ADEONA PHARMACEUTICALS, INC.
Form 10-K
March 31, 2011
UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2010

OR

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

For the transition period from_____ to_____

Commission File Number: 1-12584

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

Nevada	13-3808303
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification Number)
3985 Research Park Drive, Suite 200 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:	Name of each exchange on which registered
(Title of Class)	
Common Stock, $0.001 par value per share	NYSE AMEX

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

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

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 x

Indicate by check mark whether the issuer: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was

required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark 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. o

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

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

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

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

The aggregate market value of the issuer's common stock held by non-affiliates of the registrant as of March 25, 2011, was approximately $33,890,000 based on $1.80, the price at which the registrant's common stock was last sold on that date.

As of March 25, 2011, the issuer had 26,289,247 shares of common stock outstanding.

Documents incorporated by reference: None.

ADEONA PHARMACEUTICALS, INC.

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PART I

Forward-Looking Statements

Most of the matters discussed within this report include forward-looking statements on our current expectations and projections about future events. In some cases you can identify forward-looking statements by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar 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. Unless the context requires otherwise, references to "we," "us," "our," and "Adeona," refer to Adeona Pharmaceuticals, Inc.

Item 1. Business

We are a pharmaceutical company developing innovative medicines for the treatment of serious central nervous system diseases. Our primary strategy is to license product candidates that have demonstrated a certain level of clinical efficacy and develop them to a stage that results in a significant commercial collaboration. Currently, we have the following product candidates in development: a prescription medical food for Alzheimer's disease, and drugs for multiple sclerosis, fibromyalgia and age-related macular degeneration.

- Alzheimer's disease and mild cognitive impairment: reaZinTM (zinc cysteine) is being developed as a prescription medical food for the dietary management of patients with Alzheimer's disease and mild cognitive impairment. A randomized, double-blind, placebo-controlled clinical study is underway at 2 centers in the United States. Sixty patients were enrolled in the study, and we recently completed the treatment phase of this clinical study. It is anticipated that top-line clinical study results should be presented on April 14, 2011 at the 63rd Annual Meeting of the American Academy of Neurology.
- Multiple sclerosis: Trimesta (oral estriol) is a drug candidate being developed for the treatment of relapsing-remitting multiple sclerosis in women. A randomized, double-blind, placebo-controlled clinical trial is currently underway at 15 centers in the United States. As of March 1, 2011 127 out of 150 patients have been enrolled.
- Fibromyalgia: EffirmaTM (oral flupirtine) is a drug candidate being developed for the treatment of fibromyalgia. On May 6, 2010, we and Pipex Therapeutics, Inc. (Pipex), our wholly owned subsidiary, entered into a sublicense agreement with Meda AB, a multi-billion dollar international pharmaceutical company, covering all of our patents' rights on the use of oral flupirtine for fibromyalgia.
- Age-related macular degeneration: ZincMonoCysteine (zinc-monocysteine) is a drug candidate being developed for the treatment of age-related macular degeneration. An 80-patient, randomized, double-blind, placebo-controlled clinical trial has been completed.

Our secondary strategy is to market our core competency in measuring metabolic serum zinc and copper levels. To further this effort, we purchased HartLab, LLC, on July 13, 2009. Renamed Adeona Clinical Laboratory, the wholly owned CLIA-certified clinical testing facility provides a broad array of chemistry and microbiology diagnostic tests in the Greater Chicago area. At Adeona Clinical Laboratory, we developed and offer the CopperProofTM panel, a series of diagnostic tests for accurately measuring the metabolic serum zinc and copper status of patients with Alzheimer's disease and mild cognitive impairment. Adeona Clinical Laboratory is a licensed Medicare and Medicaid provider of clinical testing services.

Effective as of June 30, 2010, we emerged from a "Development-Stage Entity" as defined by FASB ASC 915-10. On May 6, 2010, we entered into a sublicense agreement with Meda AB of Sweden. This agreement provides that Meda AB will assume all future development costs for the commercialization of oral flupirtine for fibromyalgia. As consideration for such sublicense, we received an up-front payment of $2.5 million and are entitled to milestone payments of $5 million upon filing of an NDA with the FDA of oral flupirtine for fibromyalgia and $10 million upon marketing approval, plus royalties. We consider the agreement with Meda AB to be an indication that we have commenced our principal operations and therefore are not required to report as a development-stage entity.

Our source of liquidity as of December 31, 2010, is cash of $2,648,853. Our projected uses of cash include cash used to fund further clinical development of our drug and medical food candidates, working capital and other general corporate activities. We may also use our cash for the acquisition of businesses, technologies and products that will complement our existing assets.

On January 28, 2011, we entered into a Securities Purchase Agreement with institutional investors, relating to the offering and sale of 2,857,144 shares of common stock, par value $0.001 per share and warrants to purchase 1,428,572 shares of common stock. We raised gross proceeds of $4,000,000, before estimated offering expenses of approximately $300,000, which includes placement agent fees. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-166750), which was declared effective by the Securities and Exchange Commission (SEC) on June 14, 2010.

We believe that with the additional proceeds of the January 2011 equity financing, our cash will be sufficient to fund our planned operations for at least the next 12 months. We will need additional capital to continue the development of our product candidates and clinical programs beyond 12 months. The sale of any equity or debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain financing, we may be required to reduce the scope and timing of the planned clinical and preclinical programs, which could harm our financial condition and operating results.

Clinical Development Programs

Alzheimer’s Disease and Mild Cognitive Impairment
reaZin (zinc cysteine)

Disease

Alzheimer's is a progressive neurodegenerative disease in which affected nerve cells in the brain die, making it increasingly difficult for the brain's memory and learning areas to function properly. A person with Alzheimer's disease has problems with memory, judgment and thinking, making it hard for the person to work or take part in normal day-to-day activities. The death of the nerve cells occurs gradually over a period of years. According to the Alzheimer’s Association, it is estimated that today over 5 million Americans have Alzheimer’s disease and that America spends $183 billion caring for people with Alzheimer’s and other dementias. Dysfunction of proper zinc and copper handling in the brain is implicated in Alzheimer’s disease.

Clinical Development

Our first product candidate is reaZin (zinc cysteine) (formerly named Zinthionein) for the dietary management of Alzheimer’s disease and mild cognitive impairment. It is being developed as a prescription medical food. reaZin is a proprietary, once-daily, gastroretentive, sustained-release, oral tablet formulation of zinc and cysteine. All constituents included in reaZin are believed to have Generally Regarded as Safe (GRAS) status according to Food and Drug Administration (FDA) standards. reaZin was invented and developed by us to achieve the convenience of once-daily dosing, high bioavailability (the quantity or fraction of the ingested dose that is absorbed) and to minimize gastrointestinal side effects of oral zinc therapy.

Our CopperProof-2 clinical trial is a controlled, randomized, double-blind, placebo-controlled clinical study evaluating reaZin. The study was divided into two parts. Part 1 was a 13-patient, three-arm, single-dose, comparator study in Alzheimer's disease and mild cognitive impairment patients that compared the tolerability and bioavailability of oral reaZin to Galzin®(the only FDA-approved zinc preparation) and placebo. Results from Part 1 of the study demonstrated a superior serum zinc bioavailability and a substantially lower incidence of adverse effects in Alzheimer's disease and mild cognitive impairment patients in favor of reaZin compared to Galzin®.

Part 2 of the CopperProof-2 study, underway at 2 centers in the United States, enrolled 60 Alzheimer's disease and mild cognitive impairment patients and randomized them to receive either once-daily oral reaZin or matching placebo for six months. Primary assessments of patients included 3 and 6 month serum parameters of zinc and copper, and secondary assessments including changes in cognitive function using standard clinical measures used for Alzheimer's disease and mild cognitive impairment patients. We recently completed the treatment phase of this clinical study. It is anticipated that top-line clinical study results should be presented on April 14, 2011 at the 63rd Annual Meeting of the American Academy of Neurology.

In November 2010, we were awarded a grant in the amount of $244,480 under the Qualifying Therapeutic Discovery Project Program to support our Alzheimer's disease program currently in clinical testing.

Relapsing-Remitting Multiple Sclerosis in Women
Trimesta (oral estriol)

Disease

Multiple sclerosis is a progressive neurological disease in which the body loses the ability to transmit messages along central nervous system nerve cells, leading to a loss of muscle control, paralysis, cognitive impairment and in some cases death. According to the National Multiple Sclerosis Society, currently, more than 2.5 million people worldwide (approximately 400,000 patients in the United States) have been diagnosed with multiple sclerosis. Mainly young adults, ages 20 to 50, and two to three times as many women than men are diagnosed with multiple sclerosis. According to the National Multiple Sclerosis Society, approximately 85% of multiple sclerosis patients are initially diagnosed with the relapsing-remitting form, compared to 10-15% with other progressive forms. Despite the availability of 8 FDA-approved therapies for the treatment of relapsing-remitting multiple sclerosis, the disease is highly underserved and exacts a heavy economic toll. Multiple sclerosis costs the United States more than $10.6 billion annually in medical care and lost productivity according to the Society for Neuroscience.

Background

It has been scientifically demonstrated that pregnant women with certain autoimmune diseases experience a spontaneous reduction of disease symptoms during pregnancy, especially in the third trimester. The PRIMS study (Pregnancy In Multiple Sclerosis), a landmark clinical study published in the New England Journal of Medicine, followed 254 women with multiple sclerosis during 269 pregnancies and for up to one year after delivery. The PRIMS study demonstrated that relapse rates were significantly reduced by 71 percent ($p < 0.001$) through the third trimester of pregnancy compared to pre-pregnancy-rates, and that relapse rates increased by 120 percent ($p < 0.001$) during the first three months after birth (post-partum) before returning to pre-pregnancy rates. It has been hypothesized that the female hormone, estriol, plays a role in so-called “fetal immune privilege”, a process that prevents a mother’s immune system from attacking and rejecting her fetus. The autoimmune benefits of pregnancy may be partially attributable to estriol, the effects of which may also be partially responsible for the favorable effects on multiple sclerosis during pregnancy. Maternal levels of estriol increase in a linear fashion through the third trimester of pregnancy until birth, whereupon they abruptly return to low circulating levels.

Rhonda Voskuhl, M.D.,Director, University of California Los Angeles (UCLA) multiple sclerosis program, UCLA Department of Neurology, has found that pregnancy levels of estriol, a hormone that is produced by the placenta during pregnancy, has potent immunomodulatory effects and that estriol may have therapeutic benefit to non-pregnant female multiple sclerosis patients by, in effect, mimicking the spontaneous reduction in relapse rates seen in multiple sclerosis patients during pregnancy.

Estriol has been approved and marketed for over 40 years throughout Europe and Asia for the treatment of post-menopausal hot flashes. It has never been approved by the FDA for any indication in the United States.

Clinical Development

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

A randomized, double-blind, placebo-controlled clinical trial is currently underway at 15 centers in the United States. The purpose of this clinical trial is to study whether 8 mg of oral Trimesta taken daily over a 2 year period will reduce the rate of relapses in a large population of female patients with relapsing-remitting multiple sclerosis. Investigators are administering either Trimesta along with glatimer acetate (Copaxone®) injections, an FDA-approved therapy for multiple sclerosis, or a placebo plus glatimer acetate injections to women between the ages of 18 to 50 who have been recently diagnosed with relapsing-remitting multiple sclerosis. The primary endpoint is relapse rates at two years with an interim analysis one year following full enrollment using standard clinical measures of multiple sclerosis disability. As of March 1, 2011, 127 out of 150 patients have been enrolled in this clinical trial. Tentatively, we anticipate full enrollment by the second half of 2011; however, no assurances can be given that such study enrollment will be completed in such time period.

The preclinical and clinical development of Trimesta has been primarily financed by a $5 million grant from the National Multiple Sclerosis Society(NMSS) in partnership with the NMSS's Southern California chapter, with support from the National Institutes of Health. In January of 2010, it was announced that an additional $860,440 in grant funding had been received through the American Recovery and Reinvestment Act allowing the number of clinical sites currently enrolling patients in the clinical study to increase from 7 clinical sites to 15. In November of 2010, we were awarded a grant in the amount of $244,480 under the Qualifying Therapeutic Discovery Project Program to support our multiple sclerosis program currently in clinical testing. In March of 2011, the Trimesta clinical trial was awarded an additional $409,426 in grant funding from the NMSS.

Fibromyalgia
Effirma (oral flurpirtine)

Disease

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

Clinical Development

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

Corporate Partnership

On May 6, 2010, we and Pipex, our wholly owned subsidiary, entered into a sublicense agreement with Meda AB, a multi-billion dollar international pharmaceutical company, pursuant to which Meda AB will assume all future development costs and may commericialize oral flupirtine for fibromyalgia in the U.S. As consideration for such sublicense, we received an up-front payment of $2.5 million and are entitled to milestone payments of $5 million upon filing of a New Drug Application (NDA) with the FDA for oral flupirtine for fibromyalgia and $10 million upon FDA approval of such NDA. Pursuant to the sublicense agreement, we will also receive a 7% royalty on sales of oral flupirtine for fibromyalgia in the United States, Canada and Japan, with such royalties being shared equally with our licensor, McLean Hospital, a Harvard hospital.

Flupirtine is approved and marketed by Meda AB and its distributors in Europe and other countries for indications other than fibromyalgia and has been prescribed to millions of patients worldwide. We believe that such substantial human experience of flupirtine should greatly assist the U.S. FDA in its evaluation of the safety of flupirtine upon review of an NDA of flupirtine for fibromyalgia.

Age-Related Macular Degeneration
ZincMonoCysteine (zinc-monocysteine)

Disease

Age-related macular degeneration affects over 10 million Americans and is the leading cause of severe vision loss in people over age 55. It occurs when the small central portion of the retina, known as the macula, deteriorates. The retina is the light-sensing central nervous system tissue at the back of the eye. Although it rarely causes complete blindness, age-related macular degeneration can be a source of significant vision loss.

Clinical Development

Our fourth product candidate is ZincMonoCysteine (zinc-monocysteine) for the treatment of age-related macular degeneration. ZincMonoCysteine is an oral complex of zinc and the amino acid cysteine that we believe may have improved therapeutic properties compared to currently marketed zinc-based nutritional products. ZincMonoCysteine was invented and developed by the late David A. Newsome, M.D., former Chief of the Retinal Disease Section of the National Eye Institute and our former Senior Vice President of Research and Development. The late Dr. Newsome was the first to pioneer and demonstrate the benefits of oral zinc therapy in age-related macular degeneration. Oral

zinc-containing nutritional products now represent the standard of care for the chronic treatment of age-related macular degeneration and have annual world-wide sales of approximately $300 million according to IMS Health.

ZincMonoCysteine has completed an 80-patient, randomized, double-blind, placebo-controlled, Investigational Review Board (IRB) approved clinical trial conducted by the late Dr. Newsome in dry age-related macular degeneration and demonstrated highly statistically significant improvements in central retinal function. These results were published in a peer-reviewed journal in 2008. Currently, we are conducting further preclinical and manufacturing activities on ZincMonoCysteine and planning the clinical development strategy. No assurance can be given that we will successfully complete these pre-clinical and manufacturing activities.

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

Mclean Hospital Exclusive License Agreement and Meda AB Sub-License Agreement

In 2005, as amended in 2007 and 2010, Pipex, our wholly owned subsidiary, entered into an exclusive license agreement with the McLean Hospital, a Harvard University teaching 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, Pipex paid an upfront fee of $20,000 and back patent costs of approximately $41,830 and agreed to pay McLean royalties on net sales of oral flupirtine equal to 3.5% of net sales of oral flupirtine for indications covered by the issued patents, reduced to 1.75% if Pipex has a license to other intellectual property covering those indications. In addition, Pipex agreed to use its best efforts to commercialize oral flupirtine for the therapeutic uses embodied in the patent applications. Furthermore, Pipex agreed to reimburse McLean Hospital all future patent costs and pay the following milestone payments: $150,000 upon the initiation of a pivotal Phase III clinical trial of oral flupirtine; $300,000 upon the filing of an NDA for oral flupirtine; and $600,000 upon FDA approval of oral flupirtine. The due diligence requirements of the exclusive license agreement were amended in April of 2010 and further amended by a Non-Disturbance Agreement that was signed with Pipex, McLean Hospital and Meda. The agreement remains in effect until the later of (i) the date all issued patents and filed patent applications within the Patent Rights (as defined in the agreement) expire or are abandoned and (ii) one year after the last Commercial Sale (as defined in the agreement) for which royalty is due or ten years after expiration or abandonment date set forth in clause (i) above, whichever is earlier. Pipex has the right to terminate the agreement at any time upon 90 days notice. In addition, Mclean may terminate the agreement (i) upon 10 days notice for nonpayment unless payment is made within such 10 days, (ii) immediately upon written notice if Pipex fails to maintain required insurance or become insolvent, make an assignment for the benefit of creditors or petition for bankruptcy is filed for or against Pipex or (ii) if Pipex, its affiliates or its sublicensees default in performance of their obligations under the agreement and such default is not cured within 60 days.

Effective May 6, 2010, we and Pipex, our wholly owned subsidiary, entered into a Sublicense Agreement with Meda AB of Sweden. Pursuant to this agreement, Meda has been granted an exclusive sublicense to all of Pipex's patents covering the use of oral flupirtine for fibromyalgia. These patents have been issued in the U.S. and are pending in Canada and Japan (the "Territory"). This agreement provides that Meda will assume all future development costs for the commercialization of oral flupirtine for fibromyalgia. As consideration for this sublicense, Pipex received an up-front payment of $2.5 million upon execution of this agreement and is entitled to milestone payments of $5 million upon filing of an NDA with the FDA for oral flupirtine for fibromyalgia and $10 million upon marketing approval.. This agreement also provides that Pipex is entitled to receive royalties of 7% of net sales of oral flupirtine approved for the treatment of fibromyalgia covered by issued patent claims in the Territory. Pursuant to the terms of Pipex's agreement with our university licensor, Pipex is obligated to share half of the royalties it receives with the university licensor, McLean Hospital, and Pipex is obligated to pay them $375,000 upon receipt of an upfront payment, which it did pay in May 2010 when it received the payment from Meda. The agreement continues in effect country by country until the earlier of the expiration of the Royalty Period (as defined in the agreement) or the termination of the Mclean license. Meda has the right to terminate the agreement at any time upon 90 days notice. In addition, a party may terminate the agreement upon 30 days notice if the other party breached material obligations and such breach is not cured within a period of time set forth in the agreement. The parties also have the right to terminate the agreement upon 60 days notice in the event of the filing by a party of a bankruptcy petition, the filing of an involuntary petition not dismissed within 60 days, a party proposes a written agreement of composition or extension of its debt, a party becomes Insolvent (as defined in the agreement), liquidates, dissolves, ceases to conduct business or makes an assignment for the benefit of creditors. Upon a termination, all licenses revert to Pipex.

The Regents of University of California License Agreement

In July 2005, we were granted an exclusive worldwide license agreement with the Regents of the University of California(Regents) relating to issued U.S. Patent No. 6,936,599 and pending patent applications covering the uses of

the drug candidate Trimesta (oral esteriol). 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. We also agreed to pay 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 Trimesta covered by the licensed patents. We may be permitted to partially pay milestone payments in the form of equity. The duration of this agreement is from the effective date of July 11, 2005 until the last-to-expire patent in Regent's Patent Rights, or until the last patent application licensed under this agreement is abandoned and no patent in Regent's Patent Rights ever issues. We have the right to terminate this agreement at any time and termination will be effective 90 days after the effective date of the termination notice. The Regents may terminate the agreement with a written notice of default if we violate or fail to perform any material term or covenant of this agreement. However, we have 60 days after the effective date of the notice of default to repair the default.

Zinc-monocysteine License Agreement

In July of 2007, we entered into an exclusive worldwide license agreement with the late David A. Newsome, M.D., and David Tate, M.S., relating to zinc-monocysteine for all uses. Pursuant to this agreement, we paid an upfront license fee of $65,000 and reimbursed patent expenses of $25,000. Milestone payments totaling $1,400,000 may be due upon the achievement of certain milestones, as well as royalties of 3% on net sales for the licensed technology covered by the licensed patents. We have the ability to make these milestone payments in the form of equity. The duration of this agreement is from the effective date of July 1, 2007 until the expiration of the last to expire patent licensed under this agreement. We can terminate this agreement with a 90-day written notice to the inventors. The inventors may terminate the agreement with written notice to us in the event that we fail to satisfy our developmental diligence obligations or file a petition or an intention to file a petition for bankruptcy or if a third party has filed or intends to file an involuntary petition of bankruptcy.

Manufacturing

We utilize contract manufacturing firms to produce the investigation products, reaZin and ZincMonoCysteine in accordance with “current good manufacturing processes” (cGMP) guidelines outlined by the FDA. Our Trimesta investigation product is manufactured by Organon NV, a European pharmaceutical company which has manufactured the active ingredient in Trimesta for nearly 40 years. Organon has recently discontinued supply of estriol tablets. We believe that we have sufficient quantities of Trimesta required to satisfy the ongoing clinical trial in relapsing-remitting multiple sclerosis. Accordingly, prior to initiation of additional clinical studies and/or commercial launch of oral estriol, we may need to identify and execute supply agreement(s) on terms suitable to us with an alternate supplier of estriol tablets. There can be no assurance that we will be able to negotiate such agreements on terms that are favorable.

Sales and Marketing

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

We have no experience in marketing a prescription medical food such as reaZin, nor can we provide any assurance that the results of our on-going CopperProof-2 trial will be successful, or even if successful, demonstrate sufficient clinical benefit to permit us to obtain reimbursement from health insurance payers nor permit us to profitably market such prescription medical food with or without health insurance reimbursement.

Research and Development

During the years ended December 31, 2010 and 2009, we spent $1,579,891 and $948,891, respectively, on research and development.

Competitive Environment

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multi-national pharmaceutical companies and biotechnology companies developing both generic and proprietary compounds to treat central nervous system diseases. Many of these companies are well-established and possess technical, human, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, many of our potential competitors have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry

competitors that afford these companies potential research and development and commercialization advantages in the therapeutic areas we are currently pursuing. Academic research centers, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being developed by us. In addition, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before us.

In the general area of both generic and proprietary compound development for the treatment of central nervous system diseases, we potentially compete with a variety of companies, most of whom are pharmaceutical or biotechnology companies. These include: Pfizer, GlaxoSmithKline Pharmaceuticals, Merck & Co., Eli Lilly & Co., Biogen Idec, Forest Laboratories, Novartis, Teva Pharmaceuticals, Prana Biotechnology, Merz & Co., Alcon and Bausch and Lomb.

Employees

As of March 1, 2011, we employed approximately 13 individuals on a full time equivalent basis. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical product companies. None of our employees are covered by collective bargaining agreements, and management considers relations with our employees to be good.

Available Information

Additional information about Adeona is contained at our website, www.adeonapharma.com. Information on our website is not incorporated by reference into this report. We make available on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K as soon as reasonably practicable after those reports are filed with the Securities and Exchange Commission. The following Corporate Governance documents are also posted on our website: Code of Conduct, Code of Ethics for Financial Management, and the Charters for the Audit Committee, Compensation Committee and Nominations Committee of the Board of Directors. Our phone number is (734) 332-7800 and our facsimile number is (734) 332-7878.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. In addition to the risks related to our business set forth in this Form 10-K and the other information included and incorporated by reference in this Form 10-K, you should carefully consider the risks described below before purchasing our common stock. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Relating to Our Business

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

With the exception of the quarter ended June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. We expect to incur additional operating losses in the future and therefore our cumulative losses to increase. To date, other than the licensing fee we received from Meda AB for the development of and commercialization of Effirma (oral flupirtine) for fibromyalgia and laboratory revenues from Adeona Clinical Laboratory, we have generated very minimal revenues. As of December 31, 2010, our accumulated deficit totaled approximately $43.7 million on a consolidated basis. 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 or prescription medical food and therefore will not have product revenues. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees, and grants. If the upfront licensing fee we received is not sufficient to sustain our operations, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical 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, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We have not been able to sustain profitability.

Other than with respect to the quarter ended June 30, 2010, we have a history of losses and we had incurred and continue to incur substantial losses and negative operating cash flow. Even if we succeed in developing and commercializing one or more of our product candidates, we may still incur substantial losses for the foreseeable future and may not sustain profitability. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will substantially increase in the foreseeable future as we do the following:

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

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

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

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

- continuing to undertake preclinical 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 preclinical trials and Phase I/II, and Phase II and Phase III clinical trials of our principal product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

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

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

We have no experience in marketing a prescription medical food such as reaZin, nor can we provide any assurance that the results of our on-going CopperProof-2 trial will be successful, or even if successful, demonstrate sufficient clinical benefit to permit us to obtain reimbursement from health insurance payers nor permit us to profitably market such prescription medical food with or without health insurance reimbursment.

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

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

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

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

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

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

reporting systems and other infrastructure and hiring adequate laboratory and other personnel;

- the availability of adequate study samples for validation studies for any diagnostic tests we develop, the success of such validation studies and our ability to publish study results in peer-reviewed journals;
- the availability of alternative and competing tests or products and technological innovations or other advances in medicine that cause our technologies to be less competitive;
- compliance with federal, state and foreign regulations governing laboratory testing and the sale and marketing of diagnostic or other tests, including copper and zinc; status tests;
- the accuracy rates of such tests, including rates of false-negatives and/or false-positives;
- concerns regarding the safety effectiveness or clinical utility of our tests;
- changes in the regulatory environment affecting health care and health care providers, including changes in laws regulating laboratory testing and/or device manufacturers and any laws regulating diagnostic testing;
- the extent and success of our sales and marketing efforts and ability to drive adoption of our diagnostic tests;
- coverage and reimbursement levels by government payers and private insurers;
- the level of physician and customer adoption of any diagnostic tests we develop;

- pricing pressures and changes in third-party payer reimbursement policies;
- general changes or developments in the market for Alzheimer's disease diagnostics or diagnostics in general;
- ethical and legal issues concerning the appropriate use of the information resulting from Alzheimer's disease diagnostic tests or other tests;
- our ability to promote and protect our products and technology; and
- intellectual property rights held by others or others infringing our intellectual property rights.

We have experienced several management changes.

We have had significant changes in management in the past two years. Effective July 1, 2008, Nicholas Stergis was appointed our Chief Executive Officer; however, effective March 29, 2009, Mr. Stergis resigned his position, but remained a director of the Company until August 20, 2009. The Board then appointed Steve H. Kanzer as our interim Chief Executive Officer and President. Effective June 26, 2009, Max Lyon was appointed our Chief Executive Officer and President, while Mr. Kanzer remained as Chairman of the Board of the Company. Effective February 6, 2010, James S. Kuo, M.D., M.B.A., was appointed our Chairman of the Board, Chief Executive Officer and President and Mr. Lyon resigned from his position as Chief Executive Officer, President and director. Changes in key positions in our Company, as well as additions of new personnel and departures of existing personnel, can be disruptive, might lead to additional departures of existing personnel and could have a material adverse effect on our business, operating results, financial results and internal controls over financial reporting.

We only acquired our CLIA-certified reference laboratory in July of 2009 and have limited experience operating a diagnostic and microbiology testing laboratory. Our ability to successfully develop and commercialize diagnostic and microbiology tests will depend on our ability to successfully operate our CLIA-certified reference laboratory and obtain and maintain required regulatory certifications.

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

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

licenses, certificates and authorizations, which could adversely affect our business and results of operations.

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

We will need FDA approval to commercialize some of our product candidates in the United States and approvals from equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval for any of our product candidates, we must submit to the FDA an NDA, demonstrating that the product candidate is safe for humans and effective for its intended use and that the product candidate can be consistently manufactured and is stable. This demonstration requires significant research and animal tests, which are referred to as "preclinical 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 preclinical 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.

The on-going and future development and commercialization of Effirma (oral flupirtine) for fibromyalgia is the responsibility of Meda AB and no assurance can be given that Meda will gain FDA approval of oral flupirtine for fibromyalgia.

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

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

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

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

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

Some of the products we have developed and additional products that we hope to develop involve new and unproven approaches or involve applications in markets that we are only beginning to explore. They are based on the assumption that information about the roles of copper and zinc in the progression and development of neurodegenerative diseases such as Alzheimer's disease, dementia and mild cognitive impairment may help scientists and clinicians better understand and treat conditions or complex disease processes. We cannot be certain that this type of information will play a key role in the development of therapeutics, diagnostics or other products in the future, or

that any of our findings would be accepted by clinicians, researchers or by any other potential market or industry partner or customer. If we are unable to generate additional valuable information and data about the usefulness of copper and zinc status testing, the demand for our products, applications, and services will be reduced and our business will be harmed.

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

In addition to our own patent applications, we also currently rely on licensing agreements with third party patent holders/licensors for our products. Pipex, our wholly owned subsidiary, has an exclusive license agreement with the McLean Hospital relating to the use of oral flupirtine to treat fibromyalgia which was recently sublicensed to Meda AB; an exclusive license agreement with the Regents of the University of California relating to our Trimesta technology and an exclusive license agreement with the late Dr. Newsome and Mr. Tate relating to zinc-monocysteine. Each of these agreements requires us or our sublicensee to use our best efforts to commercialize each of the technologies as well as meet certain diligence requirements and timelines in order to keep the license agreement in effect. In the event we or our sublicensee are not able to meet our diligence requirements, we may not be able to retain the rights granted under our agreements or renegotiate our arrangement with these institutions on reasonable terms, or at all. Given the recent passing of Dr. Newsome, matters relating to our license agreements are expected to be handled by his estate and heirs.

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 diseases include: Pfizer, GlaxoSmithKline Pharmaceuticals, Merck & Co., Eli Lilly & Co., Biogen Idec, Forest Laboratories, Novartis, Teva Pharmaceuticals, Prana Biotechnology, Merz & Co., Alcon and Bausch and Lomb. Many of our competitors have significant financial and human resources. In addition, academic research centers may develop technologies that compete with our Trimesta, ZincMonoCysteine, reaZin gastroretentive sustained release oral high dose zinc preparations and oral flupirtine technologies. Should clinicians or regulatory authorities view these therapeutic regiments as more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid and private insurers. No assurance can be given that our current clinical trial of once daily reaZin for the dietary management of Alzheimer's disease and mild cognitive impairment will prove to be safe and effective.

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

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

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

provide any assurances that a competitor will not obtain FDA approval for a product that contains the same active ingredients as our products.

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

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

Our competitiveness may be adversely affected if we are unable to protect our proprietary technologies. Other than our ZincMonoCysteine program, we do not have composition of matter patents for Trimesta or Effirma, or their respective active ingredients oral estriol and oral flupirtine. We rely on issued patent and pending patent applications for use of Trimesta to treat multiple sclerosis (issued United States Patent No. 6,936,599) and various other therapeutic indications, which have been exclusively licensed to us. We have exclusively licensed an issued patent for the treatment of fibromyalgia with oral flupirtine, which we have sublicensed to Meda AB.

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

Our reaZin (gastroretentive sustained zinc and cysteine tablets) is the subject of United States and international pending patent applications, such as published United States patent application Ser. No. 11/621,962 and corresponding international applications that claim priority to January 10, 2006 as well as additional unpublished patent applications. No assurance can be given that such pending patent applications will issue or issue with claims satisfactorily broad enough to prevent others from developing and marketing competing products.

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

We may also rely on the United States Drug Price Competition and Patent Term Restoration Act, commonly known as the “Hatch-Waxman Amendments,” to protect some of our current product candidates, specifically Trimesta and ZincMonoCysteine 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, scientific advisors, 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 December 31, 2010, we have 13 employees. We have also engaged regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. Our future performance will depend in part on our ability to successfully integrate newly hired officers into our management team and our ability to develop an effective working relationship among senior management.

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

Losing key personnel or failing to recruit necessary additional personnel would impede our ability to attain our development objectives. David A. Newsome, M.D., our former Senior Vice President of Research and Development recently passed away. There is intense competition for qualified personnel in the drug-development field, and we may not be able to attract and retain the qualified personnel we would need to develop our business.

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

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

In order to successfully commercialize our product candidates, we and our sublicensees must be able to manufacture our products in commercial quantities, in compliance with regulatory requirements, at acceptable costs, and in a timely manner. Manufacture of the types of biopharmaceutical products that we propose to develop present various risks. For example, the manufacture of zinc-monocysteine is a complex process that can be difficult to scale up for purposes of producing large quantities at an acceptable cost. This process can also be subject to delays, inefficiencies, and poor or low yields of quality products. As such, we can give no assurances that we will be able to scale up the manufacturing of zinc-monocysteine.

For manufacturing and nonclinical information for Trimesta (oral estriol), we have relied upon an agreement with Organon, a division of Schering-Plough for access to clinical, nonclinical, stability and drug supply relating to oral estriol, the active ingredient in Trimesta, which is currently in clinical trial for multiple sclerosis. Should Organon terminate our agreement or be unable or unwilling to continue to supply Trimesta to us, this might delay enrollment and commercialization plans for our Trimesta clinical trial program. Organon has manufactured oral estriol the active ingredient of Trimesta for the European and Asian market for approximately 40 years but has never been approved in the United States. Organon has recently informed us of their decision to discontinue supply of estriol tablets beyond that required to satisfy the planned future needs of the ongoing clinical trial in relapsing-remitting multiple sclerosis. Accordingly, prior to initiation of additional clinical studies and/or commercial launch of oral estriol, we may need to identify and execute supply agreement(s) on terms suitable to us with an alternate supplier of estriol tablets.

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

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

In addition, any contract manufacturer that we select to manufacture our product candidates might fail to maintain a current “good manufacturing practices” (cGMP) manufacturing facility.

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

or sold by others that we need for comparison purposes in clinical trials and studies for our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

Physicians and patients may not accept and use our technologies.

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

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

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

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

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

These collaborators may also have relationships with other commercial entities, some of which may compete with us. Our collaborators assisting our competitors at our expense could harm our competitive position. For example, we are highly dependent on scientific collaborators for our Trimesta and ZincMonoCysteine development programs. Specifically, all of the clinical trials have been conducted under physician-sponsored investigational new drug applications (INDs), not corporate-sponsored INDs. Generally, we have experienced difficulty in collecting data generated from these physician-sponsored clinical trials for our programs. We cannot provide any assurances that we will not experience any additional delays in the future. We have experienced similar difficulties with our zinc-monocysteine program.

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

The on-going and future development and commercialization of Effirma (oral flupirtine) for fibromyalgia is the responsibility of Meda AB and no assurance can be given that Meda will gain FDA approval of oral flupirtine for fibromyalgia.

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

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

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

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

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

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

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

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

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies, or other public and private research organizations. Many of these competitors have therapies to treat 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 preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

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

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

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

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

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

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

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

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

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

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

RISKS RELATING TO OUR STOCK

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

We expect to seek to raise additional capital in the future to help fund development of our proposed products. If we raise additional capital through the issuance of equity (as we recently have) or of 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 substantially controlled by our current officers, directors, and principal stockholders.

Currently, our directors, executive officer, and principal stockholders beneficially own a substantial number of shares 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. Our executive officer, directors and principal stockholders beneficially owned approximately 12.1 million shares of our common stock, including the stock options and warrants exercisable within 60 days of March 25, 2011. Because our common stock has from time to time been “thinly traded”, the sale of these shares by our executive officer, 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 continued listing standards of the NYSE Amex (formerly the American Stock Exchange) or NYSE Alternext US. The NYSE Amex requires companies to meet certain continued listing criteria including certain minimum stockholders' equity and equity prices per share as outlined in the Exchange Company Guide. We may not be able to maintain such minimum stockholders' equity or prices per share or may be required to 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 NYSE Amex. If we are delisted from the Exchange then our common stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our common stock could further depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the Exchange could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities. In order to remain listed on NYSE Amex, we are required to maintain a minimum stockholders' equity of $6 million, which exceeded our stockholders' equity as of December 31, 2010, but at the present time does not exceed our stockholders' equity due to the receipt of proceeds from our recent offering.

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

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

We have never paid dividends.

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

RISKS RELATED TO OUR INDUSTRY

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

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

The United States Dietary Supplement Health and Education Act of 1994, or DSHEA, revised the provisions of the Federal Food, Drug and Cosmetic Act, or FFDCA, concerning the composition and labeling of dietary supplements and, we believe, the revisions are generally favorable to the dietary supplement industry. The legislation created a new

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Satisfaction of these and other regulatory requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures on our activities. We cannot be certain that the FDA or other regulatory agencies will approve any of our products on a

timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from preclinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications or uses.

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

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

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

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

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

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

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

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

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

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

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

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

and further inspections may occur over the product's life.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Hatch-Waxman also provides for differing periods of statutory protection for new drugs approved under an NDA. Among the types of exclusivity are those for a "new molecular entity" and those for a new formulation or indication for a previously-approved drug. If granted, marketing exclusivity for the types of products that we are developing, which include only drugs with innovative changes to previously-approved products using the same active ingredient, would prohibit the FDA from approving an ANDA or 505(b)(2) NDA relying on safety and efficacy data for three years. This three-year exclusivity, however, covers only the innovation associated with the original NDA. It does not prohibit the FDA from approving applications for drugs with the same active ingredient but without our new innovative change. These marketing exclusivity protections do not prohibit the 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 are located at 3985 Research Park Drive, Suite 200, Ann Arbor, MI 48108. We currently rent approximately 5,936 square feet of office and laboratory space in Ann Arbor, MI for monthly rent of $4,000. This is a month-to-month lease. Our Adeona Clinical Laboratory subsidiary leases approximately 3,000 square feet of clinical

laboratory space in Bolingbrook, IL for $3,027 a month. This lease expires May 30, 2012, but is terminable at any time at our option for $250 times the number of months remaining. We believe our current offices will be adequate for the foreseeable future.

Item 3. Legal Proceedings

Not applicable.

Item 4. Removed and Reserved

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchase of Equity Securities

Our common stock has traded on the NYSE Amex (formerly the American Stock Exchange) under the symbol "AEN" since October 16, 2008. The following table states the range of the high and low sales prices of our common stock for each of the calendar quarters during the years ended December 31, 2010 and December 31, 2009. These quotations represent inter-dealer prices, without retail mark-up, markdown, or commission, and may not represent actual transactions. The last price of our common stock as reported on the NYSE Amex on March 25, 2011 was $1.80 per share. As of March 25, 2011, there were approximately 360 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, 2010		
Fourth quarter	$ 1.40	$ 0.70
Third quarter	$ 1.19	$ 0.77
Second quarter	$ 2.70	$ 1.03
First quarter	$ 2.58	$ 0.57
YEAR ENDED DECEMBER 31, 2009		
Fourth quarter	$ 0.92	$ 0.41
Third quarter	$ 1.70	$ 0.30
Second quarter	$ 1.10	$ 0.16
First quarter	$ 0.56	$ 0.10

Dividend Policy

We have never paid any cash dividends on our common stock to date, and do not anticipate paying such cash dividends in the foreseeable future. Whether we declare and pay dividends is determined by our board of directors at their discretion, subject to certain limitations imposed under Nevada corporate law. The timing, amount and form of dividends, if any, will depend on, among other things, our results of operations, financial condition, cash requirements and other factors deemed relevant by our board of directors.

Equity Compensation Plan Information

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

Recent Sales of Unregistered Securities

In July of 2010, the Company issued warrants to purchase 60,606 shares of common stock to a placement agent. The warrants have an exercise price of $1.32 and are exercisable for a period of five years. In October of 2010, the Company issued 52,180 shares of common stock to Thomas Jefferson University having a fair value of $41,250 ($0.79 per share). and 28,855 shares of common stock to the University of Southern California having a fair value of $29,087 ($1.01 per share) in payment for licensing fees. The fair value of these issuances were based upon the quoted closing price. For the year ended December 31, 2009, the Company issued 50,000 shares of common stock for the acquisition of Adeona Clinical Laboratory, having a fair value of $19,000 ($0.38 per share), based on the quoted closing trading price. These issuances 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 issuances 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 issuances. These issuances were done with no general solicitation or advertising by the Company. Based on an analysis of the above factors, the Company has met the requirements to quality for exemption under Section 4(2) of the Securities Act of 1933 for these sales.

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 year ended December 31, 2010 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

We are a pharmaceutical company developing innovative medicines for the treatment of serious central nervous system diseases. Our primary strategy is to license product candidates that have demonstrated a certain level of clinical efficacy and develop them to a stage that results in a significant commercial collaboration. Currently, we have the following product candidates in development: a prescription medical food for Alzheimer's disease, and drugs for multiple sclerosis, fibromyalgia and age-related macular degeneration.

- Alzheimer's disease and mild cognitive impairment: reaZin (zinc cysteine) is being developed as a prescription medical food for the dietary management of patients with Alzheimer's disease and mild cognitive impairment. A randomized, double-blind, placebo-controlled clinical study is underway at 2 centers in the United States. Sixty patients were enrolled in the study, and we recently completed the treatment phase of this clinical study. It is anticipated that top-line clinical study results should be presented on April 14, 2011 at the 63rd Annual Meeting of the American Academy of Neurology.
- Multiple sclerosis: Trimesta (oral estriol) is a drug candidate being developed for the treatment of relapsing-remitting multiple sclerosis in women. A randomized, double-blind, placebo-controlled clinical trial is currently underway at 15 centers in the United States. As of March 1, 2011 127 out of 150 patients have been enrolled.
- Fibromyalgia: Effirma (oral flupirtine) is a drug candidate being developed for the treatment of fibromyalgia. On May 6, 2010, we and Pipex, our wholly owned subsidiary, entered into a sublicense agreement with Meda AB, a multi-billion dollar international pharmaceutical company, covering all of our patents' rights on the use of oral flupirtine for fibromyalgia.
- Age-related macular degeneration: ZincMonoCysteine (zinc-monocysteine) is a drug candidate being developed for the treatment of age-related macular degeneration. An 80-patient, randomized, double-blind, placebo-controlled clinical trial has been completed.

As of March 31, 2011, we have discontinued our dnaJP1 (hsp peptide) clinical development program. While data from a Phase II clinical trial previously reported in November 2009 demonstrated safety and tolerability in patients with rheumatoid arthritis, the decision to discontinue was driven by economic factors, anticipated time to market and the perceived relative clinical and market potential. We will continue to focus our efforts on developing innovative medicines for the treatment of serious central nervous system diseases and to explore new opportunities.

Our secondary strategy is to market our core competency in measuring metabolic serum zinc and copper status. To further this effort, we purchased HartLab, LLC, on July 13, 2009. Renamed Adeona Clinical Laboratory, the wholly owned CLIA-certified clinical testing facility provides a broad array of chemistry and microbiology diagnostic tests in the Greater Chicago area. At Adeona Clinical Laboratory, we developed and offer the CopperProof panel, a series of diagnostic tests for accurately measuring the metabolic serum zinc and copper levels of patients with Alzheimer's disease and mild cognitive impairment. Adeona Clinical Laboratory is a licensed Medicare and Medicaid provider.

Since our inception in January 2001, our efforts and resources have been focused primarily on acquiring and developing our product candidates, our clinical trials, raising capital and recruiting personnel. As of June 30, 2010, we emerged from the development stage after entering into a sublicense agreement with Meda AB and receiving an up-front payment of $2.5 million. We consider this sublicense agreement to be an indication that we have commenced our principal operations.

To date, we have financed our operations primarily through public and private sales of our common stock, and we expect to continue to seek to obtain the required capital in a similar manner. We have incurred an accumulated deficit of $43.7 million through December 31, 2010. We cannot provide any assurance that we will be able to achieve profitability on a sustained basis, if at all, obtain the required funding, obtain the required regulatory approvals, or complete additional corporate partnering or acquisition transactions.

On October 16, 2008, we changed our name from Pipex Pharmaceuticals, Inc. to Adeona Pharmaceuticals, Inc. On October 15, 2009 we reincorporated in Nevada from Delaware pursuant to the discretionary reincorporation plan approved by our stockholders. The reincorporation was effected by our merger as a Delaware corporation, with and into a newly created, wholly owned, Nevada subsidiary corporation. In the reincorporation, each outstanding share of our common stock as a Delaware corporation was automatically converted into one share of common stock as a Nevada corporation, and all options and other rights to acquire our common stock as a Delaware corporation outstanding immediately prior to the reincorporation were automatically converted into options and rights to acquire the same number of shares of our common stock as a Nevada corporation. Stockholders were not required to exchange their existing stock certificates of the Delaware corporation which now represent the same number of shares of our common stock as a Nevada corporation. Outstanding shares of our common stock as a Nevada corporation retain the same CUSIP number as the corresponding shares prior to the reincorporation, and our common stock continues to be listed on the NYSE Amex stock exchange (formerly known as the American Stock Exchange and the NYSE Alternext US exchange) under the same symbol, “AEN”. The reincorporation did not result in any material changes in our business, offices, assets, liabilities, obligations or net worth, or our directors, officers or employees, and the Delaware corporation ceased to exist as a separate legal entity. We continue to maintain our principal executive offices in Ann Arbor, MI, and are currently located at 3985 Research Park Drive, Suite 200, Ann Arbor, MI 48108.

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

Critical Accounting Policies

The preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, net revenues and expenses, and related disclosures. We believe our estimates and assumptions are reasonable; however, actual results and the timing of the recognition of such amounts could differ from these estimates.

There are accounting policies that we believe are significant to the presentation of our consolidated financial statements. The most significant accounting policies relate to stock-based compensation, revenue recognition and accounts receivable.

Stock-Based Compensation

Calculating stock-based compensation expense requires the input of highly subjective assumptions. We apply the Black-Scholes option-pricing model to determine the fair value of our stock options. Inherent in this model are assumptions related to expected stock-price volatility, option life, risk-free interest rate and dividend yield. We estimate the volatility of our common stock at the date of grant based on historical volatility. We estimate the expected life of our option using the contractual term of the option. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected life of the options. The dividend rate is based on our historical rate, which we anticipate to remain at zero. The assumptions used in calculating the fair value of stock options represent our best estimates, however these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those stock options expected to vest over the

service period.

Revenue Recognition

We record revenue when all of the following have occurred: (1) persuasive evidence of an arrangement exists, (2) the service is completed without further obligation, (3) the sales price to the customer is fixed or determinable, and (4) collectability is reasonably assured. We recognize milestone payments or upfront payments that have no contingencies as revenue when payment is received. Our primary streams of revenue are license revenue and laboratory revenue.

License Revenues

Our licensing agreements may contain multiple elements, such as non-refundable up-front fees, payments related to the achievement of particular milestones and royalties. Fees associated with substantive at risk performance-based milestones are recognized as revenue upon completion of the scientific or regulatory event specified in the agreement. When we have substantive continuing performance obligations under an arrangement, revenue is recognized over the performance period of the obligations using a time-based proportional performance approach. Under the time-based method, revenue is recognized over the arrangement's estimated performance period based on the elapsed time compared to the total estimated performance period. Revenue recognized at any point in time is limited to the amount of non-contingent payments received or due. When we have no substantive continuing performance obligations under an arrangement, we recognize revenue as the related fees become due.

Revenues from royalties on third-party sales of licensed technologies are generally recognized in accordance with the contract terms when the royalties can be reliably determined and collectibility is reasonably assured.

Laboratory Revenues

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

We maintain a sales allowance to compensate for the difference inour clinical laboratory's billing practices and insurance company reimbursements. In determining this allowance, we look at several factors, the most significant of which is the average difference between the amount charged and the amount reimbursed by insurance carriers over the prior 18 months, otherwise known as the yearly average adjustment amount. The allowance taken is the averaged yearly average adjustment amount for these prior periods and multiplied by the period's actual gross sales to determine the actual sales allowance for each period.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are reported at realizable value, net of allowances for doubtful accounts, which is estimated and recorded in the period the related revenue is recorded. We estimate and review the collectability of our receivables based on a number of factors, including the period they have been outstanding. Historical collection and payer reimbursement experience is an integral part of the estimation process related to allowances for doubtful accounts. In addition, we regularly assess the state of our billing operations in order to identify issues, which may impact the collectability of these receivables or reserve estimates. Revisions to the allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within general and administrative expenses. Receivables deemed uncollectible are charged against the allowance for doubtful accounts at the time such receivables are written-off. Recoveries of receivables previously written-off are recorded as credits to the allowance for doubtful accounts.

Results of Operations

Year Ended December 31, 2010 and 2009

Revenues, net

Total net revenues for the year ended December 31, 2010 were $3,164,512. Total net revenues consisted of $2,125,000 from the oral flupirtine sublicense fee with Meda AB, which is net of the $375,000 payment to McLean Hospital, $550,553 of laboratory revenues from Adeona Clinical Laboratory and $488,959 of grant revenues from the Qualifying Therapeutic Discovery Project (QTDP) Program to support the our Alzheimer's disease and multiple sclerosis programs currently in clinical testing. Revenues for year ended December 31, 2009 consisted of $103,089 of laboratory revenues from Adeona Clinical Laboratory. Since purchasing Adeona Clinical Laboratory in July of 2009, the client base has increased and the in-house diagnostic testing services have been expanded to include a full array of microbiology testing.

General and Administrative Expenses

General and administrative expenses decreased slightly to $2,700,951 for the year ended December 31, 2010 from $2,708,778 for the year ended December 31, 2009. General and administrative costs in 2009 included acquisition costs relating to the purchase of Adeona Clinical Laboratory of $75,000. General and administrative expenses also include a non-cash charge relating to stock-based compensation expense of $310,098 for the year ended December 31, 2010, compared to $135,770 for the year ended December 31, 2009.

Research and Development Expenses

Research and development expenses increased to $1,579,891 for the year ended December 31, 2010, from $948,891 for the year ended December 31, 2009. This increase of 66% is primarily the result of increased costs associated with the continued development of our product candidates, including outside manufacturing costs, consultant fees, license fees and patent costs. Research and development expenses also include a non-cash charge relating to stock-based compensation expense of $90,290 for the year ended December 31, 2010, compared to $188,166 for the year ended December 31, 2009.

Costs of Laboratory Services

Costs of laboratory services increased to $467,632 for the year ended December 31, 2010, from $126,900 for the year ended December 31, 2009. This increase is primarily the result of the increased costs associated with the expansion of the client base at Adeona Clinical Laboratory, including salary and supply costs. The year ended December 31, 2010 include 12 months of costs compared to the year ended December 31, 2009, that included only 6 months (Adeona Clinical Laboratory was purchased in July of 2009).

Other Expense, net

Other expense was $127,206 compared to $49,925 for the years ended December 31, 2010 and 2009, respectively. Other expense for the year ended December 31, 2010, included an impairment loss of $120,747 relating to obsolete equipment and interest expense of $10,108, offset by a gain on the sale of equipment of $3,236 and interest income of $413. Other income for the year ended December 31, 2009, consisted of $2,965 in interest income. Other expense for the year ended December 31, 2009, included a loss on the sale of equipment of $34,399, interest expense of $9,879 and other expense of $8,612, offset by interest income of $2,965.

Net Loss

Our net loss for the year ended December 31, 2010, was $1,711,159, or $0.08 per common share compared to a $3,731,405, or $0.18 for the year ended December 31, 2009. The decrease in net loss is the result of increased revenues for the year ended December 31, 2010, that included license revenue, increased laboratory revenue and grant revenue.

Liquidity and Capital Resources

We have financed our operations since inception primarily through proceeds from equity financings and various private financings, primarily involving private sales of our common stock and other equity securities, corporate partnering license fees and to a lesser extent from the proceeds from the sale of our common stock under our registration statement on Form S-3, laboratory revenues, miscellaneous equipment sales.

Our cash totaled $2,648,853 at December 31, 2010, a decrease of $66,191 from December 31, 2009. During the year ended December 31, 2010, the primary sources of cash were $2,125,000 from the sublicense fee relating to the Meda Agreement and proceeds from the issuance of common stock to a single investor of $884,724 (net of offering costs of $115,276) and stock option exercises of $129,778. The primary uses of cash for the year ended December 31, 2010, included working capital requirements and $12,663 in capital equipment additions. Our cash at February 28, 2011, was approximately $6.0 million.

Our cash totaled $2,715,044 at December 31, 2009, the primary uses of cash were working capital requirements and the acquisition of Adeona Clinical Laboratory. The primary sources of cash were $25,200 from the sale of miscellaneous equipment and $10,734 from the exercise of stock options.

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

Current and Future Financing Needs

We have incurred an accumulated deficit of approximately $43.7 million through December 31, 2010. With the exception of the quarter ended June 30, 2010, we have incurred negative cash flow from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts.

Based on our current plans, we believe that our cash will be sufficient to enable us to meet our planned operating needs for at least the next 12 months.

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

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and

- the costs and timing of regulatory approvals; and
- profitability of our clinical laboratory diagnostic and microbiology services business.

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

License and Contractual Agreement Obligations

Below is a table of our contractual obligations for the years 2011 through 2015 as of December 31, 2010.

	Year ended December 31,					
	2011	2012	2013	2014	2015	Total
License Agreements	$ 90,000	$ 37,335	$ 5,000	$ 5,000	$ 5,000	$ 142,335
Lease Agreements	56,814	15,136	-	-	-	71,950
Total	$ 146,814	$ 52,471	$ 5,000	$ 5,000	$ 5,000	$ 214,285

Additional In-Licensed Programs

We may enter into additional license agreements relating to new product 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 Supplemental Data

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 as of December 31, 2010 and 2009 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years ended December 31, 2010 and 2009. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly in all material respects, the consolidated financial position of Adeona Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2010 and 2009, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years ended December 31, 2010 and 2009, in conformity with accounting principles generally accepted in the United States of America.

Berman & Company, P.A.

Boca Raton, Florida
March 30, 2011

Adeona Pharmaceuticals, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31, 2010	December 31, 2009
Assets		
Current Assets		
Cash	$ 2,648,853	$ 2,715,044
Accounts receivable - net	338,510	30,572
Other	343,417	8,967
Total Current Assets	3,330,780	2,754,583
Property and equipment	511,142	1,051,958
Goodwill	178,229	178,229
Deposits and other assets	90,848	90,848
Total Assets	$ 4,110,999	$ 4,075,618
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 265,722	$ 400,475
Accrued liabilities	210,027	8,163
Current portion of capital lease	24,400	17,006
Total Current Liabilities	500,149	425,644
Long Term Liabilities:		
Accounts payable	32,335	93,000
Capital lease	-	12,788
Total Liabilities	532,484	531,432
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 23,420,189 issued and 23,338,707 outstanding and 21,530,834 issued and 21,449,352 outstanding	23,339	21,449
Additional paid-in capital	47,279,416	45,552,918
Accumulated deficit	(43,724,240)	(42,013,081)
Subscription receivable	-	(17,100)
Total Stockholders' Equity	3,578,515	3,544,186
Total Liabilities and Stockholders' Equity	$ 4,110,999	$ 4,075,618

See accompanying notes to consolidated financial statements

Adeona Pharmaceuticals, Inc. and Subsidiaries
Consolidated Statements of Operations

	For the years ended December 31,	
	2010	2009
Revenues:		
License revenue, net	$2,125,000	$-
Laboratory revenues, net	550,553	103,089
Grant revenue	488,959	-
Total revenues, net	3,164,512	103,089
Operating Costs and Expenses:		
General and administrative	2,700,951	2,708,778
Research and development	1,579,891	948,891
Costs of laboratory services	467,623	126,900
Total Operating Costs and Expenses	4,748,465	3,784,569
Loss from Operations	(1,583,953)	(3,681,480)
Other Income (Expense):		
Interest income	413	2,965
Gain (loss) on sale of equipment	3,236	(34,399)
Interest expense	(10,108)	(9,879)
Other expense	-	(8,612)
Impairment loss on equipment	(120,747)	-
Total Other Expense, net	(127,206)	(49,925)
Net Loss	$(1,711,159)	$(3,731,405)
Net Loss Per Common Share – Basic and Dilutive	$(0.08)	$(0.18)
Weighted average number of common shares outstanding during the period – Basic and Dilutive	22,393,568	21,318,906

See accompanying notes to consolidated financial statements

Adeona Pharmaceuticals, Inc. and Subsidiaries
Consolidated Statements of Changes in Stockholders' Equity

	Common Stock $0.001 Par Value					
	Shares	Amount	Additional Paid In Capital	Accumulated Deficit	Subscription Receivable	Total Stockholders' Equity
Balance, December 31, 2008	20,882,839	$ 20,883	$45,025,385	$(38,281,676)	$ -	$ 6,764,592
Stock based compensation	-	-	323,936		-	323,936
Issuance of common stock for consulting fee	235,549	236	65,550	-	-	65,786
Issuance of common stock for license fee	257,813	257	40,992	-	-	41,249
Contributed services - related party	-	-	100,000	-	-	100,000
Issuance of common stock for acquisition of Hart Lab, LLC	50,000	50	18,950	-	-	19,000
Acquisition of treasury stock	(81,482)	(82)	(49,624)	-	-	(49,706)
Issuance of common stock for options exercised	104,633	105	27,729	-	(17,100)	10,734
Net loss for the year ended December 31, 2009	-	-	-	(3,731,405)		(3,731,405)
Balance, December 31, 2009	21,449,352	21,449	45,552,918	(42,013,081)	(17,100)	3,544,186
Stock based compensation	-	-	400,388	-	-	400,388
Issuance of common stock for consulting fees	279,724	280	213,369	-	-	213,649
Issuance of common stock for employee compensation	60,521	61	46,551	-	-	46,612
Issuance of common stock for license fees	81,035	81	70,256	-	-	70,337
Issuance of common stock for options exercised	255,954	256	112,422	-	17,100	129,778
Issuance of common stock, net of issuance costs of $115,276	1,212,121	1,212	883,512	-	-	884,724
Net loss for the year ended December 31, 2010	-	-	-	(1,711,159)	-	(1,711,159)
Balance, December 31, 2010	23,338,707	$ 23,339	$47,279,416	$(43,724,240)	$ -	$ 3,578,515

See accompanying notes to consolidated financial statements

Adeona Pharmaceuticals, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	For the years ended December 31, 2010	2009
Cash Flows From Operating Activities:		
Net loss	$ (1,711,159)	$ (3,731,405)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	400,388	323,936
Stock issued for consulting fees	213,649	65,786
Stock issued as compensation	46,612	-
Stock issued for license fee	70,337	41,249
Contributed services - related party	-	100,000
Depreciation	358,708	382,089
Provision for uncollectible accounts receivable	130,403	97,377
(Gain) loss on sale of equipment	(3,236)	34,399
Impairment loss on equipment	120,747	-
Changes in operating assets and liabilities:		
Accounts receivable	(438,341)	(48,292)
Other current assets	(334,450)	61,562
Deposits and other assets	-	(78,859)
Accounts payable	(195,418)	(138,264)
Accrued liabilities	201,864	(28,442)
Net Cash Used In Operating Activities	(1,139,896)	(2,918,864)
Cash Flows From Investing Activities:		
Purchases of property and equipment	(12,663)	(1,850)
Proceeds from the sale of equipment	77,260	25,200
Cash paid to acquire Adeona Clinical Laboratory (formerly Hart Lab)	-	(201,141)
Cash received from the purchase of Adeona Clinical Laboratory (formerly Hart Lab)	-	5,624
Net Cash Provided By (Used In) Investing Activities	64,597	(172,167)
Cash Flows From Financing Activities:		
Repayments under capital lease	(5,394)	(11,337)
Proceeds from issuance of common stock for stock option exercises	129,778	10,734
Acquisition of treasury stock	-	(49,706)
Proceeds from the issuance of common stock	1,000,000	-
Cash paid as direct offering costs	(115,276)	-
Net Cash Provided By (Used In) Financing Activities	1,009,108	(50,309)
Net decrease in cash	(66,191)	(3,141,340)
Cash at beginning of year	2,715,044	5,856,384
Cash at end of year	$ 2,648,853	$ 2,715,044
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 10,108	$ 2,006

Cash paid for taxes	$ -	$ -
Supplemental disclosure of non-cash investing and financing activities:		
Exchange of equipment	$ 64,016	$ -
Loss on exchange of equipment to settle accounts payable	$ -	$ 5,925

See accompanying notes to consolidated financial statements

Adeona Pharmaceuticals, Inc. and Subsidiaries
Notes to Consolidated Financial Statements
December 31, 2010 and 2009

1. Organization and Nature of Operations and Basis of Presentation

Description of Business

Adeona Pharmaceuticals, Inc. (the "Company" or Adeona") is a pharmaceutical company developing innovative medicines for the treatment of serious central nervous system diseases. The Company's primary strategy is to license product candidates that have demonstrated a certain level of clinical efficacy and develop them to a stage that results in a significant commercial collaboration. Currently, Adeona has the following product candidates in development: a prescription medical food for Alzheimer's disease, and drugs for multiple sclerosis, fibromyalgia and age-related macular degeneration.

Medical Indication	Product Candidate	Status
Alzheimer's disease and mild cognitive impairment	reaZin (zinc cysteine)	Pivotal clinical study underway
Multiple sclerosis	Trimesta (oral estriol)	Phase II clinical trial underway
Fibromyalgia	Effirma (oral flupirtine)	Partnered with Meda AB
Age-related macular degeneration	ZincMonoCysteine (zinc-monocysteine)	Phase II clinical trial complete

Adeona's secondary strategy is to advance its core competency in measuring metabolic serum zinc and copper levels. To further this effort, Adeona purchased HartLab, LLC, on July 13, 2009 and renamed it Adeona Clinical Laboratory. This wholly owned, CLIA-certified clinical testing facility provides a broad array of chemistry and microbiology diagnostic tests in the Greater Chicago area. Adeona Clinical Laboratory developed and offers the CopperProof panel, a series of diagnostic tests for accurately measuring the metabolic serum zinc and copper levels of patients with Alzheimer's disease and mild cognitive impairment. Adeona Clinical Laboratory is a licensed Medicare and Medicaid provider.

Nevada Reincorporation

On October 15, 2009, Adeona Pharmaceuticals, Inc. reincorporated to Nevada. There was no financial statement impact associated with this reincorporation.

Basis of Presentation and Corporate Structure

The Company has eight active subsidiaries, Pipex Therapeutics, Inc. ("Pipex Therapeutics"), Adeona Clinical Laboratory (formerly Hart Lab, LLC), Effective Pharmaceuticals, Inc. ("EPI"), Solovax, Inc. ("Solovax"), CD4 Biosciences, Inc. ("CD4"), Epitope Pharmaceuticals, Inc. ("Epitope"), Healthmine, Inc. ("Healthmine") and Putney Drug Corp. ("Putney"). As of December 31, 2010, EPI, Adeona Clinical Laboratory, Healthmine and Putney are wholly-owned and Pipex Therapeutics, Solovax, CD4 and Epitope are majority-owned.

For financial reporting purposes, the outstanding common stock of the Company is that of Adeona Pharmaceuticals, Inc. All statements of operations, stockholders' equity and cash flows for each of the entities are presented as consolidated. All subsidiaries were formed under the laws of the State of Delaware on January 8, 2001, except for EPI, which was incorporated in Delaware on December 12, 2000, Epitope which was incorporated in Delaware in January of 2002, Putney which was incorporated in Delaware in November of 2006, Healthmine which was formed in Delaware in December of 2007 and Adeona Clinical Laboratory which was incorporated in Illinois as a limited liability company on August 8, 2005.

2. Acquisition of Adeona Clinical Laboratory (formerly Hart Lab, LLC)

On July 10, 2009, the Company entered into a limited liability company purchase agreement to acquire Adeona Clinical Laboratory (formerly Hart Lab, LLC), an Illinois limited liability company and CLIA-certified clinical laboratory. The Company acquired Adeona Clinical Laboratory to develop and commercialize its diagnostic test panel for the detection of zinc and copper deficiencies in the mature population.

In consideration for the purchase of Adeona Clinical Laboratory the Company paid $220,141, that consisted of $201,141 in cash and 50,000 unregistered shares of the Company's common stock, having a fair value of $19,000 ($0.36 per share), based upon the quoted closing trading price, in exchange for 100% of the issued and outstanding membership interests of Adeona Clinical Laboratory. The Company also agreed to guarantee and to release the seller from the seller's personal guarantee of the remaining balance of two outstanding clinical equipment leases, totaling $78,859. This balance is included in deposits and other assets. As of December 31, 2010 this amount remained in escrow, however all personal guarantee's of the seller have been removed. In January of 2011, this capital lease was paid in full and the funds were released from escrow (see Note 7).

The purchase price of Adeona Clinical Laboratory was allocated as follows:

Consideration transferred at fair value:		
Cash	$	201,141
Common stock		19,000
Total consideration	$	220,141
Net assets acquired:		
Current assets:		
Cash	$	5,624
Accounts receivable – net of allowance of $4,192		79,657
Equipment		39,465
Total	$	124,746
Current liabilities:		
Accounts payable	$	38,324
Accrued liabilities		12,593
Capital lease		31,917
Total	$	82,834
Net assets acquired	$	41,912
Goodwill	$	178,229

All assets acquired and liabilities assumed had a book value equivalent to fair value. The Company did not record any fair value adjustment for contingencies since there were none.

The Company believed that all assets were recoverable and that no impairment or write-down to net realizable value was required. As a result of this business combination, there was no allocation for a non-controlling interest since the Company acquired a 100% controlling interest in Adeona Clinical Laboratory. Direct costs associated with the acquisition were approximately $65,000.

3. Summary of Significant Accounting Policies

Principles of Consolidation

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

Emerging from the Development Stage

During the second quarter of 2010, the Company emerged from the development stage. A development-stage enterprise is one in which planned principle operations have not commenced or if its operations have commenced, there has been no significant revenue. The Company's strategy is to license product candidates that have demonstrated a certain level of clinical efficacy and develop them to a stage that results in a significant commercial collaboration. On May 6, 2010, the Company entered into a Sublicense Agreement (the "Meda Agreement") with Meda AB of Sweden ("Meda") and received an up-front payment of $2.5 million. The execution of the Meda Agreement combined with increasing revenues from Adeona Clinical Laboratory are an indication of the commencement of principal operations, and therefore development-stage reporting is no longer required.

Use of Estimates

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

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

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are reported at realizable value, net of allowances for doubtful accounts, which is estimated and recorded in the period the related revenue is recorded. The Company estimates and reviews the collectability of its receivables based on a number of factors, including the period they have been outstanding. Historical collection and payer reimbursement experience is an integral part of the estimation process related to allowances for doubtful accounts associated with Adeona Clinical Laboratory. In addition, the Company regularly assesses the state of its billing operations in order to identify issues, which may impact the collectability of these receivables or reserve estimates. Revisions to the allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense. Receivables deemed uncollectible are charged against the allowance for doubtful accounts. Recoveries of receivables previously written-off are recorded as credits to the allowance for doubtful accounts. There were no recoveries during the years ended December 31, 2010 and 2009.

Revenue Recognition

The Company records revenue when all of the following have occurred: (1) persuasive evidence of an arrangement exists, (2) the service is completed without further obligation, (3) the sales price to the customer is fixed or determinable, and (4) collectability is reasonably assured. The Company recognizes milestone payments or upfront payments that have no contingencies as revenue when payment is received. During the year ended December 31, 2010, the Company's streams of revenue were license revenue, laboratory revenue and grant revenue. For the year ended December 31, 2009, the Company's only stream of revenue was laboratory revenue.

License Revenues

The Company's licensing agreements may contain multiple elements, such as non-refundable up-front fees, payments related to the achievement of particular milestones and royalties. Fees associated with substantive at risk performance-based milestones are recognized as revenue upon completion of the scientific or regulatory event specified in the agreement. When the Company has substantive continuing performance obligations under an arrangement, revenue is recognized over the performance period of the obligations using a time-based proportional performance approach. Under the time-based method, revenue is recognized over the arrangement's estimated performance period based on the elapsed time compared to the total estimated performance period. Revenue recognized at any point in time is limited to the amount of non-contingent payments received or due. When the Company has no substantive continuing performance obligations under an arrangement, it recognizes revenue as the related fees become due.

Revenues from royalties on third-party sales of licensed technologies are generally recognized in accordance with the contract terms when the royalties can be reliably determined and collectibility is reasonably assured. To date, the Company has not received any royalty revenues.

On May 6, 2010, the Company entered into a Sublicense Agreement (the "Meda Agreement") with Meda AB of Sweden ("Meda") for the development and commercialization of Effirma (oral flupirtine) for fibromyalgia. As consideration for the sublicense, the Company received an up-front payment of $2.5 million upon execution of the Meda Agreement. This payment was recorded as license revenue in June of 2010. Pursuant to the Company's license agreement with McLean Hospital, the Company paid 15% of the $2.5 million payment ($375,000) to McLean Hospital. The payment to McLean Hospital was netted against the revenues received from Meda AB for financial statement purposes. The Company is also entitled to additional milestone payments of $5 million upon filing of a New Drug Application with the United States Food and Drug Administration for oral flupirtine for fibromyalgia and $10 million upon marketing approval. The Meda Agreement also provides that the Company is entitled to receive net royalties of 7% of net sales of oral flupirtine approved for the treatment of fibromyalgia covered by issued patent claims in the United States and Japan. The Meda Agreement provides that Meda AB will assume all future development costs for the commercialization of oral flupirtine for fibromyalgia. Pursuant to the terms of the Company's agreement with McLean Hospital, the Company is obligated to pay them half of the royalties the Company receives. Future milestone payments will be recorded as revenue when payment is received as there are no future deliverables, and it is non-refundable. The Company will make similar disclosure for any future license agreements.

Laboratory Revenues

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

The Company maintains a sales allowance to compensate for the difference in its billing practices and insurance company reimbursements. In determining this allowance, the Company looks at several factors, the most significant of which is the average difference between the amount charged and the amount reimbursed by insurance carriers over the prior 18 months, otherwise known as the yearly average adjustment amount. The allowance taken is the averaged yearly average adjustment amount for these prior periods and multiplied by the period's actual gross sales to determine the actual sales allowance for each period.

The Company generated revenues from 3 significant insurance providers in 2010 and 2009.

Customer	2010		2009	
A	65	%	37	%
B	11	%	20	%
C	14	%	-	

Grant Revenues

On November 4, 2010, the Company was awarded two grants totaling $488,959 under the Qualifying Therapeutic Discovery Project (QTDP) Program to support the Company's Alzheimer's disease and multiple sclerosis programs currently in clinical testing. The Qualified Therapeutic Discovery Project Grants Program was included in the healthcare reform legislation and established a one-time pool of $1 billion for grants to small biotechnology companies developing novel therapeutics which show potential to: (a) result in new therapies that either treat areas of unmet medical need, or prevent, detect, or treat chronic or acute diseases and conditions; (b) reduce long-term health care costs in the United States; or (c) significantly advance the goal of curing cancer within a the 30-year period. All grant income was recognized in 2010 and there are no future obligations associated with these grants.

During 2010 and March 2011, all amounts awarded under these grants had been received.

See Note 9 regarding the taxability of grant revenues.

Revenues, net

	December 31,	
	2010	2009
License revenue	$ 2,500,000	$ -
License fees	(375,000)	-
License revenue, net	2,125,000	-
Laboratory revenues, net	550,553	103,089
Grant revenue	488,959	-
Total revenues, net	$ 3,164,512	$ 103,089

Risks and Uncertainties

The Company's operations could be subject to significant risks and uncertainties including financial, operational and regulatory risks and the potential risk of business failure. The global economic crisis has caused a general tightening

in the credit markets, lower levels of liquidity, increases in the rates of default and bankruptcy, and extreme volatility in credit, equity and fixed income markets. These conditions may not only limit our access to capital, but also make it difficult for our customers, our vendors and us to accurately forecast and plan future business activities.

Cash and Cash Equivalents

Cash and cash equivalents include cash and highly liquid short-term investments with original maturities of three months or less. At December 31, 2010 and 2009, respectively, the Company had no cash equivalents.

On December 31, 2010 and 2009, the Company had amounts in excess of FDIC insured limits totaling $2,111,554 and $0, respectively.

At December 31, 2010 and 2009, the Company had amounts in excess of FDIC insuredhe Company minimizes credit risk associated with cash by periodically evaluating the credit quality of its primary financial institution. The balance at times may exceed the federally insured limit of $250,000 per depositor, per bank.

Property and Equipment

Property and equipment is recorded at cost (greater than $1,000) and depreciated or amortized using the straight-line method over the estimated useful life of the asset or the underlying lease term for leasehold improvements, whichever is shorter. The estimated useful life by asset description is noted in the following table.

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

Depreciation expense was $358,708 and $382,089 for the years ended December 31, 2010 and 2009, respectively. When assets are disposed of, the cost and accumulated depreciation are removed from the accounts. Repairs and maintenance are charged to expense as incurred.

During 2010, the Company reviewed property and equipment for impairment and determined that certain items had been impaired due to obsolescence. As a result of this review, the Company recorded an impairment loss of $120,747 that is recorded as impairment loss on equipment. For the year ended December 31, 2009, there were not significant events or changes in circumstances were identified by the Company that would indicate that the carrying value of an asset was not recoverable.

Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such an event or change in circumstances occurs and potential impairment is indicated because the carrying values exceed the estimated future undiscounted cash flows of the asset, the Company would measure the impairment loss as the amount by which the carrying value of the asset exceeds its fair value.

Goodwill

Goodwill is not amortized, and is tested for impairment at the reporting unit level annually and in interim periods if certain events occur indicating that the carrying value of goodwill may be impaired. A reporting unit is an operating segment for which discrete financial information is available and is regularly reviewed by management. The Company has one reporting unit, Adeona Clinical Laboratory, to which goodwill is assigned.

ASC No. 350 requires a two-step approach to test goodwill for impairment for each reporting unit. The first step tests for impairment by applying fair value-based tests to a reporting unit. The second step, if deemed necessary, measures the impairment by applying fair value-based tests to specific assets and liabilities within the reporting unit. Application of the goodwill impairment tests require judgment, including identification of reporting units, assignment of assets and liabilities to each reporting unit, assignment of goodwill to each reporting unit, and determination of the fair value of each reporting unit. The determination of fair value for a reporting unit could be materially affected by changes in these estimates and assumptions.

The Company will continue to evaluate goodwill for impairment annually. During the years ended December 31, 2010 and 2009, the Company did not identify any indication of goodwill impairment.

Beneficial Conversion Feature

For conventional convertible debt where the rate of conversion is below market value, the Company records a "beneficial conversion feature" ("BCF") and related debt discount.

When the Company records a BCF, the relative fair value of the BCF would be recorded as a debt discount against the face amount of the respective debt instrument. The discount would be amortized to interest expense over the life of the debt.

Derivative Liabilities

Fair value accounting requires bifurcation of embedded derivative instruments such as conversion features in convertible debt or equity instruments, and measurement of their fair value for accounting purposes. In determining the appropriate fair value, the Company uses the Black-Scholes option-pricing model. In assessing the convertible debt instruments, management determines if the convertible debt host instrument is conventional convertible debt and further if there is a beneficial conversion feature requiring measurement. If the instrument is not considered conventional convertible debt, the Company will continue its evaluation process of these instruments as derivative financial instruments.

Once determined, derivative liabilities are adjusted to reflect fair value at each reporting period end, with any increase or decrease in the fair value being recorded in results of operations as an adjustment to fair value of derivatives. In addition, the fair value of freestanding derivative instruments such as warrants, are also valued using the Black-Scholes option-pricing model.

Debt Issue Costs and Debt Discount

The Company may pay debt issue costs, and record debt discounts in connection with raising funds through the issuance of convertible debt. These costs are amortized over the life of the debt to interest expense. If a conversion of the underlying debt occurs, a proportionate share of the unamortized amounts is immediately expensed.

Original Issue Discount

For certain convertible debt issued, the Company may provide the debt holder with an original issue discount. The original issue discount was recorded to debt discount reducing the face amount of the note and is being amortized to interest expense over the life of the debt.

Net Loss per Share

Net earnings (loss) per share is computed by dividing net earnings (loss) less preferred dividends for the period by the weighted average number of common shares outstanding. Diluted earnings (loss) per share is computed by dividing net income (loss) less preferred dividends by the weighted average number of common shares outstanding including the effect of common share equivalents. Since the Company reported a net loss for the years ended December 31, 2010 and 2009, all common equivalent shares would be anti-dilutive; as such there is no separate computation for diluted loss per share. The number of options and warrants for the purchase of common stock, that were excluded from the computations of net loss per common share for the year ended December 31, 2010 were 1,990,444 and 1,070,472, respectively and for the year ended December 31, 2009 were 1,837,583 and 1,070,472, respectively.

Research and Development Costs

The Company expenses research and development costs as incurred. Research and development expenses consist primarily of license fees, manufacturing costs, salaries, stock-based compensation and related personnel costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and other expenses relating to the design, development, testing and enhancement of the Company’s product candidates.

Fair Value of Financial Instruments

The fair value accounting standards define fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are rated on a three-tier hierarchy as follows: