

ADEONA PHARMACEUTICALS, INC.  
 Form 424B5  
 July 02, 2010

PROSPECTUS SUPPLEMENT  
 (To Prospectus dated June 14, 2010)

Filed pursuant to Rule 424(b)(5)  
 Registration No. 333-166750

1,212,121 Shares of Common Stock

ADEONA PHARMACEUTICALS, INC.

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering to an investor 1,212,121 shares of our common stock (“Shares”).

Our common stock is traded on the NYSE AMEX LLC under the symbol “AEN.” On June 30, 2010, the last reported sale price for the common stock was \$1.10 per share. You are urged to obtain current market quotations of the common stock.

Investing in our securities involves a high degree of risk. Before buying any securities, you should read the discussion of material risks of investing in our common stock under the heading “Risk factors” starting on page S-12 of this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

We have retained Enclave Capital LLC to act as our exclusive placement agent in connection with this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of securities but will use its best efforts to arrange for the sale of all of the Shares. We have agreed to pay the placement agent a cash fee and to issue warrants to the placement agent. See “Plan of Distribution” for more information regarding these arrangements.

	Per share(1)	Maximum Offering Amount (1)
Offering price	\$ .825	\$ 1,000,000
Placement agent fees (maximum) (2)	\$	\$ 70,000
Proceeds, before expenses, to us (maximum) (3)	\$	\$ 930,000

- (1) We estimate the total expenses of this offering, excluding placement agent fees, will be approximately \$60,000.
- (2) We have agreed to pay the placement agent a cash fee representing 7% of the gross purchase price paid for the Shares at the closing. The placement agent fees shown are the fees to be paid by us to the placement agent.
- (3) The proceeds shown exclude proceeds that we may receive upon exercise of the Placement Agent Warrants.

The date of this prospectus is July 2, 2010.



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We are offering to sell, and seeking offers to buy, shares of our common stock and warrants only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the offering of the common stock and warrants in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the common stock and warrants and the distribution of this prospectus supplement outside the United States. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

This prospectus supplement is not complete without, and may not be utilized except in connection with, the accompanying prospectus dated June 14, 2010 and any amendments to such prospectus. This prospectus supplement provides supplemental information regarding us and updates certain information contained in the accompanying prospectus and describes the specific terms of this offering. The accompanying prospectus gives more general information, some of which may not apply to this offering. We incorporate important information into this prospectus supplement and the accompanying prospectus by reference.

## ABOUT THIS PROSPECTUS

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part is the accompanying prospectus, which gives more general information about the shares of our common stock and other securities we may offer from time to time under our shelf registration statement, some of which may not apply to the securities offered by this prospectus supplement. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference therein, on the other hand, the information in this prospectus supplement shall control.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreement, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

You should rely only on the information contained or incorporated by reference in this prospectus supplement and contained or incorporated by reference in the accompanying prospectus. We have not authorized anyone, including the placement agent, and the placement agent has not authorized anyone, to provide you with different information. We are offering to sell, and seeking offers to buy, our securities only in jurisdictions where offers and sales are permitted. The information contained or incorporated by reference in this prospectus supplement and contained or incorporated by reference in the accompanying prospectus is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus, or of any sale of our securities offered hereby. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents we have referred you to in “Incorporation of Certain Documents by Reference” in this prospectus supplement and “Where You Can Find More Information” in the accompanying prospectus.

Unless otherwise indicated, “Adeona,” the “Company,” “we,” “us,” “our” and similar terms refer to Adeona Pharmaceuticals, Inc. and its subsidiaries.

This offering of common stock is being made under a registration statement on Form S-3 (Registration File no. 333-166750) that we filed with the Securities and Exchange Commission, or the SEC, as part of a “shelf” registration process and that the SEC declared effective on June 14, 2010. Under the shelf registration process, we may offer to sell shares of our common stock, \$0.001 par value, and warrants to purchase shares of our common stock, and/or units consisting of two or more of any such securities from time to time in one or more offerings up to a total dollar amount of \$15,000,000.

We are not making any representation to you regarding the legality of an investment in the common stock by you under applicable law. You should consult with your own advisors as to the legal, tax, business, financial and related aspect of a purchase of the common stock.

## NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters in this prospectus supplement constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts, included in this prospectus supplement that address activities, events or developments that we expect or anticipate will or may occur in the future, including such matters as our projections, future capital expenditures, business strategy, competitive strengths, goals, expansion, market and industry developments and the growth of our businesses and operations, are forward-looking statements. These statements can be identified by introductory words such as "expects," "anticipates," "plans," "intends," "believes," "will," "estimates," "projects" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Our forward-looking statements address, among other things:

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a failure of our product candidates to be demonstrably safe and effective;

a failure to obtain regulatory approval for our products or to comply with ongoing regulatory requirements;

a lack of acceptance of our product candidates in the marketplace;

a failure by us to become or remain profitable;

an inability by us to obtain the capital necessary to fund our research and development activities; and

a loss of any of our key scientist or management personnel.

Additional factors that could affect future results are set forth below in this prospectus supplement under the caption Risk Factors. We caution investors that the forward-looking statements contained in this prospectus supplement must be interpreted and understood in light of conditions and circumstances that exist as of the date of this prospectus supplement. We expressly disclaim any obligation or undertaking to update or revise forward-looking statements made in this prospectus supplement to reflect any changes in management's expectations resulting from future events or changes in the conditions or circumstances upon which such expectations are based.

Each forward-looking statement should be read in context with, and in understanding of, the various other disclosures concerning our company and our business made elsewhere in this prospectus supplement and accompanying prospectus as well as our public filings with the SEC. You should not place undue reliance on any forward-looking statement as a prediction of actual results or developments. We are not obligated to update or revise any forward-looking statements contained in this prospectus supplement or any other filing to reflect new events or circumstances unless and to the extent required by applicable law.

## SUMMARY

This summary highlights selected information appearing elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus and may not contain all of the information that is important to you. This prospectus supplement and the accompanying prospectus include or incorporate by reference information about the shares we are offering as well as information regarding our business and detailed financial data. You should read this prospectus supplement and the accompanying prospectus in their entirety, including the information incorporated by reference.

### ABOUT ADEONA PHARMACEUTICALS, INC.

In this prospectus supplement, “Adeona Pharmaceuticals,” “Adeona” “we,” “us,” and “our” refer to Adeona Pharmaceuticals, Inc., a Nevada corporation and each of its subsidiaries, considered as a single enterprise.

Adeona Pharmaceuticals, Inc., a Nevada corporation, (“Adeona” or the “Company”) is a pharmaceutical company developing new medicines for serious central nervous systems diseases. Adeona’s primary strategy is to in-license clinical-stage drug candidates that have already demonstrated a certain level of clinical efficacy and develop them further to either commercialization or a development collaboration.

Our executive offices are located at 3930 Varsity Drive, Ann Arbor, Michigan 48108. Our telephone number is (734) 332-7800, fax number is (734) 332-7878. Our website address is [www.adeonapharma.com](http://www.adeonapharma.com). The information on our website is not incorporated by reference into this prospectus supplement.

Trimesta (estriol) is an investigational oral drug for the treatment of relapsing remitting multiple sclerosis. A 150-patient, 16-center, randomized, double-blind, placebo-controlled clinical trial is currently underway. Effirma (flupirtine) is a novel centrally-acting investigational oral drug for the treatment of fibromyalgia syndrome. We recently entered into a sublicense agreement with Meda AB pursuant to which we granted an exclusive license to all of our patents covering the use of flupirtine for fibromyalgia. Zinthionein ZC (zinc cysteine) is an oral, gastro-retentive, sustained-release medical food candidate being developed for the dietary management of Alzheimer’s disease and mild cognitive impairment. In December of 2009, Adeona initiated a 60-patient clinical study. dnaJP1 (hsp peptide) is an investigational oral drug for the treatment of rheumatoid arthritis. It has completed a 160-patient, multi-center, randomized, double-blind, placebo-controlled clinical trial. ZincMonoCysteine (zinc-monocysteine) is an investigational oral drug for the treatment of dry age-related macular degeneration. It has completed an 80-patient, randomized, double-blind, placebo-controlled clinical trial.

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

Program	Medical Indication	Stage of Development
Trimesta (estriol)	Treatment of relapsing remitting multiple sclerosis in women	10-patient, 22-month, single-agent, crossover clinical trial completed, and a 150-patient, 16-center, randomized, double-blind, placebo-controlled clinical trial underway
Effirma (flupirtine)	Treatment of fibromyalgia	IND approved and IRB reviewed for 90-patient clinical trial

Zinithionein ZC (zinc cysteine)	Dietary management of Alzheimer's disease and mild cognitive impairment	60-patient, randomized, double-blind, placebo-controlled clinical study underway
dnaJP1 (hsp peptide)	Treatment of rheumatoid arthritis	160-patient, multi-center, randomized, double-blind, placebo-controlled clinical trial completed
ZincMonoCysteine (zinc-monocysteine)	Treatment of dry age-related macular degeneration	80-patient, randomized, double-blind, placebo-controlled clinical trial completed

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

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In addition, we are seeking United States, European and Asian corporate partners for the further development of the investigational CD4 inhibitor 802-2 (cyclic heptapeptide) for prevention of severe graft-versus-host disease and oral tetrathiomolybdate drug for treating Alzheimer's disease, Parkinson's disease and Huntington's disease.

## Product Candidates

### Trimesta

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

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

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

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

### Clinical Trial Results of Trimesta in Relapsing Remitting Multiple Sclerosis Patients

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

During this clinical trial, a 14-percent improvement in Paced Auditory Serial Addition Test (PASAT) cognitive testing scores ( $p = 0.04$ ) was also observed in the multiple sclerosis patients at six months of therapy. PASAT is a routine cognitive test performed in patients with a wide variety of neuropsychological disorders such as multiple sclerosis. The PASAT scores were expressed as a mean percent change from baseline and were significantly improved in the relapsing-remitting group. The study investigators concluded that a larger, placebo-controlled clinical trial of Trimesta is warranted in women with relapsing remitting multiple sclerosis. In addition, they added that this novel treatment strategy of using Trimesta in multiple sclerosis has relevance to other autoimmune diseases that also improve during pregnancy.

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

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

### Trimesta Grant Funding

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

### Trimesta Market Opportunity

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

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

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

## Effirma

Effirma (flupirtine) is a centrally-acting investigational oral drug for the treatment of fibromyalgia syndrome. It is a selective neuronal potassium channel opener that also has NMDA receptor antagonist properties. Flupirtine is a non-opioid, non-NSAID, non-steroidal, analgesic. Flupirtine was originally developed by Asta Medica and has been approved in Europe since 1984 for the treatment of pain, although it has never been introduced to the United States market for any indication.

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 antinociceptive effects has been observed. One common link between neuroprotection, nociception, and Effirma may be the N-methyl-D-aspartic acid glutamate system, a major receptor subtype for the excitotoxic neurotransmitter, glutamate. Effirma has strong inhibitory actions on N-methyl-D-aspartic acid-mediated neurotransmission.

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#### Effirma Clinical Trial Status

Adeona's scientific collaborator has demonstrated preliminary encouraging evidence of clinical efficacy in a small number of patients treated with Effirma whom were suffering from fibromyalgia refractory to other analgesics and therapies. Effirma was well tolerated by these patients with no untoward side effects. In addition, substantial improvement in signs and symptoms was demonstrated in this difficult-to-treat fibromyalgia patient population. Adeona's scientific collaborator filed an investigator-initiated Investigational New Drug with the Food and Drug Administration to test flupirtine in a clinical trial of 90 fibromyalgia patients. During 2008, this proposed clinical trial and Investigational New Drug was approved by the Food and Drug Administration. Additionally, this protocol has been reviewed by an institutional review board.

#### Effirma Sublicense

In May of 2010, Adeona and its wholly owned subsidiary, Pipex Therapeutics, Inc. ("Pipex") entered into a Sublicense Agreement (the "Agreement") pursuant to which Pipex granted Meda AB ("Meda") an exclusive sublicense to all of its patents covering the use of flupirtine for fibromyalgia. The Agreement provides that the Meda will assume all future development costs for the commercialization of flupirtine for fibromyalgia. As consideration for such sublicense, Pipex received an up-front payment of \$2.5 million upon execution of the Agreement and are entitled to milestone payments of \$5 million upon filing of a New Drug Application with the Food and Drug Administration for flupirtine for fibromyalgia and \$10 million upon marketing approval. The Agreement also provides that Pipex is entitled to receive royalties of 7% of net sales of flupirtine approved for the treatment of fibromyalgia covered by issued patent claims in the Territory. Pursuant to the terms of Pipex's agreement with the company's university licensor, Adeona is obligated to share half of the royalties we receive with the company's university licensor.

#### Effirma Market Opportunity

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 estimates the United States market for fibromyalgia to be near \$1 billion at the time of potential launch of flupirtine.

#### Zinthionein ZC

Zinthionein ZC is an investigational once-daily, gastroretentive, sustained-release, proprietary, oral tablet formulation of zinc and cysteine for the dietary management of Alzheimer's disease and mild cognitive impairment. It is being developed as a prescription medical food. All of Zinthionein ZC's constituents have GRAS (Generally Regarded as Safe) status. Zinthionein ZC was specially invented and developed by Adeona to achieve the convenience of once-daily dosing, high bioavailability and to minimize gastrointestinal side effects of oral zinc therapy. Zinthionein ZC is protected by multiple U.S. and international pending patent applications held by Adeona.

In April of 2010, Adeona announced positive results of Part 1 of its CopperProof-2 clinical study of Zinthionein ZC (zinc cysteine) in Alzheimer's disease and mild cognitive impairment. Adeona's CopperProof-2 clinical study seeks to compare Zinthionein ZC to placebo, as well as a currently marketed prescription zinc product, Galzin® (zinc acetate). The clinical study, "A Prospective, Randomized, Double Blind Trial of a Novel Oral Zinc Cysteine Preparation in Alzheimer's Disease (CopperProof-2)" previously received institutional review board approval to proceed. The principal investigator of the study is Diana Pollock, M.D., Associate Director, Memory Disorder Center, Clearwater,

Florida.

CopperProof-2 is designed as a controlled, 60-patient, randomized, double-blind, placebo-controlled clinical study and is divided into two parts. Part 1, recently completed, is a 13-subject, three-arm, single-dose, comparator study in Alzheimer's disease and mild cognitive impairment subjects that compared the tolerability and bioavailability of Zinthionein ZC to Galzin®, the only Food and Drug Administration-approved zinc preparation and placebo. The Galzin® arm tested two separate individual dose levels, 50 mg and 100 mg zinc acetate (two 50 mg doses taken together). Part 2 of the study has 60 Alzheimer's disease and mild cognitive impairment subjects randomized to receive either once-daily Zinthionein ZC or matching placebo for six months.

## Results

### Tolerability

Results from Part 1 of the study, announced today, demonstrate a substantially lower incidence of adverse effects in Alzheimer's disease and mild cognitive impairment subjects (33% versus 100%) in favor of Zinthionein ZC (containing 150 mg of elemental zinc acetate and 100 mg of

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cysteine) compared to Galzin® (containing either 50 mg or 100 mg of elemental zinc as zinc acetate). 100% of the Galzin® subjects experienced gastrointestinal distress, ranging from 100% nausea to 40% vomiting, 40% diarrhea, and 20% heartburn. The high rate of gastrointestinal adverse effects of Galzin® are consistent with prior published results of oral zinc therapy. In comparison, only 33% of Zinthionein ZC subjects experienced nausea, with only one of such subjects (17% of group) having experienced vomiting. No adverse effects were noted in the placebo group.

Adverse effects for the three groups are as follows:

	Galzin		Galzin		Galzin		Zinthionein ZC			
	Placebo	%	100 mg	%	50 mg	%	All	%	150 mg	%
Any Adverse Effect	(0/2)	0%	(3/3)	100%	(2/2)	100%	(5/5)	100%	(2/6)	33%
Nausea	(0/2)	0%	(3/3)	100%	(2/2)	100%	(5/5)	100%	(2/6)	33%
Vomiting	(0/2)	0%	(1/3)	33%	(1/2)	50%	(2/5)	40%	(1/6)	17%
Diarrhea	(0/2)	0%	(1/3)	33%	(1/2)	50%	(2/5)	40%	(0/6)	0%
Dizziness	(0/2)	0%	(0/3)	0%	(0/2)	0%	(0/5)	0%	(0/6)	0%
Abdominal Pain	(0/2)	0%	(0/3)	0%	(0/2)	0%	(0/5)	0%	(1/6)	17%
Heartburn	(0/2)	0%	(0/3)	0%	(1/2)	50%	(1/5)	20%	(0/6)	0%

#### Bioavailability

Zinthionein ZC also demonstrated superior serum zinc bioavailability in Alzheimer's disease and mild cognitive impairment subjects compared to both the 50 mg and 100 mg dose levels of Galzin®. Average baseline serum zinc levels of the subjects was 76.8 microg/dL (range: 63-92 microg/dL), consistent with Adeona's earlier findings of a subclinical zinc deficiency in Alzheimer's disease patients. The area under the curve (a serum measurement of bioavailability) of Zinthionein ZC was approximately 166% that of the 50 mg Galzin® dose and 116% that of 100 mg Galzin® dose (two 50 mg doses taken together).

The bioavailability results are also supplemented from results of a separate uncontrolled repeat dose pilot study conducted by Adeona in a small number of normal subjects who took Zinthionein ZC once-daily for 14 weeks, also being announced today. Following 14 weeks, subjects demonstrated an average 80% increase in serum zinc levels from baseline measured at least 12 hours after last dose, demonstrating Zinthionein ZC's ability to maintain consistently elevated serum zinc levels. In addition, a 17% reduction in serum copper levels was observed after 14 weeks, demonstrating Zinthionein ZC's ability to favorably improve serum copper/zinc ratios with once-daily dosing.

#### Part 2 of the Clinical Study

Part 2 of the clinical study is intended to enroll 60 Alzheimer's disease and mild cognitive impairment subjects and is currently ongoing with 11 of 13 enrolled subjects from Part 1 electing to continue to Part 2 of the study. In Part 2, subjects are randomized on a 50:50 basis to either Zinthionein ZC or matching placebo. Subjects will be assessed at 3 and 6 months for serum parameters of zinc and copper as well as changes in cognitive function using standard clinical tests used in Alzheimer's disease and mild cognitive impairment. Some subjects have now completed three months of therapy. Adeona recently added two additional clinical sites in Florida to further expedite enrollment and complete Part 2 of the study.

#### Background of Zinc Therapy for Alzheimer's Disease and Mild Cognitive Impairment

The CopperProof-2 study grew out of observations by Adeona and now others documenting a subclinical zinc deficiency in Alzheimer's disease patients as well as a significant body of published evidence implicating chronic copper exposure and elevated free serum copper levels in the progression of Alzheimer's disease and mild cognitive impairment. In 1992, results from an uncontrolled study of zinc therapy in Alzheimer's disease was reported to demonstrate cognitive improvement in 80% of subjects in as little as 3 to 6 months of treatment. Due to the significant gastrointestinal side effects and intolerability of oral zinc therapy in such study, oral zinc therapy was discontinued and subjects were switched to zinc injections administered every other day, further underscoring the need for a better tolerated, convenient oral zinc therapy such as Zinthisonein ZC.

The hippocampus, an area of the brain that plays a critical role in short-term memory and is generally most affected in Alzheimer's disease, is believed to contain the highest levels of zinc in the brain. Hippocampal zinc is believed to play an important dual role as a synaptic neurotransmitter that modulates NMDA (N-methyl-D-aspartic acid) receptor activity limiting excitotoxicity and is a key component of hundreds of neuroprotective enzymes, a number of which are responsible for the degradation of amyloid beta. Alzheimer's disease subjects have been reported to have lower levels of zinc in their cerebral spinal fluid, and cerebral spinal fluid levels of copper and zinc highly correlate

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with levels of amyloid beta 42 in cerebral spinal fluid, a biomarker of Alzheimer's disease. Zinc's role as an important NMDA receptor antagonist implies that by ameliorating the cerebral spinal fluid zinc deficiency in Alzheimer's disease patients, Zinthionein ZC may demonstrate near term acute cognitive benefits, such as those demonstrated in the 1992 study described above, as well as reducing neurodegeneration in the longer term. Current NMDA-receptor antagonists for Alzheimer's disease, such as Namenda® and Axura® (memantine), currently have estimated annualized sales of \$2.6 billion.

#### dnaJP1

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

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

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

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

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

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

Institutes of Health. It sought to test 2 hypotheses 1) whether mucosal induction of immune tolerance to dnaJP1 would lead to a qualitative change from a proinflammatory phenotype to a more tolerogenic functional phenotype and 2) whether immune deviation of responses to an inflammatory epitope might translate into clinical improvement. One hundred sixty patients with active rheumatoid arthritis were randomized to receive oral doses of 25 mg of dnaJP1 or placebo daily for 6 months.

Results of the published study showed the following:

1. dnaJP1 appeared to be safe and well-tolerated;
2. There was a significant reduction in the percentage of T cells producing the proinflammatory cytokine tumor necrosis factor alpha (TNF-alpha) ( $p < 0.0007$ );
3. The primary efficacy end point (meeting the American College of Rheumatology 20% improvement criteria at least once on day 112, 140, or 168) showed a difference between treatment groups ( $p = 0.09$ ) that became significant in post hoc analysis using generalized estimating equations (GEE) ( $p = 0.04$ ).

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

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

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

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

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

#### dnaJP1 Market Opportunity

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

#### ZincMonoCysteine

ZincMonoCysteine (zinc-monocysteine) is an investigational oral drug for the treatment of dry age-related macular degeneration. It is a complex of zinc and the amino acid cysteine that Adeona believes may have improved properties compared to currently marketed zinc-based products. ZincMonoCysteine was invented and developed by David A.

Newsome, M.D., former Chief of the Retinal Disease Section of the National Eye Institute. Dr. Newsome was the first to pioneer and demonstrate the benefits of oral high dose zinc therapy in dry age-related macular degeneration. Oral high dose zinc containing products now represent the standard of care for dry age-related macular degeneration affecting over 10 million Americans and have annual sales of approximately \$300 million.

ZincMonoCysteine has completed an 80-patient, randomized, double-blind, placebo-controlled clinical trial in dry age-related macular degeneration and demonstrated highly statistically significant improvements in central retinal function. These results were published in a peer-reviewed journal in 2008. Adeona believes that the patent-pending, modified-release formulations of ZincMonoCysteine and may offer the significant advantages of convenient once-a-day dosing and improved gastrointestinal tolerability compared to currently-marketed oral high dose zinc-containing products. During the third quarter of 2009, Adeona did further manufacturing and scale up of ZincMonoCysteine to support the further nonclinical testing and cGMP manufacturing required to support further drug development.

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### Copper and Zinc Metabolism Clinical Diagnostic Test

During the first quarter of 2009, Adeona analyzed patient samples from an institutional review board-approved, prospective, observational, blinded clinical study that was sponsored and conducted during 2007 and 2008. The study enrolled 90 subjects, 30 with Alzheimer's disease, 30 with Parkinson's disease and 30 age-matched normal subjects. The purpose of the study was to evaluate serum markers of copper status and compare these results across the three groups of patients. The results of the study indicate highly statistically significant differences in serum markers of copper status between Alzheimer's disease and normal subjects. Adeona believes that the differences observed suggest that Alzheimer's patients have impaired metabolic functioning that decreases their protection from chronic copper toxicity, which may contribute to the progression of their disease. The results from this study also appear to indicate a subclinical zinc deficiency in Alzheimer's disease patients. In July of 2009, Adeona announced the presentation of the findings from this study at the 2009 International Conference on Alzheimer's disease. There is an estimated 5.8 million, 1.5 million and 15 million persons in the United States with Alzheimer's disease, Parkinson's disease and mild cognitive impairment, respectively, that may benefit from Adeona's panel of clinical diagnostic tests.

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

In November of 2009, Adeona announced the launch of the HartLab subsidiary's diagnostic test panel, the CopperProof™ Panel, for the evaluation of zinc and copper status in patients with Alzheimer's disease and mild cognitive impairment. The CopperProof™ Panel provides a comprehensive analysis of the metabolic serum copper and zinc status of Alzheimer's disease and mild cognitive impairment patients, the status of which has been shown to be impaired in this patient population. Defects in copper metabolism and high free copper levels are increasingly being recognized as significant factors in the progression of neurodegenerative diseases, including Alzheimer's disease and mild cognitive impairment. Adeona believes that this panel will allow physicians to determine the copper and zinc metabolic status of these patients as an aid in their continued treatment program.

### Intellectual Property

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

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

### McLean Hospital Exclusive License Agreement

In 2005, as amended in 2007 and 2010, Pipex, Adeona's wholly owned subsidiary, entered into an exclusive license agreement with the McLean Hospital, a Harvard University hospital, relating to U.S. Patent No. 6,610,324 and its foreign equivalents, entitled "Flupirtine in the treatment of fibromyalgia and related conditions." Pursuant to this agreement, 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 flupirtine equal to 3.5% of net sales of flupirtine for indications covered by the issued patents, reduced to 1.75% if Pipex has a license to other intellectual property covering those indications; use Pipex's best efforts to commercialize flupirtine for the therapeutic uses embodied in the patent applications; reimburse future patent costs and pay the following milestone payments: \$150,000 upon the initiation of a pivotal phase 3 clinical trial of flupirtine; \$300,000 upon the filing of a New Drug Application for flupirtine; and \$600,000 upon Food and Drug

Administration approval of flupirtine. The due diligence requirements of the exclusive license agreement were amended in April 2010 and further amended by a Non-Disturbance Agreement that was signed with Pipex, McLean Hospital and Meda.

Effective May 6, 2010, Pipex and Adeona entered into a Sublicense Agreement (the "Agreement") with Meda AB of Sweden. Pursuant to the Agreement, Meda has been granted an exclusive sublicense to all of Pipex's patents covering the use of flupirtine for fibromyalgia. These patents have been issued in the U.S. and are pending in Canada and Japan (the "Territory"). The Agreement provides that Meda will assume all future development costs for the commercialization of flupirtine for fibromyalgia. As consideration for such sublicense, Pipex received an up-front payment of \$2.5 million upon execution of the Agreement and are entitled to milestone payments of \$5 million upon filing of a New Drug Application with the Food and Drug Administration for flupirtine for fibromyalgia and \$10 million upon marketing approval. The Agreement also provides that Pipex is entitled to receive royalties of 7% of net sales of flupirtine approved for the treatment of fibromyalgia covered by issued patent claims in the Territory. Pursuant to the terms of Pipex's agreement with the company's university licensor, Pipex is obligated to share half of the royalties it receives with the university licensor and Pipex is obligated to pay them \$375,000 upon receipt of an upfront payment.

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#### Thomas Jefferson University License Agreement

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

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

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

#### Zinc Monocysteine License Agreement

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

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

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

## THE OFFERING

Common stock we are offering	1,212,121 shares
Common stock to be outstanding after this offering	22,960,226 shares
Placement Agent Warrants	At the closing, we will issue the placement agent a warrant to purchase 60,606 shares of common stock as compensation for its services in connection with this offering. The number of shares underlying the Placement Agent Warrant will be equal to 5% of the sum of the number of shares purchased by the investor at the closing. The exercise price per share will be equal to \$1.32. The Placement Agent Warrant will be exercisable commencing 183 days after its issue date until the fifth anniversary of the effective date of our shelf registration statement.
Use of proceeds	Working capital and/or general corporate purposes.
American Stock Exchange Symbol	AEN
Risk Factors	This investment involves a high degree of risk. See “Risk Factors” and other information included or incorporated into this prospectus supplement and the accompanying prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities.

The number of shares of common stock shown above to be outstanding after this offering is based on the 21,748,105 shares outstanding as of June 30, 2010 and assumes the sale of all Shares. Unless otherwise indicated, the number of shares of common stock presented in this prospectus supplement excludes (i) 2,556,176 shares of our common stock that, as of the date of this prospectus supplement, are issuable upon the exercise of outstanding options under our stock plans and (ii) 1,070,472 shares of our common stock that, as of the date of this prospectus supplement, are issuable upon the exercise of outstanding warrants other than those covered by this prospectus supplement. Unless otherwise indicated, this prospectus supplement assumes the sale of the maximum number of common shares offered hereunder.

## 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 prospectus supplement, the accompanying prospectus and the other information included and incorporated by reference in this prospectus supplement and accompanying prospectus, 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 are a development stage company. We currently have very minimal product revenues and will need to raise additional capital to operate our business.

We are a development stage company that has experienced significant losses since inception and has a significant accumulated deficit. We expect to incur additional operating losses in the future and expect our cumulative losses to increase. To date, we have generated very minimal product revenues. As of March 31, 2010, we have expended approximately \$29.7 million on a consolidated basis acquiring and developing our current product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our drugs and will not have product revenues. Therefore, for the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees, and grants. If the upfront licensing fee we recently received is not sufficient to sustain our operations, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts, and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We are not currently profitable and may never become profitable.

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

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

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

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

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

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

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

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

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

neurodegenerative diseases.

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

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

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

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

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

reliance on our HartLab operations, which are subject to routine governmental oversight and inspections for continued operation pursuant to CLIA and other regulations;

our ability to establish and maintain adequate infrastructure to support the commercial launch and sale of our diagnostic tests through our HartLab subsidiary, including establishing adequate laboratory space, information technology infrastructure, sample collection and tracking systems and electronic ordering and reporting systems and other infrastructure and hiring adequate laboratory and other personnel;

the availability of adequate study samples for validation studies for any diagnostic tests we develop, the success of such validation studies and our ability to publish study results in peer-reviewed journals;

the availability of alternative and competing tests or products and technological innovations or other advances in medicine that cause our technologies to be less competitive;

compliance with federal, state and foreign regulations governing laboratory testing and the sale and marketing of diagnostic or other tests, including copper and zinc; status tests;

the accuracy rates of such tests, including rates of false-negatives and/or false-positives;

concerns regarding the safety or effectiveness or clinical utility of our tests;

changes in the regulatory environment affecting health care and health care providers, including changes in laws regulating laboratory testing and/or device manufacturers and any laws regulating diagnostic testing;

the extent and success of our sales and marketing efforts and ability to drive adoption of our diagnostic tests;

coverage and reimbursement levels by government payors and private insurers;

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

pricing pressures and changes in third-party payor reimbursement policies;

general changes or developments in the market for Alzheimer's disease diagnostics or diagnostics in general;

ethical and legal issues concerning the appropriate use of the information resulting from Alzheimer's disease diagnostic tests or other tests;

our ability to promote and protect our products and technology; and

intellectual property rights held by others or others infringing our intellectual property rights.

We have experienced several management changes.

We have had significant changes in management in the past two years. Effective July 1, 2008, Charles L. Bisgaier resigned as our President and Corporate Secretary and as a director of our Company. Also effective on July 1, 2008, Steve H. Kanzer resigned as our Chief Executive Officer (although he did remain as our Chairman of the Board). Effective July 1, 2008, Nicholas Stergis was appointed our Chief Executive Officer; however effective March 29, 2009, Mr. Stergis resigned his position, but remained a director of the Company until August 20, 2009.

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

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

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

As a clinical laboratory HartLab 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. HartLab is also subject to regulation of laboratory operations under state clinical laboratory laws. State clinical laboratory laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. Certain states, including Maryland, New York, Pennsylvania and Rhode Island, each require that you obtain licenses to test specimens from patients residing in those states and additional states may require similar licenses in the future. If we are unable to obtain licenses from these states or there is delay in obtaining such licenses, we will not be able to process any samples from patients located in those states until we have obtained the requisite licenses. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could adversely affect our business and results of operations.

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

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

approvals to commence such studies may delay our initiation of such planned additional studies.

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

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

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

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

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

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

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

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

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

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

In addition to our own patent applications, we also currently rely on licensing agreements with third party patent holders/licensors for our products. We have an exclusive license agreement with the McLean Hospital relating to the use of flupirtine to treat fibromyalgia syndrome which was recently sublicensed to Meda; an exclusive license agreement with Thomas Jefferson University relating to our CD4 inhibitor program; an exclusive license agreement with the Regents of the University of California relating to our Trimesta technology; an exclusive license to our oral immunotherapeutic tolerance program, named dnaJP1 from University of California San Diego (UCSD) and an



exclusive license agreement with Dr. Newsome and Mr. Tate relating to zinc-monocysteine. Each of these agreements requires us or our sublicensee to use our best efforts to commercialize each of the technologies as well as meet certain diligence requirements and timelines in order to keep the license agreement in effect. In the event we or our sublicensee are not able to meet our diligence requirements, we may not be able to retain the rights granted under our agreements or renegotiate our arrangement with these institutions on reasonable terms, or at all. In addition, our agreement with UCSD requires our Epitope subsidiary to expend at least \$400,000 on the development of oral dnaJP1 for the period comprising July 1, 2009, through June 30, 2010, and secure access to \$2.5 million in funds on or before June 30, 2010, in order to maintain this license agreement in effect as well as to make other payments. Our license agreement with the University of Michigan relating to tetrathiomolybdate requires that we manufacture cGMP material and support the filing of an investigational new drug application (IND) with the FDA on or before the first half of 2010 in order to maintain this license agreement in effect. If we fail to meet these milestones we could lose such licenses.

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

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

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

Companies that currently sell or are developing both generic and proprietary pharmaceutical compounds to treat central-nervous-system and autoimmune diseases include: Pfizer, Inc., Rigil Pharmaceuticals, Incyte Pharmaceuticals, Chelsea Therapeutics International, Inc., Aton Pharma, GlaxoSmithKline Pharmaceuticals, Alcon, Inc., Shire Pharmaceuticals, Plc., Schering-Plough, Organon NV, Merck & Co., Eli Lilly & Co., Serono, SA, Biogen Idec, Inc., Achillion, Ltd., Active Biotech, Inc., Panteri Biosciences, Meda, Merrimack Pharmaceuticals, Inc., Merck-Schering AG, Forest Laboratories, Inc., Attenuon, LLC, Cypress Biosciences, Inc., Genentech, Neurotech, Amgen, Inc., Centocor/Johnson and Johnson, UCB Group, Abbott, Wyeth, OM Pharma, Cel-Sci Pharmaceuticals, Novartis, Axcan Pharma, Inc., Teva Pharmaceuticals, Inc., Intermune, Inc. Fibrogen, Inc., Active Biotech, CNSBio, Pty., Rare Disease Therapeutics, Inc., Prana Biotechnology, Inc., Merz & Co., AstraZeneca Pharmaceuticals, Inc., Chiesi Pharmaceuticals, Inc., Alcon, Inc., Bausch and Lomb, Inc., Targacept, Inc., and Johnson & Johnson, Inc. Alternative technologies or alternative delivery or dosages of already approved therapies are being developed to treat dry AMD, autoimmune inflammatory, rheumatoid arthritis, psoriasis, Fibromyalgia, MS, Huntington's, Alzheimer's and Wilson's diseases, several of which may be approved or are in early and advanced clinical trials, such as zinc based combinations, Syk inhibitors, Jak inhibitors, connective tissue growth factors (CTGF), FTY-720, Laquinimod, pirfenidone, milnacipram, Lyrica, anti-depressant combinations, Rituxan, Enbrel, Cimzia, Humira, Remicade, Cymbalta, Effexor, Actimmune and other interferon preparations. Unlike us, many of our competitors have significant financial and human resources. In addition, academic research centers may develop technologies that compete with our Trimesta, ZincMonoCysteine, Zinthionein ZC gastro-retentive sustained release oral high dose zinc preparations, oral dnaJP1, CD4 inhibitors and flupirtine technologies. Should clinicians or regulatory authorities view these therapeutic regimens as more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid and private insurers. No assurance can be given that our current clinical trial of once daily Zinthionein ZC for the dietary management of Alzheimer's and mild cognitive impairment will achieve superior or sufficient tolerability compared to existing zinc-based oral products in order to confer a significant competitive market advantage for this product.

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

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

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

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

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

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

Our competitiveness may be adversely affected if we are unable to protect our proprietary technologies. Other than our CD4 inhibitor, oral dnaJP1 and ZincMonoCysteine program, we do not have composition of matter patents for Trimesta, flupirtine, oral TTM or their respective active ingredients estriol, flupirtine, and ammonium tetrathiomolybdate. We also expect to rely on patent protection from an issued U.S. Patent for the use of oral TTM and related compounds to treat Alzheimer's disease (U.S. Patent No 7,416,741). These patents have been exclusively licensed to us. We have also filed various pending patent applications which cover various formulations, packaging, distribution & monitoring methods for oral TTM. We rely on issued patent and pending patent applications for use of Trimesta to treat multiple sclerosis (issued U.S. Patent No. 6,936,599) and various other therapeutic indications which have been exclusively licensed to us. We have exclusively licensed issued U.S. Patent No. 5,773,570, 6,153,200, 6,946,132, 6,989,146, 7,094,597, 7,301,005, including foreign equivalents along with several patent applications which cover dnaJP1, related compositions methods and uses; we have also exclusively licensed an issued patent for the treatment of fibromyalgia with flupirtine, which we have sublicensed to Meda.

Our ZincMonoCysteine product candidate is exclusively licensed from its inventors, David A. Newsome, M.D., and David Tate, Jr. ZincMonoCysteine is the subject of two issued U.S. patents, 7,164,035 and 6,586,611 and pending U.S. patent application ser. no. 11/621,380 which cover composition of matter claims. In our annual report on Form 10-KSB for the year ending December 31, 2007 that was filed March 31, 2008 (page 23), we described our receipt in March 2008 (and potential impact on claim 1 of our exclusively licensed issued U.S. patent 7,164,035) of an English translation of a Russian disclosure, Zegzhda et. al. Chemical Abstracts Vol. 85 Abstract No. 186052 (1976) that was cited by the U.S. patent examiner during our prosecution of the pending divisional U.S. patent application Ser. No. 11/621,390. In April 2008, we analyzed the zinc-cysteine complex described by Zegzhda and concluded that such complex describes an insoluble zinc salt and does not describe a non-zinc salt zinc monocysteine complex and therefore believe that such disclosure should not affect the validity of any of our issued U.S. patent claims relating our

zinc-monocysteine composition-of-matter claims. We have filed a response and declaration describing the results of our analysis with the U.S. Patent and Trademark Office with respect to the Zegzhda reference with respect to U.S. patent application ser. no. 11/621,380. In an office action dated August 20, 2008, the U.S. patent examiner did not accept our arguments filed May 23, 2008 in connection with the Zegzhda reference under pending divisional application ser. no. 11/621,390, to which we intend to respond. Public copies of relevant and future communications can be obtained using the electronic PAIR system of the U.S. Patent and Trademark Office.

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

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

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

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

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

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

As of June 30, 2010, we have 11 full-time employees. We have also engaged regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. Our future performance will depend in part on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management.

Effective March 29, 2009, Nicholas Stergis resigned as our Chief Executive Officer and effective August 20, 2009 he resigned as a director. Steve H. Kanzer was appointed our President and Chief Executive Officer. Effective June 26, 2009, Steve H. Kanzer resigned as our President and Chief Executive Officer upon the appointment of Max Lyon as President and Chief Executive Officer. Effective February 6, 2010, James S. Kuo, M.D., M.B.A. was appointed our Chairman of the Board, Chief Executive Officer and President and Max Lyon resigned as Chief Executive Officer and President.

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

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

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

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

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

In order to successfully commercialize our product candidates, we 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, manufacture of zinc-monocysteine, dnaJP1, flupirtine, and TTM is a complex process that can be difficult to scale up for purposes of producing large quantities. This process can also be subject to delays, inefficiencies, and poor or low yields of quality products. Furthermore, zinc-monocysteine has been difficult to scale up at larger quantities. As such, we can give no assurances that we will be able to scale up the manufacturing of zinc-monocysteine.

Oral TTM is also known to be subject to a loss of potency as a result of prolonged exposure to moisture and other normal atmospheric conditions. The active ingredient of our dnaJP1 program is a peptide. Traditionally, peptide manufacturing is costly, time consuming, resulting in low yields and poor stability. We cannot give any assurances that we will not encounter this issue when scaling up manufacturing for dnaJP1. We are developing proprietary formulations and specialty packaging solutions to overcome this stability issue, but we can give no assurances that we will be successful in meeting the stability requirements required for approval by regulatory authorities such as the FDA or the requirements that our new proprietary formulations and drug product will demonstrate satisfactory comparability to less stable formulations utilized in prior clinical trials. We may experience delays in demonstrating satisfactory stability requirements and drug product comparability requirements that could delay our planned clinical trials of for any of our products.

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

Our plans to launch oral Zinthionein ZC as prescription medical food for the dietary management zinc deficiency in Alzheimer's disease and Mild Cognitive Impairment (MCI) will depend upon the successful cGMP manufacture, quality control and acceptable results of stability studies to be performed for Zinthionein ZC for which we are utilizing and intend to engage third party contract manufacturers and analytic testing services, as well as the successful completion and results of the first part of our CopperProof-2 clinical trial to be conducted at Clearwater, Florida. We are currently experiencing delays from our outside cGMP manufacturer and packager of Zinthionein ZC, which delays our plans to launch this product as a prescription medical food. We are currently unsure when and if these delays will be resolved and are in the process of evaluating alternative manufacturers.

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

candidate and might delay development of other product candidates. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Any delay in, or termination of, our clinical trials would delay our obtaining FDA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

Physicians and patients may not accept and use our technologies.

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

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

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

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

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

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

clinical studies of oral TTM. Our license agreement with University of Michigan requires that we obtain an IND to conduct a clinical trial with oral TTM before July 2010 in order to maintain our license agreement. Since we do not currently plan on filing such an IND for oral TTM, unless circumstances change, our license agreement may become subject to termination in July of this year. Should we or a future sublicensee elect to seek to conduct additional clinical trials of oral TTM, we or such sublicensee as the case may be would be expected to be required to file a new IND with the FDA for oral TTM and gain FDA approval for such IND prior to initiating any clinical studies and would be subject to the risks and potential delays associated with obtaining such approval. Any delay or inability to obtain any data, and any such regulatory issues, might result our inability to advance our products through the regulatory process or obtain pharmaceutical partners for them.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### RISKS RELATING TO OUR STOCK

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

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

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



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

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

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

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became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give stockholders any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

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

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

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

We cannot assure you that we will be able to maintain the listing standards of the NYSE Amex formerly the American Stock Exchange or NYSE Alternext US. The NYSE Amex requires companies to meet certain continued listing criteria including certain minimum stockholders' equity and equity prices per share as outlined in the Exchange Company Guide. We may not be able to maintain such minimum stockholders' equity or prices per share or may be required to affect a reverse stock split to maintain such minimum prices and/or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSE Amex. If we are delisted from the Exchange then our common stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our common stock could further depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the Exchange could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities. Currently, in order to remain listed on NYSE Amex, we were required to maintain a minimum stockholders' equity of \$4 million.

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

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

We have never paid dividends.

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

## RISKS RELATED TO OUR INDUSTRY

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

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

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The U.S. Dietary Supplement Health and Education Act of 1994, or DSHEA, revised the provisions of the Federal Food, Drug and Cosmetic Act, or FFDCFA, 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 FFDCFA. Internationally, the majority of products marketed by us are classified as foods or food supplements.

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

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

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

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

Some of the products marketed by us are considered conventional foods and are currently labeled as such. Within the United States, this category of products is subject to the Nutrition, Labeling and Education Act, or NLEA, and regulations promulgated under the NLEA. The NLEA regulates health claims, ingredient labeling and nutrient content claims characterizing the level of a nutrient in the product. The ingredients added to conventional foods must either be

generally recognized as safe by experts, or GRAS, or be approved as food additives under FDA regulations. Our zinc-monocysteine complexes are comprised of zinc (a GRAS ingredient) and cysteine (an amino acid that also has GRAS status). While many chelated zinc products are currently on the market and are generally not considered new dietary ingredients, we cannot provide any assurance that zinc-monocysteine will be similarly considered by the FDA.

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

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

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

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

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

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

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

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

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

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

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

We cannot be certain that we will successfully complete phase I, phase II, or phase III testing of our product candidates within any specific time period, if at all. Furthermore, the FDA, an IRB or the IND sponsor may suspend clinical trials at any time on various grounds, including a finding that subjects or patients are exposed to unacceptable

health risk. Concurrent with these trials and studies, we also develop chemistry and physical characteristics data and finalize a manufacturing process in accordance with good manufacturing practice (“GMP”) requirements. The manufacturing process must conform to consistency and quality standards, and we must develop methods for testing the quality, purity, and potency of the final products. Appropriate packaging is selected and tested, and chemistry stability studies are conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life. Results of the foregoing are submitted to the FDA as part of a NDA for marketing and commercial shipment approval. The FDA reviews each NDA submitted and may request additional information.

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

In the U.S., the E.U. and elsewhere, pharmaceutical sales are dependent in part on the availability and adequacy of reimbursement from third party payers such as governments and private insurance plans. Third party payers are increasingly challenging established prices, and new products that are more expensive than existing treatments may

have difficulty finding ready acceptance unless there is a clear therapeutic benefit.

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

The E.U. generally provides options for member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement. Member states can opt for a "positive" or "negative" list, with the former listing all covered medicinal products and the latter designating those excluded from coverage. The E.U., the U.K. and Spain have negative lists, while France uses a positive list. Canadian provinces establish their own reimbursement measures. In some countries, products may also be subject to clinical and cost effectiveness reviews by health technology assessment bodies. Negative determinations in relation to our products could affect prescribing practices. In the U.K., the National Institute for Clinical Excellence ("NICE") provides such guidance to the National Health Service, and

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doctors are expected to take it into account when choosing drugs to prescribe. Health authorities may withhold funding from drugs not given a positive recommendation by NICE. A negative determination by NICE may mean fewer prescriptions. Although NICE considers drugs with orphan status, there is a degree of tension on the application of standard cost assessment for orphan drugs, which are often priced higher to compensate for a limited market. It is unclear whether NICE will adopt a more relaxed approach toward the assessment of orphan drugs.

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

We could be subject to challenges under fraud and abuse laws

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

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

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

The law also restores a portion of a product’s patent term that is lost during clinical development and NDA review, and provides statutory protection, known as exclusivity, against FDA approval or acceptance of certain competitor

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

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

## USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of common shares to be offered by this prospectus supplement will be approximately \$870,000, after deducting the estimated expenses of the closing. Unless otherwise indicated, we intend to use the net proceeds from this offering for working capital and/or general corporate purposes, including to continue clinical trials, develop and commercialize products and general and administrative expenses.

Until we use the net proceeds of this offering for the above purposes, we intend to invest the funds in short-term, investment grade, interest-bearing securities. We cannot predict whether the proceeds invested will yield a favorable return. We have not yet determined the amount or timing of the expenditures for the categories listed above, and these expenditures may vary significantly depending on a variety of factors. As a result, we will retain broad discretion over the use of the net proceeds from this offering.

## DIVIDEND POLICY

We have not paid dividends on our common stock in the past and have no present intention of paying dividends in the foreseeable future.

## DESCRIPTION OF CAPITAL STOCK

In this offering, we are offering 1,212,121 shares of our common stock. We are also issuing a warrant to purchase up to 60,606 shares of common stock as compensation to the placement agent for its services in connection with the offering. The following description of certain terms of our capital stock does not purport to be complete and is qualified in its entirety by reference to our Articles of Incorporation, our bylaws and provision of the Nevada Revised Statute. For more information on how you can obtain our Articles of Incorporation and bylaws, see "Where You Can Find more Information." We urge you to read our Articles of Incorporation and bylaws in their entirety.

### Authorized Capital Stock

We are authorized to issue 100 million shares of common stock, par value \$.001 per share, and 10 million shares of preferred stock, par value \$.001 per share. At June 30, 2010, we had 21,748,105 shares of common stock outstanding and no shares of preferred stock outstanding. Although our board of directors has no present intention to do so, it could issue common stock or a series of preferred stock that could, depending on the terms of such securities, impede the completion of a merger, tender offer or take-over attempt. Our board of directors will make any determination to issue such shares based upon its judgment and the best interests of us and our shareholders.

### Common Stock

Our common stock currently trades on the NYSE AMEX under the symbol "AEN." Holders of shares of common stock have the right to cast one vote for each share of common stock in their name on the books of our company, whether represented in person or by proxy, on all matters submitted to a vote of holders of common stock, including election of directors. There is no right to cumulative voting in election of directors. Except where a greater requirement is provided by statute, by our Articles of Incorporation, or by our bylaws, the presence, in person or by proxy duly authorized, of the one or more holders of a majority of the outstanding shares of our common stock constitutes a quorum for the transaction of business. The vote by the holders of a majority of outstanding shares is required to effect certain fundamental corporate changes such as liquidation, merger, or amendment of our Articles of Incorporation.

Except as otherwise provided by the Nevada Revised Statute or our Articles of Incorporation, holders of our common stock share ratably in all dividends and distributions, as may be declared from time to time by our board of directors

from funds legally available therefore, whether upon liquidation or distribution or otherwise. There are no restrictions in our Articles of Incorporation or bylaws that prevent us from declaring dividends. The Nevada Revised Statute does, however, prohibit us from declaring dividends where, after giving effect to the distribution of the dividend (1) we would not be able to pay our debts as they become due in the usual course of business or (2) our total assets would be less than the sum of our total liabilities plus the amount that would be needed to satisfy the rights of stockholders who have preferential rights superior to those receiving the distribution.

We have not declared any dividends, and we do not plan to declare any dividends in the foreseeable future.

Holders of shares of our common stock are not entitled to preemptive or subscription or conversion rights, and no redemption or sinking fund provisions are applicable to our common stock. All outstanding shares of common stock are, and the shares of common stock sold in this offering will be when issued, fully paid and non-assessable.

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#### Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Corporate Stock Transfer, Inc. of Denver, Colorado.

#### Listing

Our common stock is listed on the American Stock Exchange under the symbol "AEN."

#### Placement Agent Warrants

The material terms and provisions of the Placement Agent Warrant being offered pursuant to this prospectus supplement and the accompanying prospectus are summarized below. The summary is subject to, and qualified in its entirety by, the form of Placement Agent Warrant, which will be provided to the investors in this offering and filed as an exhibit to a Current Report on Form 8-K.

The Placement Agent Warrant will provide for an exercise price of \$1.32 per share and will be exercisable at the option of the holder for a period of five years commencing 183 days after the issue date of the Placement Agent Warrant.

The exercise price of the Placement Agent Warrant will be subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The holder will not have the right to exercise any portion of the warrant if the holder, together with its affiliates, would, subject to limited exceptions, beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after the exercise. The holder may elect to waive this beneficial ownership limitation upon 60 days' prior written notice to us.

The holder may surrender payment in cash of the exercise price of the shares being acquired upon exercise of the Placement Agent Warrant. The Placement Agent Warrant may also be exercised on a "net" or "cashless" basis.

The Placement Agent Warrant shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 183 days immediately following the date of effectiveness or commencement of sales of the public offering, except as provided by FINRA Rules.

#### PLAN OF DISTRIBUTION

Pursuant to a letter agreement between us and Enclave Capital LLC ("Enclave"), we have retained Enclave to act as our placement agent in connection with this offering. The placement agent is not purchasing or selling any of the securities we are offering and is not required to arrange the purchase or sale of any specific number of securities or dollar amount, but Enclave has agreed to use best efforts to arrange for the sale of the securities. The placement agency agreement does not give rise to any commitment by the placement agent to purchase any of our securities, and the placement agent will have no authority to bind us by virtue of the placement agency agreement.

We have agreed to pay Enclave a cash fee representing 7% of the gross purchase price paid for the Shares at the closing for an aggregate of \$70,000. In addition, at the closing, we will issue Enclave, or its permitted assigns, a five-year warrant to purchase shares of our common stock representing 5% of the sum of the number of Shares issued at such closing. The Placement Agent Warrant issued in connection with the closing on July 2, 2010 will have an exercise price equal to \$1.32, will be exercisable at the option of the holder commencing 183 days after its issue date until the fifth anniversary of the effective date of our shelf registration statement in accordance with FINRA Rule 5110(f)(2)(H)(i), and will otherwise comply with the rules of FINRA.



In compliance with the guidelines of FINRA, the maximum consideration or discount to be received by the placement agent or any other FINRA member may not exceed 8% of the gross proceeds to us in this offering or any other offering in the United States.

We have agreed to indemnify and hold harmless Enclave against certain liabilities in connection with the sale of our common stock under the Agreement.

The placement agency agreement with Enclave will be included as an exhibit to a Current Report on Form 8-K that we will file with the SEC and that will be incorporated by reference into the registration statement.

On July 2, 2010, we entered into a Common Stock Purchase Agreement, or Agreement, with Seaside 88, LP, or Seaside. The Agreement requires us to issue and Seaside to buy 1,212,121 shares of our common. The Shares will be sold at a price of \$.825 per share which represents a 25% discount from the closing sale price of our common stock on June 30, 2010. We will deliver the Shares to be issued to Seaside upon receipt of funds for the purchase of the Shares offered pursuant to this prospectus supplement. We expect to deliver the Shares being offered pursuant to this prospectus supplement on July 2, 2010.

The Agreement contains representations and warranties and covenants for each party, which must be true and have been performed at the closing. Seaside has agreed not to engage in short sales of our common stock during the term of the Agreement. We have agreed to indemnify and hold harmless Seaside against certain liabilities in connection with the sale of our common stock under the Agreement.

At the closing under the Agreement on July 2, 2010, we will reimburse Seaside \$18,000 for fees and expenses of its counsel.

This is a brief summary of the material provisions of the Agreement and does not purport to be a complete statement of its terms and conditions. A copy of the Agreement will be filed with the SEC and incorporated by reference into the registration statement of which this prospectus supplement forms a part. See “Where You Can Find More Information” below.

Seaside may sell the securities being offered hereby in one or more of the following methods from time to time:

through ordinary brokerage transactions and transactions in which the broker solicits purchasers;

directly to investors in privately negotiated transactions;

to a broker or dealer, including sales to a broker or dealer as principal and resale by such broker or dealer for its own account pursuant to this prospectus supplement and the accompanying prospectus;

through a block trade, which may involve crosses, in which the broker or dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;

through agents to the public or to investors;

to underwriters for resale to the public or to investors; or

through a combination of any of these methods of sale.

The securities may be sold from time to time in one or more transactions at:

fixed prices, which may be changed;

the prevailing market price at the time of sale;

varying prices determined at the time of sale; or

at negotiated prices.

Sales may be effected in transactions:

on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, including the NYSE AMEX;

in the over-the-counter market; or

any other method permitted pursuant to applicable law.

Seaside also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that the criteria and requirements of that rule have been satisfied.

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Seaside might be, and any broker-dealers that act in connection with the sale of securities may be, deemed to be “underwriters” within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by such broker-dealers and any profit on the resale of the securities sold by them while acting as principals may be deemed to be underwriting discounts or commissions under the Securities Act.

The estimated offering expenses payable by us, in addition to the placement agent fees, are approximately \$60,000, which includes legal, accounting and printing costs and various other fees associated with registering and listing the common stock. After deducting certain fees due to the placement agent and our estimated offering expenses, we expect the net proceeds from this offering to be approximately \$870,000.

#### LEGAL MATTERS

Certain legal matters pertaining to the validity of the securities being offered hereby will be passed on by Gracin & Marlow, LLP, 450 Lexington Avenue, 26th Floor, New York, New York 10174.

#### EXPERTS

The audited financial statements for the fiscal years ended December 31, 2009 and 2008 incorporated in this prospectus supplement, the accompanying prospectus and elsewhere in the registration statement by reference to the Annual Report on Form 10-K for the year ended December 31, 2009 have been audited by Berman & Company, P.A., an independent registered public accounting firm as stated in their report which is incorporated herein by reference.

#### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file at the Commission’s public reference room located at 100 F Street N.E., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the operation of the public reference room. Our public filings are also available to the public at the Commission’s web site at <http://www.sec.gov>.

This prospectus supplement is part of a registration statement on Form S-3 that we have filed with the Commission under the Securities Act. This prospectus supplement does not contain all of the information in the registration statement. We have omitted certain parts of the registration statement, as permitted by the rules and regulations of the Commission. You may inspect and copy the registration statement, including exhibits, at the Commission’s public reference room or Internet site.

#### INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The Commission allows us to “incorporate by reference” the information we file with it which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus supplement. The information incorporated by reference is considered to be part of this prospectus supplement, and later information that we file with the Commission will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the Commission under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus supplement and the termination of the offering:

Our annual report on Form 10-K for the fiscal year ended December 31, 2009.

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The description of our common stock set forth in our registration statement on Form 8-A, filed with the Commission on January 29, 1993 (File No. 000-21156).

Our Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2010.

Our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 9, 2010.

Our Current Report on Form 8-K filed with the Securities and Exchange Commission on March 16, 2010.

Our Current Report on Form 8-K/A filed with the Securities and Exchange Commission on March 31, 2010.

Our Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2010.

Our Current Report on Form 8-K filed with the Securities and Exchange Commission on May 11, 2010.

Our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 17, 2010.

Our Current Report on Form 8-K filed with the Securities and Exchange Commission on June 3, 2010.

You may obtain, free of charge, a copy of any of these documents (other than exhibits to these documents unless the exhibits are specifically incorporated by reference into these documents or referred to in this prospectus) by writing or calling us at the following address and telephone number:

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ADEONA PHARMACEUTICALS, INC.  
3930 Varsity Drive  
Ann Arbor, MI 48108  
Attention: Corporate Secretary  
(734) 332-7800

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PROSPECTUS

\$ \_\_\_\_\_  
Common Stock  
Warrants  
Units

We may offer and sell, from time to time, shares of our common stock, preferred stock, warrants and/or units consisting of two or more of any such securities on terms to be determined at the time of sale. The preferred stock may be convertible into shares of our common stock and the warrants may be exercisable for shares of our common stock or shares of our preferred stock. We may offer these securities separately or together in one or more offerings with a maximum aggregate offering price of \$\_\_\_\_\_.

Specific terms of the securities being sold as well specific terms of these offerings will be provided in supplements to this prospectus. You should read this prospectus and any prospectus supplements, including any information incorporated herein or therein, carefully before you invest.

The securities being sold may be sold on a delayed basis or continuous basis directly by us, through dealers, agents or underwriters designated from time to time, or through any combination of these methods. If any dealers, agents or underwriters are involved in the sale of the securities in respect of which this prospectus is being delivered, we will disclose their names and the nature of our arrangements with them in any prospectus supplement. The net proceeds we expect to receive from any such sale will also be included in the applicable prospectus supplement.

Our common stock is listed on the American Stock Exchange under the symbol "AEN." The last sale price of our common stock on June 30, 2010, as reported by AMEX, was \$1.14 per share. None of the other securities offered under this prospectus are publicly traded.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 3 to read about the factors you should consider before investing .

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This prospectus may not be used to offer and sell securities unless accompanied by a prospectus supplement for the securities being sold.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is June 14, 2010

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The registration statement containing this prospectus, including the exhibits to the registration statement, provides additional information about us and the common stock offered under this prospectus. The registration statement, including the exhibits and the documents incorporated herein by reference, can be read on the Securities and Exchange Commission website or at the Securities and Exchange Commission offices mentioned under the heading “Where You Can Find More Information.”

## ABOUT THIS PROSPECTUS

This prospectus is a part of a registration statement that we filed with the Securities and Exchange Commission utilizing a “shelf-registration process.” Under this shelf registration process, we may, from time to time, sell up to \$15 million of our common stock and warrant separately, together or as units in one or more offerings as described in this prospectus. However, in no event will we sell securities with a value exceeding more than one-third of our “public float” (the market value of our common stock held by non-affiliates) in any 12 month period. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities under this shelf registration, we will provide a prospectus supplement that will contain specific information about the terms of that offering and the manner in which securities will be offered, including the specific amount, price and terms of the securities offered. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under “Where You Can Find More Information.”

We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and the accompanying supplement to this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or the accompanying prospectus supplement. This prospectus and the accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and the accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus and the accompanying prospectus supplement is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus and any accompanying prospectus supplement is delivered or shares of common stock are sold on a later date.

## ABOUT ADEONA PHARMACEUTICALS, INC.

In this prospectus, “Adeona Pharmaceuticals,” “Adeona” “we,” “us,” and “our” refer to Adeona Pharmaceuticals, Inc., a Nevada corporation and each of its subsidiaries, considered as a single enterprise. .

Adeona Pharmaceuticals, Inc., a Nevada corporation, (“Adeona” or the “Company”) is a pharmaceutical company developing new medicines for serious central nervous systems diseases. Adeona’s primary strategy is to in-license clinical-stage drug candidates that have already demonstrated a certain level of clinical efficacy and develop them further to either commercialization or a development collaboration.

Trimesta (estriol) is an investigational oral drug for the treatment of relapsing remitting multiple sclerosis. A 150-patient, 16-center, randomized, double-blind, placebo-controlled clinical trial is currently underway. Effirma (flupirtine) is a novel centrally-acting investigational oral drug for the treatment of fibromyalgia syndrome. We recently entered into a sublicense agreement with Meda AB pursuant to which we granted an exclusive license to all of our patents covering the use of flupirtine for fibromyalgia. Zinthionein ZC (zinc cysteine) is an oral, gastro-retentive, sustained-release medical food candidate being developed for the dietary management of Alzheimer’s disease and mild cognitive impairment. In December of 2009, Adeona initiated a 60-patient clinical study. dnaJP1 (hsp peptide) is an investigational oral drug for the treatment of rheumatoid arthritis. It has completed a 160-patient, multi-center, randomized, double-blind, placebo-controlled clinical trial. ZincMonoCysteine (zinc-monocysteine) is an investigational oral drug for the treatment of dry age-related macular degeneration. It has completed an 80-patient, randomized, double-blind, placebo-controlled clinical trial.

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

Program	Medical Indication	Stage of Development
Trimesta (estriol)	Treatment of relapsing remitting multiple sclerosis in women	10-patient, 22-month, single-agent, crossover clinical trial completed, and a 150-patient, 16-center, randomized, double-blind, placebo-controlled clinical trial underway
Effirma (flupirtine)	Treatment of fibromyalgia	IND approved and IRB reviewed for 90-patient clinical trial

Program	Medical Indication	Stage of Development
Zinthionein ZC (zinc cysteine)	Dietary management of Alzheimer's disease and mild cognitive impairment	60-patient, randomized, double-blind, placebo-controlled clinical study underway
dnaJP1 (hsp peptide)	Treatment of rheumatoid arthritis	160-patient, multi-center, randomized, double-blind, placebo-controlled clinical trial completed
ZincMonoCysteine (zinc-monocysteine)	Treatment of dry age-related macular degeneration	80-patient, randomized, double-blind, placebo-controlled clinical trial completed

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

In addition, we are seeking United States, European and Asian corporate partners for the further development of the investigational CD4 inhibitor 802-2 (cyclic heptapeptide) for prevention of severe graft-versus-host disease and oral tetrathiomolybdate drug for treating Alzheimer's disease, Parkinson's disease and Huntington's disease.

#### Product Candidates

##### Trimesta

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

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

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

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

Clinical Trial Results of Trimesta in Relapsing Remitting Multiple Sclerosis Patients

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

During this clinical trial, a 14-percent improvement in Paced Auditory Serial Addition Test (PASAT) cognitive testing scores ( $p = 0.04$ ) was also observed in the multiple sclerosis patients at six months of therapy. PASAT is a routine cognitive test performed in patients with a wide variety of neuropsychological disorders such as multiple sclerosis. The PASAT scores were expressed as a mean percent change from baseline and were significantly improved in the relapsing-remitting group. The study investigators concluded that a larger, placebo-controlled clinical trial of Trimesta is warranted in women with relapsing remitting multiple sclerosis. In addition, they added that this novel treatment strategy of using Trimesta in multiple sclerosis has relevance to other autoimmune diseases that also improve during pregnancy.

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

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

#### Trimesta Grant Funding

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

#### Trimesta Market Opportunity

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

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

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

## Effirma

Effirma (flupirtine) is a centrally-acting investigational oral drug for the treatment of fibromyalgia syndrome. It is a selective neuronal potassium channel opener that also has NMDA receptor antagonist properties. Flupirtine is a non-opioid, non-NSAID, non-steroidal, analgesic. Flupirtine was originally developed by Asta Medica and has been approved in Europe since 1984 for the treatment of pain, although it has never been introduced to the United States market for any indication.

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 antinociceptive effects has been observed. One common link between neuroprotection, nociception, and Effirma may be the N-methyl-D-aspartic acid glutamate system, a major receptor subtype for the excitotoxic neurotransmitter, glutamate. Effirma has strong inhibitory actions on N-methyl-D-aspartic acid-mediated neurotransmission.

## Effirma Clinical Trial Status

Adeona's scientific collaborator has demonstrated preliminary encouraging evidence of clinical efficacy in a small number of patients treated with Effirma whom were suffering from fibromyalgia refractory to other analgesics and therapies. Effirma was well tolerated by these patients with no untoward side effects. In addition, substantial improvement in signs and symptoms was demonstrated in this difficult-to-treat fibromyalgia patient population. Adeona's scientific collaborator filed an investigator-initiated Investigational New Drug with the Food and Drug Administration to test flupirtine in a clinical trial of 90 fibromyalgia patients. During 2008, this proposed clinical trial and Investigational New Drug was approved by the Food and Drug Administration. Additionally, this protocol has been reviewed by an institutional review board.

## Effirma Sublicense

In May of 2010, Adeona and its wholly owned subsidiary, Pipex Therapeutics, Inc. ("Pipex") entered into a Sublicense Agreement (the "Agreement") pursuant to which Pipex granted Meda AB ("Meda") an exclusive sublicense to all of its patents covering the use of flupirtine for fibromyalgia. The Agreement provides that the Meda will assume all future development costs for the commercialization of flupirtine for fibromyalgia. As consideration for such sublicense, Pipex received an up-front payment of \$2.5 million upon execution of the Agreement and are entitled to milestone payments of \$5 million upon filing of a New Drug Application with the Food and Drug Administration for flupirtine for fibromyalgia and \$10 million upon marketing approval. The Agreement also provides that Pipex is entitled to receive royalties of 7% of net sales of flupirtine approved for the treatment of fibromyalgia covered by issued patent claims in the Territory. Pursuant to the terms of Pipex's agreement with the company's university licensor, Adeona is obligated to share half of the royalties we receive with the company's university licensor.

## Effirma Market Opportunity

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 estimates the United States market for fibromyalgia to be near \$1 billion at the time of potential launch of flupirtine.



## Zinthionein ZC

Zinthionein ZC is an investigational once-daily, gastroretentive, sustained-release, proprietary, oral tablet formulation of zinc and cysteine for the dietary management of Alzheimer's disease and mild cognitive impairment. It is being developed as a prescription medical food. All of Zinthionein ZC's constituents have GRAS (Generally Regarded as Safe) status. Zinthionein ZC was specially invented and developed by Adeona to achieve the convenience of once-daily dosing, high bioavailability and to minimize gastrointestinal side effects of oral zinc therapy. Zinthionein ZC is protected by multiple U.S. and international pending patent applications held by Adeona.

In April of 2010, Adeona announced positive results of Part 1 of its CopperProof-2 clinical study of Zinthionein ZC (zinc cysteine) in Alzheimer's disease and mild cognitive impairment. Adeona's CopperProof-2 clinical study seeks to compare Zinthionein ZC to placebo, as well as a currently marketed prescription zinc product, Galzin® (zinc acetate). The clinical study, "A Prospective, Randomized, Double Blind Trial of a Novel Oral Zinc Cysteine Preparation in Alzheimer's Disease (CopperProof-2)" previously received institutional review board approval to proceed. The principal investigator of the study is Diana Pollock, M.D., Associate Director, Memory Disorder Center, Clearwater, Florida.

CopperProof-2 is designed as a controlled, 60-patient, randomized, double-blind, placebo-controlled clinical study and is divided into two parts. Part 1, recently completed, is a 13-subject, three-arm, single-dose, comparator study in Alzheimer's disease and mild cognitive impairment subjects that compared the tolerability and bioavailability of Zinthionein ZC to Galzin®, the only Food and Drug Administration-approved zinc preparation and placebo. The Galzin® arm tested two separate individual dose levels, 50 mg and 100 mg zinc acetate (two 50 mg doses taken together). Part 2 of the study has 60 Alzheimer's disease and mild cognitive impairment subjects randomized to receive either once-daily Zinthionein ZC or matching placebo for six months.

## Results

### Tolerability

Results from Part 1 of the study, announced today, demonstrate a substantially lower incidence of adverse effects in Alzheimer's disease and mild cognitive impairment subjects (33% versus 100%) in favor of Zinthionein ZC (containing 150 mg of elemental zinc acetate and 100 mg of cysteine) compared to Galzin® (containing either 50 mg or 100 mg of elemental zinc as zinc acetate). 100% of the Galzin® subjects experienced gastrointestinal distress, ranging from 100% nausea to 40% vomiting, 40% diarrhea, and 20% heartburn. The high rate of gastrointestinal adverse effects of Galzin® are consistent with prior published results of oral zinc therapy. In comparison, only 33% of Zinthionein ZC subjects experienced nausea, with only one of such subjects (17% of group) having experienced vomiting. No adverse effects were noted in the placebo group.

Adverse effects for the three groups are as follows:

	Galzin		Galzin		Galzin		Zinthionein ZC			
	Placebo	%	100 mg	%	50 mg	%	All	%	150 mg	%
Any Adverse Effect	(0/2)	0%	(3/3)	100%	(2/2)	100%	(5/5)	100%	(2/6)	33%
Nausea	(0/2)	0%	(3/3)	100%	(2/2)	100%	(5/5)	100%	(2/6)	33%
Vomiting	(0/2)	0%	(1/3)	33%	(1/2)	50%	(2/5)	40%	(1/6)	17%
Diarrhea	(0/2)	0%	(1/3)	33%	(1/2)	50%	(2/5)	40%	(0/6)	0%
Dizziness	(0/2)	0%	(0/3)	0%	(0/2)	0%	(0/5)	0%	(0/6)	0%
Abdominal Pain	(0/2)	0%	(0/3)	0%	(0/2)	0%	(0/5)	0%	(1/6)	17%
Heartburn	(0/2)	0%	(0/3)	0%	(1/2)	50%	(1/5)	20%	(0/6)	0%

### Bioavailability

Zinthionein ZC also demonstrated superior serum zinc bioavailability in Alzheimer's disease and mild cognitive impairment subjects compared to both the 50 mg and 100 mg dose levels of Galzin®. Average baseline serum zinc levels of the subjects was 76.8 microg/dL (range: 63-92 microg/dL), consistent with Adeona's earlier findings of a subclinical zinc deficiency in Alzheimer's disease patients. The area under the curve (a serum measurement of bioavailability) of Zinthionein ZC was approximately 166% that of the 50 mg Galzin® dose and 116% that of 100 mg Galzin® dose (two 50 mg doses taken together).

The bioavailability results are also supplemented from results of a separate uncontrolled repeat dose pilot study conducted by Adeona in a small number of normal subjects who took Zinthionein ZC once-daily for 14 weeks, also being announced today. Following 14 weeks, subjects demonstrated an average 80% increase in serum zinc levels from baseline measured at least 12 hours after last dose, demonstrating Zinthionein ZC's ability to maintain

consistently elevated serum zinc levels. In addition, a 17% reduction in serum copper levels was observed after 14 weeks, demonstrating Zinthionein ZC's ability to favorably improve serum copper/zinc ratios with once-daily dosing.

#### Part 2 of the Clinical Study

Part 2 of the clinical study is intended to enroll 60 Alzheimer's disease and mild cognitive impairment subjects and is currently ongoing with 11 of 13 enrolled subjects from Part 1 electing to continue to Part 2 of the study. In Part 2, subjects are randomized on a 50:50 basis to either Zinthionein ZC or matching placebo. Subjects will be assessed at 3 and 6 months for serum parameters of zinc and copper as well as changes in cognitive function using standard clinical tests used in Alzheimer's disease and mild cognitive impairment. Some subjects have now completed three months of therapy. Adeona recently added two additional clinical sites in Florida to further expedite enrollment and complete Part 2 of the study.

## Background of Zinc Therapy for Alzheimer's Disease and Mild Cognitive Impairment

The CopperProof-2 study grew out of observations by Adeona and now others documenting a subclinical zinc deficiency in Alzheimer's disease patients as well as a significant body of published evidence implicating chronic copper exposure and elevated free serum copper levels in the progression of Alzheimer's disease and mild cognitive impairment. In 1992, results from an uncontrolled study of zinc therapy in Alzheimer's disease was reported to demonstrate cognitive improvement in 80% of subjects in as little as 3 to 6 months of treatment. Due to the significant gastrointestinal side effects and intolerability of oral zinc therapy in such study, oral zinc therapy was discontinued and subjects were switched to zinc injections administered every other day, further underscoring the need for a better tolerated, convenient oral zinc therapy such as Zinthionein ZC.

The hippocampus, an area of the brain that plays a critical role in short-term memory and is generally most affected in Alzheimer's disease, is believed to contain the highest levels of zinc in the brain. Hippocampal zinc is believed to play an important dual role as a synaptic neurotransmitter that modulates NMDA (N-methyl-D-aspartic acid) receptor activity limiting excitotoxicity and is a key component of hundreds of neuroprotective enzymes, a number of which are responsible for the degradation of amyloid beta. Alzheimer's disease subjects have been reported to have lower levels of zinc in their cerebral spinal fluid, and cerebral spinal fluid levels of copper and zinc highly correlate with levels of amyloid beta 42 in cerebral spinal fluid, a biomarker of Alzheimer's disease. Zinc's role as an important NMDA receptor antagonist implies that by ameliorating the cerebral spinal fluid zinc deficiency in Alzheimer's disease patients, Zinthionein ZC may demonstrate near term acute cognitive benefits, such as those demonstrated in the 1992 study described above, as well as reducing neurogeneration in the longer term. Current NMDA-receptor antagonists for Alzheimer's disease, such as Namenda® and Axura® (memantine), currently have estimated annualized sales of \$2.6 billion.

## dnaJP1

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

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

Computer-aided, rational drug design techniques of dnaJP1 resulted in a short synthetic peptide derived from a heat shock protein dnaJ. Heat shock proteins and dnaJ are upregulated during cellular stress, including inflammation and autoimmune diseases. Heat shock protein responses have been found in several other autoimmune diseases other than

rheumatoid arthritis, including juvenile idiopathic arthritis, multiple sclerosis, and inflammatory bowel disease. The mechanism of action of dnaJP1 relies on selectively inducing an immune shift of a T-cell function from inflammatory to regulatory, thus inhibiting disease-related inflammation and inducing a tolerogenic immunologic response.

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

## Clinical Trial Results of dnaJP1 in Rheumatoid Arthritis Patients

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

Results of the published study showed the following:

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

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

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

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

### dnaJP1 Market Opportunity

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

### ZincMonoCysteine

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

ZincMonoCysteine has completed an 80-patient, randomized, double-blind, placebo-controlled clinical trial in dry age-related macular degeneration and demonstrated highly statistically significant improvements in central retinal function. These results were published in a peer-reviewed journal in 2008. Adeona believes that the patent-pending, modified-release formulations of ZincMonoCysteine and may offer the significant advantages of convenient once-a-day dosing and improved gastrointestinal tolerability compared to currently-marketed oral high dose zinc-containing products. During the third quarter of 2009, Adeona did further manufacturing and scale up of ZincMonoCysteine to support the further nonclinical testing and cGMP manufacturing required to support further drug development.

### Copper and Zinc Metabolism Clinical Diagnostic Test

During the first quarter of 2009, Adeona analyzed patient samples from an institutional review board-approved, prospective, observational, blinded clinical study that was sponsored and conducted during 2007 and 2008. The study enrolled 90 subjects, 30 with Alzheimer's disease, 30 with Parkinson's disease and 30 age-matched normal subjects. The purpose of the study was to evaluate serum markers of copper status and compare these results across the three groups of patients. The results of the study indicate highly statistically significant differences in serum markers of copper status between Alzheimer's disease and normal subjects. Adeona believes that the differences observed suggest that Alzheimer's patients have impaired metabolic functioning that decreases their protection from chronic copper toxicity, which may contribute to the progression of their disease. The results from this study also appear to indicate a subclinical zinc deficiency in Alzheimer's disease patients. In July of 2009, Adeona announced the presentation of the findings from this study at the 2009 International Conference on Alzheimer's disease. There is an estimated 5.8 million, 1.5 million and 15 million persons in the United States with Alzheimer's disease, Parkinson's disease and mild cognitive impairment, respectively, that may benefit from Adeona's panel of clinical diagnostic tests.

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



greater Chicago area.

In November of 2009, Adeona announced the launch of the HartLab subsidiary's diagnostic test panel, the CopperProof TM Panel, for the evaluation of zinc and copper status in patients with Alzheimer's disease and mild cognitive impairment. The CopperProof TM Panel provides a comprehensive analysis of the metabolic serum copper and zinc status of Alzheimer's disease and mild cognitive impairment patients, the status of which has been shown to be impaired in this patient population. Defects in copper metabolism and high free copper levels are increasingly being recognized as significant factors in the progression of neurodegenerative diseases, including Alzheimer's disease and mild cognitive impairment. Adeona believes that this panel will allow physicians to determine the copper and zinc metabolic status of these patients as an aid in their continued treatment program.

## Intellectual Property

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

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

### McLean Hospital Exclusive License Agreement

In 2005, as amended in 2007 and 2010, Pipex, Adeona's wholly owned subsidiary, entered into an exclusive license agreement with the McLean Hospital, a Harvard University hospital, relating to U.S. Patent No. 6,610,324 and its foreign equivalents, entitled "Flupirtine in the treatment of fibromyalgia and related conditions." Pursuant to this agreement, 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 flupirtine equal to 3.5% of net sales of flupirtine for indications covered by the issued patents, reduced to 1.75% if Pipex has a license to other intellectual property covering those indications; use Pipex's best efforts to commercialize flupirtine for the therapeutic uses embodied in the patent applications; reimburse future patent costs and pay the following milestone payments: \$150,000 upon the initiation of a pivotal phase 3 clinical trial of flupirtine; \$300,000 upon the filing of a New Drug Application for flupirtine; and \$600,000 upon Food and Drug Administration approval of flupirtine. The due diligence requirements of the exclusive license agreement were amended in April 2010 and further amended by a Non-Disturbance Agreement that was signed with Pipex, McLean Hospital and Meda.

Effective May 6, 2010, Pipex and Adeona entered into a Sublicense Agreement (the "Agreement") with Meda AB of Sweden. Pursuant to the Agreement, Meda has been granted an exclusive sublicense to all of Pipex's patents covering the use of flupirtine for fibromyalgia. These patents have been issued in the U.S. and are pending in Canada and Japan (the "Territory"). The Agreement provides that Meda will assume all future development costs for the commercialization of flupirtine for fibromyalgia. As consideration for such sublicense, Pipex received an up-front payment of \$2.5 million upon execution of the Agreement and are entitled to milestone payments of \$5 million upon filing of a New Drug Application with the Food and Drug Administration for flupirtine for fibromyalgia and \$10 million upon marketing approval. The Agreement also provides that Pipex is entitled to receive royalties of 7% of net sales of flupirtine approved for the treatment of fibromyalgia covered by issued patent claims in the Territory. Pursuant to the terms of Pipex's agreement with the company's university licensor, Pipex is obligated to share half of the royalties it receives with the university licensor and Pipex is obligated to pay them \$375,000 upon receipt of an upfront payment.

### Thomas Jefferson University License Agreement

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

manufacturing information relating to anti-CD4 802-2. As partial consideration for this license, TJU was issued shares representing 5% of the common stock of CD4 Biosciences Inc. Adeona also agreed that TJU would receive anti-dilution protection on those CD4 shares through the first \$2 million in financing to CD4. Adeona also agree to indemnify TJU against certain liabilities.

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

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

### Zinc Monocysteine License Agreement

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

### The Regents of University of California License Agreement

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

## RISK FACTORS

You should carefully consider the specific risks set forth under the caption “Risk Factors” in the applicable prospectus supplement and under the caption “Risk Factors” in any of our filings with the Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), incorporated by reference herein, including the Risk Factors set forth in our Form 10-K for our fiscal year ended December 31, 2009 before making an investment decision. Each of the risks described in these sections and documents could materially and adversely affect our business, financial condition, results of operations and prospects and could result in partial or complete loss of your investment. For more information, see “Where You Can Find More Information.”

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and 21E of the Securities Exchange Act of 1934. You should not place undue reliance on these statements. These forward-looking statements include statements that reflect the current views of our senior management with respect to our financial performance and future events with respect to our business and our industry in general. Statements that include the words “expect,” “intend,” “plan,” “believe,” “project,” “forecast,” “estimate,” “may,” “should,” “anticipate” statements of a future or forward-looking nature identify forward-looking statements. Forward-looking statements address matters that involve risks and uncertainties. Accordingly, there are or will be important factors that could cause our actual results to differ materially from those indicated in these statements. We believe that these factors include, but are not limited to, the following:

- a failure of our product candidates to be demonstrably safe and effective;

- a failure to obtain regulatory approval for our products or to comply with ongoing regulatory requirements;

- a lack of acceptance of our product candidates in the marketplace;

a failure by us to become or remain profitable;

an inability by us to obtain the capital necessary to fund our research and development activities;

a loss of any of our key scientist or management personnel.

The foregoing factors should not be construed as exhaustive and should be read together with the other cautionary statements included in this prospectus and other reports we file with the Securities and Exchange Commission, including the information under “Item 1A. Risk Factors” of Part I of our Annual Report on Form 10-K for our fiscal year ended December 31, 2009. The forward-looking statements speak as of the date made and are not guarantees of future performance. If one or more events related to these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may differ materially from what we anticipate. We undertake no obligation to publicly update or revise any forward-looking statement, other than as required by law.

## USE OF PROCEEDS

Unless otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities under this prospectus for general corporate purposes, which may include general working capital, capital expenditures, research and development expenditures, regulatory affairs expenditures, clinical trial expenditures, acquisitions of new technologies and investments. Additional information on the use of net proceeds from the sale of securities offered by this prospectus may be set forth in the prospectus supplement relating to that offering. Pending the application of the net proceeds, we intend to invest the net proceeds in short-term, investment-grade, interest-bearing securities.

## DESCRIPTION OF CAPITAL STOCK

The following description of certain terms of our capital stock does not purport to be complete and is qualified in its entirety by reference to our articles of incorporation, our bylaws and provision of the Nevada Revised Statute. For more information on how you can obtain our Articles of Incorporation and bylaws, see “Where You Can Find more Information.” We urge you to read out Articles of Incorporation and bylaws in their entirety.

### Authorized Capital Stock

We are authorized to issue 100 million shares of common stock, par value \$.001 per share, and 10 million shares of preferred stock, par value \$.001 per share. At May 3, 2010, we had 21,698,945 shares of common stock outstanding and no shares of preferred stock outstanding. Although our board of directors has no present intention to do so, it could issue common stock or a series of preferred stock that could, depending on the terms of such securities, impede the completion of a merger, tender offer or take-over attempt. Our board of directors will make any determination to issue such shares based upon its judgment and the best interests of us and our shareholders.

### Common Stock

We may offer shares of our common stock. Our common stock currently trades on the AMEX under the symbol “AEN.” Holders of shares of common stock have the right to cast one vote for each share of common stock in their name on the books of our company, whether represented in person or by proxy, on all matters submitted to a vote of holders of common stock, including election of directors. There is no right to cumulative voting in election of directors. Except where a greater requirement is provided by statute, by our articles of incorporation, or by our bylaws, the presence, in person or by proxy duly authorized, of the one or more holders of a majority of the outstanding shares of our common stock constitutes a quorum for the transaction of business. The vote by the holders of a majority of outstanding shares is required to effect certain fundamental corporate changes such as liquidation, merger, or amendment of our articles of incorporation.

Except as otherwise provided by the Nevada Revised Statute or our Articles of Incorporation, holders of our common stock share ratably in all dividends and distributions, as may be declared from time to time by our board of directors from funds legally available therefore, whether upon liquidation or distribution or otherwise. There are no restrictions in our articles of incorporation or bylaws that prevent us from declaring dividends. The Nevada Revised Statute does, however, prohibit us from declaring dividends where, after giving effect to the distribution of the dividend (1) we would not be able to pay our debts as they become due in the usual course of business or (2) our total assets would be less than the sum of our total liabilities plus the amount that would be needed to satisfy the rights of stockholders who have preferential rights superior to those receiving the distribution.

We have not declared any dividends, and we do not plan to declare any dividends in the foreseeable future.

Holders of shares of our common stock are not entitled to preemptive or subscription or conversion rights, and no redemption or sinking fund provisions are applicable to our common stock. All outstanding shares of common stock are, and the shares of common stock sold in the offering will when issued, fully paid and non-assessable.

### Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Corporate Stock Transfer, Inc. of Denver, Colorado.

### Listing

Our common stock is listed on the American Stock Exchange under the symbol "AEN."



## DESCRIPTION OF WARRANTS

### General

We may issue warrants to purchase common stock (which we refer to as common stock warrants). Any of these warrants may be issued independently or together with any other securities offered by this prospectus and may be attached to or separate from the other securities. If warrants are issued, they will be issued under warrant agreements.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from a current report on Form 8-K that we file with the SEC, the form of warrant agreement that describes the terms of the warrants we are offering, and any supplemental agreements, before the issuance of the warrants. The following summaries of material terms and provisions of the warrants are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement and any supplemental agreements applicable to those warrants. We urge you to read the applicable prospectus supplements related to the particular warrants that we sell under this prospectus, as well as the complete warrant agreement and any supplemental agreements that contain the terms of the warrants.

### Terms of the Warrants

The applicable prospectus supplement will describe the following terms of common stock warrants offered under this prospectus:

- (1) the title;
- (2) the securities issuable upon exercise;
- (3) the issue price or prices;
- (4) the number of warrants issued with each share of common stock;
- (5) any provisions for adjustment of (a) the number or amount of shares of common stock receivable upon exercise of the warrants or (b) the exercise price;
- (6) if applicable, the date on and after which the warrants and the related common stock will be separately transferable;
- (7) if applicable, a discussion of the material United States federal income tax considerations applicable to the exercise of the warrants;
- (8) any other terms, including terms, procedures and limitations relating to exchange and exercise;
- (9) the commencement and expiration dates of the right to exercise; and
- (10) the maximum or minimum number that may be exercised at any time.

### Exercise of Warrants

Each warrant will entitle the holder to purchase for cash the amount of shares of common stock at the applicable exercise price set forth in, or determined as described in, the applicable prospectus supplement. Warrants may be

exercised at any time up to the close of business on the expiration date set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Warrants may be exercised by delivering to us or any other person indicated in the applicable prospectus supplement (a) the warrant certificate properly completed and duly executed and (b) payment of the amount due upon exercise. As soon as practicable following exercise, we will forward the shares of common stock purchasable upon exercise. If less than all of the warrants represented by a warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

## PLAN OF DISTRIBUTION

We may sell the securities being offered by us in this prospectus:

- directly to purchasers;
- through agents;
- through dealers;
- through underwriters; or
- through a combination of any of these methods of sale.

In addition, the manner in which we may sell some or all of the securities covered by this prospectus includes, without limitation, through:

- a block trade in which a broker-dealer will attempt to sell as agent, but may position or resell a portion of the block, as principal in order to facilitate the transaction
- purchases by a broker-dealer, as principal, and resale by the broker-dealer for its account; or
- ordinary brokerage transactions and transaction in which a broker solicits purchasers.

Furthermore, we may enter into derivative or hedging transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. In connection with such a transaction, the third parties may sell securities covered by and pursuant to this prospectus and an applicable prospectus supplement or other offering materials, as the case may be. If so, the third party may use securities borrowed from us or others to settle such sales and may use securities received from us to close out any related short positions. We may also loan or pledge securities covered by this prospectus and an applicable prospectus supplement to third parties, who may sell the loaned securities or, in an event of default in the case of a pledge, sell the pledged securities pursuant to this prospectus and the applicable prospectus supplement or other offering materials, as the case may be.

We and our agents and underwriters may sell the securities being offered by us in this prospectus from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to the prevailing market prices; or
- at negotiated prices.

We may solicit directly offers to purchase securities. We may also designate agents from time to time to solicit offers to purchase securities. Any agent, who may be deemed to be an “underwriter” as that term is defined in the Securities Act of 1933, as amended (the “Securities Act”) may then resell the securities to the public at varying prices to be determined by that agent at the time of resale.

In the sale of the securities, underwriters, dealers or agents may receive compensation from us or from purchasers of the securities, for whom they may act as agents, in the form of discounts, concessions or commissions. Underwriters may sell the securities to or through dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agents. Underwriters, dealers and agents that participate in the distribution of the securities may be deemed to be underwriters under the Securities Act and any discounts or commissions they receive from us and any profit on the resale of securities they realize may be deemed to be underwriting discounts and commissions under the Securities Act. The applicable prospectus supplement will, where applicable:

- identify any underwriter or agent;

describe any compensation in the form of discounts, concessions, commissions or otherwise received from us by each underwriter, dealer or agent and in the aggregate to all underwriters, dealers and agents; identify the purchase price and proceeds from that sale; identify the amounts underwritten; identify the nature of the underwriter's obligation to take the securities; and identify any quotation systems or securities exchanges on which the securities may be quoted or listed.

Underwriters, dealers, agents and other persons may be entitled, under agreements that may be entered into with us, to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments that they may be required to make in respect of these liabilities. Underwriters and agents may engage in transactions with, or perform services for, us in the ordinary course of business.

If so indicated in the applicable prospectus supplement, we will authorize underwriters, dealers, or other persons to solicit offers by certain institutions to purchase the securities offered by us under this prospectus pursuant to contracts providing for payment and delivery on a future date or dates. The obligations of any purchaser under any these contracts will be subject only to those conditions described in the applicable prospectus supplement, and the prospectus supplement will set forth the price to be paid for securities pursuant to these contracts and the commission's payable for solicitation of these contracts.

Any underwriter may engage in over-allotment, stabilizing and syndicate short covering transactions and penalty bids only in compliance with Regulation M of the Securities Exchange Act of 1934. If we offer securities in an "at the market" offering, stabilizing transactions will not be permitted. Over-allotment involves sales in excess of the offering size, which creates a short position. Stabilizing transactions involve bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Syndicate short covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the underwriters to reclaim selling concessions from dealers when the securities originally sold by the dealers are purchased in covering transactions to cover syndicate short positions. These transactions may cause the price of the securities sold in an offering to be higher than it would otherwise be. We do not make any representation or prediction as to the direction or magnitude of any effect that the transactions described above might have on the price of the securities. These transactions, if commenced, may be discontinued by the underwriters at any time.

Each series of securities offered under this prospectus will be a new issue with no established trading market, other than the common stock, which is listed on the American Stock Exchange. Any shares of common stock sold pursuant to a prospectus supplement will be listed on the American Stock Exchange, subject to official notice of issuance. Any underwriters to whom we sell securities for public offering and sale may make a market in the securities, but these underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We may elect to list any of the securities we may offer from time to time for trading on an exchange or on the American Stock Exchange, but we are not obligated to do so.

The anticipated date of delivery of the securities offered hereby will be set forth in the applicable prospectus supplement relating to each offering.

Underwriters, dealers and agents may engage in transactions with us or perform services for us in the ordinary course of business.

To comply with applicable state securities laws, the securities offered by this prospectus will be sold, if necessary, in such jurisdictions only through registered or licensed brokers or dealers. In addition, securities may not be sold in some states unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

In compliance with the guidelines of the Financial Industry Regulatory Authority ("FINRA"), the aggregate maximum discount, commission, or agency fees or other items of underwriting compensation to be received by an FINRA member or independent broker-dealer will not exceed 8% of any offering pursuant to this prospectus and any prospectus supplement or other offering materials, as the case may be.

If 5% or more of the net proceeds of any offering of securities made under this prospectus will be received by a FINRA member participating in the offering or affiliates or associated persons of such FINRA member, the offering will be conducted in accordance with NASD Conduct Rule 2720.

## LEGAL MATTERS

The legality of the Shares offered hereby has been passed upon for us by Gracin & Marlow, LLP, New York, New York.

#### EXPERTS

The financial statements incorporated in this prospectus from our Annual Report on Form 10-K for the year ended December 31, 2009 have been audited by Berman & Company, P.A., an independent registered public accounting firm, as stated in their report, which is incorporated by reference, which report expresses an unqualified opinion. The financial statements have been incorporated upon the authority of said firm as experts in accounting and auditing in giving said reports.

### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file at the Commission's public reference room located at 100 F Street N.E., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the operation of the public reference room. Our public filings are also available to the public at the Commission's web site at <http://www.sec.gov>.

This prospectus is part of a registration statement on Form S-3 that we have filed with the Commission under the Securities Act. This prospectus does not contain all of the information in the registration statement. We have omitted certain parts of the registration statement, as permitted by the rules and regulations of the Commission. You may inspect and copy the registration statement, including exhibits, at the Commission's public reference room or Internet site.

### INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The Commission allows us to "incorporate by reference" the information we file with it which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the Commission will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the Commission under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the termination of the offering:

- Our annual report on Form 10-K for the fiscal year ended December 31, 2009;
- The description of our common stock set forth in our registration statement on Form 8-A, filed with the Commission on January 29, 1993 (File No. 000-21156).
- Our Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2010.
- Our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 9, 2010.
- Our Current Report on Form 8-K filed with the Securities and Exchange Commission on March 16, 2010.
- Our Current Report on Form 8-K/A filed with the Securities and Exchange Commission on March 31, 2010.
- Our Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2010.
- Our Current Report on Form 8-K filed with the Securities and Exchange Commission on May 11, 2010.
- Our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 17, 2010.
- Our Current Report on Form 8-K filed with the Securities and Exchange Commission on June 3, 2010.

You may obtain, free of charge, a copy of any of these documents (other than exhibits to these documents unless the exhibits are specifically incorporated by reference into these documents or referred to in this prospectus) by writing or calling us at the following address and telephone number:

ADEONA PHARMACEUTICALS, INC.  
3930 Varsity Drive  
Ann Arbor, MI 48108  
Attention: Corporate Secretary  
(734) 332-7800





ADEONA PHARMACEUTICALS, INC.

UP TO \$15 Million

PROSPECTUS DATED JUNE 14, 2010

Common Stock  
Warrants

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information. You should not assume that the information contained or incorporated by reference in this prospectus is accurate as of any date other than the date of this prospectus. We are not making an offer of these securities in any state where the offer is not permitted.