ADEONA PHARMACEUTICALS, INC.
Form 10-K
March 31, 2009

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2008

OR

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

For the transition period from_____
to_____

Commission File Number: 1-12584

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

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

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

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

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

(Title of Class)

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

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 ý

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 ý No o

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. ý

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

Large accelerated filer	¨	Accelerated filer	¨
Non-Accelerated filer	¨	Smaller reporting company	ý
(Do not check if a smaller reporting company			

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

The aggregate market value of the issuer's common stock held by non-affiliates of the registrant as of March 26, 2009, was approximately $3,602,853 based on $0.17, the price at which the registrant's common stock was last sold on that date.

As of March 26, 2009, the issuer had 21,193,254 shares of common stock outstanding.

Documents incorporated by reference: None.

ADEONA PHARMACEUTICALS, INC.

FORM 10-K
TABLE OF CONTENTS

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 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. (together with its subsidiaries, "Adeona" or the "Company") is a specialty pharmaceutical company that is preparing to commercialize a series of proprietary products for the prevention and treatment of degenerative conditions that we believe involve subclinical zinc deficiency and/or chronic copper toxicity. We believe that such conditions are highly prevalent and under-recognized in the aging population and that they may contribute to the progression of dry age-related macular degeneration (dry AMD), Alzheimer's disease (AD), and mild cognitive impairment (MCI).

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

Zinc-monocysteine is a complex of zinc and the amino acid cysteine that we believe may have improved properties compared to currently marketed zinc–based products. Zinc-monocysteine was invented and developed by David A. Newsome, M.D., former Chief of the Retinal Disease Section of the National Eye Institute (NEI). Dr. Newsome was the first to demonstrate the benefits of oral high dose zinc therapy in dry AMD. Oral high dose zinc containing products now represent the standard of care for dry AMD affecting over 10 million Americans and have annual sales of approximately $300 million. Zinthionein™ has completed an 80-patient, randomized, double-masked, placebo controlled clinical trial in dry AMD and demonstrated highly statistically significant improvements in central retinal function, the results of which were published in a peer-reviewed journal in 2008. In addition, we believe that our patent pending modified-release formulations of zinc-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.

Our sales and marketing plans include promoting prevention through public awareness, physician and patient education including current research, the research and development of potential proprietary diagnostic products to aid in the identification of individuals who may be at increased risk as well as the commercialization of our proprietary zinc-based products intended for the treatment and/or nutritional support of conditions characterized by subclinical

zinc deficiency and chronic copper toxicity.

We also have a number of proprietary drug candidates at various stages of clinical development, including; dnaJP1 for the induction of immune tolerance in rheumatoid arthritis which has completed a 160-patient, multicenter, randomized, double blind, placebo-controlled clinical trial; and TRIMESTA™ (oral estriol) for relapse-remitting multiple sclerosis in female patients. TRIMESTA™ is currently the subject of a 150-patient, multicenter, double-blind, randomized, placebo-controlled clinical trial that is currently fully funded by a $5 million grant from the National Multiple Sclerosis Society and National Institutes of Health (NIH).

Below is a table of our product candidates, their respective therapeutic indication and their respective stage of development:

Product	Therapeutic Indication	Stage of Development
Zinthionein™ (oral high dose zinc)	Dry Age-Related Macular Degeneration	80-patient trial of zinc-monocysteine in dry AMD completed and published
dnaJP1™ (oral dnaJP1 hsp peptide)	Induction of Immune Tolerance for Rheumatoid Arthritis	160-patient phase II completed
Trimesta™ (oral estriol)	Relapsing-Remitting Multiple Sclerosis in Female Patients	150-patient phase IIb ongoing
Effirma™ (oral flupirtine)	Fibromyalgia	90-patient phase II IND and IRB approved
CD4 Inhibitor 802-2 (oral cyclic heptapeptide)	Immune Tolerance Induction for Prevention of Severe GvHD	24-patient phase I/II completed

Product Summary

The following is a summary of the product candidates that we are developing:

Products for Subclinical Zinc Deficiency and Chronic Copper Toxicity

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

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

Our sales and marketing plans include promoting prevention through public awareness, physician and patient education including current research, the research and development of potential proprietary diagnostic products to aid in the identification of individuals who may be at increased risk as well as the commercialization of our proprietary zinc-based products intended for the treatment and/or nutritional support of conditions characterized by subclinical zinc deficiency and chronic copper toxicity. We recently completed an observational clinical study in 90 subjects that we believe demonstrates a statistically significant subclinical zinc deficiency and increased chronic copper toxicity susceptibility in subjects AD subjects compared to normal subjects and intend to publish these results in the future. We intend to seek relationships with third parties to develop proprietary diagnostic products based on our findings. We intend to launch a branded website, educational materials and marketing campaign to increase public awareness aimed at the prevention of chronic copper toxicity and market product solutions. Our EyeDaily™ brand of oral zinc-based therapies is expected to utilize patent-pending product packaging that incorporates an eye-self test to improve compliance and convenience of patients with dry AMD.

Oral dnaJP1

Oral dnaJP1 is our oral, once-daily candidate for immune tolerance induction and treatment of rheumatoid arthritis (RA). Oral dnaJP1 has completed a 160-patient, six-month, multi-center, double-blind, randomized, placebo-controlled Phase II clinical trial for the treatment of RA. This clinical trial was funded by a $5 million grant from the National Institutes of Health. Rheumatoid arthritis is an autoimmune disease which affects approximately 20 million people worldwide. Oral dnaJP1 is a 15 amino acid sequence delivered orally to RA patients. The dnaJP1 amino acid sequence is expressed on the surface of cells during an immune response and is expressed by an estimated

70% of RA patients. The intended mechanism of action of oral dnaJP1 is to induce immune tolerance to the dnaJP1 peptide in RA patients and thereby modify the course of disease.

Oral dnaJP1 is a heat shock protein (hsp)-derived peptide which was previously identified as a contributor of T-cell mediated inflammation in RA. Immune responses to hsp are often found at sites of inflammation and have an initial amplifying effect that upregulates the autoimmune disease.

Phase II Clinical Trial Results with oral dnaJP1

The response data from the phase II clinical trial for oral dnaJP1 at the ACR20 endpoint along with the percentage of ACR20 response at day 112, 140 and 168 (AUC p=0.09 (primary endpoint)) as well as day 112, 140 and 168 and day 196 follow-up without further drug therapy (AUC p=0.04). ACR20 is a composite endpoint developed the American College of Rheumatology and is generally accepted as an FDA approvable scoring criteria.

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. Oral 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-value=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 HCQ, corticosteroids, sulfasalazine, analgesics, NSAIDS, but not on disease modifying agents or biologics. Potential side effects noted in this study included leucopenia and anemia in 11% and 25%, respectively, of treated patients and 1.3% and 18%, respectively, in placebo patients but was not considered to be statistically significant.

From an immunologic standpoint, oral dnaJP1 also demonstrated an 80% reduction in the production in-vitro 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.

Our clinical collaborators are planning an end-of-phase II meeting with the FDA to discuss a proposed further clincial trial of dnaJP1 for the treatment of rheumatoid arthritis.

Market Opportunity for oral dnaJP1

Rheumatoid arthritis 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. 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. DMARDs, including biologics, accounted for nearly $5.0 billion of that figure.

TRIMESTATM (oral, once-daily estriol)

We are developing TRIMESTATM (oral estriol) as an oral immunomodulatory and anti-inflammatory bio-identical estrogenic agent for the North American market. Estriol has been approved and marketed throughout Europe and Asia as a mild estrogenic agent for over 40 years for the treatment of post-menopausal hot flashes. Estriol is an important endogenous hormone that is produced in the placenta by women 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.

Our scientific collaborator of TRIMESTA TM has explored the role that estriol plays in affording immunologic privilege to the fetus so as to prevent its rejection by the mother. It is a widely observed phenomenon that pregnant women with autoimmune diseases (such as multiple sclerosis and rheumatoid arthritis) experience a spontaneous reduction of 80% of relapse rates ($p<0.001$) during pregnancy (especially in the third trimester) as well as high rates of relapse during the post-partum period (especially in the three-month post-partum period). Based upon these insights, our scientific collaborator of TRIMESTA TM has conducted an initial clinical trial of TRIMESTA TM in multiple sclerosis patients and has demonstrated encouraging results, the results of which were published.

Phase IIb Clinical Trial of TRIMESTA TM in Relapsing-Remitting MS

TRIMESTA TM is currently the subject of an ongoing 150 patient double-blind phase IIb clinical in relapsing-remitting MS patients. TRIMESTA TM will be given in combination with subcutaneously injected Copaxone®, a standard treatment for MS. The primary endpoint is evaluating effects of the treatment combination on relapse rates using several clinical and magnetic resonance imaging measures of disability progression. This clinical trial is expected to be enrolled up to 16 sites within the U.S. and has received a $5 million grant from the National Multiple Sclerosis Society (NMSS) in partnership with the National MS Society's Southern California chapter, with support from the National Institutes of Health (NIH).

TRIMESTA TM for Relapsing-Remitting Multiple Sclerosis (MS)

Current Therapies for Relapsing-Remitting MS.
There are currently five FDA-approved therapies for the treatment of relapsing-remitting multiple sclerosis: Betaseron ®, Rebif ®, Avonex ®, Novantrone, Copaxone ® and Tysabri ®. These therapies provide only a modest benefit for patients with relapsing-remitting MS and therefore serve to only delay progression of the disease. All of these drugs 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. An estimated two-thirds of MS patients are women.

Phase II Clinical Trial Results of TRIMESTA in Relapsing-Remitting MS
TRIMESTA TM has completed an initial 10-patient, 16-month, single-agent, crossover, phase IIA clinical trial in the U.S. for the treatment of MS. The results of this study were encouraging.

Decrease in Volume and Number of Myelin Lesions
In relapsing-remitting MS patients treated, the total volume and number of pathogenic gadolinium enhancing myelin lesions (an established neuroimaging measurement of disease activity in MS) decreased during the treatment period as compared to a six-month pre-treatment baseline period. The median total enhancing lesion volumes decreased by 79% ($p = 0.02$) and the number of lesions decreased by 82% ($p = 0.09$) within the first three months of treatment with TRIMESTA TM . Over the next three months, lesion volumes decreased by 82% ($p = 0.02$) and the number of lesions decreased by 82% ($p = 0.02$) compared to baseline. During a three-month re-treatment phase of this clinical trial, relapsing-remitting MS patients again showed a decrease in enhancing lesion volumes (88%) ($p = 0.008$) and a decrease in the number of lesions (48%) ($p = 0.04$) compared to baseline.

Market Opportunities for TRIMESTA TM

Multiple Sclerosis

MS is a progressive neurological disease in which the body loses the ability to transmit messages along nerve cells, leading to a loss of muscle control, paralysis, and, in some cases, death. Currently, more than 2.5 million people worldwide (approximately 400,000 patients in the US), mainly young adults aged 18-50, are afflicted with MS and 66% of these patients are women. The most common form of MS is relapsing-remitting MS, which accounts for approximately 75% of MS patients.

MS exacts a heavy toll on our healthcare system. According to a published study, the total annual cost for all people with MS in the U.S. is estimated to be more than $9 billion. The average annual cost of MS 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 MS is approximately $65,000 per year per person. The average lifetime costs for people with MS are more than $2.2 million per person.

Oral Flupirtine

We are developing oral flupirtine, a non-opiate, non-addictive oral therapy for the treatment of fibromyalgia and other ophthalmic indications. 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 U.S. market for any indication.

Preclinical data and clinical experience suggests that flupirtine 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. Flupirtine is especially attractive because it operates through non-opiate pain pathways, exhibits no known abuse potential, and lacks withdrawal effects. In addition, no tolerance to its antinocioceptive effects has been observed. One common link between neuroprotection, nocioception, and flupirtine may be the NMDA (N-methyl-D-aspartate) glutamate system, a major receptor subtype for the excitotoxic neurotransmitter, glutamate. Flupirtine has strong inhibitory actions on NMDA-mediated neurotransmission.

Flupirtine for Fibromyalgia

Our scientific collaborator has demonstrated preliminary anecdotal efficacy of flupirtine for the treatment of fibromyalgia in a small number of U.S. patients suffering from fibromyalgia that were refractive to other analgesics and therapies. Flupirtine 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. Our scientific collaborator filed an investigator initiated IND with the FDA to conduct a phase II clinical trial in

fibromyalgia patients with oral flupirtine. During 2008, this proposed clinical trial and IND have been approved the FDA. Additionally, this protocol has received institutional review board (IRB) approval although we do not currently plan to immediately initiate this study.

Fibromyalgia is an arthritis-related condition that is characterized by generalized muscular pain and fatigue. It is a chronic and debilitating condition 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.

We estimate that there are approximately 6 million Americans with fibromyalgia. During 2007, Lyrica®, which is marketed by Pfizer, was the only FDA-approved medication for fibromyalgia, recorded $1.8 billion in sales and $1.2 billion during its first year on the market.

CD4 Inhibitors

We are developing 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.

Our lead CD4 inhibitor molecule, named 802-2, has demonstrated preliminary safety and efficacy in a number of animal models of autoimmune disease models, and it has been evaluated in a phase I/II clinical trial for the prevention of graft-vs.-host disease. Anti-CD4 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.

Market Opportunity for Anti-CD4 802-2 and Small Molecule CD4 Inhibitors

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

Intellectual Property

Our goal is to (a) obtain, maintain, and enforce patent protection for our 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. We seek, where appropriate, the broadest intellectual property protection for product candidates, proprietary information, and proprietary technology through a combination of contractual arrangements and patents.

We have exclusively licensed from various universities issued patent and patent applications, including foreign equivalents relating to our product candidates. We also file patent applications for inventions invented or discovered by us.

Some of our products also have various regulatory exclusivities, such as “Waxman-Hatch” designations including, TRIMESTA and Flupirtine. Waxman-Hatch exclusivities provide 5 years of market exclusivity in the U.S. These regulatory exclusivities combined with our patents and patent applications provide for supplemental intellectual property protection for our products against competitors.

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

The Regents of University of California License Agreement

We have an exclusive worldwide license agreement with the Regents of the University of California relating to a issued and pending U.S. and international patents and patent applications covering the composition of matter and uses of an epitope specific immunotherapeutic technology for which dnaJP1 is the lead product candidate. Pursuant to this agreement, we have paid an upfront license fee, reimbursed patent expenses as well as annual maintenance fees, success based milestone payments totaling $11 million as well as royalties on net sales of products covered by the licensed patents.

The Regents of University of California License Agreement

We have an exclusive worldwide license agreement with the Regents of the University of California relating to issued U.S. Patent No. 6,936,599 and pending patent applications covering the uses of the TRIMESTA TM technology. 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 an NDA, and on approval of an NDA with the FDA, as well

as royalties on net sales of the TRIMESTA TM technology covered by the licensed patents. If we become public or are acquired by a public company, we may be permitted to partially pay milestone payments in the form of equity.

McLean Hospital Exclusive License Agreement

We have 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, we 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 we have a license to other intellectual property covering those indications; use our best efforts to commercialize flupirtine for the therapeutic uses embodied in the patent applications; reimburse back patent costs of approximately $41,830; and pay the following milestone payments: $150,000 upon the initiation of a pivotal phase III clinical trial of flupirtine; $300,000 upon the filing of an NDA for flupirtine; and $600,000 upon FDA approval of flupirtine.

Thomas Jefferson University License Agreement

Our majority-owned subsidiary CD4 Biosciences Inc. has 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 anti-CD4 802-2 and CD4 inhibitor technology. We are obligated to pay annual maintenance fees, milestone payments upon the filing of an NDA and approval of an NDA with the FDA, as well as royalties on net sales of anti-CD4 802-2 and other anti-CD4 molecules covered by the licensed patents. We also received rights to valuable data generated under any IND 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. We also agreed that TJU would receive anti-dilution protection on those CD4 shares through the first $2 million in financing to CD4. We also agree to indemnify TJU against certain liabilities.

University of Michigan (UM) Exclusive License Agreement

We have entered into an exclusive worldwide license agreement with the University of Michigan (UM) for all uses of U.S. Patent No. 6,855,340, corresponding international applications, and a related corresponding patent application that relates to various uses of anti-copper therapeutics to treat inflammatory and fibrotic diseases. Pursuant to this agreement, we will use our best efforts to commercialize oral TTM for the therapeutic uses embodied in the issued patent and pending patent application; reimburse UM for patent expenses; pay UM royalties equal to 2% of net sales of oral TTM for uses covered by the UM patents; issue UM shares of our common stock; pay UM success-based milestone fees totaling $350,000 (the first of which is due when we file an NDA and the second of which is due when we receive FDA approval for oral TTM in an indication covered by the UM patents), and indemnify UM against certain liabilities.

Research and License Agreements Terminated in 2009 and First Quarter of 2009

During 2008 and the first quarter of 2009, we terminated our research agreement with the University of Michigan as well our license agreements with Maine Medical Institute, Oregon Health & Sciences Center (OHSU), University of Southern California (USC), and Children's Hospital-Boston.

Manufacturing

We utilize contract manufacturing firms to produce the bulk active ingredients for CD4 Inhibitor 802-2 and dnaJP1 in accordance with "current good manufacturing processes" (cGMP) guidelines outlined by the FDA. Our 17,675 square feet of primary office, laboratory and manufacturing facility in Ann Arbor, MI includes approximately 6,000 square feet of cleanroom suites, cGMP areas and QA/QC analytical lab that we utilize to perform formulation and process development, ingredient storage, milling, sieving, blending, tableting, capsuling, dissolution testing, stability testing and potential commercial production of our Zinthionein™ and modified-release zinc formulation finished products. Our monthly rent is $15,033.80 and our lease expires on February 28, 2011, but extendable at our option for an additional three years. We are currently seeking to sublease some or all of our excess space at this facility. Our Trimesta bulk and finished product is manufactured by Organon NV, a European subsidiary of Schering-Plough which has manufactured the active ingredient in Trimesta for nearly 40 years.

Sales and Marketing

We currently do not market any products. We may hire a Vice President of Sales and Marketing and develop our own marketing team and/or 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, 2008, we have expended approximately $23.0 million on a consolidated basis acquiring and developing our current product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Therefore, for the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees, and grants. We will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We are not currently profitable and may never become profitable.

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

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

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

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

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

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

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

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. Effective March 29, 2009, Nicholas Stergis resigned as our Chief Executive Officer. Mr. Stergis remains a director of the Company and Steve H. Kanzer was appointed our Chief Executive Officer and President. 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 reputations, business, operating results, financial results and internal controls over financial reporting.

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

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

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

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

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

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

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

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

In addition to our own patent applications, we also currently rely on licensing agreements with third party patent holders/licensors for our products. We have an exclusive license agreement with the McLean Hospital relating to the use of flupirtine to treat fibromyalgia syndrome; an exclusive license agreement with Thomas Jefferson University relating to our CD4 inhibitor program; an exclusive license agreement with the Regents of the University of California relating to our TRIMESTA™ technology; an exclusive license to our oral immunotherapeutic tolerance program, named dnaJP1 from UCSD and an exclusive license agreement with Dr. Newsome and Mr. Tate relating to our Zinthionein program. Each of these agreements requires us to use our best efforts to commercialize each of the technologies as well as meet certain diligence requirements and timelines in order to keep the license agreement in effect. In the event we are not able to meet our diligence requirements, we may not be able to retain the rights granted under our agreements or renegotiate our arrangement with these institutions on reasonable terms, or at all.

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

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

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

Companies that currently sell or are developing both generic and proprietary pharmaceutical compounds to treat central-nervous-system and autoimmune diseases include: Pfizer, Inc., Rigil Pharmaceuticals, Incyte Pharmaceuticals, Chelsea Therapeutics International, Inc., Aton Pharma, GlaxoSmithKline Pharmaceuticals, Alcon, Inc., Shire Pharmaceuticals, Plc., Schering-Plough, Organon NV, Merck & Co., Eli Lilly & Co., Serono, SA, Biogen Idec, Inc.,

Achillion, Ltd., Active Biotech, Inc., Panteri Biosciences, Meda, Merrimack Pharmaceuticals, Inc., Merch-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, Zinthionein, dnaJP1, CD4 inhibitors and flupirtine technologies. Should clinicians or regulatory authorities view these therapeutic regiments as more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid and private insurers.

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

Since we do not have composition of matter patent claims for, flupirtine and TRIMESTA, others may obtain approvals for other uses of these products which are not covered by our issued or pending patents. For example, the active ingredients in both flupirtine and TRIMESTA have been approved for marketing in overseas countries for different uses. Other companies, including the original developers or licensees or affiliates may seek to develop flupirtine or TRIMESTA or their respective active ingredient(s) for other uses in the US or any country we are seeking approval for. We cannot provide any assurances that any other company may obtain FDA approval for products that contain flupirtine or TRIMESTA in various formulations or delivery systems that might adversely affect our ability to develop and market these products in the US. We are aware that other companies have intellectual property protection using the active ingredients and have conducted clinical trials of flupirtine, and TRIMESTA 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 different indications. We are aware that a potential competitor has an exclusive license from the University of Michigan (UM) to an issued U.S. patent that relates to the use of tetrathiomolybdate to treat angiogenic diseases (the "Angiogenic Patent") and is currently in phase I and phase II clinical trials for the treatment of various forms of cancer. To our knowledge, this competitor and UM have filed additional patent applications claiming various analog structures and formulations of tetrathiomolybdate to treat various diseases. Further, we cannot predict whether our competitor might obtain approval in the U.S. or Europe to market tetrathiomolybdate for cancer or another indication ahead of us. We also cannot predict whether, if issued, any patent corresponding to the Angiogenic Patent may prevent us from conducting our business or result in lengthy and costly litigation or the need for a license. Furthermore, if we need to obtain a license to these or other patents in order to conduct our business, we may find that it is not available to us on commercially reasonable terms, or is not available to us at all.

If the FDA approves other 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.

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 inflammatory and fibrotic diseases (U.S. Patent No 6,855,340). These patents have been exclusively licensed to us. We have also filed various pending patent applications which cover various

formulations, packaging, distribution & monitoring methods for oral TTM. We rely on issued patent and pending patent applications for use of TRIMESTA to treat MS (issued U.S. Patent No. 6,936,599) and various other therapeutic indications which have been exclusively licensed to us. We have 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, methods and its uses, We have also exclusively licensed an issued patent for the treatment of fibromyalgia with flupirtine.

Our Zinthionein product candidate is exclusively licensed from its inventors, David A. Newsome, M.D. and David Tate, Jr. Zinthionein 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 Form 10-KSB for the year ending December 31, 2007 filed March 31, 2008 (page 23), we described our receipt in March 2008 (and potential impact on claim 1 of our exclusively licensed issued U.S. patent 7,164,035) of an English translation of a Russian disclosure, Zegzhda et. al. Chemical Abstracts Vol. 85 Abstract No. 186052 (1976) that was cited by the U.S. patent examiner during our

prosecution of the pending divisional U.S. patent application Ser. No. 11/621,390. In April 2008, we analyzed the zinc-cysteine complex described by Zegzhda and concluded that such complex describes an 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.

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

We may also rely on the United States Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Amendments," to protect some of our current product candidates, specifically oral TTM, dnaJP1, TRIMESTA, zinc-monocystine, CD4 inhibitor, flupirtine and other future product candidates we may develop. Once a drug containing a new molecule is approved by the FDA, the FDA cannot accept an abbreviated NDA for a generic drug containing that molecule for five years, although the FDA may accept and approve a drug containing the molecule pursuant to an NDA supported by independent clinical data. Recent amendments have been proposed that would narrow the scope of Hatch-Waxman exclusivity and permit generic drugs to compete with our drug.

Others may file patent applications or obtain patents on similar technologies or compounds that compete with our products. We cannot predict how broad the claims in any such patents or applications will be, and whether they will be allowed. Once claims have been issued, we cannot predict how they will be construed or enforced. We may infringe intellectual property rights of others without being aware of it. If another party claims we are infringing their technology, we could have to defend an expensive and time consuming lawsuit, pay a large sum if we are found to be infringing, or be prohibited from selling or licensing our products unless we obtain a license or redesign our product, which may not be possible.

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

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

As of March 28, 2009, we have 3 full-time employees and 3 part-time employees. We have also engaged regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. We intend to recruit certain key executive officers, including a Vice President of Sales and Marketing and Vice President of Business Development during 2009. Our future performance will depend in part on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management.

Effective March 29, 2009, Nicholas Stergis resigned as our Chief Executive Officer. Mr. Stergis remains a director of the Company. In order to fill the vacancy, Steve H. Kanzer was appointed our President and Chief Executive Officer. The Company has engaged an executive search firm to identify potential candidates for the Chief Executive Officer position.

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

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

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

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

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

In order to successfully commercialize our product candidates, we must be able to manufacture our products in commercial quantities, in compliance with regulatory requirements, at acceptable costs, and in a timely manner. Manufacture of the types of biopharmaceutical products that we propose to develop present various risks. For example, manufacture of the active ingredient in oral TTM and Zinthionein is a complex process that can be difficult to scale up for purposes of producing large quantities. This process can also be subject to delays, inefficiencies, and poor or low yields of quality products. Furthermore, the active ingredient of Zinthionein 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 Zinthionein. 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.

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 reachieve cGMP status for our facility.

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

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

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

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

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

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

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

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

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

The results of our clinical trials may not support our product candidate claims.

Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product-candidate claims. Success in pre-clinical testing and phase II clinical trials does not ensure that later phase II or phase III clinical trials will be successful. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and pre-clinical testing. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. Any such failure could cause us to abandon a product candidate and might delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay our obtaining FDA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

Physicians and patients may not accept and use our technologies.

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

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

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

We depend on researchers who are not under our control.

Since we have in-licensed some of our product candidates, we depend upon independent investigators and scientific collaborators, such as universities and medical institutions or private physician scientists, to conduct our pre-clinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs or the timing of their procurement of clinical-trial data or their compliance with applicable regulatory guidelines. Should any of these scientific inventors/advisors become disabled or die unexpectedly, or should they fail to comply with applicable regulatory guidelines, we may be forced to scale back or terminate development of that program. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking those programs ourselves. Failing to devote sufficient time and resources to our drug-development programs, or substandard performance and failure to comply with regulatory guidelines, could result in delay of any FDA applications and our commercialization of the drug candidate involved.

These collaborators may also have relationships with other commercial entities, some of which may compete with us. Our collaborators assisting our competitors at our expense could harm our competitive position. For example, we are highly dependent on scientific collaborators for our dnaJP1, TRIMESTA, Zinthionein, 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 Zinthionein program. George J. Brewer, M.D., our initial clinical collaborator for oral TTM for Wilson's disease, has retired from University of Michigan, will no longer participate as a clinical investigator and no longer has an IND for oral TTM. We do not plan to conduct any further clinical studies of oral TTM. Should we or a future sublicensee elect to seek to conduct additional clinical trials of oral TTM, we or such sublicensee as the ase 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 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 have no experience selling, marketing, or distributing products and do not have the capability to do so.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

health care providers. In addition, third-party payers are increasingly challenging the necessity and prices charged for medical products, treatments and services.

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

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

RISKS RELATING TO OUR STOCK

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

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

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

Currently, our directors, executive officers, and principal stockholders beneficially own a majority of our common stock. As a result, they will be able to exert substantial influence over the election of our board of directors and the vote on issues submitted to our stockholders. In January 2009, we registered for sale under the Securities Act of 1933, as amended, 8,816,918 shares of our outstanding common stock held by our officers, directors and principal stockholders and 1,148,753 shares of common stock issuable upon the exercise of warrants held by our officers, directors and principal stockholders. Because our common stock has from time to time been “thinly traded”, the sale of these shares by our officers, directors and principal stockholders could have an adverse effect on the market for our stock and our share price.

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

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

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

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

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

We cannot assure you that we will be able to maintain the listing standards of the NYSEAmex formerly the American Stock Exchange or NYSE Alternext US. The NYSEAmex 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 effect 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 NYSEAmex. 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.

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.

Our board has approved a plan to re-incorporate the Company from the State of Delaware to the State of Nevada

During the Company’s annual shareholder meeting held during June 2008, the Company received authorization to re-incorporate from the State of Delaware to the State of Nevada. The Company intends to complete this re-incorporation during the second quarter of 2009.

We have never paid dividends.

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

RISKS RELATED TO OUR INDUSTRY

Government Regulation

In the United States, the formulation, manufacturing, packaging, storing, labeling, promotion, advertising, distribution and sale of our products are subject to regulation by various governmental agencies, including (1) the Food and Drug Administration, or FDA, (2) the Federal Trade Commission, or FTC, (3) the Consumer Product Safety Commission, or CPSC, (4) the United States Department of Agriculture, or USDA. Our proposed activities may also be regulated by various agencies of the states, localities and foreign countries in which our proposed products may be manufactured, distributed and sold. The FDA, in particular, regulates the formulation, manufacture and labeling of over-the-counter, or OTC, drugs, conventional foods, dietary supplements, and cosmetics such as those that we intend to distribute. FDA regulations require us and our suppliers to meet relevant current good manufacturing practice, or cGMP, regulations for the preparation, packing and storage of foods and OTC drugs. On June 25, 2007, the FDA published its final rule regulating cGMPs for dietary supplements. The final rule became effective August 24, 2007 and small companies with less than 20 employees, such as us, have until June 2010 to achieve compliance. As a result of inactivity and the removal and sale of certain equipment, our facility in Ann Arbor, Michigan is no longer currently

cGMP compliant.

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

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

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

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

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

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

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

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

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

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

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

We will submit the preclinical test results, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we begin human clinical trials. The IND automatically becomes effective 30 days after filing, unless the FDA

raises questions about conduct of the trials outlined in the IND and imposes a clinical hold, as occurred with oral TTM, in which case, the IND sponsor and FDA must resolve the matters before clinical trials can begin. It is possible that our submission may not result in FDA authorization to commence clinical trials.

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

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

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

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

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

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

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

Submission of a NDA with clinical data requires payment of a fee (for fiscal year 2008, $1,178,500). In return, the FDA assigns a goal of ten months for issuing its "complete response," in which the FDA may approve or deny the NDA, or require additional clinical data. Even if these data are submitted, the FDA may ultimately decide the NDA does not satisfy approval criteria. If the FDA approves the NDA, the product becomes available for physicians prescription. Product approval may be withdrawn if regulatory compliance is not maintained or safety problems occur. The FDA may require post-marketing studies, also known as phase IV studies, as a condition of approval, and requires surveillance programs to monitor approved products that have been commercialized. The agency has the power to require changes in labeling or prohibit further marketing based on the results of post-marketing surveillance.

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

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

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

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

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

Other Regulatory Requirements

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

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

European Product Approval

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

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

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

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

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

Pricing Controls

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

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

Third-Party Reimbursements

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

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

The E.U. generally provides options for member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement. Member states can opt for a "positive" or "negative" list, with the former listing all covered medicinal products and the latter designating those excluded from coverage. The E.U., the U.K. and Spain have negative lists, while France uses a positive list. Canadian provinces establish their own

reimbursement measures. In some countries, products may also be subject to clinical and cost effectiveness reviews by health technology assessment bodies. Negative determinations in relation to our products could affect prescribing practices. In the U.K., the National Institute for Clinical Excellence ("NICE") provides such guidance to the National Health Service, and doctors are expected to take it into account when choosing drugs to prescribe. Health authorities may withhold funding from drugs not given a positive recommendation by NICE. A negative determination by NICE may mean fewer prescriptions. Although NICE considers drugs with orphan status, there is a degree of tension on the application of standard cost assessment for orphan drugs, which are often priced higher to compensate for a limited market. It is unclear whether NICE will adopt a more relaxed approach toward the assessment of orphan drugs.

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

Fraud and Abuse Laws

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

Patent Restoration and Marketing Exclusivity

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

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

Hatch-Waxman also provides for differing periods of statutory protection for new drugs approved under an NDA. Among the types of exclusivity are those for a “new molecular entity” and those for a new formulation or indication for

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our primary offices, laboratories and manufacturing facility is located at 3930 Varsity Drive, Ann Arbor, MI 48108. We currently rent approximately 17,675 square feet of office, laboratory and production space for monthly rent of $15,033.80. This lease expires on February 28, 2011, but extendable at our option for an additional three years. We believe our current offices will be adequate for the foreseeable future and we are currently seeking to sublease some or all of our excess space at this facility. Our phone number is (734) 332-7800 and our facsimile number is (734) 332-7878. Our website is located at 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, management believes the lawsuit is without merit. The Company has engaged legal counsel to respond to this matter.

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

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES 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 American Stock Exchange. 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 American Stock Exchange on March 4, 2009 was $0.15 per share. As of March 4, 2009, there were approximately 379 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
YEAR ENDED DECEMBER 31, 2008		
Fourth quarter	$ 0.55	$ 0.03
Third quarter	$ 1.02	$ 0.48
Second quarter	$ 1.40	$ 0.65
First quarter	$ 5.25	$ 0.80
YEAR ENDED DECEMBER 31, 2007		
Fourth quarter	$ 7.10	$ 4.68
Third quarter	$ 8.00	$ 4.30
Second quarter	$ 8.10	$ 3.71
First quarter	$ 30.00	$ 3.06

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 Delaware 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, 2008:

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
	0	$ 0	0	0

Month Ended October 31, 2008				
Month Ended November 30, 2008	0	0	0	0
Month Ended December 31, 2008	0	0	0	0
Total	0	$0	0	0

Equity Compensation Plan Information

See Item 11 for equity compensation plan information.

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

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, 2008, 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 2001, our efforts and resources have been focused primarily on acquiring and developing our pharmaceutical products, costs associated with operating a publicly traded company, raising capital and recruiting personnel. We are a development stage company and have had no product sales to date and we will not have any prescription product sales until and unless we receive approval from the FDA or receive approval from equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates. Our major sources of working capital have been proceeds from equity financings from an affiliate of our Chairman and Chief Executive Officer and various private financings, primarily involving private sales of our common stock and other equity securities.

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

was therefore accounted for as a reverse acquisition with Pipex Therapeutics as the acquiring party and Sheffield as the acquired party. Accordingly, when we refer to our business and financial information relating to periods prior to the merger, we are referring to the business and financial information of Pipex Therapeutics, unless the context indicates otherwise.

Critical Accounting Policies

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

Research and development expenses consist primarily of manufacturing costs, license fees, salaries and related personnel costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and

organizational affairs and other expenses relating to the design, development, testing, and enhancement of our product candidates, as well as an allocation of overhead expenses incurred by the Company. We expense our research and development costs as they are incurred.

General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development and general legal activities, as well as an allocation of overhead expenses incurred by the Company. We expense our general and administrative expenses as they are incurred.

Our results include non-cash compensation expense as a result of the issuance of stock and stock option grants. Compensation expense for options granted to employees represents the fair value of the award at the date of grant. All share-based payments to employees since inception have been recorded and expensed in the statements of operations as applicable under SFAS No. 123R “Share-Based Payment”.

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

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

Results of Operations

Year Ended December 31, 2008 and 2007.

Research and Development Expenses. For the year ended December 31, 2008, research and development expense was $4,643,570 as compared to $6,327,726 for the year ended December 31, 2007. The decrease of $1,684,156 is due primarily to a decrease in salaries and payroll taxes of approximately $739,000, a decrease of approximately $684,000 associated with payments related to further the development of our licensed clinical drug candidates and a decrease in stock based compensation charges of approximately $214,000.

General and Administrative Expenses. For the year ended December 31, 2008, general and administrative expense was $2,675,636 as compared to $3,810,585 for the year ended December 31, 2007. The decrease of $1,134,949 is due primarily to a decrease in stock based compensation charge of approximately $952,000 and an decrease in salaries and payroll taxes of approximately $160,000.

Other Income (Expense), net. For the year ended December 31, 2008, other income-net was $114,048 compared to $245,878 for the year ended December 31, 2007. For the year ended December 31, 2008, interest income was $128,236 as compared to $298,807 for the year ended December 31, 2007. Interest income was lower for the period in 2008 as compared to the same period in 2007, due to lower interest rates and lower levels of cash in interest bearing accounts. For the year ended December 31, 2008, interest expense was $13,831 as compared to $52,929 for the year ended December 31, 2007. Interest expense for both periods relates to interest paid on the notes payable which were repaid in March 2008.

Net Loss. Net loss for the year ended December 31, 2008, was $7,205,158 as compared to $9,892,433 for the year ended December 31, 2007. This decrease in net loss is attributable primarily to a decrease in research and

development expenses of $1,684,156 and a decrease in general and administrative expenses of $1,134,149 as discussed above.

Net Loss Applicable to Common Shareholders. The net loss applicable to common shareholders for the year ended December 31, 2007 includes a non-cash charge of $12,409,722 related to the acquisition of Effective Pharmaceuticals, Inc (“EPI”). The total of the non-cash charges was reflected through equal and offsetting adjustments to additional paid-in-capital with no net impact on stockholders’ equity. This amount was considered in the determination of the Company’s loss per common share amounts for the year ended December 31, 2007 and for the period from January 8, 2001 (inception) to December 31, 2008.

Liquidity and Capital Resources

During the year ended December 31, 2008, we had a net decrease in cash of $5,636,418. Total cash resources as of December 31, 2008 was $5,856,384. During the year ended December 31, 2008 and 2007, net cash used in operating activities was $4,851,675 and $6,606,859 respectively. This cash was used to fund our operations for the periods, adjusted for non-cash expenses and changes in operating assets and liabilities.

Net cash provided by investing activities for the year ended December 31, 2008 was $110,867 compared to $1,965,574 net cash used in investing activities for the year ended December 31, 2007. 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 n the amount of $21,398. The net cash used in investing activities for the year ended December 31, 2007 resulted from the acquisition of property and equipment totaling $1,965,574.

Net cash used in financing activities was $895,610 the year ended December 31, 2008 compared to $7,872,809 net cash provided by financing activities for the year ended December 31, 2007. 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. The net cash proceeds from financing activities for the year ended December 31, 2007 resulted from $7,552,378 for proceeds from the exercise of warrants, less $579,569 paid as direct offering costs. In addition, the Company raised $1,100,000 in proceeds from notes payable under term loans, less $200,000 of repayments under these loans.

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 $38,281,676 through December 31, 2008. We have incurred negative cash flow from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts. Based on our current plans, we believe that our cash will be sufficient to enable us to meet our planned operating needs at least for the next 18 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.

License and Contractual Agreement Obligations

Below is a table of our contractual obligations for the years 2009 through 2013 as of December 31, 2008.

	Year					
	2009	2010	2011	2012	2013	Total
License Agreements	$ 82,000	$ 95,000	$95,000	$120,000	$155,000	$547,000
Lease Agreements	$145,733	$150,152	$25,148	0	0	$321,033
Consulting Agreements	$ 40,000	$ 30,000	0	0	0	$ 70,000
Total	$267,733	$275,152	$120,148	$120,000	$155,000	$938,033

Product Candidates

Zinthionein TM (oral zinc-monocysteine complex)

We plan to initially develop Zinthionein TM as an oral treatment for the support of subclinical zinc deficiency and/or chronic copper toxicity dry age-related macular degeneration (“dry AMD”). Zinthionein has completed a six month double blind randomized placebo controlled trial in 80 dry AMD patients with statistically significant improvements in visual acuity, contrast sensitivity and photorecovery times. During July 2008, we announced detailed results following the publication of the study results in a peer-reviewed ophthalmic journal. Through December 31, 2008, we have incurred approximately $410,000 of costs related to our development of Zinthionein of which $154,000 was incurred during 2007 and $256,000 was incurred in 2008.

Oral dnaJP1

In June 2008, we acquired Oral dnaJP1, an oral, candidate for the treatment of rheumatoid arthritis (RA) which has completed a 160 patient, multi-center, double-blind, randomized, placebo-controlled Phase II clinical trial for the treatment of RA. Rheumatoid arthritis is an autoimmune disease which affects approximately 20 million people worldwide. Oral dnaJP1 is a epitope specific immunotherapy for RA patients. Oral dnaJP1 is a heat shock protein (hsp)-derived peptide which was previously identified as a contributor of T cell mediated inflammation in RA. Immune responses to hsp are often found at sites of inflammation and have an initially amplifying effect that needs to be downregulated to prevent tissue damage. The mechanisms for this regulation involve T cells with regulatory function that are specific for hsp-derived antigens. This regulatory function is one of the key components of a "molecular dimmer" whose physiologic function is to modulate inflammation independently from its trigger. This function is impaired in autoimmunity and could be restored for therapeutic purposes. Through December 31, 2008, we have incurred approximately $219,000 of costs related to our development of Oral dnaJP1 all of which has been incurred in 2008.

TRIMESTA TM (oral estriol)

In June 2007, a two year seven U.S. center, placebo controlled 150 patient phase IIb clinical trial using TRIMESTA TM for the treatment of relapsing-remitting Multiple Sclerosis (MS) was initiated under a $5 million grant from the Southern California Chapter of the National Multiple Sclerosis Society and NIH. This phase IIb clinical trial builds upon our encouraging results from an earlier phase IIa clinical trial. The primary purpose of this study is to evaluate the safety and efficacy of TRIMESTA TM in a larger MS patient population with a one year blinded interim analysis.

The preclinical and clinical development of TRIMESTA TM has been primary financed by grants from the NIH and various non-profit foundations. Through December 31, 2008, we have incurred approximately $685,000 of costs related to our development of TRIMESTA TM of which approximately $49,500, $185,500 and 194,000 was incurred in fiscal years 2005, 2006 and 2007, respectively, and approximately $256,000 was incurred in 2008. During 2009, this clinical trial was expanded to include 16 total clinical trial sites.

Oral flupirtine

A scientific collaborator of ours has filed and received an IND with the FDA to conduct a phase II clinical trial with flupirtine in fibromyalgia patients. Our scientific collaborator also received institutional review board (IRB) approval to conduct this study. Through December 31, 2008, we have incurred approximately $112,000 of costs related to our development of flupirtine, of which $85,000 was incurred during 2007 and $27,000 was incurred during 2008. During 2008, we obtained an option to license issued and pending patent applications relating to flupirtines use in the treatment of ophthalmic indications. We are seeking potential U.S. and international corporate partners for the further development of flupirtine for various indications.

Freebound TM (metals diagnostic device)

We were, but no longer are, developing a proprietary electrochemical diagnostic device, Freebound TM capable of measuring levels of free and bound metals in biological samples. Through December 31, 2008, we have incurred approximately $56,000 of costs related to our development of Freebound TM, of which $38,000 was incurred during 2008. We are no longer actively developing this electrochemical device and instead are seeking potential U.S. and international corporate partners for the further development of FreeBound.

Oral TTM (oral tetrathiomolybate)

Through December 31, 2008, we have incurred approximately $3,612,000 of costs related to our development of oral TTM, of which approximately $150,000, $1,061,000 and $1,676,000 was incurred in fiscal years 2005, 2006 and 2007, respectively, and approximately $725,000 was incurred during 2008.

We are seeking potential U.S. and international corporate partners for the further development of Oral TTM for Wilson's Disease, idiopathic pulmonary fibrosis (IPF), Alzheimer’s disease and Huntington’s Disease.

Anti-CD4 802-2

Through December 31, 2008, we have incurred $1,465,000 of costs related to our development of anti-CD4 802-2 of which $58,000, $332,000, $303,000, $295,000, $113,000, $161,000 and $121,000 was incurred in fiscal years 2001, 2002, 2003, 2004, 2005, 2006 and 2007 respectively and approximately $82,000 has been incurred in 2008.

CORRECTA TM (clotrimazole emema)

In November 2008, we provided Children's Hospital Boston notice of termination of the license agreement relating to this product candidate.

Through December 31, 2008, and prior to our termination of this agreement, we incurred approximately $364,000 of costs related to our development of CORRECTA TM of which approximately $103,000, $107,000 and $36,000 was incurred in fiscal years 2005, 2006 and 2007, respectively, and $118,000 has been incurred during 2008.

Solovax TM (multivalent T-cell vaccine for MS)

In November 2008, we provided University of Southern California notice of termination of the license agreement relating to this product candidate.

Through December 31, 2008, and prior to our termination of this agreement, we have incurred approximately $814,000 of costs related to our development of SOLOVAX of which $107,000, $158,000, $164,000, $163,000, $67,000, $21,000 and $8,000 was incurred in fiscal 2001, 2002, 2003, 2004, 2005, 2006 and 2007, respectively, and $126,000 has been incurred during 2008.

Based on our current capital expenditures, we believe we currently have sufficient capital to fund development activities of our principal products for at least the next 18 months. However, if our business does not generate any cash flow through corporate partnering transactions, we will need to raise additional capital to continue operations beyond the second half of 2010. 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.

Additional Licenses

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)

TABLE OF CONTENTS

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, 2008 and 2007 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years ended December 31, 2008 and 2007 and for the period from January 8, 2001 (inception) to December 31, 2008. 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 audit 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, 2008 and 2007, and the consolidated results of their operations, changes in stockholders' equity and cash flows for the years ended December 31, 2008 and 2007, and for the period from January 8, 2001 (inception) to December 31 2008, in conformity with accounting principles generally accepted in the United States of America.

Berman & Company, P.A.
Boca Raton, Florida
March 12, 2009, except for Note 9, as to which the date is March 30, 2009.

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

Assets	December 31, 2008	2007
Current Assets		
Cash	$ 5,856,384	$ 11,492,802
Other receivables	55,419	-
Prepaid expenses	15,109	63,636
Total Current Assets	5,926,912	11,556,438
Property and Equipment, net of accumulated depreciation of $591,876 and $232,564	1,446,407	2,063,233
Deposits and other assets	11,989	13,381
Total Assets	$ 7,385,308	$ 13,633,052
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 574,896	$ 728,119
Accrued liabilities	45,820	59,409
Notes payable	-	900,000
Total Current Liabilities	620,716	1,687,528
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 20,882,839 and 20,433,467 shares issued and outstanding	20,883	20,433
Additional paid-in capital	45,025,385	43,001,609
Deficit accumulated during the development stage	(38,281,676)	(31,076,518)
Total Stockholders' Equity	6,764,592	11,945,524
Total Liabilities and Stockholders' Equity	$ 7,385,308	$ 13,633,052

See accompanying notes to consolidated financial statements

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

	For the years ended December 31,		For the Period from January 8, 2001 (Inception) to December 31,
	2008	2007	2008
Operating Expenses:			
Research and development	$ 4,643,570	$ 6,327,726	$ 15,804,365
General and administrative	2,675,636	3,810,585	9,520,847
Total Operating Expenses	7,319,206	10,138,311	25,325,212
Loss from Operations	(7,319,206)	(10,138,311)	(25,325,212)
Other Income (Expense):			
Interest income	128,236	298,807	471,625
Loss on sale of equipment	(357)	-	(357)
Interest expense	(13,831)	(52,929)	(66,760)
Total Other Income, net	114,048	245,878	404,508
Net Loss	$ (7,205,158)	$ (9,892,433)	$ (24,920,704)
Less: Preferred stock dividend - subsidiary	-	-	(951,250)
Less: Merger dividend	-	(12,409,722)	(12,409,722)
Net Loss Applicable to Common Shareholders	$ (7,205,158)	$ (22,302,155)	$ (38,281,676)
Net Loss Per Share - Basic and Diluted	$ (0.35)	$ (1.27)	$ (6.14)
Weighted average number of shares outstanding during the year/period - basic and diluted	20,651,027	17,597,120	6,235,691

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, 2008 and 2007 and for the period from January 8, 2001 (inception) to December 31, 2008

	Series A, Convertible Preferred Stock $0.001 Par Value		Common Stock $0.001 Par Value		Additional Paid-in Capital	Deficit accumulated during development stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance, January 8, 2001 (inception)	-	$ -	-	$ -	$ -	$ -	$ -
Issuance of common stock to founders in exchange for subcription 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)
Balance, December 31, 2001	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	-	-	-	-	5,890	-	5,890

- subsidiary							
Net loss for the year ended December 31, 2002	-	-	-	-	-	(768,508)	(768,508)
Balance, December 31, 2002	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)
Balance, December 31, 2003	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)
Balance, December 31, 2004	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	-	-	-	-	14,057	-	14,057

compensation - subsidiary							
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)
Balance, December 31, 2005	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	-	-	-	-	3,017	-	3,017

contributed capital - former related party							
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
Recogntion 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)
Balance, December 31, 2006	-	-	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 acquistion ($19.95/share)	-	-	765,087	765	12,408,957	(12,409,722)	0

							-
Issuance of common stock for consideration of common shares in EPI acquistion ($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)
	-	-	20,433,467	20,433	43,001,609	(31,076,518)	11,945,524

Balance, December 31, 2007							
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)
Balance, December 31, 2008	-	$ -	20,882,839	$ 20,883	$ 45,025,385	$ (38,281,676)	$ 6,764,592

See accompanying notes to consolidated financial statements

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

	For the year ended December 31,		For the Period from January 8, 2001 (Inception) to December 31,
	2008	2007	2008
Cash Flows From Operating Activities:			
Net loss	$ (7,205,158)	$ (9,892,433)	$ (24,920,704)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based consulting	366,683	673,271	1,527,670
Stock-based compensation	1,224,975	1,483,123	3,161,621
Stock issued as compensation	55,385	-	55,385
Stock issued as compensation in acquisition of subsidiary	-	601,712	601,712
Stock issued for consulting fees	104,042	-	104,042
Stock issued for milestone payment	50,000	25,000	75,000
Stock issued for license fee	145,000	20,000	553,691
Contributed services - related party	73,750	275,645	349,395
Depreciation	404,623	199,629	637,187
Loss on sale of equipment	357	-	357
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	1,793	(37,934)	(61,843)
Deposits and other assets	1,392	(13,381)	(11,989)
Accounts payable	(60,928)	187,999	667,191
Accrued liabilities	(13,589)	(129,490)	48,838
Net Cash Used In Operating Activities	(4,851,675)	(6,606,859)	(17,212,447)
Cash Flows From Investing Activities:			
Purchases of property and equipment	(21,398)	(1,965,574)	(2,032,805)
Proceeds from the sale of equipment	132,265	-	132,265
Cash paid to acquire shell in reverse acquisition	-	-	(665,000)
Net Cash Provided By (Used In) Investing Activities	110,867	(1,965,574)	(2,565,540)
Cash Flows From Financing Activities:			
Proceeds from loans payable - related party	-		3,210,338
Repayments of loans payable - related party	-		(220,000)
Proceeds from notes payable	-	1,100,000	1,100,000
Repayments of notes payable	(900,000)	(200,000)	(1,100,000)
Proceeds from issuance of common stock for stock option exercises	4,390	-	4,390
Proceeds from issuance of preferred and common stock	-	-	1,150,590
Proceeds from sale of common stock and warrants in private placements	-	-	13,926,362
Proceeds from sale of common stock in connection with warrant exercise	-	7,552,378	7,552,378

Cash paid as direct offering costs in private placements and warrant call	-	(579,569)	(1,739,987)
Proceeds from issuance of Series B, convertible preferred stock - subsidiary	-	-	1,902,500
Direct offering costs in connection with issuance of series B, convertible preferred stock - subsidiary	-	-	(152,200)
Net Cash Provided By (Used In) Financing Activities	(895,610)	7,872,809	25,634,371
Net increase (decrease) in cash and cash equivalents	(5,636,418)	(699,624)	5,856,384
Cash and cash equivalents at beginning of year/period	11,492,802	12,192,426	-
Cash and cash equivalents at end of year/period	$ 5,856,384	$ 11,492,802	$ 5,856,384
Supplemental disclosures of cash flow information:			
Cash paid for interest	$ 13,831	$ 52,929	$ 66,760
Cash paid for taxes	$ -	$ -	$ -
Supplemental disclosure of non-cash investing and financing activities:			
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	$ 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, 2008 and 2007

Note 1 Organization and Nature of Operations

(A) Description of the Business

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

(B) Corporate Name Change

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

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

The Company has seven subsidiaries, Pipex Therapeutics, Inc. ("Pipex Therapeutics"), Effective Pharmaceuticals, Inc. ("EPI"), Solovax, Inc. ("Solovax"), CD4 Biosciences, Inc. ("CD4"), Epitope Pharmaceuticals, Inc. ("Epitope"), Healthmine Inc. ("Healthmine") and Putney Drug Corp. ("Putney") which were previously under common control. As of December 31, 2008, EPI, Healthmine and Putney are wholly owned and Pipex Therapeutics, Solovax, CD4 and Epitope are majority owned. The combinations of these entities prior to 2006 were accounted for in a manner similar to a pooling of interests. As of December 31, 2008, Healthmine remains inactive.

For financial accounting purposes, the outstanding preferred stock and common stock of the Company is that of Adeona, the legal registrant. All statements of operations, stockholders' equity and cash flows for each of the entities are presented as consolidated since January 8, 2001 (inception) due to the existence of common control since that date. All subsidiaries were incorporated on January 8, 2001, except for EPI, which was incorporated on December 12, 2000, Epitope which was incorporated in January of 2002, Putney which was incorporated in November of 2006 and Healthmine which was incorporated in December 2007. All of the subsidiaries were incorporated under the laws of the State of Delaware.

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

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

(D) Reverse Stock Split

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

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

(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. Sheffield did not have any operations at the time of the merger, and this was treated as a recapitalization of Pipex Therapeutics. Since Pipex Therapeutics acquired a controlling voting interest in a public shell corporation, it was deemed the accounting acquirer, while Sheffield was deemed the legal acquirer. The historical financial statements of the Company are those of Pipex Therapeutics, EPI, Solovax and CD4 since inception, and of the consolidated entities from the date of Merger and subsequent. On December 11, 2006, Sheffield changed its name to Pipex Pharmaceuticals, Inc.

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

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

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

(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; these shareholders comprise the non-controlling shareholder base of CD4.

2. Pipex Therapeutic's Acquisition of Solovax

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

received pursuant to the terms of the contribution.

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

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 at December 31, 2007, 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 $601,682 as the stock was issued to an officer and director of the Company.

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

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

Finally, in connection with EITF Topic D-42, "The Effect on the Calculation of Earnings Per Share for the Redemption or Induced Conversion of Preferred Stock" , The Company has determined that the fair value of the consideration transferred to the holders of EPI Series B, convertible preferred stock over the carrying amount of the preferred stock

represents a return to the preferred stockholders. The difference is $12,409,722, which is included as a component of paid in-kind dividends. This amount is included as an additional reduction in net loss applicable to common shareholders for purposes of computing loss per share in the accompanying financial statements for the years ended December 31, 2008 and 2007 and for the period from January 8, 2001 (inception) to December 31, 2008.

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

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

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

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

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

Note 2 Summary of Significant Accounting Policies

(A) Principles of Consolidation

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

(B) Development Stage

The Company's consolidated financial statements are presented as those of a development stage enterprise. For the period from January 8, 2001 (inception) to date, the Company has been a development stage enterprise, and accordingly, the Company's operations have been directed primarily toward the acquisition and creation of intellectual properties and certain research and development activities to improve current technological concepts. As the Company is devoting its efforts to research and development, there have been no sales, license fees or royalties earned. Additionally, the Company continually seeks sources of debt or equity based funding to further its intended research and development activities. The Company has experienced net losses since its inception, and had an accumulated deficit of $38,281,676 at December 31, 2008.

(C) Use of Estimates

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

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

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

(D) Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. At December 31, 2008 and 2007, 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, 2008 and 2007, the balance exceeded the federally insured limit by $5,653,635 and $11,009,126, respectively.

(E) Property and Equipment

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

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

(F) Long Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. There were no impairment charges taken during the years ended December 31, 2008 and 2007 and for the period from January 8, 2001 (inception) to December 31, 2008.

(G) Derivative Liabilities

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

(H) Net Loss per Share

Basic earnings (loss) per share is computed by dividing the net income (loss) less preferred dividends for the period by the weighted average number of common shares outstanding. Diluted earnings per share is computed by dividing net income (loss) less preferred dividends by the weighted average number of common shares outstanding including the

effect of share equivalents. Since the Company reported a net loss at December 31, 2008 and 2007 and for the period from January 8, 2001 (inception) to December 31, 2008, respectively, all common stock equivalents would be anti-dilutive; as such there is no separate computation for diluted earnings per share.

The Company's net loss per share for the years ended December 31, 2008 and 2007 and for the period from January 8, 2001 (inception) to December 31, 2008 was computed assuming the recapitalization associated with the reverse acquisition, as such, all share and per share amounts have been retroactively restated. Additionally, the numerator for computing net loss per share was adjusted for preferred stock dividends recorded during the year ended December 31, 2006 and the period from January 8, 2001 (inception) to December 31, 2008, 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.

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

(I) Research and Development Costs

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

(J) Income Taxes

The Company accounts for income taxes under the liability method in accordance with Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes." Under this method, deferred income tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

The Company adopted the provisions of FASB Interpretation No. 48; "Accounting for Uncertainty in Income Taxes-An Interpretation of FASB Statement No. 109" ("FIN 48"). FIN 48 contains a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not, that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount, which is more than 50% likely of being realized upon ultimate settlement. The Company considers many factors when evaluating and estimating the Company's tax positions and tax benefits, which may require periodic adjustments. At December 31, 2008 and 2007, the Company did not record any liabilities for uncertain tax positions. (See Note 7)

(K) Fair Value of Financial Instruments

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

(L) Stock Based Compensation

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

(M) Non-Employee Stock Based Compensation

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

44

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

(N) Recent Accounting Pronouncements

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

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

In June 2007, the Emerging Issues Task Force (“EITF”) issued EITF No. 07-01, Accounting for Collaborative Arrangements, (“EITF 07-1”). EITF 07-1 provides guidance for companies in the biotechnology or pharmaceutical industries that may enter into agreements with other companies to collaboratively develop, manufacture, and market a drug candidate (Collaboration Agreements) and is effective for fiscal years beginning after December 15, 2007. The adoption of EITF 07-1 did not have a material effect on the Company’s financial position, results of operations or cash flows.

In June 2007, the EITF issued EITF No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities ,(“EITF 07-3”). EITF 07-3 provides guidance for upfront payments related to goods and services of research and development costs and is effective for fiscal years beginning after December 15, 2007. The adoption of EITF 07-3 did not have a material effect on the Company’s financial position, results of operations or cash flows.

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

In December 2007, the FASB issued SFAS 141R, Business Combinations ("SFAS 141R"), which replaces FASB SFAS 141, Business Combinations. This Statement retains the fundamental requirements in SFAS 141 that the acquisition method of accounting be used for all business combinations and for an acquirer to be identified for each business combination. SFAS 141R defines the acquirer as the entity that obtains control of one or more businesses in the business combination and establishes the acquisition date as the date that the acquirer achieves control. SFAS 141R will require an entity to record separately from the business combination the direct costs, where previously these costs were included in the total allocated cost of the acquisition. SFAS 141R will require an entity to recognize the assets acquired, liabilities assumed, and any non-controlling interest in the acquired at the acquisition date, at their fair values as of that date. This compares to the cost allocation method previously required by SFAS No. 141. SFAS 141R will require an entity to recognize as an asset or liability at fair value for

certain contingencies, either contractual or non-contractual, if certain criteria are met. Finally, SFAS 141R will require an entity to recognize contingent consideration at the date of acquisition, based on the fair value at that date. This Statement will be effective for business combinations completed on or after the first annual reporting period beginning on or after December 15, 2008. Early adoption of this standard is not permitted and the standards are to be applied prospectively only. Upon adoption of this standard, there would be no impact to the Company's results of operations and financial condition for acquisitions previously completed. The adoption of SFAS No. 141R is not expected to have a material effect on its financial position, results of operations or cash flows.

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

In April 2008, the FASB issued FASB Staff Position ("FSP") SFAS No. 142-3, "Determination of the Useful Life of Intangible Assets" . This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"). The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R, and other GAAP. This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company does not expect the adoption of SFAS FSP 142-3, to have a material impact on its financial position, results of operations or cash flows.

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

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

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

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

Note 3 Property and Equipment

Property and Equipment consisted of the following at December 31,

	2008	2007
Leasehold improvements	$ 862,359	$ 850,302
Manufacturing equipment	777,928	1,054,289
Computer and office equipment	232,569	227,274
Laboratory equipment	165,427	163,932
Total	2,038,283	2,295,797
Less accumulated depreciation	(591,876)	(232,564)
Property and equipment, net	$ 1,446,407	$ 2,063,233

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 on the sale of $14,430.

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

Note 4 Debt

During 2007, the Company borrowed $1,100,000 and repaid $200,000. These notes were secured by all assets of the Company as well as the stock certificates of the subsidiaries; the notes bore interest at 9.25% (prime plus 2%) and were due March 30, 2010. These borrowings represented a 100% concentration of debt at December 31, 2007. On March 6, 2008, all of the outstanding principal and accrued interest was repaid.

An affiliate of the Company's founders, current Chairman and President and Chief Executive Officer has advanced working capital to or on behalf of the Company. Loan activity for the Company was as follows since inception:

Total loans/ (repayments) per year	Amount
Year ended December 31, 2001 — loans	$ —
Year ended December 31, 2002 — loans	130,520
Year ended December 31, 2003 — loans	244,640
Year ended December 31, 2004 — loans	785,281
Year ended December 31, 2005 — loans	968,943
Year ended December 31, 2005 — repayments	(200,000)
Year ended December 31, 2006 — loans	1,365,344
Year ended December 31, 2006 — repayments	(20,000)
Year ended December 31, 2006 — conversion to equity	(3,274,728)
Balance, December 31, 2006	$ —

On October 31, 2006, the non-interest bearing loans payable to an affiliate of the Company's founder and Chairman, which amounted to $3,274,728, were converted into 1,665,211 shares of common stock and 832,606 warrants to purchase common stock. On January 14, 2009 the warrants were forfeited. (See Note (6(D))

Note 5 Stockholders' Equity

(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(F)(4))

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

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 CEO and Chairman of the Board of Pipex in exchange for $300,000 ($0.055 per share). On October 31, 2006, pursuant to the reverse acquisition with Sheffield, these shares were cancelled and retired.

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

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

(B) Series A Convertible Preferred Stock

The Company and some of its subsidiaries has each authorized Series A Convertible Preferred Stock. (See Note 1(F) for conversion of Pipex Series A convertible preferred stock.)

The terms of the Series A Convertible Preferred Stock for the Company and its subsidiaries is summarized below. The terms are the same for each of the entities.

1. Dividends

Each share of Series A Convertible Preferred Stock is entitled to receive dividends in an amount equal to dividends declared and paid with respect to that number of shares of common stock into which one share of Series A Convertible Preferred Stock is then convertible. For the period from January 8, 2001 (inception) to December 31, 2007, neither the Company, nor any of its majority owned subsidiaries has declared any Series A Convertible Preferred Stock dividends.

2. Liquidation Preference

Upon liquidation, holders of the Series A Convertible Preferred Stock will be entitled to the greater of (1) a per share amount equal to the original purchase price plus any dividends accrued but not paid and (2) the amount that the holder would receive in respect of a share of Series A, preferred if immediately prior to dissolution and liquidation, all shares of Series A Convertible Preferred Stock were converted into shares of common stock.

3. Conversion

Each share of Series A Convertible Preferred Stock is immediately convertible on a one for one basis at the option of the holder. The conversion ratio is determined by dividing the original issue price of the Series A Convertible Preferred Stock by the conversion price for the Series A, convertible preferred stock in effect on the date the

certificate is surrendered for conversion. The conversion price will initially be the original issue price, which is subject to future adjustment. At December 31, 2007, the conversion ratio is 1.00.

4. Voting Rights

Each holder of Series A, convertible preferred stock is entitled to one vote for each share of common stock into which each share of Series A Convertible Preferred Stock could then be converted.

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

5. Beneficial Conversion Feature and Derivative Liability

The Company and its subsidiaries has reviewed each of the provisions of its Series A Convertible Preferred Stock and noted no required accounting for a beneficial conversion feature pursuant to the guidance in EITF No.'s 98-5 or 00-27. Upon issuance, the original issue price, its fair value, and conversion price were equivalent.

Additionally, there is no required accounting or financial statement impact for derivative instruments. None of the Company or its subsidiaries Series A Convertible Preferred Stock has embedded features requiring such treatment.

(C) Series B Convertible Preferred Stock

Pipex Therapeutics has authorized Series B Convertible Preferred Stock. At December 31, 2008, Pipex Therapeutics has not issued any of its Series B Convertible Preferred Stock. Pipex Therapeutics has not yet designated their Series B Convertible Preferred Stock as it pertains to dividends, liquidation preference, conversion, voting rights, and other rights and preferences.

(D) Common Stock Issuances of Issuer

For the Year Ended 2008

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

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

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

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

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

For the Year Ended 2007

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

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

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

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

For the Year Ended 2006

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

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

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

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

(E) 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 $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.

(F) Stock Option Plan

During 2001, Pipex Therapeutics' Board and stockholders adopted the 2001 Stock Incentive Plan (the "2001 Stock Plan"). This plan was assumed by Pipex in the merger, in October 2006. As of the date of the merger, there were 1,489,353 options issued and outstanding. The total number of shares of stock with respect to which stock options and stock appreciation rights may be granted to any one employee of the Company or a subsidiary during any one-year period shall not exceed 1,250,000. All awards pursuant to the Plan shall terminate upon the termination of the grantee's employment for any reason. Awards include options, restricted shares, stock appreciation rights, performance shares and cash-based awards (the "Awards"). The Plan contains certain anti-dilution provisions in the event of a stock split, stock dividend or other capital adjustment, as defined in the Plan. The Plan provides for a Committee of the Board to grant awards and to determine the exercise price, vesting term, expiration date and all other terms and conditions of the awards, including acceleration of the vesting of an award at any time. As of December 31, 2008, there are 1,229,987 options issued and outstanding under the 2001 Stock Plan.

On March 20, 2007, the Company's Board of Directors approved the Company's 2007 Stock Incentive Plan (the "2007 Stock Plan") for the issuance of up to 2,500,000 shares of common stock to be granted through incentive stock options, nonqualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards to officers, other employees, directors and consultants of the Company and its subsidiaries. The exercise price of stock options under the plan is determined by the compensation committee of the Board of Directors, and may be equal to or greater than the fair market value of the Company's common stock on the date the option is granted. Options become exercisable over various periods from the date of grant, and generally expire ten years after the grant date. As of December 31, 2008, there are 1,521,676 options issued and outstanding under the 2007 Stock Plan. This plan was approved by stockholders on November 2, 2007.

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

Pursuant to the provisions of SFAS No. 123R, in the event of termination, the Company will cease to recognize compensation expense. Fair value of share-based payments is recognized ratably over the stated vesting period.

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

	Year Ended December 31,	
	2008	2007
Exercise price	$0.53 - $5.10	$0.09 - $22.50
Expected dividends	0%	0%
Expected volatility	170.09% - 225.79%	103.29% - 200.94%
Risk fee interest rate	3.52% - 4.02%	3.83% - 5.16%
Expected life of option	10 years	5-10 years
Expected forfeitures	0%	0%

Pursuant to FAS 123R, the Company records stock based compensation based upon the stated vested provisions in the related agreements, with recognition of expense recorded on the straight line basis over the term of the related agreement. The vesting provisions for these agreements have various terms as follows: immediate vesting, half vesting immediately and the remainder over three years, quarterly over three years, annually over three years, one-third immediate vesting and remaining annually over two years, one half immediate vesting with remaining vesting over six months and one quarter immediate vesting with the remaining over three years. All option grants are expensed in the appropriate period based upon each award vesting terms, in each case with an offsetting credit to additional paid in capital. The stock-based compensation expense recorded by the Company for the years ended December 31, 2008 and 2007 and the period from January 8, 2001 (inception) to December 31, 2008 with respect to awards under the Plan and awards issued under warrants is as follows:

	Year Ended December 31,		Inception to December 31,
	2008	2007	2008
Research and development:			
employees	$ 823,605	$ 1,226,687	$ 2,289,488
non-employees	334,391	145,783	540,164
General and administrative:			
employees	401,546	858,148	1,455,699
non-employees	32,116	527,488	970,890
	$1,591,658	$ 2,758,106	$ 5,256,241

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

A summary of stock option activity for Adeona for the years ended December 31, 2008 and 2007 is as follows:

	Number of Shares	Weighted Average Exercise Price
Balance at December 31, 2006	1,613,855	$ 1.45
Granted	700,176	$ 5.97
Exercised	—	$ —
Forfeited	(16,667)	$ 15.75
Balance at December 31, 2007	2,297,364	$ 2.72
Granted	1,180,666	$ 1.00
Exercised	(37,948)	$ 0.12
Forfeited	(688,419)	$ 5.07
Balance at December 31, 2008	2,751,663	$ 1.43

The total fair market value of options granted in 2008 totals $933,332.

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
$0.09 - $0.50	550,780	4.58 Years	$ 0.10	521,777	$ 0.10
$0.51 - $0.75	874,999	9.54 Years	$ 0.70	252,777	$ 0.69
$0.76 - $0.99	75,000	9.44 Years	$ 0.81	12,500	$ 0.81
$1.00 - $1.99	442,834	7.41 Years	$ 1.83	442,834	$ 1.83
$2.00 - $2.99	587,227	8.37 Years	$ 2.05	587,227	$ 2.05
$3.00 - $3.99	64,158	8.14 Years	$ 3.87	64,158	$ 3.87
$4.00 - $4.99	25,000	3.42 Years	$ 4.40	8,334	$ 4.40

$5.00 - $9.99	128,332	6.68 Years	$ 5.91	89,166	$ 5.91
$10.00 - $22.50	3,333	8.02 Years	$22.50	1,111	$ 22.50
	2,751,663	7.73 Years	$ 1.43	1,979,884	$1.56

At December 31, 2008, the Company had 479,083 stock options outstanding that had an exercise price less than the market price on that date for an aggregate intrinsic value of $43,117.

Of the total 2,751,663 options outstanding 1,399,829 are held by related parties of which 796,043 are fully vested, exercisable and non-forfeitable.

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

(G) 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/share. The warrant call had occurred due to the terms by which the Company sold its common stock and warrants in private placement offerings. The net proceeds from the warrant call were $6,972,809, which included cash paid as direct offering costs of $579,569.

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

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

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

On January 5, 2007, the Company issued warrants to purchase 68,858 shares of common stock as part of the acquisition of EPI. (See Note (1)(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 Chairman and Chief Executive Officer with the majority of these warrants being reissued to the Company's former CEO. The warrants have an exercise price of $2.22. Since these warrants were granted as compensation in connection with an equity raise, the Company has treated these warrants as a direct offering cost. The result of the transaction has a $0 net effect to equity. The warrants are fully vested and non-forfeitable. On January 14, 2009, 381,020 of these warrants representing all of the warrants held by an affiliate of the Company's Chairman and Chief Executive Officer were cancelled.

On October 31, 2006, the loans payable to the Company's founder, President and CEO were converted into 1,665,211 shares of common stock and 832,606 warrants to purchase common stock. The warrants have an exercise price of $2.22 and a life of 5 years. (See Note 4) The warrants were forfeited on January 14, 2009.

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

A summary of warrant activity for Adeona for the years ended December 31, 2008 and 2007 is as follows:

	Number of Shares
Balance as December 31, 2006	5,242,407
Granted	437,981
Exercised	(3,401,972)
Forfeited	—
Balance as December 31, 2007	2,278,416
Granted	13,333
Exercised	—
Forfeited	—
Balance as December 31, 2008	2,291,749

As of December 31, 2008, all outstanding warrants are fully vested and exercisable.

Warrants Outstanding and Exercisable		
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life
$ 0.41	5,000	2.38 Years
$ 2.22	1,840,435	3.82 Years
$ 3.30	68,858	6.41 Years
$ 3.75	41,667	7.13 Years
$ 6.36	327,456	3.86 Years
	2,291,749	5.02 Years

(H) Options and Warrants of Subsidiaries

CD4 has 30,000 options outstanding and exercisable, with an exercise price of $0.20 and a remaining weighted average remaining contractual life of 1.98 years as of December 31, 2008.

Epitope has 50,000 options outstanding and none exercisable, with an exercise price of $0.001 and a remaining contractual life of 9.50 years as of December 31, 2008. These options vest annually over 5 years and have a fair value of $50 which was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%; expected volatility of 200%, risk free interest rate of 2.47% and an expected life of 10 years.

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

Note 6 Commitments and Contingencies

(A) License Agreements

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

In connection with these agreements, the Company may be obligated to make milestone payments up to $16,175,000. Some of these payments may be fulfilled through the issuance of the Company's common stock, at the Company's option. As of December 31, 2008, the Company has achieved two milestones which the Company fulfilled by issuing common stock having a fair value of $75,000. See Note (5(D)). The Company can give no assurances that any other milestones will be achieved. In addition to the milestone payments, the Company may be obligated to make royalty payments on future sales pursuant to the agreements. The schedule below does not include the value of these commitments.

(B) Research Agreement

In September 2005, the Company entered into a three-year research agreement with a University. Pursuant to that agreement, the Company paid approximately $460,000 per year. On March 20, 2008, the Company provided the University with written notice of termination of the agreement.

(C) Consulting Agreements

In August 2005, Adeona entered into an agreement with an individual to provide consulting services for the Company's research and development. The consultant was paid $25,000 upon the execution of the agreement. The consultant will receive annual consulting fees of $120,000 for each of the next three years. The consultant also received 216,847 options having a fair value $59,960 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 200%, risk free interest rate of 1.81% and an expected life of 10 years. On March 24, 2008, the Company granted the individual an additional 216,667 options having a fair value of $437,667 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%; expected volatility of 221%, risk free interest rate of 3.56% and an expected life of 10 years. Effective October 1, 2008, this agreement was amended whereby the consultant will receive an hourly consulting rate of $300 per hour for a minimum of 10 hours per month, payable in either cash or restricted common stock rather than a quarterly fee of $30,000.

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

(D) Employment Agreements

On July 1, 2008, the Company's Board of Directors approved a compensation package with its Chief Executive Officer. Under the terms of arrangement, the Chief Executive Officer will receive an annual salary of $195,000. The Chief Executive Officer is also eligible for a bonus at the discretion of the Board of Directors. In the event of termination, the Company will provide six-month severance, payable over the Company's ordinary pay periods. The Company has also granted 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. These options expire 90 days from the termination date. These options shall vest in full should the Company be acquired. 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, Nicholas Stergis resigned as our Chief Executive Officer. Mr. Stergis remains a director of the Company.

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

In January 2005, the Company entered into a four-year employment agreement with the Company's Chairman and former Chief Executive Officer. Pursuant to this agreement, the Chairman was paid an annual base salary of $297,000, an annual bonus equal to 30% of base salary and a ten-year option to acquire 271,058 shares of common stock at the completion of the Company's private placement that occurred on October 31, 2006. As of December 31, 2008, all of these stock options have vested. The fair value of the options totaled $544,827 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 200%, risk free interest rate of 4.61% and an expected life of 10 years.

On July 20, 2007, the Board of Directors approved an amended and restated employment agreement with the Chairman and former Chief Executive Officer. The amended employment agreement provides that he be paid a base salary of $195,000 per year plus a guaranteed bonus of $100,000 and may also be entitled to discretionary transactional bonuses. In addition, the amended agreement provides that the Chairman and former Chief Executive Officer waived the receipt of any salary and bonus payable under the original agreement, which amounted to $275,645, for no additional consideration. This amount was treated as a capital contribution to the Company in September 2007.

On July 1, 2008, the former Chief Executive Officer resigned his position with the Company but remains as Chairman. On January 6, 2009, the Chairman entered into an amended agreement with the Company which extends his employment agreement through January 9, 2010 with an annual salary of $1. Also, the Chairman agreed to forego the $100,000 guaranteed bonus otherwise due to him on January 1, 2009. The amount of $100,000 will be recorded on the Company's books as a capital contribution during the first quarter of 2009. On March 29, 2009, the Chairman was reappointed as our President and Chief Executive Officer.

The Company entered into an employment agreement with its former President on May 24, 2006. Pursuant to this agreement, Adeona paid an annual base salary of $295,000 and a guaranteed bonus of one-third of base salary. Adeona also granted a ten-year option to purchase 664,252 shares of common stock, of which 442,834 have vested as of December 31, 2008. On March 5, 2008, the Company's former President agreed to work for no cash compensation. Additionally, the former President agreed to eliminate severance provisions of his agreement. The Company has recorded contributed services from a related party totaling $73,750 during 2008. On July 1, 2008 the President resigned his position with the Company.

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

(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, 2008:

2009:	$ 146,000
2010:	150,000
2011:	25,000
Total:	$ 321,000

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

During the years ended December 31, 2008 and 2007 and for the period from January 8, 2001 (inception) to December 31, 2008, the Company recognized rent expense of $193,557, $202,361 and $784,386, respectively.

The following schedule shows committed amounts due for license agreements, patent cost reimbursements and consulting fees as of December 31, 2008:

2009:	$ 122,000
2010:	125,000
2011:	95,000
2012:	120,000
2013:	155,000
Total:	$ 617,000

(F) Litigation

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

Note 7 Income Taxes

There was no income tax expense for the years ended December 31, 2008 and 2007 due to the Company's net losses.

The Company's tax expense differs from the "expected" tax expense for the years ended December 31, 2008 and 2007, (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:

	2008	2007
Computed "expected" tax expense (benefit) - Federal	$ (2,315,000)	$ (3,178,000)
Computed "expected" tax expense (benefit) - State	(396,000)	(544,000)
Meals and Entertainment	1,000	3,000
Non-deductible stock and stock based compensation	599,000	1,055,000
Contributed services – related party	28,000	103,000
Change in valuation allowance	2,083,000	2,561,000
	$ -	$ -

Adeona Pharmaceuticals, Inc. and Subsidiaries
(A Development Stage Company)
Notes to Consolidated Financial Statements
December 31, 2008 and 2007

The effects of temporary differences that gave rise to significant portions of deferred tax assets at December 31, 2008 and 2007 are as follows:

Deferred tax assets:	2008	2007
Stock issued for services	$ (48,000)	$-
Net operating loss carry-forward	(7,045,000)	(5,010,000)
Total gross deferred tax assets	(7,093,000)	(5,010,000)
Less valuation allowance	7,093,000	5,010,000
Net deferred tax assets	$ -	$ -

At December 31, 2008, the Company has a net operating loss carry-forward of $18,722,000 available to offset future taxable income expiring through 2028. 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, 2007 was $5,010,000. The net change in valuation allowance during the year ended December 31, 2008 was an increase of $2,083,000. 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, 2008.

Note 8 Corporate Restructuring

Corporate Restructuring

On March 11, 2008, the Company implemented cost reduction measures in order to substantially reduce operating expenses given the delay in refilling its New Drug Application for oral tetrathiomolybdate (oral TTM) for the treatment of initially presenting neurologic Wilson's disease. As part of the corporate restructuring, the Company eliminated positions in the areas of manufacturing, analytical, quality control, quality assurance, clinical, regulatory, diagnostic product development, principally relating to the development of oral TTM and diagnostics division.

On July 8, 2008, the Company announced changes in senior management. See Note (6)(D).

Note 9 Subsequent Event

Effective March 29, 2009, Nicholas Stergis resigned as our Chief Executive Officer. Mr. Stergis remains a director of the Company. In order to fill the vacancy, Steve H. Kanzer was appointed our President and Chief Executive Officer. The Company has engaged an executive search firm to identify potential candidates for the Chief Executive Officer position.

59

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 on that evaluation, the Chief Executive Office and Principal Financial Officer concluded that the disclosure controls and procedures are effective.

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(f). 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, 2008, 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 have been no changes in internal controls over the financial reporting that occurred during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal controls 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 AND CORPORATE GOVERNANCE

Below is certain information regarding our directors and executive officers as of March 31, 2009:

Name	Age	Position
Steve H. Kanzer, CPA, JD.	45	Director, Chairman, President and Chief Executive Officer
Nicholas Stergis, M.S.	34	Director, Vice Chairman of the Board
Jeffrey J. Kraws	44	Director
Jeff Wolf, Esq.	45	Director
James S. Kuo, M.D., M.B.A.	44	Director

STEVE H. KANZER, C.P.A., J.D. Mr. Kanzer is our co-founder, Chairman and, effective March 29, 2009, our President and Chief Executive Officer. Mr. Kanzer served as our President from our inception in February 2001 until May 2006. Mr. Kanzer previously served as our Chief Executive Officer from September 2004 until July of 2008. 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. From 1996 through June 2007, Mr. Kanzer served as director and Chairman of DOR BioPharma, Inc., a publicly traded biotechnology company developing orBec® for GvHD, a product acquired from the parent company of IDR in 2001. 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. 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.

NICHOLAS STERGIS, M.S. Mr. Stergis is our co-founder and Vice Chairman of our board of directors. Mr. Stergis served as our Chief Executive Officer and our subsidiaries from July 1, 2008 to March 29, 2009. Mr. Stergis previously served as our Chief Operating Officer from our founding during 2001 through October 2006 and Vice Chairman of the board of directors from April 2007 through present. Prior to co-founding Adeona, Mr. Stergis was a co-founder, Chief Operating Officer and director of Developmental Therapeutics, Inc., a cardiovascular drug development company, until its acquisition in October 2003 by Titan Pharmaceuticals, Inc. (AMEX: TTP), a publicly-traded pharmaceutical company. Mr. Stergis was also a founder of Flower Ventures LLC and Encode Pharmaceuticals, Inc., a drug development company until its acquisition by Raptor Pharmaceuticals, Inc., a publicly traded company. From December 2000 until July 2008, Mr. Stergis was also a co-founder and Managing Director of Accredited Ventures Inc., a venture capital firm and its affiliated FINRA member firm, Accredited Equities, Inc. Prior to co-founding Accredited Ventures, Mr. Stergis was the Interim Director of Corporate Development for Corporate Technology Development, Inc. (CTD), a biopharmaceutical company based in Miami, Florida, until its merger with DOR BioPharma, Inc. (DOR), a publicly traded biotechnology company. During his tenure at CTD, he was responsible for all development tasks associated with the company's lead product, orBec ®.. He was also instrumental in CTD's restructuring, including its divestiture of important botulinum toxin intellectual property to Allergan, Inc. (NYSE:AGN), a publicly traded specialty pharmaceutical company as well as the divestiture of another operating subsidiary to Ivax Corp. (AMEX: IVX). Prior to joining CTD, Mr. Stergis was a Technology Associate at Paramount Capital, a New York based private

equity, venture capital, investment banking and asset management group specializing in the biotechnology and pharmaceutical industries. There, he participated in the startup, acquisition and financing of various biotechnology companies, including CTD. Mr. Stergis received his M.S. in Biology from New York University as well as a B.S. in Biology from the University at Albany, State University of New York.

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 . 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 Nationsbanc 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 biopolymer–based 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. Dr. Kuo is the Chairman and Chief Executive Officer of CorDex Therapeutics, Inc., a public biopharmaceutical company. 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.

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 Dr. James Kuo. 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 Dr. Kuo qualifies as an "audit committee financial expert" as that term is used in Section 407 of the Sarbanes-Oxley Act of 2002.

To date, we have conducted research and development operations and generated no revenue since inception. In light of the foregoing, and upon evaluating our internal controls, our board of directors determined that our internal controls are adequate to insure that financial information is recorded, processed, summarized and reported in a timely and accurate manner in accordance with applicable rules and regulations of the SEC.

Compensation Committee and Nominating Committee

Our Compensation Committee consists of Jeff Wolf and Jeff Kraws. Our Nominating Committee consists of Jeff Wolf and Dr. James Kuo. 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.

When selecting a new director nominee, the committee first determines whether the nominee must be independent for NYSE Amex purposes or whether the candidate must qualify as an Audit Committee Financial Expert. The committee then uses its network of contacts to compile a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm to assist in the identification of qualified director candidates. The nominating committee also will consider nominees recommended by our stockholders. The nominating committee does not distinguish between nominees recommended by our stockholders and those recommended by other parties.

Shareholders wishing to directly recommend candidates for election to the board of directors at an annual meeting must do so by giving written notice to: Chairman of the Nominating Committee, Adeona Pharmaceuticals, Inc., 3930 Varsity Drive, Ann Arbor, Michigan 48108. Any such notice must, for any given annual meeting, be delivered to the chairman not less than 120 days prior to the anniversary of the preceding year's annual meeting. The notice must state (1) the name and address of the shareholder making the recommendations; (2) the name, age, business address, and residential address of each person recommended; (3) the principal occupation or employment of each person recommended; (4) the class and number of shares of the Company's stock that are beneficially owned by each person recommended and by the recommending shareholder; (5) any other information concerning the persons recommended that must be disclosed in nominee and proxy solicitations in accordance with Regulation 14A of the Securities Exchange Act of 1934, as amended; and (6) a signed consent of each person recommended stating that he or she consents to serve as a director of the Company if elected.

In considering any person recommended by one of our shareholders, the committee will look for the same qualifications that it looks for in any other person that it is considering for a position on the board of directors. Any shareholder nominee recommended by the committee and proposed by the board of directors for election at the next annual meeting of shareholders will be included in the company's proxy statement for that annual meeting.

The nominating committee operates under a formal charter that governs its duties and standards of performance. A copy of the charter is available at the Investor Information section of our website at www.adeonapharma.com ..

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 believes that all filing requirements applicable to its directors, executive officers and greater than 10 percent stockholders were complied with during 2008.

Code of Ethics

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.

ITEM 11. EXECUTIVE COMPENSATION

The following table discloses information for the fiscal year ended December 31, 2008 regarding the total compensation we paid to our principal executive officer and two other most highly compensated executive officer who was serving as an executive officer on December 31, 2008, and our former two other most highly compensated executive officers who would have been among our most highly compensated executive officers if they had been serving as executive officers on December 31, 2008.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards (1)	All Other Annual Compensation	Total
Nicholas Stergis	2008	$ 171,760	$ -	$ 576,000	$ -	$ 747,760
Former Chief Executive Officer (2)	2007	$ 137,500	$ 17,500	$ -	$ -	$ 155,000
Steve H. Kanzer, CPA, JD	2008	$ 195,000	$ -	$ -	$ -	$ 195,000
Chairman and Chief Executive Officer (3)	2007	$ 87,750	$ 45,205			$ 132,955
John Althaus	2008	$ 86,250	$ -	$ -	$ -	$ 86,250
Vice President, Advanced Technology	2007	$ 100,000	$ 15,000	$ 87,750		$ 202,750
David Newsome, M.D.	2008	$ 157,039	$ -	$ -	$ -	$ 157,039
Former Chief Medical Officer	2007					
Charles Bisgaier, Ph.D.	2008	$ 57,044	$ -	$ -	$ -	$ 57,044
Former President	2007	$ 295,000	$ 100,000	$ -	$ -	$ 395,000

(1)The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model. The assumptions used for the valuation of these option awards are as follows: expected dividend yield 0%; expected volatility 225.79%; risk free interest rate of 3.95%; expected life of 10 years.

(2)Mr. Stergis resigned as our Chief Executive Officer effective March 29, 2009. He remains a director and Vice-Chairman of our Board of Directors.

(3)Mr. Kanzer was appointed our President and Chief Executive Officer effective March 29, 2009.

The following table contains information relating to grants of stock options made during the fiscal year ended December 31, 2008, to our senior 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
Nicholas Stergis Former Chief Executive Officer	800,000	85.21%	$ 0.72	7/6/2018
Yingxi Zhang, MD Vice President, Clinical Development	75,000	7.99%	$ 0.81	6/8/2018

The following table discloses information regarding outstanding equity awards as of December 31, 2008 for each of our senior executive officers.

Outstanding Equity Awards at Fiscal Year-End

Name and Principal Position	Number of securities underlying unexercised options/exercisable	Number of securities underlying unexercised options/un-exercisable	Option exercise price	Option expiration date
Nicholas Stergis, Former Chief Executive Officer and Vice Chairman (1)	215,278	584,722	$ 0.72	7/16/2018
Steve H. Kanzer, CPA, JD, Chairman, President Chief Executive Officer (2)	271,058	-	$ 2.01	10/30/2016
John Althaus,				
Vice President, Advanced	49,694	4,518	$ 0.18	2/5/2016
Technology	7,500	7,500	$ 5.85	11/1/2017
David Newsome,	-	-	-	-
Former Chief Medical Officer				
Charles Bisgaier, Ph.D.	442,852	-	$ 1.83	5/29/2016
Former President				

(1) Mr. Stergis resigned as our Chief Executive Officer effective March 29, 2009. He remains a director and Vice-Chairman of our Board of Directors.

(2) Mr. Kanzer was appointed our Chief Executive Officer and President effective March 29, 2009.

Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2008 regarding the compensation of our directors who are not also named executive officers.

Name	Fees earned or paid in cash	Option awards (1)	Other compensation	Total
Jeffrey Kraws	$ 9 ,000	$ 4,416	$ -	$ 13,416
James Kuo	$ 15,500	$ 4,416	$ -	$ 19,916
Jeffrey Wolf	$ 16,500	$ 4,416	$ -	$ 20,916

(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, 2007 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 170.09%, risk free interest rate of 3.66% 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, 2008, 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
2001 Stock Incentive Plan	1,229,987	$ 1.14	259,366
2007 Stock Incentive Plan	1,521,676	$ 1.66	978,324
Total	2,751,663	$ 1.43	1,237,690

Employment Agreements

On July 1, 2008, the Company's Board of Directors approved an additional compensation package with Nicholas Stergis, our former Chief Executive Officer and Vice Chairman as a result of his additional appointment as Chief Executive Officer. Under the terms of arrangement, his annual salary was increased to $195,000 for full-time service to the Company. He was also eligible for a bonus at the discretion of the Board of Directors. In the event of termination for any reason, the Company would provide six-month's severance, payable over the Company's ordinary pay periods. The Company has also granted 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. These options expire 90 days from the date of termination. These options shall vest in full should the Company be acquired. 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, Nicholas Stergis resigned as our Chief Executive Officer. Mr. Stergis remains a director of the Company.

In January 2005, the Company entered into a four-year employment agreement with Steve H. Kanzer. Pursuant to this agreement, Adeona paid an annual base salary of $297,000, an annual bonus equal to 30% of base salary and a ten-year option to acquire 271,058 shares of common stock at the completion of the Company's private placement that occurred on October 31, 2006. As of December 31, 2008, all of these stock options have vested. The fair value of the options totaled $544,827 and was determined using the Black-Scholes model with the following assumptions: expected dividend yield of 0%, expected volatility of 200%, risk free interest rate of 4.61% and an expected life of 10 years. On July 20, 2007, the Board of Directors approved an amended and restated employment agreement with Steve H. 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 and may also be entitled to discretionary transactional bonuses. In addition, the amended agreement provided that Steve H. Kanzer waived the receipt of any salary and bonus payable under the original agreement, which amounted to $275,645, for no additional consideration. This amount was treated as a capital contribution to the Company in September 2007. On July 1, 2008, Steve H. Kanzer's employment agreement was amended to resign his title of Chief Executive Officer and continue to serve as Chairman on a full-time basis . On January 6, 2009, the Company entered into an amended agreement with Mr. Kanzer pursuant to which Mr. Kanzer agreed to continue to serve as Chairman on a full-time basis through January 9, 2010 with an annual salary of $1.00. Mr. Kanzer agreed to forego the $100,000 guaranteed bonus otherwise due to him on January 1, 2009. The

amount of $100,000 will be recorded on the Company's books as a capital contribution during the first quarter of 2009. Mr. Kanzer pays for health insurance under our corporate policy at his own expense and reimburses the Company for this expense. On March 29, 2009, Steve H. Kanzer was appointed our Chief Executive Officer and President.

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

The Company entered into an employment agreement with Charles Bisgaier, its former President on May 24, 2006. Pursuant to this agreement, Adeona paid an annual base salary of $295,000 and a guaranteed bonus of one-third of base salary. Adeona also granted a ten-year option to

purchase 664,252 shares of common stock, of which 442,834 have vested as of December 31, 2008. On March 5, 2008, the Company's President agreed to work for no cash compensation. Additionally, the former President agreed to eliminate severance provisions of his agreement. The Company has recorded contributed services from a related party totaling $73,750 during 2008. On July 1, 2008 the President resigned his position with the Company.

During January 2006, the Company entered into an employment letter agreement with our director Jeffrey Kraws to serve as Vice President of Business Development, pursuant to which we agreed to pay him an annual base salary of $75,000 following the closing of a financing and granted him an option to purchase 228,773 shares of common stock, at an exercise price of $0.09 per share, with 114,387 vested upon execution of his employment agreement and the remainder vesting annually over three years. During March 2007, the Company entered into an amended agreement with Mr. Kraws whereby he agreed forgo any cash compensation and continued as a director in exchange for 38,129 options vesting. Mr. Kraws was not paid any cash compensation pursuant under his original or amended agreement.

Pursuant to an employment letter agreement, our subsidiary EPI paid Dr. Rudick $175,000 per annum, paid life and disability insurance on behalf of Dr. Rudick and he received an option to purchase 262,500 shares of EPI common stock. Following the acquisition of EPI, Dr. Rudick agreed to reduce his annual base salary to $95,000 per annum, forgo any life or disability reimbursement from us and agree to cancel an unvested option to purchase 294,071 shares of our common stock. As a result of the acquisition of EPI, Dr. Rudick's vested stock options converted into options to purchase 27,106 of Adeona common stock at an exercise price of $0.09 per share which expire on September 13, 2014. His shares of EPI common stock converted to 30,161 shares of Adeona common stock and his EPI warrants converted into 42,845 warrants to purchase Adeona common stock at an exercise price of $3.30 per share with an expiration date of May 30, 2015. As of November 1, 2007, Dr. Rudick is no longer employed by the Company.

During November 2005, we entered into an employment agreement as amended with John Althaus, MS, the Vice President of Advanced Technology. We currently pay Mr. Althaus $45,000 per year and we issued have issued him a total of 69,212 options to acquire our common stock.

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 5, 2008 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 5, 2009, 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 effective on April 25, 2007.

Principal Stockholders Table

Name of Owner	Shares Owned	Percentage of Shares Outstanding
Accredited Venture Capital, LLC	7,086,380(1)	33.44%
Steve H. Kanzer, CPA, JD	7,732,684(2)	37.29%
Nicholas and Jennifer Stergis Tenancy by Entirety	1,955,195(3)	8.97%
Firebird Capital	1,496,550(4)	7.01%
Chestnut Ridge Partners	1,185,820(5)	5.60%
Jeffrey J. Kraws	226,375(6)	1.06%
Jeffrey Wolf, Esq.	41,666(7)	*
James S. Kuo	41,666(8)	*
All officers and directors as a group (5 persons)	10,268,644	47.71%

* 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 1,355,292 shares of common stock, warrants to purchase 346,418 and 7,651 shares of common stock, issued to Mr. Stergis and 245.834 shares issuable upon stock options presently exercisable or exercisable with 60 days. If unexercised, these options will expire within 90 days of termination. Does not include 554,116 shares issuable upon stock options that are not presently exercisable. Mr. Stergis's business address is 9100 South Dadeland Blvd., Suite 1809, Miami FL 33156 .

(4) 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.

(5) Consists of 1,185,820 shares of common stock issued to Chestnut Ridge Capital Partners. Chestnut Ridge Capital Partners address is 50 Tice Blvd. Suite 18, Woodcliff Lake, NJ 07677-7603.

(6) Assumes the exercise of a vested option to purchase 226,375 shares of our common stock presently exercisable. Mr. Kraws' business address is 800 Third Avenue, 17th Fl., New York, NY 10022.

(7) Assumes the exercise of an option to purchase 41,666 shares of our common stock. Mr. Wolf's business address is 119 Washington Ave., Suite 401, Miami, Florida 33139.

(8) Consists of 41,666 options to purchase common stock. Mr. Kuo's business address is 470 Nautilus St, Suite 300, La Jolla, California, 92037.

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 Chairman. 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 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 Company.

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 Chairman 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, of which $489,755 was paid to Mr. Stergis, a former managing director of AEI and Vice Chairman and $68,850 was paid to Dr. Joseph Rudick, a former director, and a former registered representative of AEI. A selected dealer not affiliated with AEIwas 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. Mr. Nicholas Stergis, our co-founder and Vice Chairman, was the managing director of AEI and AVI in November 2006. In January 2009, the placement warrants allocated to Accredited Venture Capital, LLC an affiliate of Mr. Kanzer were agreed to be cancelled.

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 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, an affiliate of Mr. Kanzer, our Chairman and Mr. Stergis, our Vice Chairman, 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, 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. During 2006, EPI 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.

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.

From April 2007 through July 1, 2008, Mr. Stergis served as our Vice Chairman on a part-time basis in Miami FL pursuant to which the Company paid Mr. Stergis an annual salary of $150,000. From inception through October 2006, Mr. Stergis served as Chief Operating Officer of the Company on a part-time basis for an annual salary $72,000 per year.

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 results 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 Chairman 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, 2008 and 2007, for processional services performed by Berman & Company, P.A. were as follows:

	2008	2007
Audit Fees and Expenses	$ 74,000	$ 68,000
Audit-Related Fees	0	0
Tax Fees	0	0
All Other Fees	0	0
Total	$ 74,000	$ 68,000

Your 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.

The Board of Directors anticipates that representatives of Berman & Company, P.A. will be present at our 2009 annual meeting of Stockholders to respond to appropriate questions, and will have an opportunity, if they desire, to make a statement.

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, 2008.

1. Independent Auditor's Report

2. Consolidated Balance Sheets as of December 31, 2008 and 2007

3. Consolidated Statements of Operations for the years ended December 31, 2008 and 2007 and for the period from January 8, 2001 (inception) to December 31, 2008

4. Consolidated Statements of changes in Stockholders' Equity for the years ended December 31, 2008 and 2007 and for the period from January 8, 2001 (inception) to December 31, 2008

5. Consolidated Statements of Cash Flows for the years ended December 31, 2008 and 2007 and for the period from January 8, 2001 (inception) to December 31, 2008

6. Notes to Consolidated Financial Statements

(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 By-Laws (2)

4.1 Form of Warrant Certificate (3)

4.2/10.25 2001 Stock Incentive Plan (4)*

4.3/10.26 2007 Stock Incentive Plan (4)*

10.1 Employment Agreement with Charles L. Bisgaier (5)*

10.2 Consulting Agreement with George J. Brewer (5)

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

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

10.6 First Amendment to Option and License Agreement between University of Southern California and Solovax, Inc. (formerly Autoimmune Vaccines, Inc.) (5)

10.7 License Agreement between Children's Medical Center Corporation and Effective Pharmaceuticals, Inc. (5)

10.8 License Agreement between Thomas Jefferson University and Quantas Biopharmaceuticals, Inc. (5)

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

10.10 Private Stock Purchase Agreement with Michael Manion (5)

10.11 Lock-up Agreement with Michael Manion (5)

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

10.13 Lock-up Agreement with Nicholas Stergis (5)

10.14 Lock-up Agreement with Joseph Rudick (5)

10.15 Lock-up Agreement with Jeffrey Kraws (5)

10.16 Lock-up Agreement with Jeffrey Wolf (5)

10.17 Lock-up Agreement with Charles Bisgaier (5)

10.18 Unit Purchase Agreement (3)

10.19 First Amendment to License Agreement between Children's Medical Center Corporation and Effective Pharmaceuticals, Inc. (6)

10.20 License Agreement between Maine Medical Center and Pipex Pharmaceuticals, Inc. (7)

10.21 License Agreement between The Regents of the University of California and Epitope Pharmaceuticals, Inc. (8)

10.22 Consulting Agreement between Salvatore Albani, M.C. Ph.D. and Epitope Pharmaceuticals, Inc. (8)

10.23 Form of Director/Officer Indemnification Agreement (9)*

10.24 Amendment to Employment Agreement of Steve H. Kanzer (10)*

31.1 Certification pursuant to Rule 13a-14(a)/15d-14(a) (11)

31.2 Certification pursuant to Rule 13a-14(a)/15d-14(a) (11)

32.1 Certification pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 (11)

---

(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.

(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 10.2 of the Registrant's Current Report on Form 8-K filed January 6, 2009.

(11) 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/ Steve H. Kanzer
Steve H. Kanzer
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)
Date: March 31, 2009

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/ Steve H. Kanzer Steve H. Kanzer Director, Chairman and President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)
Date: March 31, 2009	By: /s/ Nicholas Stergis Nicholas Stergis Director, and Vice Chairman
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/ James S. Kuo James S. Kuo Director