, Adeona's CD4 Inhibitor molecules are non-T-cell depleting, non-immunogenic and potentially orally available.

Adeona's lead CD4 Inhibitor molecule, named 802-2, has demonstrated preliminary safety and efficacy in a number of animal models of autoimmune disease. It has been evaluated in an investigator-initiated, 23-patient clinical trial for the prevention of severe graft-vs.-host disease. CD4 Inhibitor 802-2 may represent the first clinical-stage, non-antibody-based molecule capable of inducing immune tolerance for a variety of CD4-mediated autoimmune diseases. Adeona is seeking potential United States, European and Asian corporate partners to assist in the further manufacturing, testing and clinical development for various indications.

### Market Opportunity for CD4 Inhibitor 802-2 and Small Molecule CD4 Inhibitors

From a commercial perspective, CD4 Inhibitor 802-2 and other anti-CD4 molecules address an autoimmune disease market estimated at \$21 billion as measured in 2006 with an anticipated annual growth rate of 15%. Autoimmune diseases represent the third-largest category of illnesses in the industrialized world, after heart disease and cancer. A partial list of such diseases includes multiple sclerosis, psoriasis, and rheumatoid arthritis, as well as "non-typical" CD4-mediated diseases such as allergy and asthma.

### **Copper and Zinc Metabolism Clinical Diagnostic Test**

During the first quarter of 2009, Adeona analyzed patient samples from an institutional review board-approved, prospective, observational, blinded clinical study that was sponsored and conducted during 2007 and 2008. The study enrolled 90 subjects, 30 with Alzheimer's disease, 30 with Parkinson's disease 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 the study indicate highly statistically significant differences in serum markers of copper status between Alzheimer's disease and normal subjects. Adeona believes 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 Alzheimer's disease patients. In July of 2009, Adeona announced the presentation of the findings from this study at the 2009 International Conference on Alzheimer's disease. There is an estimated 5.8 million, 1.5 million and 15 million persons in the United States with Alzheimer's disease, Parkinson's disease and mild cognitive impairment, respectively, that may benefit from Adeona's panel of clinical diagnostic tests.

In July of 2009 Adeona acquired HartLab, LLC, an Illinois limited liability company and clinical laboratory through which we have launched our panel of copper and zinc metabolism clinical diagnostic tests. Adeona also intends to develop other specialty diagnostic tests through HartLab and also to grow the core clinical laboratory business in the greater Chicago area.

In November of 2009, Adeona announced the launch of the HartLab subsidiary's diagnostic test panel, the CopperProof™ Panel, for the evaluation of zinc and copper status in patients with Alzheimer's disease and mild cognitive impairment. The CopperProof™ Panel provides a comprehensive analysis of the metabolic serum copper and zinc status of Alzheimer's disease and mild cognitive impairment patients, the status of which 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 Alzheimer's disease and mild

cognitive impairment. Adeona believes that this panel will allow physicians to determine the copper and zinc metabolic status of these patients as an aid in their continued treatment program.

### ***tetrathiomolybdate***

Adeona is seeking potential United States, European and Asian corporate partners to assist in the further manufacturing, testing and clinical development of tetrathiomolybdate for Alzheimer's disease, Parkinson's disease and Huntington's disease.

### **Intellectual Property**

Adeona's goal is to (a) obtain, maintain, and enforce patent protection for its products, formulations, processes, methods, and other proprietary technologies, (b) preserve our trade secrets, and (c) operate without infringing on the proprietary rights of other parties, worldwide. Adeona seeks, where appropriate, the broadest intellectual property protection for product candidates, proprietary information, and proprietary technology through a combination of contractual arrangements and patents.

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

#### McLean Hospital Exclusive License Agreement

In 2005, as amended in 2007, Adeona entered into an exclusive license agreement with the McLean Hospital, a Harvard University hospital, relating to U.S. Patent No. 6,610,324 and its foreign equivalents, entitled "Flupirtine in the treatment of fibromyalgia and related conditions." Pursuant to this agreement, Adeona paid an upfront fee of \$20,000 and back patent costs of approximately \$41,830 and agreed to pay McLean royalties on net sales of flupirtine equal to 3.5% of net sales of flupirtine for indications covered by the issued patents, reduced to 1.75% if Adeona has a license to other intellectual property covering those indications; use Adeona's best efforts to commercialize flupirtine for the therapeutic uses embodied in the patent applications; reimburse future patent costs and pay the following milestone payments: \$150,000 upon the initiation of a pivotal phase 3 clinical trial of flupirtine; \$300,000 upon the filing of a New Drug Application for flupirtine; and \$600,000 upon Food and Drug Administration approval of flupirtine.

#### Thomas Jefferson University License Agreement

In 2002, as amended in 2009, Adeona's majority owned subsidiary CD4 Biosciences Inc. entered into an exclusive worldwide license agreement with Thomas Jefferson University (TJU) relating to certain U.S. and foreign issued patents and patent applications relating to all uses of CD4 Inhibitor 802-2 and CD4 inhibitor technology. Pursuant to this agreement we paid an upfront license fee of \$80,000, an additional \$25,000 was paid at the 12 month anniversary of the agreement, and \$25,000 was paid at the 18 month anniversary of the agreement. Adeona is obligated to pay annual maintenance fees, milestone payments of \$200,000 upon the filing of a New Drug Application and \$500,000 upon approval of a New Drug Application with the Food and Drug Administration, as well as royalties on net sales of anti-CD4 802-2 and other anti-CD4 molecules covered by the licensed patents. Adeona also received rights to valuable data generated under any Investigation New Drug application filing, which includes toxicology and manufacturing information relating to anti-CD4 802-2. As partial consideration for this license, TJU was issued shares representing 5% of the common stock of CD4 Biosciences Inc. Adeona also agreed that TJU would receive anti-dilution protection on those CD4 shares through the first \$2 million in financing to CD4. Adeona also agree to indemnify TJU against certain liabilities.

#### The Regents of University of California License Agreement

In 2005, Adeona was granted an exclusive worldwide license agreement with the Regents of the University of California relating to an issued US Patent No. 6,936,599 and pending patent applications covering the uses of the drug candidate Trimesta. Pursuant to this agreement, we paid an upfront license fee of \$20,000, reimbursed patent expenses of \$41,000 and agreed to pay a license fee of \$25,000 during 2006, as well as annual maintenance fees, milestone payments totaling \$750,000 that are payable on filing a New Drug Application, and on approval of a New Drug Application with the Food and Drug Administration, as well as royalties on net sales of Trimesta covered by the licensed patents. We may be permitted to partially pay milestone payments in the form of equity.

#### Zinc Monocysteine License Agreement

In July of 2007, Adeona entered into an exclusive worldwide license agreement with David A. Newsome, M.D., and David Tate, M.S., relating to zinc monocyteine for all uses. Pursuant to this agreement, Adeona paid an upfront license fee of \$65,000 and reimbursed patent expenses of \$25,000. Milestone payments totaling \$1,400,000 may be due upon the achievement of certain milestones, as well as royalties of three percent (3%) on net sales for the licensed technology covered by the licensed patents. Adeona has the ability to make these milestone payments in the form of equity.

#### The Regents of University of California License Agreement

In July of 2008, Adeona entered into an exclusive worldwide license agreement with the Regents of the University of California relating to a series of issued US patents and pending patent applications covering novel uses of an orally active immunotherapeutic technology, dnaJP1 a candidate which has completed a 160-patient, double-blind, placebo-controlled phase II clinical trial for treatment of rheumatoid arthritis. Pursuant to this agreement, Adeona paid an upfront license fee of \$25,000, reimbursed patent expenses as well as future patent and expenses annual maintenance fees of \$50,000 per year, milestone payments ranging from \$75,000 to \$5,000,000 that are payable on various clinical and regulatory milestones, as well as royalties on net sales of the licensed technology covered by the licensed patents.

#### **Manufacturing**

We utilize contract manufacturing firms to produce the bulk active ingredients for Zinthionein, CD4 inhibitor, dnaJP1, and flupirtine in accordance with "current good manufacturing processes" (cGMP) guidelines outlined by the FDA. We leased a 18,000 square foot facility in Ann Arbor, MI to produce oral capsule products under cGMP conditions. Although this lease expires during February 2011, we are currently exploring strategic options for this facility. These options may include sale of the equipment and/or sublease of the Facility. Our Trimesta bulk and finished product is manufactured by Organon NV, a European pharmaceutical company which has manufactured the active ingredient in Trimesta for nearly 40 years.

#### **Sales and Marketing**

We do not have a sales and marketing effort for our products. We may choose to enter into a co-promotion or licensing agreement for specific territories with biotechnology or pharmaceutical companies to market our products.

#### **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 December 31, 2010, we have expended approximately \$28.6 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 limited experience in commercializing diagnostic testing technologies and therefore we may not be effective in developing and commercializing products.***

Many of our technologies, particularly our copper and zinc diagnostic testing technologies, are at an early stage of commercialization. We continue to develop and commercialize new diagnostic products and create new applications for our products through our 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 profits 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 profitably market this test panel or other diagnostic tests. We have limited experience in performing, selling or marketing diagnostic test panel or any other tests. If we are not able to profitably market or sell our diagnostic tests we may develop for any reason, we will not generate any profits 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 have experienced several management changes.***

We have had significant changes in management in the past two years. Effective July 1, 2008, Charles L. Bisgaier resigned as our President and Corporate Secretary and as a director of our Company. Also effective on July 1, 2008, Steve H. Kanzer resigned as our Chief Executive Officer (although he did remain as our Chairman of the Board). Effective July 1, 2008, Nicholas Stergis was appointed our Chief Executive

Officer; however effective March 29, 2009, Mr. Stergis resigned his position, but remained a director of the Company until August 20, 2009. The Board then appointed Steve H. Kanzer as our interim Chief Executive Officer and President. Effective June 26, 2009, Max Lyon was appointed our Chief Executive Officer and President, while Mr. Kanzer remained as Chairman of the Board of the Company. Effective February 6, 2010, Dr. James Kuo was appointed our Chairman of the Board, Chief Executive Officer and President and Mr. Lyon resigned from his position as Chief Executive Officer, President and director. Changes in key positions in our Company, as well as additions of new personnel and departures of existing personnel, can be disruptive, might lead to additional departures of existing personnel and could have a material adverse effect on our business, operating results, financial results and internal controls over financial reporting.

***We only recently acquired our CLIA-certified laboratory and have limited experience operating a diagnostic laboratory. Our ability to successfully develop and commercialize diagnostic tests will depend on our ability to successfully operate our CLIA-certified laboratory and obtain and maintain required regulatory certifications.***

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.

***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.

***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 (IVDMIA), 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.

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

Some of the products we have developed and additional products that we hope to develop involve new and unproven approaches or involve applications in markets that we are only beginning to explore. They are based on the assumption that information about the roles of copper and zinc in the progression and development of neurodegenerative diseases such as Alzheimer's disease, dementia and mild cognitive impairment may help scientists and clinicians better understand and treat conditions or complex disease processes. We cannot be certain that this type of information will play a key role in the development of diagnostics or other products in the future, or that any of our findings would be accepted by clinicians, researchers or by any other potential market or industry partner or customer. If we are unable to generate additional valuable information and data about the usefulness of copper and zinc status testing, the demand for our products, applications, and services will be reduced and our business will be harmed.

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

In addition to our own patent applications, we also currently rely on licensing agreements with third party patent holders/licensors for our products. We have an exclusive license agreement with the McLean Hospital relating to the use of flupirtine to treat fibromyalgia syndrome; 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 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 as well as to make other payments and initiate a Phase II before the end of 2010. 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, pirfenidone, milnacipram, Lyrica, anti-depressant combinations, Rituxan, Enbrel, Cimzia, Humira, Remicade, Cymbalta, Effexor, Actimmune and other interferon preparations. Unlike us, many of our competitors have significant financial and human resources. In addition, academic research centers may develop technologies that compete with our TRIMESTA, zinc-monocysteine, Zinthionein™ ZC GS-150 gastro-retentive sustained release oral high dose zinc preparations, oral dnaJPI, 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. No assurance can be given that our current clinical trial of once daily Zinthionein ZC for the dietary management of Alzheimer's and mild cognitive impairment will achieve superior or sufficient tolerability compared to existing zinc-based oral products in order to confer a significant competitive market advantage for this product.

***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 second 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 (see. U.S. Ser. No 11/621,962), which may not provide substantial protection from competitive products until, if and when, such pending patents issue, if at all. As a prescription medical food, no regulatory protection is afforded through FDA regulations to prevent others from marketing similar products. No assurance can be given that our current clinical trial of once daily Zinthionein ZC for the dietary management of Alzheimer’s and mild cognitive impairment will achieve superior or sufficient tolerability compared to existing zinc-based oral products in order to achieve a significant competitive market advantage. 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 monocyteine complex and therefore believe that such disclosure should not affect the validity of any of our issued U.S. patent claims relating our zinc-monocysteine composition-of-matter claims. We 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.

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

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

We may also rely on the United States Drug Price Competition and Patent Term Restoration Act, commonly known as the “Hatch-Waxman Amendments,” to protect some of our current product candidates, specifically oral TTM, dnaJP1, TRIMESTA, zinc-monocysteine, 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 March 28, 2010, we have 10 full-time employees. We have also engaged regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. Our future performance will depend in part on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management.

Effective March 29, 2009, Nicholas Stergis resigned as our Chief Executive Officer and effective August 20, 2009 he resigned as a director. 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. Effective February 6, 2010 Dr James Kuo was appointed our Chairman of the Board, Chief Executive Officer and President and Max Lyon resigned as Chief Executive Officer and President.

Certain of our directors, (Jeffrey Kraws, a director and former VP of Business Development, Jeffrey Wolf, a director, Mr . Kanzer, a director and former Chairman and CEO, and Mr. Riley, a director ) scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies 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.

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. Organon has recently informed us of their decision to discontinue supply of estriol tablets beyond that required to satisfy the planned future needs of the on going clinical trial in relapse remitting multiple sclerosis. Accordingly, prior to initiation of additional clinical studies and/or commercial launch of oral estriol, we will need to identify and execute supply agreement(s) on terms suitable to us with an alternate supplier of estriol tablets.

Our plans to launch oral Zinthionein™ 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™ 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. We are currently experiencing delays from our outside cGMP manufacturer and packager of Zinthionein™ ZC GS-150, which delays are delaying our plans to launch this product as a prescription medical food. We are currently unsure when and if these delays will be resolved and are in the process of evaluating alternative manufacturers.

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

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

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

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

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

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

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

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

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

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

***Physicians and patients may not accept and use our technologies.***

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

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

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

***We depend on 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 license agreement with University of California for dnaJP1 requires that initiate patient dosing in a phase II clinical trial before the end of 2010 in order to maintain the license in effect. We may not be able to achieve such milestone in and may our license agreement may become subject to termination. Our initial clinical collaborator for oral TTM for Wilson's disease, has retired from University of Michigan, will no longer participate as a clinical investigator and no longer has an IND for oral TTM. We do not plan to conduct any further clinical studies of oral TTM. Our license agreement with University of Michigan requires that we obtain an IND to conduct a clinical trial with oral TTM before July 2010 in order to maintain our license agreement. Since we do not currently plan on filing such an IND for oral TTM, unless circumstances change, our license agreement may become subject to termination in July of this year. 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 no sales, marketing, or distribution capabilities. We do not anticipate having significant resources in the foreseeable future to allocate to selling and marketing our proposed products. Our success will depend, in part, on whether we are able to enter into and

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

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

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

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

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

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

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

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

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

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

If any other person files patent applications, or is issued patents, claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the 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 do not currently have product liability or malpractice insurance and may not be able to obtain adequate insurance coverage against product liability claims.***

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

## **RISKS RELATING TO OUR STOCK**

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

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

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

Currently, our directors, executive officers, and principal stockholders beneficially own a majority of our common stock. As a result, they will be able to exert substantial influence over the election of our board of directors and the vote on issues submitted to our stockholders. As of March 28, 2010, our officers, directors and principal stockholders beneficially owned approximately 8 million shares of our common stock, which number excludes shares of common stock issuable upon the exercise of warrants held by our officers, directors and principal stockholders. Because our common stock has from time to time been “thinly traded”, the sale of these shares by our officers, directors and principal stockholders could have an adverse effect on the market for our stock and our share price.

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

Our common stock has from time to time been “thinly-traded,” meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we



became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or nonexistent, 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 2010, due to our history of losses, in order to remain listed on NYSE Amex, we will be required to maintain a minimum stockholders' equity of \$6 million or our stock may be subject to delisting.

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

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

***We have never paid dividends.***

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

## **RISKS RELATED TO OUR INDUSTRY**

***We are subject to Government Regulation, compliance with which can be costly and difficult.***

In the United States, the formulation, manufacturing, packaging, storing, labeling, promotion, advertising, distribution and sale of our products are subject to regulation by various governmental agencies, including (1) the Food and Drug Administration, or FDA, (2) the Federal Trade Commission, or FTC, (3) the Consumer Product Safety Commission, or CPSC, (4) the United States Department of Agriculture, or USDA. Our proposed activities may also be regulated by various agencies of the states, localities and foreign countries in which our proposed products may be manufactured, distributed and sold. The FDA, in particular, regulates the formulation, manufacture and labeling of over-the-counter, or OTC, drugs, conventional foods, dietary supplements, and cosmetics such as those that we intend to distribute. FDA regulations require us and our suppliers to meet relevant current good manufacturing practice, or cGMP, regulations for the preparation, packing and storage of foods and OTC drugs. 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 FDCA. 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 manufacturer's obligations to substantiate structure/function claims. The FDA also issued a Structure/Function Claims Small Entity Compliance Guide. In addition, the agency permits companies to use FDA-approved full and qualified health claims for products containing specific ingredients that meet stated requirements.

In order to make disease claims, we may seek to market some of 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)) as "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. (). 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.

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

The 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.

***Failure To Comply With Requirements of the European Union can be costly and time consuming.***

Prior regulatory approval for human healthy volunteer studies (phase I studies) is required in member states of the European Union (E.U.). Summary data from successful phase I studies are submitted to regulatory authorities in member states to support applications for phase II

studies. E.U. authorities typically have one to three months (which often may be extended in their discretion) to raise objections to the proposed study. One or more independent ethics committees (similar to 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.

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

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

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

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

In the 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.

***We could be subject to challenges under 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.

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

The 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.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

Our primary offices and manufacturing facility is located at 3930 Varsity Drive, Ann Arbor, MI 48108. We currently rent approximately 18,000 square feet of office, laboratory and production space in Ann Arbor, MI for monthly rent of \$15,033.80. This lease expires on February 28, 2011, but extendable at our option for an additional three years. Our HartLab subsidiary leases approximately 3,000 square feet of lab space in Bolingbrook, IL for \$2,985 a month. This lease expires May 30, 2012, but is terminable at any time at the option of HartLab for a one time fee of \$250 times the number of months remaining under such lease. We believe our current offices will be adequate for the foreseeable future. Our phone number is (734) 332-7800 and our facsimile number is (734) 332-7878. Our website is located at [www.adeonapharma.com](http://www.adeonapharma.com).

**ITEM 3. LEGAL PROCEEDINGS**

On January 13, 2009, a subsidiary of the Company was served with legal action from an individual regarding a claim for payment of past consulting services and associated expenses from 2005. The Company does not have a written agreement executed by both parties, and management believes the lawsuit is without merit. The Company has engaged legal counsel to respond to this matter.

**ITEM 4. Removed and Reserved**

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASE OF EQUITY SECURITIES

Our common stock has traded on the NYSEAmex (formerly the American Stock Exchange) under the symbol "AEN" since October 16, 2008. Prior to this, our common stock traded under the symbol "PP" on the American Stock Exchange since July 2007. We were previously listed on the OTC Bulletin Board under the name "PPXP" beginning on December 18, 2006. The following table states the range of the high and low bid-prices per share of our common stock for each of the calendar quarters during the last two fiscal years while our common stock was quoted on the OTC Bulletin Board and the high and sale price while our common stock has traded on the NYSE Amex. These quotations represent inter-dealer prices, without retail mark-up, markdown, or commission, and may not represent actual transactions. The last price of our common stock as reported on the NYSE Amex on March 28 2010 was \$1.95 per share. As of March 28, 2010, there were approximately 358 stockholders of record of our common stock. This number does not include beneficial owners from whom shares are held by nominees in street name.

	High	Low
<b>YEAR ENDED DECEMBER 31, 2009</b>		
Fourth quarter	\$ .92	\$ .41
Third quarter	\$1.70	\$ .30
Second quarter	\$1.10	\$ .16
First quarter	\$ .56	\$ .10
<b>YEAR ENDED DECEMBER 31, 2008</b>		
Fourth quarter	\$0.55	\$0.03
Third quarter	\$1.02	\$0.48
Second quarter	\$1.40	\$0.65
First quarter	\$5.25	\$0.80

#### Dividend Policy

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

The following table provides information about Company purchases of its equity securities that are registered pursuant to Section 12 of the Exchange Act during the quarter ended December 31, 2009:

#### ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
Month Ended October 31, 2008	0	\$ .00	0	0
Month Ended November 30, 2008	81,482	.61	81,482	0
Month Ended December 31, 2008	0	.00	0	0
<b>Total</b>	<b>81,482</b>	<b>\$ .61</b>	<b>81,482</b>	<b>0</b>



## Equity Compensation Plan Information

See Item 11 – Executive compensation for equity compensation plan information.

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

During the year ended December 31, 2009, the Company issued 104,633 shares of common stock, in connection with the exercise of stock options, for proceeds of \$27,834; issued 235,538 shares of common stock for consulting fees, having a fair value of \$65,786 (\$0.28 per share), based on the quoted closing trading prices; issued 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; and issued 50,000 shares of common stock for the acquisition of Hart Lab, LLC, having a fair value of \$19,000 (\$0.38 per share), based on the quoted closing trading price. 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 October, November and December 2008, we issued a total of 44,312 shares of our common stock to 2 consultants for services rendered. These offering 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 August and September 2008, we issued a total of 113,958 shares of our common stock to 2 consultants for services rendered and 31,875 shares to 2 universities for license fees. These offering 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 May and June 2008, we issued a total of 106,630 shares of our common stock to 2 universities for license fees and 39,370 shares to a university for a milestone payment. 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.

In April 2008, we issued a total of 37,603 shares of our common stock to 8 of our employees and 13,887 shares of our common stock to a consultant for services rendered. These offerings and sales of shares qualified for exemption under Section 4(2) of the Securities Act of 1933 since the issuance did not involve a public offering. The 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.

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

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

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

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

## **ITEM 6. SELECTED FINANCIAL DATA**

Not applicable because the Company is a smaller reporting company.

## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion of our financial condition and results of operations should be read in conjunction with the audited financial statements and notes thereto for the fiscal year ended December 31, 2009, found in this report. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward looking statements by using words such as "anticipate," "believe," "intends," or similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in Part I, Item 1A of this Report.*

### **Overview**

Since our inception 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 were 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.

## **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 develop 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 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 year ended December 31, 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 year ended December 31, 2009, we did not identify any indication of goodwill impairment.

#### **Results of Operations**

##### ***Year Ended December 31, 2009 and 2008.***

Research and Development Expenses. For the year ended December 31, 2009, research and development expense was \$1,203,930 as compared to \$4,643,570 for the year ended December 31, 2008. The decrease of \$3,439,640 is due primarily to a substantial decrease in salaries and payroll taxes as a result of cost cutting measures.

General and Administrative Expenses. For the year ended December 31, 2009, general and administrative expense was \$2,580,639 as compared to \$2,675,636 for the year ended December 31, 2008. The decrease of \$94,997 is due primarily to a decrease in stock based compensation charges.

Other Income (Expense), net. For the year ended December 31, 2009, other income-net was \$(49,925) compared to \$114,048 for the year ended December 31, 2008. For the year ended December 31, 2009, interest income was \$2,965 as compared to \$128,236 for the year ended December 31, 2008. Interest income was lower for the period in 2009 as compared to the same period in 2008, due to lower interest rates and lower levels of cash in interest bearing accounts. For the year ended December 31, 2009, interest expense was \$9,879 as compared to \$13,831 for the year ended December 31, 2008. Interest expense in 2009 relates to interest paid on a capital lease while interest expense for 2008 related to interest paid on notes payable which were repaid in March 2008.

Net Loss. Net loss for the year ended December 31, 2009, was \$3,731,405 as compared to \$7,205,158 for the year ended December 31, 2008. This decrease in net loss is attributable primarily to a decrease in payroll and to a lesser extent, an overall decrease in general and administrative expenses.

### **Liquidity and Capital Resources**

During the year ended December 31, 2009, we had a net decrease in cash of \$3,141,340. Total cash resources as of December 31, 2009 was \$2,715,044. During the year ended December 31, 2009 and 2008, net cash used in operating activities was \$2,918,864 and \$4,851,675 respectively. This cash was used to fund our operations for the periods, adjusted for non-cash expenses and changes in operating assets and liabilities.

Net cash used in investing activities for the year ended December 31, 2009 was \$172,167 compared to \$110,867 net cash provided by investing activities for the year ended December 31, 2008. The net cash used in investing activities for the year ended December 31, 2009 resulted from the acquisition of HartLab LLC in the net amount of \$195,517, offset by the net proceeds of the sale/purchase of certain equipment in the amount of \$23,350. The net cash provided by investing activities for the year ended December 31, 2008 resulted from the proceeds from the sale of equipment in the amount of \$132,265, offset by the purchase of property and equipment in the amount of \$21,398.

Net cash used in financing activities was \$50,310 for the year ended December 31, 2009 compared to \$895,610 for the year ended December 31, 2008. The net cash used in financing activities for the year ended December 31, 2009 resulted from 49,706 for the acquisition of treasury stock, \$11,337 for the repayment of a capital lease, less proceeds of \$10,734 from the issuance of common stock. The net cash used in financing activities for the year ended December 31, 2008 resulted from \$900,000 for the repayment on notes payable, less proceeds of \$4,390 from the issuance of common stock.

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

### **Current and Future Financing Needs**

We have incurred an accumulated deficit of \$42,013,081 through December 31, 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.

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.

Based on our current capital expenditures, we believe we currently have sufficient capital to fund development activities of our principal products through April 2011. However, if our business does not generate any cash flow through corporate partnering transactions, we will need to raise additional capital to continue development of the product beyond April 2011. To the extent additional capital is not available when we need it, we may be forced to sublicense our rights to our product candidates, abandon our development efforts altogether, or lose our licenses to our product candidates, any of which would have a material adverse effect on the prospects of our business. See also the risks identified under the section entitled "Risk Factors" in this report.

#### License and Contractual Agreement Obligations

Below is a table of our contractual obligations for the years 2010 through 2014 as of December 31, 2009.

	Year					Total
	2010	2011	2012	2013	2014	
License Agreements	\$ 152,563	\$ 140,000	\$ 137,335	\$ 105,000	\$ 105,000	\$ 639,898
Lease Agreements	\$ 201,282	\$ 92,725	\$ 14,919	\$ -	\$ -	\$ 308,926
Consulting Agreements	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Total	\$ 353,845	\$ 232,725	\$ 152,254	\$ 105,000	\$ 105,000	\$ 948,823

#### Additional In-Licensed Programs

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

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Not applicable because the Company is a smaller reporting company.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**INDEX TO FINANCIAL STATEMENTS**

**ADEONA PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**(A Development Stage Company)**

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Report of Independent Registered Public Accounting Firm



REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of:  
Adeona Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Adeona Pharmaceuticals, Inc. and Subsidiaries (a development stage company) as of December 31, 2009 and 2008 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years ended December 31, 2009 and 2008 and for the period from January 8, 2001 (inception) to December 31, 2009. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included the consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly in all material respects, the consolidated financial position of Adeona Pharmaceuticals, Inc. and Subsidiaries (a development stage company) as of December 31, 2009 and 2008, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years ended December 31, 2009 and 2008, and for the period from January 8, 2001 (inception) to December 31 2009, in conformity with accounting principles generally accepted in the United States of America.

Berman & Company, P.A.

Boca Raton, Florida  
March 30, 2010

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**Adeona Pharmaceuticals, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Consolidated Balance Sheets**

<u>Assets</u>	<u>December 31, 2009</u>	<u>December 31, 2008</u>
<b>Current Assets</b>		
Cash	\$ 2,715,044	\$ 5,856,384
Accounts receivable - net of allowance of \$21,481	30,572	-
Prepays	-	15,109
Other	8,967	55,419
<b>Total Current Assets</b>	<u>2,754,583</u>	<u>5,926,912</u>
<b>Property and equipment - net</b>	1,051,958	1,446,407
<b>Goodwill</b>	178,229	-
<b>Deposits and other assets</b>	90,848	11,989
<b>Total Assets</b>	<u>\$ 4,075,618</u>	<u>\$ 7,385,308</u>
<b><u>Liabilities and Stockholders' Equity</u></b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 400,475	\$ 574,896
Accrued liabilities	8,163	45,820
Current portion of capital lease	17,006	-
<b>Total Current Liabilities</b>	<u>425,644</u>	<u>620,716</u>
<b>Long Term Liabilities:</b>		
Accounts payable	93,000	-
Capital lease	12,788	-
<b>Total Liabilities</b>	<u>531,432</u>	<u>620,716</u>
<b>Stockholders' Equity</b>		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, \$0.001 par value; 100,000,000 shares authorized, 21,530,834 issued and 21,449,322 outstanding and 20,882,839 shares issued and outstanding	21,449	20,883
Additional paid-in capital	45,552,918	45,025,385
Deficit accumulated during the development stage	(42,013,081)	(38,281,676)
Subscription Receivable	(17,100)	-
<b>Total Stockholders' Equity</b>	<u>3,544,187</u>	<u>6,764,592</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 4,075,618</u>	<u>\$ 7,385,308</u>

See accompanying notes to consolidated financial statements

**Adeona Pharmaceuticals, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Consolidated Statements of Operations**

	<b>For the years ended December 31,</b>		<b>For the Period</b>
	<b>2009</b>	<b>2008</b>	<b>from January</b>
			<b>8, 2001</b>
			<b>(Inception) to</b>
			<b>December 31,</b>
			<b>2009</b>
<b>Net Revenues</b>	\$ 103,089	\$ -	\$ 103,089
<b>Operating Expenses:</b>			
Research and development	1,203,930	4,643,570	17,008,295
General and administrative	2,580,639	2,675,636	12,101,486
<b>Total Operating Expenses</b>	<u>3,784,569</u>	<u>7,319,206</u>	<u>29,109,781</u>
<b>Loss from Operations</b>	(3,681,480)	(7,319,206)	(29,006,692)
<b>Other Income (Expense):</b>			
Interest income	2,965	128,236	474,591
Loss on sale of equipment	(34,399)	(357)	(34,756)
Interest expense	(9,879)	(13,831)	(66,760)
Other Expense	(8,612)	-	(8,612)
<b>Total Other Income, net</b>	<u>(49,925)</u>	<u>114,048</u>	<u>364,463</u>
<b>Net Loss</b>	<u>\$ (3,731,405)</u>	<u>\$ (7,205,158)</u>	<u>\$ (28,642,229)</u>
<b>Less: Preferred stock dividend - subsidiary</b>	-	-	(951,250)
<b>Less: Merger dividend</b>	-	-	(12,409,722)
<b>Net Loss Applicable to Common Shareholders</b>	<u>\$ (3,731,405)</u>	<u>\$ (7,205,158)</u>	<u>\$ (42,003,201)</u>
<b>Net Loss Per Share - Basic and Diluted</b>	<u>\$ (0.18)</u>	<u>\$ (0.35)</u>	<u>\$ (5.31)</u>
<b>Weighted average number of shares outstanding</b>			
<b>during the period - basic and diluted</b>	<u>21,318,906</u>	<u>20,651,027</u>	<u>7,916,053</u>

See accompanying notes to consolidated financial statements

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

**Consolidated Statements of Stockholders' Equity**

**For the years ended December 31, 2009 and 2008 and for the period from January 8, 2001 (inception) to December 31, 2009**

	Series A, Convertible Preferred Stock \$0.001 Par Value		Common Stock \$0.001 Par Value		Additional Paid-In Capital	Deficit accumulated during development stage	Subscription Receivable	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
<b>Balance, January 8, 2001 (inception)</b>	-	\$ -	-	-	-	-	-	-
Issuance of common stock to founders in exchange for subscription receivable (\$0.00003/share)	-	-	1,572,136	1,572	(1,222)	-	-	350
Issuance of preferred stock to founder for cash (\$0.055/share)	5,421,554	5,422	-	-	294,578	-	-	300,000
Issuance of preferred and common stock to founder for cash - subsidiaries	-	-	-	-	850,540	-	-	850,540
Net loss for the period ended December 31, 2001	-	-	-	-	-	(277,868)	-	(277,868)
<b>Balance, December 31, 2001</b>	5,421,554	5,422	1,572,136	1,572	1,143,896	(277,868)	-	873,022
Issuance of common stock for compensation and consulting - subsidiary	-	-	-	-	119	-	-	119
Grant of stock options for consulting services - subsidiary	-	-	-	-	5,890	-	-	5,890
Net loss for the year ended December 31, 2002	-	-	-	-	-	(768,508)	-	(768,508)
<b>Balance, December 31, 2002</b>	5,421,554	5,422	1,572,136	1,572	1,149,905	(1,046,376)	-	110,523
Grant of stock options for compensation - subsidiary	-	-	-	-	17,984	-	-	17,984
Net loss for the year ended December 31, 2003	-	-	-	-	-	(719,307)	-	(719,307)
<b>Balance, December 31, 2003</b>	5,421,554	5,422	1,572,136	1,572	1,167,889	(1,765,683)	-	(590,800)
Issuance of common stock for cash - subsidiary	-	-	-	-	50	-	-	50
Grant of stock options for consulting services - subsidiary	-	-	-	-	10,437	-	-	10,437
Net loss for the year ended December 31, 2004	-	-	-	-	-	(602,493)	-	(602,493)
<b>Balance, December 31, 2004</b>	5,421,554	5,422	1,572,136	1,572	1,178,376	(2,368,176)	-	(1,182,806)
Recognition of stock based consulting in connection with stock options grants	-	-	-	-	59,960	-	-	59,960
Recognition of stock based compensation in connection with stock option grants	-	-	-	-	10,493	-	-	10,493
Recognition of deferred compensation - subsidiary	-	-	-	-	14,057	-	-	14,057
Issuance of Series B, convertible preferred stock for cash - subsidiary	-	-	-	-	1,902,500	-	-	1,902,500
Cash paid as direct offering costs in connection with sale of Series B, convertible preferred stock - subsidiary	-	-	-	-	(152,200)	-	-	(152,200)
10% in-kind Series B, convertible preferred stock dividend - subsidiary	-	-	-	-	190,250	(190,250)	-	-
Net loss for the year ended December 31, 2005	-	-	-	-	-	(1,355,842)	-	(1,355,842)
<b>Balance, December 31, 2005</b>	5,421,554	5,422	1,572,136	1,572	3,203,436	(3,914,268)	-	(703,838)
Conversion of related party loan to common stock (\$2.02/share)	-	-	1,665,211	1,665	3,273,063	-	-	3,274,728
Issuance of common stock for cash - private placement (\$2.02/share)	-	-	6,900,931	6,901	13,919,462	-	-	13,926,363
Cash paid as direct offering costs in private placements	-	-	-	-	(1,160,418)	-	-	(1,160,418)
Issuance of common stock for license fees (\$0.92/share)	-	-	422,314	422	388,269	-	-	388,691
Conversion of accrued expenses to contributed capital - former related party	-	-	-	-	3,017	-	-	3,017
Deemed issuance to shareholders of legal acquiror and recapitalization	-	-	245,824	246	(665,246)	-	-	(665,000)
Conversion of Series A, convertible preferred stock to common stock	(5,421,554)	(5,422)	5,421,554	5,422	-	-	-	-
Recognition of stock based consulting in connection with stock option grants	-	-	-	-	411,310	-	-	411,310
Recognition of stock based compensation in connection with stock option grants	-	-	-	-	410,639	-	-	410,639
10% in-kind Series B, convertible preferred stock dividend - subsidiary	-	-	-	-	190,250	(190,250)	-	-
30% in-kind Series B, convertible preferred stock dividend - subsidiary	-	-	-	-	570,750	(570,750)	-	-
Net loss for the year ended December 31, 2006	-	-	-	-	-	(4,099,095)	-	(4,099,095)
<b>Balance, December 31, 2006</b>	-	-	16,227,970	16,228	20,544,532	(8,774,363)	-	11,786,397
Issuance of common stock for consideration of preferred shares in EPI acquisition (\$19.95/share)	-	-	765,087	765	12,408,957	(12,409,722)	-	0
Issuance of common stock for consideration of common shares in EPI acquisition (\$19.95/share)	-	-	30,161	30	601,682	-	-	601,712
Cash paid as direct offering costs in private placements	-	-	-	-	(579,569)	-	-	(579,569)
Issuance of common stock for license fees (\$6.85/share)	-	-	2,920	3	19,997	-	-	20,000
Issuance of common stock for milestone payment (\$4.90/share)	-	-	5,102	5	24,995	-	-	25,000
Recognition of stock based consulting in connection with stock option grants	-	-	-	-	673,271	-	-	673,271
Recognition of stock based compensation in connection with stock option grants	-	-	-	-	1,483,123	-	-	1,483,123
Sale of common stock in connection with warrants exercise	-	-	3,401,967	3,402	7,548,976	-	-	7,552,378
Contributed services - related party	-	-	-	-	275,645	-	-	275,645
Rounding of shares due to reverse split	-	-	260	-	-	-	-	-
Net loss for the year ended December 31, 2007	-	-	-	-	-	(9,892,433)	-	(9,892,433)
<b>Balance, December 31, 2007</b>	-	-	20,433,467	20,433	43,001,609	(31,076,518)	-	11,945,524
Recognition of stock based consulting in connection with stock option grants	-	-	-	-	366,683	-	-	366,683
Recognition of stock based compensation in connection with stock option grants	-	-	-	-	1,224,975	-	-	1,224,975
Recognition of stock based compensation in connection with issuance of common stock	-	-	61,392	61	55,324	-	-	55,385
Issuance of common stock for consulting fee	-	-	172,157	172	103,870	-	-	104,042
Issuance of common stock for milestone payment	-	-	39,370	39	49,961	-	-	50,000
Issuance of common stock for license fee	-	-	138,505	139	144,861	-	-	145,000
Issuance of common stock for stock option exercises	-	-	37,948	38	4,352	-	-	4,390
Contributed services - related party	-	-	-	-	73,750	-	-	73,750
Net loss for year ended December 31, 2008	-	-	-	-	-	(7,205,158)	-	(7,205,158)
<b>Balance, December 31, 2008</b>	-	\$ -	20,882,839	20,883	45,025,385	(38,281,676)	-	6,764,592
Stock based compensation	-	-	-	-	323,936	-	-	323,936
Issuance of common stock for options exercised	-	-	104,633	105	27,729	-	(17,100)	10,734
Issuance of common stock for consulting fee	-	-	235,549	236	65,550	-	-	65,786
Issuance of common stock for license fee	-	-	257,813	258	40,992	-	-	41,250
Issuance of common stock for acquisition of Hart Lab, LLC	-	-	50,000	50	18,950	-	-	19,000
Contributed services - related party	-	-	-	-	100,000	-	-	100,000
Acquisition of treasury stock	-	-	(81,482)	(81)	(49,624)	-	-	(49,706)
Net loss for the year ended December 31, 2009	-	-	-	-	-	(3,731,405)	-	(3,731,405)
<b>Balance, December 31, 2009</b>	-	-	21,449,352	21,449	45,552,918	(42,013,081) \$	(17,100)	3,544,187

See accompanying notes to consolidated financial statements

**Adeona Pharmaceuticals, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Consolidated Statements of Cash Flows**

	For the years ended December 31,		For the period from January 8, 2001 (Inception) to December 31,
	2009	2008	2009
<b>Cash Flows From Operating Activities:</b>			
Net loss	\$ (3,731,405)	\$ (7,205,158)	\$ (28,652,109)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	323,936	1,647,043	5,068,612
Stock issued for consulting fees	65,786	104,042	169,828
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	382,089	404,623	1,019,276
Provision for uncollectible accounts receivable	97,377	-	97,377
Loss on sale of equipment	34,399	357	34,756
Changes in operating assets and liabilities:			
Accounts receivable	(48,292)	-	(48,292)
Prepaid expenses and other current assets	61,561	1,793	(282)
Deposits and other assets	(78,859)	1,392	(90,848)
Accounts payable	(138,264)	(60,928)	528,926
Accrued liabilities	(28,442)	(13,589)	20,396
<b>Net Cash Used In Operating Activities</b>	<b>(2,918,864)</b>	<b>(4,851,675)</b>	<b>(20,131,312)</b>
<b>Cash Flows From Investing Activities:</b>			
Purchases of property and equipment	(1,850)	(21,398)	(2,034,655)
Proceeds from the sale of equipment	25,200	132,265	157,465
Cash paid to acquire Hart Lab	(201,141)	-	(201,141)
Cash received from Acquisition of Hart Lab	5,624	-	5,624
<b>Net Cash Used In Investing Activities</b>	<b>(172,167)</b>	<b>110,867</b>	<b>(2,737,707)</b>
<b>Cash Flows From Financing Activities:</b>			
Repayments of notes payable	-	(900,000)	(1,100,000)
Repayments under capital lease	(11,337)	-	(11,337)
Proceeds from issuance of common stock for stock option exercises	10,734	4,390	15,125
Acquisition of treasury stock	(49,706)	-	(49,706)
<b>Net Cash Provided By (Used In) Financing Activities</b>	<b>(50,310)</b>	<b>(895,610)</b>	<b>25,584,063</b>
<b>Net increase (decrease) in cash</b>	<b>(3,141,340)</b>	<b>(5,636,418)</b>	<b>2,715,044</b>
Cash at beginning of year/period	5,856,384	11,492,802	-
<b>Cash at end of year/period</b>	<b>\$ 2,715,044</b>	<b>\$ 5,856,384</b>	<b>\$ 2,715,044</b>
<b>Supplemental disclosures of cash flow information:</b>			
Cash paid for interest	\$ 2,006	\$ 13,831	\$ 11,885
Cash paid for taxes	\$ -	\$ -	\$ -
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Loss on exchange of equipment to settle accounts payable	\$ 5,925	\$ -	\$ 98,219
Sale of equipment in exchange for other receivables	\$ -	\$ 8,685	\$ 8,685
Sale of equipment in exchange for accounts payable	-	\$ 92,294	\$ 92,294
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 consolidated financial statements

**Adeona Pharmaceuticals, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**  
**December 31, 2009 and 2008**

**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 a pharmaceutical company developing new medicines for serious central nervous systems and autoimmune diseases.

**(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. There was no financial statement impact associated with this reincorporation.

**(C) Basis of Presentation and Corporate Structure**

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”). As of December 31, 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. 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 results of operations and cash flows is included in the Company’s consolidated financial statements as of its acquisition date of July 10, 2009 (see Note 2).

For financial reporting 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.

**(D) 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.

**(E) 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.

## **(F) 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.

### **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(F)(1), 1(F)(2) and 1(F)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.

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 December 31, 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 Acquisition of Hart Lab, LLC**

On July 10, 2009, the Company entered into a limited liability company purchase agreement to acquire Hart Lab LLC, an Illinois limited liability company and CLIA-certified clinical laboratory.

The Company acquired HartLab to be able to develop and commercialize its diagnostic test panel for the detection of zinc and copper deficiencies in the mature population. The Company paid a total of \$220,141 in consideration, consisting of \$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 100% of the issued and outstanding membership interests of HartLab. 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, this balance has been included in deposits. As of December 31, 2009 this amount remains in escrow, however all personal guarantee’s of the seller have been removed and the company expects to have these funds returned in the near term.

The purchase price of HartLab was allocated as follows:

<b><u>Consideration transferred at fair value:</u></b>	
Cash	\$201,141
Common stock	19,000
Total consideration	<u>\$220,141</u>
<b><u>Net assets acquired:</u></b>	
Current assets	\$124,746
Current liabilities	82,834
Total net assets acquired	<u>\$ 41,912</u>
Goodwill at fair value	<u>\$178,229</u>

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:

	December 31, 2009	December 31, 2008
Revenues	\$ 196,328	\$ 134,832
Net income (loss)	\$ (289,880)	\$ 9,659
Net income (loss) per common share	\$ (.01)	\$ 0.00
Weighted average common shares outstanding – basic and diluted	21,382,561	20,701,027
Revenues of HartLab for the period from July 10, 2009 to December 31, 2009	\$ 102,588	
Net loss of HartLab for the period from July 10, 2009 to December 31, 2009	\$ (296,245)	

Direct costs associated with the acquisition were approximately \$65,000.

### **Note 3 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 limited 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 \$42,013,081 at December 31, 2009.

#### **(C) Use of Estimates**

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

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

#### **(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. 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 year ended December 31, 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.

The Company generated revenues from 2 significant insurance providers in 2009. The Company did not have any revenues in 2008.

<b>Customer</b>	<b>2009</b>
A	37%
B	20%

#### **(F) Risks and Uncertainties**

The Company's operations will be subject to significant risk and uncertainties including financial, operational, regulatory and other risks associated with a development stage company, including the potential risk of business failure. The recent global economic crisis has caused a general tightening in the credit markets, lower levels of liquidity, increases in the rates of default and bankruptcy, and extreme volatility in credit, equity and fixed income markets. These conditions not only limit 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 December 31, 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 December 31, 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:

<u>Description</u>	<u>Estimated Useful Life</u>
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

## (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 years ended December 31, 2009 and 2008 and for the period from January 8, 2001 (inception) to December 31, 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.

## (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(F)(4)), all issued and outstanding shares of Series A and B, convertible preferred stock were cancelled and retired. Consequentially, no potential derivative liabilities 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 2,561,332 stock options and 1,070,472 warrants. Since the Company reported a net loss for the years ended December 31, 2009 and 2008 and for the period from January 8, 2001 (inception) to December 31, 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 years ended December 31, 2009 and 2008 and for the period from January 8, 2001 (inception) to December 31, 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 December 31, 2009, in connection with the acquisition of EPI (See Note 1(F)(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 research and development costs as incurred. Research and development expenses consist primarily of license fees, manufacturing costs, salaries, stock based compensation and related personnel costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and other expenses relating to the design, development, testing and enhancement of the Company's product candidates, as well as an allocation of overhead expenses incurred by the Company.

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

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

## **(O) Share-Based Payment Arrangements**

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

## **(P) Income Taxes**

The Company accounts for income taxes in accordance with accounting guidance now codified as FASB ASC Topic 740, "*Income Taxes*," which requires that the Company recognize deferred tax liabilities and assets based on the differences between the financial statement carrying amounts and the tax bases of assets and liabilities, using enacted tax rates in effect in the years the differences are expected to reverse. Deferred income tax benefit (expense) results from the change in net deferred tax assets or deferred tax liabilities. A valuation allowance is recorded when it is more likely than not that some or all deferred tax assets will not be realized.

Accounting guidance now codified as FASB ASC Topic 740-20, "*Income Taxes – Intraproduct Tax Allocation*," clarifies the accounting for uncertainties in income taxes recognized in accordance with FASB ASC Topic 740-20 by prescribing guidance for the recognition, de-recognition and measurement in financial statements of income tax positions taken in previously filed tax returns or tax positions expected to be taken in tax returns, including a decision whether to file or not to file in a particular jurisdiction. FASB ASC Topic 740-20 requires that any liability created for unrecognized tax benefits is disclosed. The application of FASB ASC Topic 740-20 may also affect the tax bases of assets and liabilities and therefore may change or create deferred tax liabilities or assets. The Company would recognize interest and penalties related to unrecognized tax benefits in income tax expense. At December 31, 2009 and 2008, respectively, the Company did not record any liabilities for uncertain tax positions.

## **(Q) Recent Accounting Pronouncements.**

In April 2009, the FASB issued guidance now codified as FASB ASC Topic 820, "*Fair Value Measurements and Disclosures*," which amends previous guidance to require disclosures about fair value of financial instruments in interim as well as annual financial statements in the current economic environment. This pronouncement was effective for periods ending after June 15, 2009. The adoption of this pronouncement did not have a material impact on our business, financial condition or results of operations; however, these provisions of FASB ASC Topic 820 resulted in additional disclosures with respect to the fair value of our financial instruments.

In May 2009, the FASB issued guidance now codified as FASB ASC Topic 855, "*Subsequent Events*," which establishes general standards of accounting for, and disclosures of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. This pronouncement was effective for interim or fiscal periods ending after June 15, 2009. The adoption of this pronouncement did not have a material impact on our business, results of operations or financial position; however, the provisions of FASB ASC Topic 855 resulted in additional disclosures with respect to subsequent events.

In June 2009, the Financial Accounting Standards Board (FASB) issued guidance now codified as FASB Accounting Standards Codification (ASC) Topic 105, "*Generally Accepted Accounting Principles*," as the single source of authoritative non-governmental U.S. GAAP. FASB ASC Topic 105 does not change current U.S. GAAP, but is intended to simplify user access to all authoritative U.S. GAAP by providing all authoritative literature related to a particular topic in one place. All existing accounting standard documents will be superseded and all other accounting literature not included in the FASB Codification will be considered non-authoritative. These provisions of FASB ASC Topic 105 were effective for interim and annual periods ending after September 15, 2009 and, accordingly, were effective for the current fiscal reporting period. The adoption of this pronouncement did not have an impact on our business, financial condition or results of operations, but will impact our financial reporting process by eliminating all references to pre-codification standards. On the effective date of FASB ASC Topic 105, the Codification superseded all then-existing non-SEC accounting and reporting standards, and all other non-grandfathered non-SEC accounting literature not included in the Codification became non-authoritative.

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

#### **Note 4 Property and Equipment**

Property and Equipment consisted of the following at December 31,

	<b>2009</b>	<b>2008</b>
Leasehold improvements	\$ 862,359	\$ 862,359
Manufacturing equipment	697,854	777,928
Computer and office equipment	234,419	232,569
Laboratory equipment	243,289	165,427
Total	<u>2,037,921</u>	<u>2,038,283</u>
Less accumulated depreciation/amortization	(985,963)	(591,876)
Property and equipment, net	<u>\$ 1,051,958</u>	<u>\$ 1,446,407</u>

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. As of December 31, 2008, \$7,785 remains due from this sale and is included in other receivables.

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

#### **Note 5 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 6 Stockholders' Equity and Non-Controlling Interest**

##### **(A) Preferred Stock Issuances**

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

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

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

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

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

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

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

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

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

#### **For the Year ended December 31, 2009**

During the year ended December 31, 2009, the Company issued 104,633 shares of common stock, in connection with the exercise of stock options, for proceeds of \$27,834. Of this amount \$17,100 was not received until after December 31, 2009. The average related exercise price was \$0.27 per share.

During the year ended December 31, 2009, the Company issued 235,538 shares of common stock for consulting fees, having a fair value of \$65,786 (\$0.28 per share), based on the quoted closing trading prices.

During the year ended December,31, 2009, the Company issued 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.

During the year ended December,31, 2009, the Company issued 50,000 shares of common stock for the acquisition of Hart Lab, LLC, having a fair value of \$19,000 (\$0.38 per share), based on the quoted closing trading price.

#### **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 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 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 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 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.

## **(C) Common Stock Issuances of Subsidiaries**

During the period from January 8, 2001 (inception) to December 31, 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 8 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 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 December 31, 2009, there were 1,170,354 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. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period under the 2001 plan shall not exceed 250,000. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. This plan was approved by stockholders on November 2, 2007. As of December 31, 2009, there are 1,390,978 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 Black-Scholes assumptions used in the years ended December 31, 2009 and 2008 are as follows:

	Year ended December 31,	
	2009	2008
Exercise price	\$0.37 - \$0.80	\$0.53 - \$5.10
Expected dividends	0%	0%
Expected volatility	198% - 209%	170.09% - 225.79%
Risk free interest rate	3.16% - 4.75%	3.52% - 4.02%
Expected life of option	10 years	10 years
Expected forfeitures	0%	0%

The Company records stock based compensation based upon the stated vested provisions in the related agreements, with recognition of expense recorded on the straight line basis over the term of the related agreement. The vesting provisions for these agreements have various terms as follows:

- immediate vesting,
- half vesting immediately and the remainder over three years,
- quarterly over three years,
- annually over three years,
- one-third immediate vesting and remaining annually over two years,
- one half immediate vesting with remaining vesting over nine months; and
- one quarter immediate vesting with the remaining over three years.

During 2009, the Company granted 979,999 options to employees and consultants having a fair value of \$485,799 based upon the Black-Scholes option pricing model. During 2008, the Company granted 1,180,666 options to employees and consultants having a fair value of \$1,176,579 based upon the black-Scholes option pricing model.

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Balance – 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 – December 31, 2008	2,751,663	\$1.43		
Granted	979,999	\$0.50		
Exercised	( 104,633)	\$0.27		
Forfeited	(1,065,697)	\$1.09		
Balance – December 31, 2009 - outstanding	2,561,332	\$1.26	7.16 years	303,969
Balance – December 31, 2009 – exercisable	1,837,583	\$1.51	6.25 years	247,994
Grant date fair value of options granted - 2009		\$490,000		
Weighted average grant date fair value - 2009		\$0.50		
Grant date fair value of options granted - 2008		\$933,332		
Weighted average grant date fair value - 2008		\$0.79		
Outstanding options held by related parties - 2009		1,099,828		
Exercisable options held by related parties - 2009		766,495		
Outstanding options held by related parties - 2008		1,399,828		
Exercisable options held by related parties - 2008		796,043		

The options outstanding and exercisable at December 31, 2009 are as follows:

Options Outstanding				Options Exercisable		
Range of Exercise Price	Number outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
\$ 0.09 - \$4.57	2,458,798	7.25 years	\$ 1.05	1,747,132	\$ 1.26	6.30 years
\$ 4.58 - \$9.05	100,312	5.07 years	\$ 5.92	88,229	\$ 5.92	5.22 years
\$ 9.06 - \$22.50	2,222	7.02 years	\$ 22.50	2,222	\$ 22.50	7.02 years
	2,561,332	7.16 years	\$ 1.26	1,837,583	\$ 1.51	6.25 years

The options outstanding and exercisable at December 31, 2008 are as follows:

Options Outstanding				Options Exercisable		
Range of Exercise Price	Number outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
\$ 0.09 - \$4.57	2,619,998	7.78 years	\$ 1.19	1,924,329	\$ 1.33	7.29 years
\$ 4.57 - \$9.05	128,332	6.68 years	\$ 5.91	89,166	\$ 5.91	6.77 years
\$ 18.02 - \$22.50	3,333	8.02 years	\$ 22.50	1,111	\$ 22.50	8.02 years
	2,751,633	7.73 years	\$ 1.43	2,014,606	\$ 1.55	7.26 years

The following is a summary of the Company's non-vested stock options at December 31, 2009:

	Unvested stock options	Weighted Average Grant Date Fair Value
Non-vested – December 31, 2008	737,057	\$1.14
Granted	979,999	\$0.10
Vested/Exercised	(399,697)	\$0.65
Forfeited/Cancelled	(593,610)	\$0.85
Non-vested – December 31, 2009	723,749	\$0.23
Weighted average remaining period for vesting	2.59 years	

#### (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, 2009, 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)(F)(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 then 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 then Chairman were cancelled.

On October 31, 2006, the loans payable to the Company's founder and then 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.

A summary of warrant activity for Adeona for the year ended December 31, 2009 and for the year ended December 31, 2008 is as follows:

	Number of Shares	Weighted Average Exercise Price
<b>Balance as December 31, 2007</b>	2,278,416	2.22
<b>Granted</b>	13,333	2.50
<b>Exercised</b>	—	
<b>Forfeited</b>	—	
<b>Balance at December 31, 2008</b>	2,291,749	2.87
<b>Granted</b>	—	
<b>Exercised</b>	—	
<b>Forfeited</b>	(1,221,277)	2.23
<b>Balance as December 31, 2009</b>	1,070,472	3.27

All outstanding warrants are fully vested and exercisable.

<u>Range of Exercise Price</u>	<u>Number Outstanding</u>	<u>Weighted Average Remaining Contractual Life</u>
\$ 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 December 31, 2009 a total of 20,000 options were outstanding and exercisable with an exercise price of \$0.20 and a remaining contractual life of 2.37 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 8.50 years as of December 31, 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.

#### **Note 7 Commitments**

##### **(A) License Agreements**

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 research agreement with the University of Michigan. Pursuant to that agreement, the Company sponsored approximately \$460,000 per year. On March 20, 2008, the Company terminated the agreement. On March 24, 2009 the Company entered into a plan with the University to pay the outstanding amount of \$197,335. The Company agreed to pay \$5,000 per month until the payable is paid in full. The current balance at December 31, 2009 for this transaction is approximately \$153,000. The Company has recorded \$60,000 as a short term payable, the remaining \$93,000 is a long term payable.

### **(C) Employment & Consulting 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; on February 6, 2010 he also resigned his position as Chairman, but remained a Director of the Board.

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

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 (the then 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 next 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 President & Chief Executive Officer. Pursuant with the employment agreement Mr. Lyon received a base salary of \$190,000 per year and was eligible for discretionary performance and transactional bonus payments. 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.

Effective February 6, 2010, Mr. Lyon resigned from his positions of (i) director of Adeona and (ii) CEO and President of Adeona. In connection with his resignation, Mr. Lyon received a severance payment in the form of shares of stock valued at \$22,613 pursuant to a Separation Agreement dated February 6, 2010 between Mr. Lyon and Adeona.

On February 6, 2010, James S. Kuo, M.D., was appointed Chairman, Chief Executive Officer and President of Adeona. In connection with his appointment, Dr. Kuo entered into a three-year employment agreement with Adeona (the "Employment Agreement"). Pursuant to the Employment Agreement, Dr. Kuo will be entitled to an annual base salary of \$199,000 and will be eligible for discretionary performance and transactional bonus payments. Additionally, Dr. Kuo was granted options to purchase 400,000 shares of the Company's common stock with an exercise price equal to the Company's per share market price on the date of issue. Of these options, 100,000 vested immediately upon grant and the remainder will vest pro rata, on a monthly basis, over the following thirty-six months. The fair value of the options totaled \$327,680 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 204.5%; risk free interest rate of 3.59% and an expected life of 10 years.

#### **(D) Other Commitments**

The following schedule shows committed amounts due for license agreements as of December 31, 2009:

2010:	\$ 153,000
2011:	140,000
2012:	137,000
2013:	105,000
2014:	105,000
Total:	<u>\$ 640,000</u>

#### **(E) Operating Lease**

During 2007, the Company entered into a non-cancelable operating lease for office, laboratory and production space. This lease expires on February 28, 2011.

The following schedule shows committed amounts due for the lease agreement as of December 31, 2009:

2010:	\$ 201,000
2011:	93,000
2012:	15,000
Total:	<u>\$ 309,00</u>

During the years ended December 31, 2009 and 2008 and for the period from January 8, 2001 (inception) to December 31, 2008, the Company recognized rent expense of \$207,160, \$193,557, and \$991,546, respectively.

#### **(F) Capital Lease**

In June 2006, the Company acquired \$65,000 of equipment, as discussed in Note 3, under a non-cancelable capital lease. The effective interest rate of the lease is 8.51%. Related monthly payments of principal and interest were \$1,417 for sixty months. In September 2008, the lessor extended the term for repayment by eight months, with a final maturity date of January 2012.

Future minimum capital lease payments are as follows:

**Year Ended December 31.**

2010	\$
	17,006
2011	17,006
2012	4,001
Total minimum lease payments	38,013
Less: amount representing interest	(8,219)
Present value of net minimum lease payments	29,794
Less: current portion of capital lease obligation	(17,006)
Long term portion of capital lease obligation	<u>\$12,788</u>

**(G) 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 8 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 and no later than December 31, 2009, 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. As of December 31, 2009, the Company had repurchased 81,482 shares for approximately \$50,000 (\$0.61/share), based upon the quoted closing trading price. These treasury shares are not included in the computation of earnings (loss) per share.

**Note 9 Income Taxes**

There was no income tax expense for the years ended December 31, 2009 and 2008 due to the Company's net losses.

The Company's tax expense differs from the "expected" tax expense for the years ended December 31, 2009 and 2008, (computed by applying the Federal Corporate tax rate of 34% to loss before taxes and 5.5% for Michigan State Corporate taxes, the blended rate used was 37.63%), as follows:

	<u>2009</u>	<u>2008</u>
Computed "expected" tax expense (benefit) - Federal	\$ (1,199,000)	\$ (2,315,000)
Computed "expected" tax expense (benefit) - State	(205,000)	(396,000)
Meals and Entertainment and Other	54,000	2,000
Non-deductible stock based compensation	162,000	599,000
Contributed services – related party	38,000	28,000
Change in valuation allowance	<u>\$ 1,150,000</u>	<u>\$ 2,083,000</u>

The effects of temporary differences that gave rise to significant portions of deferred tax assets at December 31, 2009 and 2008 are as follows:

<b>Deferred tax assets:</b>	<b>2009</b>	<b>2008</b>
Stock issued for services	\$ -	\$ (48,000)
Net operating loss carry-forward	(8,243,000)	(7,045,000)
Total gross deferred tax assets	(8,243,000)	(7,093,000)
Less valuation allowance	8,243,000	7,093,000
Net deferred tax assets	<u>\$ -</u>	<u>\$ -</u>

At December 31, 2009, the Company has a net operating loss carry-forward of approximately \$18,700,000 available to offset future taxable income expiring through 2029. Utilization of these net operating losses may be limited due to potential ownership changes under Section 382 of the Internal Revenue Code.

The valuation allowance at December 31, 2008 was approximately \$7,093,000. The net change in valuation allowance during the year ended December 31, 2009 was an increase of approximately \$1,150,000. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on consideration of these items, Management has determined that enough uncertainty exists relative to the realization of the deferred income tax asset balances to warrant the application of a full valuation allowance as of December 31, 2009.

#### **Note 10 Subsequent Event**

The Company has evaluated for subsequent events between the balance sheet date of December 31, 2009 and March 31, 2010, the date the financial statements were issued.

The Company issued 138,444 shares of common stock, in connection with the exercise of stock options, for proceeds of \$46,199. The average related exercise price was \$0.33 per share.

The Company issued 33,118 shares of common stock, in connection with consulting agreements valued at \$33,270. The average related exercise price was \$1.00 per share.

The Company issued 50,521 shares of common stock for compensation, having a fair value of \$33,632 (\$0.67 per share).



## ITEM 9. CHANGES IN AND DISCUSSIONS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

### ITEM 9A(T). CONTROLS AND PROCEDURES

#### *Disclosure Controls and Procedures*

The Company has adopted and maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Form 10-K, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the Securities and Exchange Commission. The Company's disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. As required under Exchange Act Rule 13a-15, the Company's management, including the Chief Executive Officer and Principal Financial Officer, has conducted an evaluation of the effectiveness of disclosure controls and procedures 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.

#### *Management's Report on Internal Control Over Financial Reporting*

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15. The Company's internal control over financial reporting is designed to provide reasonable assurance to the Company's management and Board of Directors regarding the preparation and fair presentation of published financial statements. Management conducted an assessment of the Company's internal control over financial reporting based on the framework and criteria established by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control – Integrated Framework. Based on the assessment, management concluded that, as of December 31, 2009, the Company's internal control over financial reporting is effective based on those criteria.

The Company's management, including its Chief Executive Officer and Principal Financial Officer, does not expect that the Company's disclosure controls and procedures and its internal control processes will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of error or fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that the breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

#### *Changes in Internal Control*

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 December 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

### ITEM 9B. OTHER INFORMATION

None.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CORPORATE GOVERNANCE

Below is certain information regarding our directors and executive officers.

Name	Age	Position
James S. Kuo, M.D., M.B.A.	45	Chairman, Chief executive Officer, President
Steve H. Kanzer, CPA, JD	46	Director
Jeffrey J. Kraws	45	Director
Jeff Wolf, Esq.	46	Director
Jeff Riley, M.B.A.	47	Director

**STEVE H. KANZER, CPA, JD.** Mr. Kanzer is our co-founder and served as our President from our inception in February 2001 until May 2006. Mr. Kanzer previous served as our Chief Executive Officer from September 2004 until July of 2008, Chairman of the Board until February 6, 2010 and currently serves as a director. Mr. Kanzer has also been a director and officer of our subsidiaries, including Solovax, Inc., Effective Pharmaceuticals, Inc., Putney Drug Corp. and CD4 Biosciences, Inc. Since December 2000, he has served as co-founder and Chairman of Accredited Ventures Inc. and Accredited Equities Inc., a venture capital firm and FINRA-member investment bank, respectively, which both specialize in the biotechnology industry. Mr. Kanzer was co-founder, Chairman, President and Chief Executive Officer of Developmental Therapeutics, Inc., a cardiovascular drug development company which was developing an oral thyroid hormone analog, DITPA, for congestive heart failure. Developmental Therapeutics was acquired in October 2003 by Titan Pharmaceuticals, Inc., a publicly traded biopharmaceutical company. Prior to founding Accredited Ventures and Accredited Equities in December 2000, Mr. Kanzer served as Senior Managing Director-Head of Venture Capital at Paramount Capital from 1991 until December 2000. While at Paramount Capital, Mr. Kanzer was involved in the formation and financing of a number of biotechnology companies and held various positions in these companies. From 1995 through 1999, Mr. Kanzer was founding Chairman of the Board of Discovery Laboratories, Inc., a public biotechnology company that has a pending NDA for a drug called SURFAXIN ® which Mr. Kanzer licensed in 1995. From 1997 until 2000, Mr. Kanzer was founding President of PolaRx Biopharmaceuticals, Inc., a biopharmaceutical company that licensed and developed TRISENOX ® (arsenic trioxide), a leukemia drug that was approved by the FDA in 2000 and which currently holds the FDA record for fastest drug ever developed from IND filing until NDA approval (30 months). PolaRx was merged with Cell Therapeutics Inc. (NASDAQ:CTIC) in January 2000, and Cephalon acquired the rights to TRISENOX ® in 2005 for \$165 million. In March 1998, Mr. Kanzer led the privatization of the Institute for Drug Research Kft. (IDR) in Budapest, Hungary, a 400-employee, 26 acre pharmaceutical research and development center. Since 1950, IDR operated as the central pharmaceutical R&D center for the country of Hungary, served the active pharmaceutical ingredients (API) needs of Eastern Europe, and performed original drug discovery research, resulting in the registration of over 80 API products. Mr. Kanzer served as Chief Executive Officer of IDR from March 1998 and led the sale of IDR to IVAX Corporation, a publicly traded corporation in October 1999. Mr. Kanzer has also been a co-founder and director of 23 biotechnology companies, including Avigen, Inc., XTLBio, Boston Life Sciences, Inc. and Titan Pharmaceuticals, Inc., all publicly traded companies. Prior to joining Paramount Capital in 1992, Mr. Kanzer was an attorney at the law firm of Skadden, Arps, Slate, Meagher & Flom in New York where he specialized in mergers and acquisitions. Mr. Kanzer received his J.D. from New York University School of Law in 1988 and a B.B.A. in Accounting from Baruch College in 1985, where he was a Baruch Scholar. Mr. Kanzer is active in university-based pharmaceutical technology licensing and has served as Co-Chair of the New York Chapter of the Licensing Executives Society.

**JEFFREY J. KRAWS.** Mr. Kraws is a director and has been since January 2006. Mr. Kraws is Chief Executive Officer and co-founder of Crystal Research Associates. Well known and respected on Wall Street, Mr. Kraws has received some of the most prestigious awards in the industry. Among other awards, he was given a “5-Star Rating” in 2001 by Zacks and was ranked the number one analyst among all pharmaceutical analysts for stock performance in 2001 by [Starmine.com](http://Starmine.com). Prior to founding Crystal Research Associates, Mr. Kraws served as co-president of The Investor Relations Group (IRG), a firm representing primarily under-followed, small-capitalization companies. Previously, Mr. Kraws served as a managing director of healthcare research for Ryan Beck & Co. and as director of research/senior pharmaceutical analyst and managing director at Gruntal & Co., LLC (prior to its merger with Ryan Beck & Company). Mr. Kraws served as managing director of the healthcare research group and senior pharmaceutical analyst at First Union Securities (formerly EVEREN Securities); as senior U.S. pharmaceutical analyst for the Swedish-Swiss conglomerate Asea Brown Boveri; and as managing director and president of the Brokerage/Investment Banking operation of ABB Aros Securities, Inc. He also served as senior pharmaceutical analyst at Nationsbank Montgomery Securities, BT Alex Brown & Sons, and Buckingham Research. Mr. Kraws also has industry experience, having been responsible for competitive analysis within the treasury group at Bristol-Myers-Squibb Company. He holds an MBA from Cornell University and a B.S.

degree from State University of New York-Buffalo. During 2006 through February 2007, Mr. Kraws served as our Vice President of Business Development, on a part-time basis.

**JEFF WOLF, Esq.** Mr. Wolf is a director and has been since June 2005. Mr. Wolf has substantial experience in creating, financing, nurturing and growing new ventures based upon breakthrough research and technology. Mr. Wolf is the founding partner of Seed-One Ventures, LLC, a venture capital group focused on seed-stage technology-based investments. Mr. Wolf has been a founder of Elusys Therapeutics, Inc., an antibody-based therapeutic company, Tyrx Pharma, Inc., a biopolymerbased company, Sensatex, Inc., a medical device company and Generation Mobile, Inc. a telecommunications company. Prior to founding Seed-One Ventures, Mr. Wolf served as the Managing Director of The Castle Group, Ltd., a biomedical venture capital firm. At both organizations, Mr. Wolf was responsible for supervising the formation and funding of new technology, biomedical, and service oriented ventures. Mr. Wolf currently sits on the board of Elusys Therapeutics and Netli, Inc. Mr. Wolf received his MBA from Stanford Business School, his JD from New York University School of Law and his BA with honors in Economics from the University of Chicago.

**JAMES S. KUO, M.D., M.B.A.** Dr. Kuo is a director and has been since February 2007. Effective February 6, 2010, Dr. Kuo was appointed as our Chairman of the Board, Chief Executive Officer and President. Dr. Kuo was the Chairman and Chief Executive Officer of Cordex Pharma, Inc., a public biopharmaceutical company until February 1, 2010 and he remained as a director until March 13, 2010.. From 2003 to 2006, he served as founder, Chairman and Chief Executive Officer of BioMicro Systems, Inc. a private venture-backed, microfluidics company. Prior to that time, Dr. Kuo was a founder, President and Chief Executive Officer of Discovery Laboratories, Inc. where he raised over \$22 million in initial private funding and was instrumental in the company going public. Dr. Kuo was also a founder and board member of Monarch Labs, LLC, a private medical device company. Dr. Kuo is the former Managing Director of Venture Analysis for Healthcare Ventures, LLC, which managed \$378 million in venture funds. He has also been a senior licensing and business development executive at Pfizer, Inc., where he was directly responsible for cardiovascular licensing and development. After studying molecular biology and receiving his B.A. at Haverford College, Dr. Kuo simultaneously received his M.D. from the University of Pennsylvania School of Medicine and his M.B.A. from the Wharton School of Business.

**JEFF RILEY** Mr. Riley has been a director since March 16, 2010. Since November 2009, Mr. Riley has served as the Managing Director of Black Crow Ventures, a life science-focused consulting firm with a commercial and transactional focus. He sits on the advisory boards of an Australia-based venture fund (Queensland Biocapital Fund) and Ruga Corporation, a Stanford University spin-out drug discovery company focused on endoplasmic reticulum stress targets. Mr. Riley has held senior corporate and commercial development positions with biotech companies Amphora Discovery, Ontogen Corporation, and AvMax. In these positions, he was responsible for raising equity and negotiating alliances including in-licensing, out-licensing, distribution agreements, technology acquisitions and research agreements with large pharmaceutical companies and government agencies. Mr. Riley's pharmaceutical experience includes commercial management and mergers and acquisition roles for Pfizer and SmithKline Beecham. Additionally, Mr. Riley served as CFO and VP Corporate Development for Nichols Institute Diagnostics, a CLIA-certified molecular diagnostics and reference lab, later acquired by Quest Diagnostics. Prior to attending university, Mr. Riley served in the U.S. Army.

#### **Directors' Term of Office**

Directors will hold office until the next annual meeting of stockholders and the election and qualification of their successors. Officers are elected annually by our board of directors and serve at the discretion of the board of directors.

#### **Audit Committee**

The Audit Committee is comprised of Jeff Wolf and Jeff Riley. The Audit Committee is responsible for recommending the Company's independent public accounting firm and reviewing management's actions in matters relating to audit functions. The Committee reviews with the Company's independent public accountants the scope and results of its audit engagement and the Company's system of internal controls and procedures. The Committee also reviews the effectiveness of procedures intended to prevent violations of laws. The Committee also reviews, prior to publication, our reports on Form 10-K and Form 10-Q. Our board has determined that all audit committee members are independent under applicable SEC regulations. Our board of directors has determined that Jeff Riley qualifies as an "audit committee financial expert" as that term is used in Section 407 of the Sarbanes-Oxley Act of 2002. Our Audit Committee charter is located on our website [www.adeonapharma.com](http://www.adeonapharma.com).

#### **Compensation Committee and Nominating Committee**

Our Compensation Committee consists of Jeff Wolf and Jeff Kraws. Our Nominating Committee consists of Jeff Wolf and Jeff Riley. These committees perform several functions, including reviewing all forms of compensation provided to our executive officers, directors, consultants and employees, including stock compensation, and recommending appointments to the board and appointment of executive officers.

One of the purposes of our nominating committee is to assist the Board in identifying qualified individuals to become members of your Board. The committee seeks individuals who have an inquisitive and objective perspective, practical wisdom and mature judgment, and the talent and expertise to understand, and provide sound and prudent guidance with respect to, the Company's activities, operations and interests. Candidates must also be individuals who have the highest personal and professional integrity, who have demonstrated exceptional ability and judgment, and who are likely to be the most effective, in conjunction with the other members of your Board, in collectively serving the long-term interests of shareholders.

The Nominating Committee will consider director nominees recommended by security holders. Recommendations should be submitted in writing and a reasonable time before we mail our proxy materials for the applicable meeting of shareholders. We recommend that any such recommendations for next year's annual meeting be submitted to Lara Guzman, Adeona Pharmaceuticals, Inc., 3930 Varsity Drive, Ann Arbor, Michigan 48108.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's executive officers, directors and persons who beneficially own more than 10 percent of a registered class of the Company's equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of the Company's common stock. Such officers, directors and persons are required by SEC regulation to furnish the Company with copies of all Section 16(a) forms that they file with the SEC.

Based solely on a review of the copies of such forms that were received by the Company, or written representations from certain reporting persons that no Form 5s were required for those persons, the Company is not aware of any failures to file reports or report transactions in a timely manner during the Company's fiscal year ended December 31, 2009 except that one form 4 was filed late for each of Messrs. Kraws, Kuo and Wolf with respect to a grant of options in December 2009 to each director for services as a director.

#### Code of Ethics

The Company has long maintained a Code of Ethical Conduct which is applicable to all directors, officers and employees of the Company. In addition, the Company has adopted a Code of Ethics for CEO and Senior Financial Officers which applies to the Company's Chief Executive Officer, Chief Financial Officer, Treasurer and Controller. Each of these codes is posted on the Company's website at [www.borgwarner.com](http://www.borgwarner.com).

The Company has adopted a code of ethics that applies to its principal executive officer, principal financial officer, principal accounting officer and controller. Such code of ethics is posted on the Company's internet website, which is located at [www.adeonapharma.com](http://www.adeonapharma.com).

#### ITEM 11. EXECUTIVE COMPENSATION

The following table discloses information for the fiscal year ended December 31, 2009 regarding the total compensation we paid to each individual who served as our principal executive officer during the year ended December 31, 2009 and any other most highly compensated executive officer whose total compensation exceeded \$100,000 during the year ended December 31, 2009.

Name and Principal Position	Salary (\$)	Bonus (\$)	Option Awards (1)	All Other Annual Compensation	Total
<b>Nicholas Stergis (1)</b> Former Chief Executive and Chief Financial Officer	\$ 146,250	\$ -	\$ 0	\$ -	\$ 146,250
<b>Steve H. Kanzer, CPA, JD (2)</b> Former Chairman & Chief Executive and Chief Financial Officer	\$ 1	\$ -	\$ 0	\$ -	\$ 1
<b>Max Lyon(3)</b> , Former Chief Executive and Chief Financial Officer	\$ 104,519	\$ -	\$ 152,000	\$ -	\$ 256,519
<b>David Newsome(4)</b> President, Healthmine	\$ 97,308	\$ -	\$ 67,200	\$ -	\$ 164,508

(1) Mr. Stergis served as CEO until March 29, 2009.

(2) Mr. Kanzer served as interim CEO from March 29, 2009 until June 26, 2009.

(3) Mr. Lyons served as CEO from June 26, 2009 until February 6, 2010. The fair value of the options he received 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.

(4) 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.

The following table contains information relating to grants of stock options made during the fiscal year ended December 31, 2009, to our executive officers. No stock options were exercised by our senior executive officers during the last fiscal year.

#### Option/SAR Grants in Last Fiscal Year

Name and Principal Position	Number of securities underlying options/SARs granted (#)	Percent of total options/SARs granted to employees in fiscal year	Exercise Price (\$/Sh)	Expiration date
Max Lyon (3) Former Chief Executive Officer	400,000	40.8%	.38	6/25/2019

The following table discloses information regarding outstanding equity awards as of December 31, 2009 for each of our senior executive officers.

#### Outstanding Equity Awards at Fiscal Year-End

Name and Principal	Number of securities underlying unexercised options/exercisable	Number of securities underlying unexercised options/un-exercisable	Option exercise price	Option expiration date
Steve Kanzer (2) Former Chief Executive Officer	271,058	0	\$ 2.01	10/30/2016
Max Lyon (3) Former Chief Executive Officer	105,000	295,000	\$ .38	6/25/2019

#### Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2009 regarding the compensation of our directors who at December 31, 2009 were not also named executive officers.

Name	Fees earned or paid in cash	Option awards (1)	Other compensation	Total
Jeffrey Kraws	\$ 7,500	\$ 4,416	\$ -	\$ 11,916
James Kuo	\$ 12,500	\$ 4,416	\$ -	\$ 16,916
Jeffrey Wolf	\$ 12,000	\$ 4,416	\$ -	\$ 16,416

(1) The amounts in the "Option awards" column reflect the dollar amounts recognized as compensation expense for the financial statement reporting purposes for stock options for the fiscal year ended December 31, 2009 in accordance with SFAS 123(R). The fair value of the options was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 235.18%, risk free interest rate of 3.24% and an expected life of 10 years.

During the first quarter of 2007, director compensation for independent members was approved at \$2,000 per board meeting that they attend in person, \$1,000 per telephonic board meeting and \$500 per committee meeting. In addition, we also grant independent members of our board of directors upon appointment to our board 25,000 stock options to purchase 25,000 shares of our common stock at an exercise price equal to the

fair market value of our common stock on the date of grant, and an additional 8,333 stock options each year. We also reimburse our directors for travel and other out-of-pocket expenses incurred in attending board of director and committee meetings.

### Equity Compensation Plan Information

As of December 31, 2009, the number of stock options and restricted common stock outstanding under our equity compensation plans, the weighted average exercise price of outstanding options and restricted common stock and the number of securities remaining available for issuance were as follows:

Plan category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans
<b>Plans Approved By Shareholders</b>			
2001 Stock Incentive Plan	1,230,354	\$ 1.10	259,366
2007 Stock Incentive Plan	1,240,978	\$ 1.44	978,324
<b>Total Plans Approved By Shareholders</b>	<b>2,561,332</b>	<b>\$ 1.26</b>	<b>1,237,690</b>
<b>Equity Plans Not approved By Shareholders</b>	<b>0</b>	<b>.00</b>	<b>0</b>
<b>Total All Plans</b>	<b>2,561,332</b>	<b>\$ 1.26</b>	<b>1,237,690</b>

### 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 today serves on the Company's Board of Directors.

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 (the then 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 President & Chief Executive Officer. Pursuant with the employment agreement Mr. Lyon received a base salary of \$190,000 per year and was eligible for discretionary performance and transactional bonus payments. 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.

On February 6, 2010 Max Lyon resigned as CEO and Jim Kuo was thereby appointed CEO. In connection with his appointment, Dr. Kuo entered into a three-year employment agreement with Adeona (the "Employment Agreement"). Pursuant to the Employment Agreement, Dr. Kuo will be entitled to an annual base salary of \$199,000 and will be eligible for discretionary performance and transactional bonus payments. Additionally, Dr. Kuo was granted options to purchase 400,000 shares of the Company's common stock with an exercise price equal to the Company's per share market price on the date of issue. Of these options, 100,000 vested immediately upon grant and the remainder will vest pro rata, on a monthly basis, over the following thirty-six months. Dr. Kuo will perform substantially all of his professional duties under the agreement from the Company's offices. The Employment Agreement also includes confidentiality obligations and inventions assignments by Dr. Kuo.

In connection with his resignation, Mr. Lyon will receive a severance payment in the form of shares of stock valued at \$22,613 pursuant to a Separation Agreement dated February 6, 2010 between Mr. Lyon and Adeona.

## **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table sets forth certain information regarding beneficial ownership of our common stock and warrants to purchase shares of our common stock as of March 28, 2010 by (i) each person (or group of affiliated persons) who is known by us to own more than five percent of the outstanding shares of our common stock, (ii) each of our directors and executive officers, and (iii) all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. The principal address of each of the stockholders listed below except as indicated is c/o Adeona Pharmaceuticals, Inc., 3930 Varsity Drive, Ann Arbor, MI 48108. We believe that all persons named in the table have sole voting and investment power with respect to shares beneficially owned by them. All share ownership figures include shares issuable upon exercise of options or warrants exercisable within 60 days of March 28, 2010, which are deemed outstanding and beneficially owned by such person for purposes of computing his or her percentage ownership, but not for purposes of computing the percentage ownership of any other person.

All references to the number of shares and per share amounts have been retroactively restated to reflect a 3 for 1 reverse stock split, of all the outstanding common stock, stock options and stock warrants of the Company, which was effected on April 25, 2007.

## Principal Stockholders Table

Name of Owner	Shares Owned	Percentage of Shares Outstanding
Accredited Venture Capital, LLC	7,086,380(1)	32.70%
Steve H. Kanzer	7,732,684(2)	35.68%
Firebird Capital	1,496,550(3)	6.91%
Jeffrey J. Kraws	253,772(4)	1.17%
Jeffrey Wolf, Esq.	49,999(5)	*
James S. Kuo	183,332(6)	*
Jeff Riley	25,000(7)	*
All officers and directors as a group (5 persons)	8,061,455	37.20%

\* represents less than 1% of our common stock

(1) Consists of 7,086,380 shares held in the name of Accredited Venture Capital, LLC.

(2) Consists of the 7,086,380 shares of common stock and 375,246 common shares, and 271,058 shares issuable upon stock options presently exercisable held directly in Mr. Kanzer's name. Pharmainvestors, LLC is the managing member of Accredited Venture Capital, LLC, and Mr. Kanzer is the managing member of Pharmainvestors, LLC. As such, Mr. Kanzer may be considered to have control over the voting and disposition of the shares registered in the name of Accredited Venture Capital, LLC. Mr. Kanzer disclaims beneficial ownership of those shares, except to the extent of his pecuniary interest.

(3) Consists of 743,275 shares of common stock issued to Firebird Global Master Fund, Ltd and 743,275 shares of common stock issued to Firebird Global Master Fund II, Ltd. Firebird's address is 152 West 57th Street, 24th Floor, New York, New York 10019.

(4) Assumes the exercise of a vested option to purchase 226,375 shares of our common stock presently exercisable. Mr. Kraws' address is c/o Adeona Pharmaceuticals, Inc. 3930 Varsity Drive, Ann Arbor, Michigan 48108.

(5) Assumes the exercise of an option to purchase 41,666 shares of our common stock. Mr. Wolf's address is c/o Adeona Pharmaceuticals, Inc. 3930 Varsity Drive, Ann Arbor, Michigan 48108.

(6) Consists of options to purchase common stock. Mr. Kuo's business address is c/o Adeona Pharmaceuticals, Inc. 3930 Varsity Drive, Ann Arbor, Michigan 48108. Excludes 266 667 options that vest monthly from on each monthly anniversary of his employment commencing the date he began employment.

(7) Consists of options to purchase common stock. Mr. Riley's address is c/o Adeona Pharmaceuticals, Inc. 3930 Varsity Drive, Ann Arbor, Michigan 48108.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

All references to the number of shares and per share amounts have been retroactively restated to reflect a 3 for 1 reverse stock split, of all the outstanding common stock, stock options and stock warrants of the Company, which was effective on April 25, 2007.

During January 2001, we sold approximately \$1.1 million of Series A Preferred Stock to Accredited Venture Capital, LLC, a company controlled by Steve H. Kanzer, our former Chairman and CEO. From 2002 until October 2006, we relied on non-interest bearing bridge loans from Accredited Ventures, Inc. (AVI), a company controlled Steve H. Kanzer, our former Chairman and Chief Executive Officer and the managing member of our largest stockholder, Accredited Venture Capital, LLC. During this 5 year period, AVI loaned us \$3,363,494 for no additional consideration. In connection with the private placement during October 2006, AVI agreed to convert these loans into units in the offering. As a result of the conversion of these loans, we issued 1,665,211 shares of common stock and 832,606 warrants to purchase common stock. In the merger, all shares of preferred stock were converted into common stock of the Registrant.

In connection with a private placement in October and November 2006, we engaged Accredited Equities Inc. (AEI), a company controlled by Steve H. Kanzer, our former Chairman and CEO as our placement agent. At the closing of our private placement during October and November 2006, we paid AEI the sum of approximately \$639,844 as commissions for its services and the selected dealer was paid a cash fee of \$327,950. AEI also received a non-accountable expense allowance of \$75,000 and a warrant to purchase 958,277 shares of common stock. Dr. Joseph Rudick, a former director, and a former registered representative of AEI. Mr. Nicholas Stergis, our co-founder and former CEO was the managing director of AEI and AVI.



As part of the October 2006 private placement, Adeona 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 Dr. Charles Bisgaier, our former President. As part of the same private placement, Adeona sold 49,552 shares of its common stock and 24,776 warrants to purchase common stock for total proceeds of \$100,000 to the father of our former Chairman. The terms on which their purchases were made were identical to the terms in which the other investors in these offerings purchased shares.

In connection with our acquisition of Effective Pharmaceuticals Inc. (EPI), Accredited Venture Capital, LLC and Mr. Stergis, a former director of Adeona contributed their 65.47% equity ownership in EPI to Adeona for no additional consideration. During 2005, EPI paid \$152,200 to AEI for placement agent services rendered in connection with the issuance of its Series B preferred stock. EPI also issued a warrant to purchase 171,225 shares of common stock to designees of AEI, including Mr. Kanzer and Mr. Stergis, who were then current members of our board of directors and Dr. Rudick, a former board member. During March 2005, EPI repaid AVI for loans totaling \$200,000 and AVI agreed to defer repayment of loans totaling \$513,886 until the next financing or a merger of EPI. These EPI loans were converted into Units as part of our October 2006 private placement. Mr. Stergis had been paid \$6,000 per month which increased to \$8,166 per month on November 1, 2006, which was increased to \$12,500 per month as of March 2007. During 2006, we paid \$2,150 per month to AVI and until March 31, 2007 we paid AVI \$1,000 per month for office space.

On January 5, 2007, we acquired the remaining 34.53% interest in our subsidiary EPI in exchange for 795,248 shares of our common stock and assumed a total of 34,685 options to purchase our common stock and 68,858 warrants to purchase our common stock. In connection therewith, Messrs. Kanzer and Stergis each exchanged their existing EPI warrants for 7,651 warrants to purchase our common stock, and Dr. Rudick exchanged EPI common stock for 30,161 shares of our common stock and exchanged his existing EPI options for 27,106 options to purchase our common stock, all of which is vested, and exchanged his EPI warrants for 42,845 warrants to purchase our common stock.

In 2007 we entered into an agreement with Crystal Research Associates, LLC, a firm in which Mr. Kraws one of our directors and VP of Business Development is the CEO to write an executive information overview. Pursuant to this agreement, we have paid Crystal Research Associates \$35,000 for the generation of the report.

We also entered into an employment agreement with Mr. Kanzer, our former interim Chief Executive Officer who is currently a director of the Company, which expired in January 2010. We also have an employment agreement with Dr. Kuo, our Chief Executive Officer and President. See "Employment Agreements" and "Risk Factors" section of this filing for further descriptive information on employment compensation.

During January 2009, we entered into a registration rights agreement with Accredited Venture Capital, LLC (AVC). Pursuant to this agreement AVC agreed to cancel warrants to purchase 1,213,626 shares of common stock of the Company exercisable at \$2.22 and 7,651 shares of common stock of Company exercisable at \$3.30 per share. This cancellation resulted in a reduction of total outstanding shares on a fully diluted basis of the Company of approximately 4.7%. The Company also agreed to register for resale the 7,086,379 shares of common stock of the Company held by AVC under the Securities Act of 1933, as amended. During February 2009, a resale registration statement covering these shares was declared effective by the SEC. Steve H. Kanzer is the managing member of Pharmainvestors LLC, the managing member of Accredited Venture Capital LLC. Mr. Kanzer currently serves as a director of the Company.

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Berman & Company, P.A. serves as our independent registered public accounting firm.

#### INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FEES AND SERVICES

Aggregate fees including expenses billed to us for the years ended December 31, 2009 and 2008, for professional services performed by Berman & Company, P.A. were as follows:

	2009	2008
Audit Fees and Expenses	\$ 63,500	74,000
Audit-Related Fees	54,140	0
Tax Fees	0	0
All Other Fees	0	0
Total	<u>\$ 117,640</u>	<u>74,000</u>

The Audit Committee has adopted procedures for pre-approving all audit and non-audit services provided by the independent registered public accounting firm, including the fees and terms of such services. These procedures include reviewing detailed back-up documentation for audit and permitted non-audit services. The documentation includes a description of, and a budgeted amount for, particular categories of non-audit

services that are recurring in nature and therefore anticipated at the time that the budget is submitted. Audit Committee approval is required to exceed the pre-approved amount for a particular category of non-audit services and to engage the independent registered public accounting firm for any non-audit services not included in those pre-approved amounts. For both types of pre-approval, the Audit Committee considers whether such services are consistent with the rules on auditor independence promulgated by the SEC and the PCAOB. The Audit Committee also considers whether the independent registered public accounting firm is best positioned to provide the most effective and efficient service, based on such reasons as the auditor's familiarity with the Company's business, people, culture, accounting systems, risk profile, and whether the services enhance the Company's ability to manage or control risks and improve audit quality. The Audit Committee may form and delegate pre-approval authority to subcommittees consisting of one or more members of the Audit Committee, and such subcommittees must report any pre-approval decisions to the Audit Committee at its next scheduled meeting. All of the services provided by the independent registered public accounting firm were pre-approved by your Audit Committee.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a)(1) The following financial statements are included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

1. Independent Auditor's Report
2. Consolidated Balance Sheets as of December 31, 2009 and 2008
3. Consolidated Statements of Operations for the years ended December 31, 2009 and 2008 and for the period from January 8, 2001 (inception) to December 31, 2009
4. Consolidated Statements of changes in Stockholders' Equity for the years ended December 31, 2009 and 2008 and for the period from January 8, 2001 (inception) to December 31, 2009
5. Consolidated Statements of Cash Flows for the years ended December 31, 2009 and 2008 and for the period from January 8, 2001 (inception) to December 31, 2009
6. Consolidated Statements of Cash Flows for the years ended December 31, 2009 and 2008 and for the period from January 8, 2001 (inception) to December 31, 2009

(a)(2) All financial statement schedules have been omitted as the required information is either inapplicable or included in the Consolidated Financial Statements or related notes.

(a)(3) The following exhibits are either filed as part of this report or are incorporated herein by reference:

3.1 Certificate of Incorporation, as amended (1)

3.2 Articles of Merger (2)

3.3 Certificate of Merger filed with the Secretary of State of Delaware (2)

3.4 Articles of Incorporation filed with the Nevada Secretary of State (2)

3.5 By-Laws (2)

4.1 Form of Warrant Certificate (3)

4.2 2001 Stock Incentive Plan (4)\*

4.3 2007 Stock Incentive Plan (4)\*

10.1 License Agreement with the Regents of the University of Michigan (5)

10.2 Option and License Agreement between University of Southern California and Autoimmune Vaccines, Inc. (5)

10.3 License Agreement between Thomas Jefferson University and Qantas Biopharmaceuticals, Inc. (5)

10.4 First Amendment to License Agreement between Thomas Jefferson University and CD4 Biosciences, Inc. (5)

10.5 Lock-up Agreement with Accredited Venture Capital, LLC (5)

10.6 Lock-up Agreement with Nicholas Stergis (5)

10.7 Lock-up Agreement with Joseph Rudick (5)

10.8 Lock-up Agreement with Jeffrey Kraws (5)

- 10.9 Lock-up Agreement with Jeffrey Wolf (5)
- 10.10 Unit Purchase Agreement (3)
- 10.11 License Agreement between The Regents of the University of California and Epitepe Pharmaceuticals, Inc. (8)
- 10.12 Form of Director/Officer Indemnification Agreement (9)\*
- 10.13 Warrant Cancellation and Registration Rights Agreement between Accredited Adventures Capital LLC and Adeona (10)\*
- 10.14 Stock purchase Agreement Colwell (11)
- 10.15 Escrow Agreement Nayaran Torke(12)
- 10.16 Consulting Agreement Nayaran Torke (12)
- 10.17 Purchase Agreement 1<sup>st</sup> Amendment HartLab LLC (12)
- 10.18 Purchase Agreement 2<sup>nd</sup> Amendment Hartlab LLC (12)
- 10.29 Agreement and Plan of Reincorporation Merger (13)
- 10.20 Employment Agreement with Dr. James Kuo (14)
- 10.21 Separation Agreement Max Lyons (15)
- 31.1 Certification pursuant to Rule 13a-14(a)/15d-14(a) (16)
- 31.2 Certification pursuant to Rule 13a-14(a)/15d-14(a) (16)
- 32.1 Certification pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 (16)

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(1) Incorporated by reference to (i) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 16, 2008, (ii) Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001 filed August 14, 2001, and (iii) Exhibits 3.1, 4.1 and 4.2 of the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1998 filed August 14, 1998.

(2) Incorporated by reference to (i) Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009 (ii) Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed October 19, 2009(iii) Exhibit 3.3 of the Registrant's Current Report on Form 8-K filed October 19, 2009 and (iv) Exhibit 3.4 of the Registrant's Current Report on Form 8-K filed October 19, 2009

(3) Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed January 6, 2009

(4) Incorporated by reference to the Registrant's Form S-8 filed on January 18, 2008.

(5) Incorporated by reference to the Registrant's Form 8-K filed on November 6, 2006.

(6) Incorporated by reference to the Registrant's Form 10QSB filed on August 14, 2007.

(7) Incorporated by reference to the Registrant's Form 10QSB filed on November 14, 2007.

(8) Incorporated by reference to the Registrant's Form 10Q filed on November 14, 2008.

(9) Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed January 6, 2009.

(10) Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed January 20, 2009.

(11) Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed April 16, 2009

(12) Incorporated by reference to (i) Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed July 16, 2009 (ii) Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed July 16, 2009 (iii) Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed July 16, 2009 and (iv) Exhibit 10.5 of the Registrant's Current Report on Form 8-K filed July 16, 2009.

(13) Incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed October 19, 2009

(14) Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed February 9, 2010

(15) Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed February 9, 2010

(16) Filed herewith.

\* Management compensation agreement.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned.

ADEONA PHARMACEUTICALS, INC  
By: /s/ James Kuo  
James Kuo  
Chief Executive Officer & Vice Chairman  
(Principal Executive Officer and Principal Financial Officer)  
Date: March 31, 2010

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: March 31, 2009                      By: /s/ James S. Kuo  
James S. Kuo  
Chief Executive Officer and Chairman  
(Principal Executive Officer and Principal Financial Officer)

Date: March 31, 2009                      By: /s/ Steve H. Kanzer  
Steve H. Kanzer  
Director

Date: March 31, 2009                      By: /s/ Jeffrey Kraws  
Jeffrey Kraws  
Director

Date: March 31, 2009                      By: /s/ Jeff Wolf  
Jeff Wolf  
Director

Date: March 31, 2009                      By: /s/ Jeff Riley  
Jeff Riley  
Director

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO RULE 13a-14 OR RULE 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, James Kuo, certify that:

1. I have reviewed this annual report on Form 10-K of Adeona Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f), for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2010

By: /s/ James Kuo  
Name: James Kuo  
Title: Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO RULE 13a-14 OR RULE 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, James Kuo, certify that:

1. I have reviewed this annual report on Form 10-K of Adeona Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f), for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the small business issuer's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2010

By: /s/ James Kuo  
Name: James Kuo  
Title: Chief Financial Officer  
(Principal Financial Officer)

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**CERTIFICATION CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Adeona Pharmaceuticals, Inc. (the “Registrant”) hereby certifies, to such officer’s knowledge, that:

- (1) the accompanying Annual Report on Form 10-K of the Registrant for the fiscal year ended December 31, 2009 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 31, 2010

By: /s/ James Kuo  
Name: James Kuo  
Title: Chief Executive Officer  
(Principal Executive Officer and Principal Financial Officer)

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